Appendix A. Literature Search Strategy

SUMMARY OF SEARCH STRATEGY – VACCINE SAFETY

Databases: MEDLINE (OVID), EMBASE, Web of Science, Cochrane SR, DARE, and CENTRAL to cover the existing clinical literature.

General approach: We combine search terms for the vaccine with general adverse event terms and specific adverse events. We searched through October, 2012.
We use generic vaccine terms as well as specific available vaccines. The list of specific adverse events for Influenza, Hib, Tetanus, Diphtheria, Pertussis, Varicella, Human Papillomavirus, Measles-Mumps-Rubella, Meningococcal, Hepatitis A, and Hepatitis B was based on the Institute of Medicine (IOM) 2011 report, Vaccine Adverse Event Reporting System (VAERS) data, and Food and Drug Administration (FDA) Mini-Sentinel data. The list of specific adverse events for Polio, Rotavirus, Zoster, and Pneumococcal (vaccines not covered by the IOM report) was based on VAERS, Mini-Sentinel, and HRSA information. General adverse event terms were used as a safeguard against missing new harms that have not yet been identified in existing summary reports.
We chose the search date of January, 2010 for the vaccines covered by the IOM report based on the IOM search date (August, 2010). For the remaining vaccines we searched without date restriction. Animal studies and editorials were excluded where possible. We combined Medical Subject Headings (MeSH) with free text terms in order to capture new publications not yet assigned controlled language in the electronic databases. The vaccine specific searches will de-duplicate within vaccines and across vaccines and combined in one master library. In addition, references of included studies, studies included in pertinent reviews and suggestions from clinical experts will be screened.

VACCINE SAFETY – SEARCH METHODOLOGIES

LANGUAGE:
English

SEARCH STRATEGY:
NOTE:
"/" =MESH heading
"exp"=exploded MESH heading
"mp"=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier
"$"= truncation/wild card

DIPHTHERIA TOXOID-, TETANUS TOXOID-, AND ACELLULAR PERTUSSIS-CONTAINING VACCINES:
diphtheria-tetanus-acellular pertussis vaccines/ OR diphtheria pertussis tetanus vaccine/ OR tetanus toxoid/ OR "diphtheria-tetanus vaccine"/ OR ("diphtheria tetanus" OR "tetanus diphtheria" OR "tetanus and diphtheria" OR "diphtheria and tetanus").ti,ab. OR "tetanus toxoid".mp. OR DTaP.mp. OR TDaP.mp. OR (vaccin$ adj5 (DT OR TD OR TT)).mp. OR "tetanus diphtheria acellular pertussis".mp. OR "tetanus diphtheria and acellular pertussis".mp.

OR ((“Diphtheria tetanus acellular pertussis” OR “tetanus diphtheria acellular pertussis” OR “diphtheria tetanus” OR “tetanus diphtheria” OR “tetanus toxoid” OR “tetanus and diphtheria” OR “diphtheria and tetanus” OR DTaP OR TDAP OR DT OR TD OR TT) adj5 (vaccin$ OR immuniz$) OR Tripedia OR Acelimune OR Infanrix OR hexavax OR “quatro virelon” OR decavac OR “acel-imune” OR “acel imune” OR certiva OR daptacel OR trihibit OR pediarix OR kinrix OR pentacel OR “tri-immunol” OR “tri immunol” OR adacel OR boostrix OR ditanrix
AND
safe$ OR harm$ OR adverse OR toxic OR toxicity OR toxicities OR "side effect" OR "side effects" OR
death OR anaphylaxis/ OR anaphylactic shock/ OR anaphyla$ OR allergic OR allergy OR allergies OR exp arthralgia/ OR exp arthritis/ OR arthropathy, neurogenic/ OR exp arthropathy/ OR arthritis OR arthralgia OR arthropath$ OR exp arthritis, rheumatoid/ OR “rheumatoid arthritis” OR exp ataxia/ OR ataxia$ OR “coordination impairment$” OR dyssynergia OR “rubral tremor” OR autistic disorder/ OR autism/ OR infantile autism/ OR Asperger syndrome/ OR Rett syndrome/ OR schizophrenia, childhood/ OR child development disorders, pervasive/ OR childhood disintegrative disorder/ OR pervasive development disorder not otherwise specified/ OR autism OR autistic OR “kanner$ syndrome” OR “autism spectrum” OR “rett$ syndrome” OR “asperger$ syndrome” OR “child$ schizophrenia” OR “pervasive child$ development$ disorder$” OR “pervasive development disorder$” OR “disintegrative disorder?” OR bell palsy/ OR “bell$ palsy” OR “facial paralys$” OR “facial neuropath$” OR chronic inflammatory demyelinating polyneuropathy/ OR polyradiculoneuropathy, chronic inflammatory demyelinating/ OR exp multiple sclerosis/ OR “chronic remitting demyelinating disease$” OR “disseminated neuropathy” OR polyneuropath$ OR polyradiculoneuropath$ OR multiple sclerosis OR exp urticaria/ OR urticaria$ OR hives OR angioedema OR exp complex regional pain syndrome/ OR exp complex regional pain syndromes/ OR “complex regional pain” OR causalgia OR “reflex sympathetic dystrophy” OR seizures/ OR seizures, febrile/ OR convulsion/ OR exp epilepsies, myoclonic/ OR spasms, infantile/ OR myoclonus epilepsy/ OR myoclonus seizure/ OR myoclonus/ OR convulsion$.ti,ab. OR epileps$ OR myoclon$ OR spasm$ OR convulsion$ OR seizure$ OR exp encephalitis/ OR exp encephalitis, viral/ OR encephalitis OR “brain inflammation” OR encephalomyelitis OR exp brain disease/ OR encephalopath$.ti,ab. OR encephal$ OR “brain disease” OR fibromyalgia/ OR fibromyalgia$ OR fibrositis OR fibrositides OR “myofascial pain syndrome” OR frozen shoulder/ OR exp bursitis/ OR shoulder impingement syndrome/ OR exp synovitis/ OR “frozen shoulder” OR bursitis OR synovitis OR synovitides OR bursitides OR adhesive capsulitis OR adhesive capsulitides OR periarthritis OR periarthritides OR “shoulder impingement” OR “subacromial impingement” OR exp purpura, thrombocytopenic, idiopathic/ OR idiopathic thrombocytopenic purpura/ OR “idiopathic thrombocytopenic purpura$” OR “werlhof$ disease” OR “autoimmune thrombocytopenic purpura$” OR “autoimmune thrombocytopenia$” OR “thrombocytopen$ purpura” OR diabetes mellitus, type 1/ OR “insulin dependent diabetes” OR “insulin-dependent diabetes” OR “type1 diabetes” OR “juvenile onset diabetes” OR “sudden-onset diabetes” OR IDDM OR “brittle diabetes” OR “autoimmune diabetes” OR “ketosis-prone diabetes” OR exp guillain barre syndrome/ OR “guillain barre” OR exp guillain- barre syndrome/ OR “guillain-barre” OR myelitis, transverse/ OR “transverse myelitis” OR encephalomyelitis, acute disseminated/ OR myelitis OR encephalomyelitis OR demyelinating OR Myocarditis/ OR myocarditis OR carditis or myocarditides OR pericarditis OR Opsoclonus-myoclonus syndrome/ OR (“Opsoclonus myoclonus syndrome” OR“dancing eyes dancing feet syndrome” OR

“opsoclonus myoclonus ataxia” OR “kinsbourne syndrome” OR exp optic neuritis/ OR “optic neuritis” OR “optic neuritides” OR neuropapillitis OR neuropapillitides OR “retrobulbar neuritis” OR serum sickness/ OR “serum sickness$” OR “serum disease” OR “plasma sensitivity” OR sudden infant death/ OR “sudden infant death” OR SIDS OR “cot death” OR“unexpected infant death” OR exp syncope/ OR syncope OR syncopes OR syncopal OR fainting OR (vasovagal adj (collapse OR attack OR shock OR reaction)) OR “spontaneous abort$” OR “congenital abnormal$” OR abnormalities, congenital/ OR “congenital defect$” OR stillbirth$ OR stillborn OR exp meningitis/ OR meningitis OR “cranial nerve$” OR paraly$ OR (tic OR tics).mp. OR uveitis OR narcolep$.mp. OR birth adj3 defect$.mp. OR exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or systemic lupus.mp. OR thrombocytopen$.mp. OR Fisher$ adj syndrome.mp. OR polyarteritis nodosa/ or polyarteritis nodosa.mp. or periarteritis nodosa.mp. or essential polyarteritis.mp. or necrotizing arteritis.mp. or smallfiber neuropath$.mp. or small fiber neuropath$.mp. OR exp stroke/ or exp death, sudden/ or cerebrovascular accident$.mp. OR vasculitis OR thromboembolism$.mp. OR exp myocardial ischemia/ OR ischemic heart disease or "heart attack" or myocardial infarction or angina OR eclampsia OR pre-eclampsia OR preeclampsia OR (preterm labor OR preterm labour).mp. OR ankylosing spondylitis.mp. OR polymyalgia rheumatica.mp. OR myoclonus OR “severe combined immune deficiency”
NOT
Editorials

HAEMOPHILUS INFLUENZA TYPE B:
haemophilus vaccines/ OR haemophilus influenza type b polysaccharide vaccine-tetanus toxin conjugate [Supplementary Concept] OR (“haemophilus b” OR “haemophilus type b” OR “haemophilus influenzae type b” OR hib) AND (vaccine$ OR vaccinate$ OR vaccination$ OR immuniz$ OR immunis$) OR acthib OR hiberix OR hibtiter OR omnihib OR pedvaxhib OR prohibit OR tetracoq
AND
safe$ OR harm$ OR adverse OR toxic OR toxicity OR toxicities OR "side effect" OR "side effects" OR
death OR mortality/ OR anaphylaxis/ OR anaphylactic shock/ OR anaphyla$ OR seizures/ OR seizures, febrile/ OR convulsion/ OR exp epilepsies, myoclonic/ OR spasms, infantile/ OR myoclonus epilepsy/ OR myoclonus seizure/ OR myoclonus/ OR convulsion$.ti,ab. OR epileps$ OR myoclon$ OR spasm$ OR convulsion$ OR seizure$ OR urticaria/ OR urticaria$ OR hives OR angioedema OR allergic OR allergy OR allergies OR intussuscept$ OR tremor$ OR hypotoni$ OR sudden infant death/ OR “sudden infant death” OR SIDS OR “cot death” OR“unexpected infant death” OR “spontaneous abort$” OR “congenital abnormal$” OR abnormalities, congenital/ OR encephalomyelitis, acute disseminated/ OR “acute disseminated encephalomyelitis” OR exp guillainbarre syndrome/ OR “guillain barre” OR myelitis, transverse/ OR “transverse myelitis” OR fibromyalgia/ OR fibromyalgia$ OR fibrositis OR fibrositides OR (susceptib$ adj3 hib) OR (susceptib$ adj3 haemophilus) OR thrombocytopenia$ OR thrombopenia$ OR exp diabetes mellitus, type 1/ OR “insulin dependent diabetes” OR “insulin--dependent diabetes” OR “type1 diabetes” OR “juvenile onset diabetes” OR “sudden-onset diabetes” OR IDDM OR “brittle diabetes” OR “autoimmune diabetes” OR “ketosis-prone diabetes” OR Idiopathic thrombocytopenic purpura OR thrombocytopenic purpura, idiopathic/ OR Purpura, Thrombocytopenic, Idiopathic/ OR (tic OR tics).mp. OR uveitis OR narcolep$.mp.

OR exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or systemic lupus.mp. OR rheumatoid arthritis.mp. OR Fisher$ adj syndrome.mp. OR exp polyarteritis nodosa/ or polyarteritis nodosa.mp. or periarteritis nodosa.mp. or essential polyarteritis.mp. or necrotizing arteritis.mp. OR ankylosing spondylitis.mp. OR polymyalgia rheumatica.mp. OR “serum sickness”.mp.
NOT
editorials

HEPATITIS A:
hepatitis a/ or hepatitis a vaccines/ or ((vaccination/ or vaccines/) and (hepatitis a/ or hepatitis a virus, human/)) or "hepatitis a vaccin$".mp. or ((vaccin$ or immuniz$ or immunis$ or immunolog$) and "hepatitis a").mp. OR (havrix or vaqta or twinrix).mp.
AND
Safe$.mp. or safety/ or (harm$ or adverse or toxic or toxicity or toxicities).mp. or "side effect$".mp. or death.mp. or mortality/ OR anaphylaxis/ or anaphylactic shock/ or anaphyla$.mp. or allergy.mp. or allergies.mp. or allergic.mp. OR ((bell$ adj2 palsy) or (facial adj2 paraly$) or (facial adj2 neuropath$)).mp. or Chronic inflammatory demyelinating polyneuropathy/ or "Chronic inflammatory demyelinating polyneuropathy".mp. or polyradiculoneuropathy, chronic inflammatory demyelinating/ or polyradiculoneuropathy.mp. or exp multiple sclerosis/ or "multiple sclerosis".mp. or "chronic remitting demyelinating disease$".mp. or "disseminated neuropath$".mp. OR frozen shoulder/ or exp bursitis/ or shoulder impingement syndrome/ or exp synovitis/ or frozen shoulder.mp. or bursitis.mp. or synovitis.mp. or synovitides.mp. or bursitides.mp. or (Adhesive capsulitis or adhesive capsulitides or periarthritis or periarthritides).mp. or (shoulder impingement or subacromial impingement).mp. OR hepatitis, autoimmune/ or autoimmune hepatitis/ or "autoimmune hepatitis".mp. OR myelitis, transverse.mp. or transverse myelitis.mp. or encephalomyelitis, acute disseminated/ OR acute disseminated encephalomyelitis or demyelinating.mp. or exp guillain-barre syndrome/ OR guillain barre.mp. or guillain-barre.mp. or "fisher syndrome".mp. or "fishers syndrome".mp. OR myelitis.mp. or exp syncope/ or syncop$.mp. or fainting.mp. or (vasovagal adj5 (collapse or attack or shock or reaction$)).mp. OR (seizure$ or convuls$ or spasm$ or "birth defect$" or spontaneous abort$ or congenital abnormal$).mp. or abnormalities, congenital/ or stillbirth$.mp. or stillborn.mp. or "still-born".mp. or "sudden infant death".mp. or sids.mp. or "cot death$".mp. or "unexpected infant death$".mp. OR exp Purpura, Thrombocytopenic, Idiopathic/ or "idiopathic thrombocytopenic purpura".mp. OR tics/ or tic.mp. or tics.mp. or (uveitis or narcolep$).mp. or exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or systemic lupus.mp. or (rheumatoid arthritis or "polyarteritis nodosa").mp. OR (Diabetes mellitus, type 1 or insulin dependent diabetes or insulin-dependent diabetes or (type 1 diabetes or type1 diabetes or juvenile onset diabetes or juvenile-onset diabetes)).mp. OR (stroke or strokes or "cerebrovascular accident" or "cerebrovascular accidents" or vasculitis).mp. OR (thromboembolis$ or exp myocardial ischemia/ OR ischemic heart disease or myocardial infarction or "heart attack" or angina or "ankylosing spondylitis" or "polymyalgia rheumatica" or fibromyalgia or "serum sickness").mp. OR narcolep$.mp. OR vasculitis OR fibromylagia/ or fibromyalg$.mp. or fibrositis.mp. or fibrositides.mp. OR Myofascial pain syndrome.mp.
NOT
Editorials

HEPATITIS B:
hepatitis b vaccines/ or ((vaccination/ or vaccines/) and (hepatitis b/ or hepatitis b virus/)) or "hepatitis b vaccin$".mp. or ((vaccin$ or immuniz$ or immunis$ or immunolog$) and "hepatitis b").mp. or "engerix-b".mp. or "engerix b".mp. or "recombivax hb".mp. or "recombivax-hb".mp. or twinrix.mp. or hexavax.mp. or .mp.
AND
safe$.mp. or safety/ or (harm$ or adverse or toxic or toxicity or toxicities).mp. or "side effect$".mp. or death.mp. or mortality/ OR anaphylaxis/ or anaphylactic shock/ or anaphyla$.mp. or allergy.mp. or allergies.mp. or allergic.mp. OR exp arthralgia/ or exp arthritis/ or arthropathy, neurogenic.mp. or exp arthropathy/ or arthritis.mp. or arthralgia.mp. or arthropath$.mp. OR rheumatoid arthritis/ or rheumatoid arthritis.mp. or brachial plexus neuritis/ or brachial neuritis.mp. or brachial plexus neuritis.mp. or neuralgia.mp. or brachial plexus neuropath$.mp. or small fiber neuropath$.mp. OR
Chronic inflammatory demyelinating polyneuropathy/ or polyradiculoneuropathy, chronic inflammatory demyelinating/ or exp multiple sclerosis/ or (polyneuropath$ or polyradiculoneuropath$ or multiple sclerosis).mp. OR demyelinat$.mp. OR neuromyelitis optica/ or chronic remitting demyelinating disease.mp. or disseminated neuropathy.mp. OR exp complex regional pain syndrome/ or exp complex regional pain syndromes/ or "complex regional pain".mp. or causalgia.mp. or "reflex sympathetic dystrophy".mp. OR Seizures, febrile/ or convulsion/ or exp epilepsies, myoclonic/ or spasms, infantile/ or Myoclonus epilepsy/ or myoclonus seizure/ or myoclonus/ or convulsion$.ti,ab. or epileps$.mp. or (myoclon$ or spasm$ or convuls$ or seizure$).mp. or exp epilepsy/ OR exp encephalitis/ or exp encephalitis, viral/ or exp brain disease/ or encephal$.ti,ab. or encephalopath$.mp. or brain inflammation.mp. or encephalomyelitis.mp. OR Brain Diseases/ OR erythema nodosum/ or "erythema nodosum".mp. or erythemat$.mp. OR fibromyalgia/ or fibromyalg$.mp. or fibrositis.mp. or fibrositides.mp. or "myofascial pain syndrome".mp. OR frozen shoulder/ or exp bursitis/ or shoulder impingement syndrome/ or exp synovitis/ or frozen shoulder.mp. or bursitis.mp. or synovitis.mp. or synovitides.mp. or bursitides.mp. or (Adhesive capsulitis or adhesive capsulitides or periarthritis or periarthritides).mp. or (shoulder impingement or subacromial impingement).mp. OR transverse myelitis.mp. or encephalomyelitis, acute disseminated/ or guillain barre.mp. OR guillian-barre.mp. OR myelitis.mp. or fisher syndrome.mp. or fishers syndrome.mp. OR myelitis.mp. or polyarteritis nodosa/ or polyarteritis nodosa.mp. or periarteritis nodosa.mp. or essential polyarteritis.mp. or necrotizing arteritis.mp. OR exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or systemic lupus.mp. OR exp syncope/ or syncop$.mp. or fainting.mp. or (vasovagal adj5 (collapse or attack or shock or reaction$)).mp. OR vasculitis/ or vasculitis.mp. or vasculitides.mp. or angiitis.mp. or angiitides.mp. or aortitis.mp. or arteritis.mp. or phlebitis.mp. or behcet syndrome.mp. or wegener granulomatosis.mp. or thrombophlebitis.mp. OR Endarteritis/ OR (Diabetes mellitus, type 1 or insulin dependent diabetes or insulin-dependent diabetes or (type 1 diabetes or type1 diabetes or juvenile onset diabetes or juvenile-onset diabetes)).mp. OR exp thyroiditis, autoimmune/ or "autoimmune thyroid".mp. or "autoimmune thyroiditis".mp. or "auto-immune thyroid".mp. or "auto-immune thyroiditis".mp. OR (spontaneous abort$ or congenital abnormal$).mp. or abnormalities, congenital/ or congenital defect$.mp. or stillbirth$.mp. or stillborn.mp. or sudden infant death/ or sudden infant death$.mp. or sids.mp. or cot death.mp. or unexpected infant death.mp. OR (tic or tics).mp. OR uveitis or narcolep$ or birth defects or stroke or

cerebrovascular accident$ or thromboembolism$ or exp myocardial ischemia/ OR ischemic heart disease or "heart attack" or myocardial infarction or angina or eclampsia or pre-eclampsia or preeclampsia or preterm or "pre-term" or "premature labor" or "premature labour" or reiter$ or ankylosing spondylitis or polymyalgia rheumatica or "serum sickness").mp. OR exp Purpura, Thrombocytopenic, Idiopathic/ or "idiopathic thrombocytopenic purpura".mp. OR (Meningitis or meningo$ or meningeal or arachnoiditis or meningitides or pachymeningitis).mp. or pachymeningitides.mp. OR "severe combined immune deficiency"
NOT
Editorials

HUMAN PAPILLOMAVIRUS:
papillomavirus vaccines/ OR (vaccination/ AND (papillomaviridae/ OR papillomavirus infections/)) OR "papillomavirus vaccin$" OR ((vaccin$ OR immuniz$) AND (papillomaviridae OR papillomavirus)) OR cervarix OR gardasil
AND
safe$ OR harm$ OR adverse OR toxic OR toxicity OR toxicities OR "side effect" OR "side effects" OR
death OR mortality/ OR amyotrophic lateral sclerosis/ OR "amyotrophic lateral sclerosis" OR anaphylaxis/ OR anaphylactic shock/ OR anaphyla$ OR allergic OR allergy OR allergies OR exp arthralgia/ OR exp arthritis/ OR arthropathy, neurogenic/ OR exp arthropathy/ OR arthritis OR arthralgia OR arthropath$ OR brachial plexus neuritis/ OR "brachial neuritis" OR "brachial plexus neuritis" OR neuralgia OR brachial plexus neuropath$ OR chronic inflammatory demyelinating polyneuropathy/ OR polyradiculoneuropathy, chronic inflammatory demyelinating/ OR exp multiple sclerosis/ OR neuromyelitis optica/ OR polyneuropath$ OR polyradiculoneuropath$ OR multiple sclerosis OR "neuromyelitis optica" OR OR seizures/ OR seizures, febrile/ or convulsion/ OR exp epilepsies, myoclonic/ OR spasms, infantile/ OR myoclonus epilepsy/ OR myoclonus seizure/ OR myoclonus/ OR convulsion$.ti,ab. OR epileps$ OR myoclon$ OR spasm$ OR convulsion$ OR seizure$ OR exp encephalitis/ OR exp encephalitis, viral/ OR encephalitis OR "brain inflammation" OR encephalomyelitis OR exp brain disease/ OR encephalopath$.ti,ab. OR encephal$ or "brain disease" OR "frozen shoulder" OR bursitis OR synovitis OR synovitides OR bursitides OR adhesive capsulitis OR adhesive capsulitides OR periarthritis OR periarthritides OR "shoulder impingement" OR "subacromial impingement" OR hypercoagulab$ OR exp guillain barre syndrome/ OR "guillain barre" OR exp guillain-barre syndrome/ OR guillain-barre" OR myelitis, transverse/ OR "transverse myelitis" OR encephalomyelitis, acute disseminated/ OR "acute disseminated encephalomyelitis" OR "cerebrovascular accident" OR stroke OR myelitis OR encephalomyelitis OR demyelinating OR exp pancreatitis/ OR pancreatitis OR exp lupus erythematosus, systemic/ OR systemic lupus OR libman-sacks disease OR exp syncope/ OR syncope OR syncopes OR syncopal OR fainting OR (vasovagal adj (collapse OR attack OR shock OR reaction)) OR thromboembolism/ or thromboembol$ OR hypercoagula$ OR appendicitis OR "spontaneous abort$" OR "congenital abnormal$" OR abnormalities, congenital/ OR Diabetes mellitus, type 1 or insulin dependent diabetes or insulin-dependent diabetes or (type 1 diabetes or type1 diabetes or juvenile onset diabetes or juvenile-onset diabetes)).mp. OR Idiopathic thrombocytopenic purpura OR thrombocytopenic purpura, idiopathic/ OR Purpura, Thrombocytopenic, Idiopathic/ OR uveitis OR narcolep$.mp. OR rheumatoid arthritis.mp. OR Fisher$ adj syndrome.mp. OR oculorespiratory syndrome$.mp. or

polyarteritis nodosa/ or polyarteritis nodosa.mp. or periarteritis nodosa.mp. or essential polyarteritis.mp. or necrotizing arteritis.mp. or smallfiber neuropath$.mp. or small fiber neuropath$.mp. OR vasculitis OR exp myocardial ischemia/ OR ischemic heart disease or "heart attack" or myocardial infarction or angina OR Pancreatitis.mp. OR ankylosing spondylitis.mp. OR fibromyalgia/ or fibromyalg$.mp. or fibrositis.mp. or fibrositides.mp. or "myofascial pain syndrome".mp. OR serum sickness.mp. OR Steril$.mp. OR infertile$.mp.
NOT
Editorials

INFLUENZA:
influenza vaccines/ or (vaccination/ and influenza, human/) or flu vaccine.mp. or influenza vaccine$.mp. OR (((vaccin$ or immuniz$ or immunis$) and (influenza or flu or haemophilus b or haemophilus type b or haemophilus influenza$ type b or hib)) or afluria or agriflu or fluarix or flu-imune or flulaval or flumist or flushield or fluvirin or fluzone).mp.
AND
Safe$.mp. or safety/ or (harm$ or adverse or toxic or toxicity or toxicities).mp. or "side effect$".mp. or death.mp. or mortality/ OR anaphylaxis/ or anaphylactic shock/ or anaphyla$.mp. or exp arthralgia/ or exp arthritis/ or arthropathy, neurogenic.mp. or exp arthropathy/ or arthritis.mp. or arthralgia.mp. or arthropath$.mp. OR (allergy or allergies or allergic).mp. OR asthma/ or status asthmaticus/ OR asthma$.mp. or (bell$ adj3 palsy).mp. or (facial adj3 paraly$).mp. or (facial adj3 neuropath$).mp. OR brachial plexus neuritis/ or brachial neuritis.mp. or brachial plexus neuritis.mp. or neuralgia.mp. or brachial plexus neuropath$.mp. or small fiber neuropath$.mp. OR exp myocardial infarction/ or exp stroke/ or exp death, sudden/ or cerebrovascular accident$.mp. or myocardial infarction$.mp. or heart attack$.mp. or stroke.mp. or sudden death.mp. OR Chronic inflammatory demyelinating polyneuropathy/ or polyradiculoneuropathy, chronic inflammatory demyelinating/ or exp multiple sclerosis/ or (polyneuropath$ or polyradiculoneuropath$ or multiple sclerosis).mp. OR neuromyelitis optica/ or chronic remitting demyelinating disease.mp. or disseminated neuropathy.mp. OR neuromyelitis optica or optic neuritis).mp. or exp complex regional pain syndromes/ or exp complex regional pain syndrome/ or (complex regional pain or causalgia or reflex sympathetic dystrophy).mp. or seizures/ OR Seizures, febrile/ or convulsion/ or exp epilepsies, myoclonic/ or spasms, infantile/ or Myoclonus epilepsy/ or myoclonus seizure/ or myoclonus/ or convulsion$.ti,ab. or epileps$.mp. OR (myoclon$ or spasm$ or convuls$ or seizure$).mp. or exp encephalitis/ or exp encephalitis, viral/ OR exp brain disease/ or encephal$.ti,ab. or encephalopath$.mp. or brain inflammation.mp. OR encephalomyelitis.mp. or fibromylagia/ or fibromyalg$.mp. or fibrositis.mp. or fibrositides.mp. OR Myofascial pain syndrome.mp. or frozen shoulder/ or exp bursitis/ or shoulder impingement syndrome/ or exp synovitis/ or frozen shoulder.mp. or bursitis.mp. or synovitis.mp. or synovitides.mp. or bursitides.mp. or (Adhesive capsulitis or adhesive capsulitides or periarthritis or periarthritides).mp. OR (shoulder impingement or subacromial impingement).mp. or exp guillain-barre syndrome/ or myelitis, transverse.mp. or transverse myelitis.mp. or encephalomyelitis, acute disseminated/ or demyelinating.mp. or guillain barre.mp. or guillain-barre.mp. or myelitis.mp. or fisher syndrome.mp. or fishers syndrome.mp. OR oculorespiratory syndrome$ or polyarteritis nodosa/ or polyarteritis nodosa.mp. or periarteritis nodosa.mp. or essential polyarteritis.mp. or necrotizing arteritis.mp. or small fiberneuropath$.mp. or small fiber neuropath$.mp. OR exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or

systemic lupus.mp. OR exp syncope/ or syncop$.mp. or fainting.mp. or (vasovagal adj5 (collapse or attack or shock or reaction$)).mp. 23-vasculitis/ or vasculitis.mp. or vasculitides.mp. or angiitis.mp. or angiitides.mp. or aortitis.mp. or arteritis.mp. or phlebitis.mp. or behcet syndrome.mp. or wegener granulomatosis.mp. or thrombophlebitis.mp. or papulosis.mp. or sickle cell.mp. OR (spontaneous abort$ or congenital abnormal$).mp. or abnormalities, congenital/ or congenital defect$.mp. or stillbirth$.mp. or stillborn.mp. or sudden infant death/ or sudden infant death$.mp. or sids.mp. or cot death.mp. or unexpected infant death.mp. OR (Diabetes mellitus, type 1 or insulin dependent diabetes or insulin-dependent diabetes).mp. or (type 1 diabetes or type1 diabetes or juvenile onset diabetes or juvenile-onset diabetes).mp. or (iddm or brittle diabetes or autoimmune diabetes or ketosis-prone diabetes).mp. OR Idiopathic thrombocytopenic purpura OR thrombocytopenic purpura, idiopathic/ OR Purpura, Thrombocytopenic, Idiopathic/ OR (Tic OR tics).mp. OR uveitis OR narcolep$.mp. OR rheumatoid arthritis.mp. OR birth adj3 defect$.mp. OR thromboembolism$.mp. OR exp myocardial ischemia/ OR ischemic heart disease or "heart attack" or myocardial infarction or angina OR eclampsia OR pre-eclampsia OR preeclampsia OR (preterm labor OR preterm labour).mp. OR “severe combined immune deficiency” OR ankylosing spondylitis.mp. OR polymyalgia rheumatica.mp. OR “serum sickness”.mp.
NOT
Editorials

MENINGOCOCCAL:
meningococcal vaccines/ OR MPSV4.mp. OR menomune.mp. OR MCV4.mp. or menactra.mp. OR ((vaccination/ or vaccines/) AND exp meningitis/)) OR mening$ vaccin$ OR ((vaccin$ OR immuniz$) AND meningitis))
AND
safe$ OR harm$ OR adverse OR toxic OR toxicity OR toxicities OR "side effect" OR "side effects" OR
death OR mortality/ OR anaphylaxis/ OR anaphylactic shock/ OR anaphyla$ OR allergic OR allergy OR allergies OR bell palsy/ OR “bell$ palsy” OR “facial paralys$” OR “facial neuropath$” OR exp headache disorders/ OR (chronic adj2 headache$) OR headache disorder$ or headache syndrome$ OR cephalgia syndrome$ OR intractable headache$ OR chronic inflammatory demyelinating polyneuropathy/ or polyradiculoneuropathy, chronic inflammatory demyelinating/ OR exp multiple sclerosis/ OR “chronic remitting demyelinating disease$” OR “disseminated neuropathy” OR polyneuropath$ OR polyradiculoneuropath$ OR multiple sclerosis OR exp encephalitis/ OR exp encephalitis, viral/ OR encephalitis or brain inflammation or encephalomyelitis OR exp brain disease/ OR encephal$.ti,ab. OR brain disease$or encephal$ OR encephalomyelitis, acute disseminated OR “acute disseminated encephalomyelitis” OR myelitis, transverse/ OR “transverse myelitis” OR demyelinating OR encephalomyelitis OR frozen shoulder/ OR exp bursitis/ OR shoulder impingement syndrome/ OR exp synovitis/ OR “frozen shoulder” OR bursitis OR synovitis OR synovitides OR bursitides OR adhesive capsulitis OR adhesive capsulitides OR periarthritis OR periarthritides OR “shoulder impingement” OR “subacromial impingement” OR exp guillain barre syndrome/ OR “guillain barre” OR exp guillain-barre syndrome/ OR “guillain-barre” OR myelitis OR exp syncope/ OR syncope OR syncopes OR syncopal OR fainting OR (vasovagal adj (collapse OR attack OR shock OR reaction)) OR “spontaneous abort$” OR “congenital abnormal$” OR abnormalities, congenital/ OR thrombocytopenia$ OR thrombopenia$ OR seizures/ OR seizures, febrile/ OR

convulsion/ OR exp epilepsies, myoclonic/ OR spasms, infantile/ OR myoclonus epilepsy/ OR myoclonus seizure/ OR myoclonus/ OR convulsion$.ti,ab. OR epileps$ OR myoclon$ OR spasm$ OR convulsion$ OR seizure$ OR purpura, schonlein-henoch/ OR “henoch-schonlein purpura$” OR diabetes mellitus, type 1/ OR “insulin dependent diabetes” OR “insulin-dependent diabetes” OR “type1 diabetes” OR “juvenile onset diabetes” OR “sudden-onset diabetes” OR IDDM OR “brittle diabetes” OR “autoimmune diabetes” OR “ketosis-prone diabetes” OR Idiopathic thrombocytopenic purpura OR thrombocytopenic purpura, idiopathic/ OR Purpura, Thrombocytopenic, Idiopathic/ OR uveitis OR narcolep$.mp. OR rheumatoid arthritis.mp. OR Fisher$ adj syndrome.mp. OR (tic OR tics).mp. OR exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or systemic lupus.mp. OR polyarteritis nodosa/ or polyarteritis nodosa.mp. or periarteritis nodosa.mp. or essential polyarteritis.mp. or necrotizing arteritis.mp. OR exp stroke/ or exp death, sudden/ or cerebrovascular accident$.mp. OR vasculitis OR thromboembolism$.mp. OR exp myocardial ischemia/ OR ischemic heart disease or "heart attack" or myocardial infarction or angina OR vasculitis OR ankylosing spondylitis.mp. OR polymyalgia rheumatica.mp. OR
fibromyalgia/ or fibromyalg$.mp. or fibrositis.mp. or fibrositides.mp. or "myofascial pain syndrome".mp.
OR “serum sickness”.mp.
NOT
Editorials

MMR:
measles mumps rubella vaccine/ or measles vaccine/ or (vaccination/ and measles/) or mumps vaccine/ or (vaccination/ and mumps/) or rubella vaccine/ or (vaccination/ and rubella/) or ((measles or mumps or rubella or mmr) adj5 (vaccin$ or immuniz$ or immunis$)).mp. or ("triviaten berna" or priorix or trimovax or virivac or pluserix or proquad or "mmr 1" or "mmr 2" or "mmr I" or "mmr II" or mmr1 or mmr2 or attenuvax or mumpsvax or meruvax).mp.
AND
safe$.mp. or safety/ or (harm$ or adverse or toxic or toxicity or toxicities).mp. or "side effect$".mp. or
death.mp. or mortality/ or anaphylaxis/ or anaphylactic shock/ or anaphyla$.mp. or exp arthralgia/ or
exp arthritis/ or arthropathy, neurogenic.mp. or exp arthropathy/ or arthritis.mp. or arthralgia.mp. or
arthropath$.mp. or autistic disorder/ or autism/ or infantile autism/ or asperger syndrome/ or rett syndrome/ or schizophrenia, childhood/ or child development disorders, pervasive/ or (childhood disintegrative disorder/ or pervasive development disorder.mp.) not otherwise specified/
or (autism or autistic or "pervasive development disorder$").mp. or (rett syndrome or retts syndrome).mp. or (asperger syndrome or kanner syndrome or (child$ adj5 schizophrenia)).mp. or
(pervasive child$ development$ disorder$ or disintegrative disorder$).mp. or exp ataxia/ or ataxi$.mp.
or brachial plexus neuritis/ or brachial plexus neuritis.mp. or brachial neuritis.mp. or exp optic neuritis/ or optic neuritis.mp. or neuromyelitis optica.mp. or brachial neuralgia.mp. or amyotroph$ neuralgi$.mp.

or (cervicobrachial neuralgi$ or cervico-brachial neuralgi$ or parsonage-turner syndrome or parsonage-aldren-turner syndrome or brachial neuritides or shoulder-girdle neuropath$).mp. or brachial plexus neuritides.mp. or chronic fatigue syndrome/ or fatigue syndrome, chronic/ or fatigue syndrome$.mp. or chronic fatigue.mp. or myalgic encephalomyelitis.mp. or fatigue disorder.mp. or (royal free disease or chronic remitting demyelinating disease$ or disseminated neuropathy).mp. or Chronic inflammatory demyelinating polyneuropathy/ or polyradiculoneuropathy, chronic inflammatory demyelinating/ or exp multiple sclerosis/ or (polyneuropath$ or polyradiculoneuropath$ or multiple sclerosis).mp. or
exp complex regional pain syndromes/ or exp complex regional pain syndrome/ or (complex regional pain or causalgia or reflex sympathetic dystrophy).mp. or seizures/ or Seizures, febrile/ or convulsion/ or exp epilepsies, myoclonic/ or spasms, infantile/ or Myoclonus epilepsy/ or myoclonus seizure/ or myoclonus/ or convulsion$.ti,ab. or epileps$.mp. or (myoclon$ or spasm$ or convuls$ or seizure$).mp. or exp encephalitis/ or exp encephalitis, viral/ or exp brain disease/ or encephal$.ti,ab. or Encephalomyelitis.mp. or fibromylagia/ or fibromyalg$.mp. or fibrositis.mp. or fibrositides.mp. encephalopath$.mp. or brain inflammation. or Myofascial pain syndrome.mp. or frozen shoulder/ or exp bursitis/ or shoulder impingement syndrome or exp synovitis/ or frozen shoulder.mp. or bursitis.mp. or synovitis.mp. or synovitides.mp. or bursitides.mp. or (Adhesive capsulitis or adhesive capsulitides or periarthritis or periarthritides).mp. or (shoulder impingement or subacromial impingement).mp. or exp hearing loss/ or (hearing adj2 loss).mp. or (deafness or hypoacusis or hypoacuses or hearing impairment).mp. or hepatitis/ or hepatitis.mp. or (Diabetes mellitus, type 1 or insulin dependent diabetes or insulin-dependent diabetes).mp. or (type 1 diabetes or type1 diabetes or juvenile onset diabetes or juvenile-onset diabetes).mp. or (iddm or brittle diabetes or autoimmune diabetes or ketosis-prone diabetes).mp. or (Meningitis or meningo$ or meningeal or arachnoiditis or meningitides or pachymeningitis).mp. or pachymeningitides.mp. or myelitis, transverse.mp. or transverse myelitis.mp. or encephalomyelitis, acute disseminated/ or demyelinating.mp. or exp guillain-barre syndrome/ or “fisher$ adj3 syndrome” or guillain barre.mp. or guillain-barre.mp. or myelitis.mp. or opsoclonus myoclonus syndrome/ or opsoclonus myoclonus syndrome.mp. or (dancing eyes dancing feet or opsoclonus myoclonus ataxia or kinsbourne syndrome).mp. or exp inflammatory bowel diseases/ or inflammatory bowel disease$.mp. or exp syncope/ or syncop$.mp. or (fainting or (vasovagal adj5 (collapse or attack or shock or reaction$)) or thrombocytopen$).mp. or ((viral or virus) and infection$ and (immunodeficien$ or immunocompromis$ or immunosuppress$)).mp. or (spontaneous abort$ or congenital abnormal$).mp. or abnormalities, congenital/ OR Idiopathic thrombocytopenic purpura OR thrombocytopenic purpura, idiopathic/ OR Purpura, Thrombocytopenic, Idiopathic/ OR (tic OR tics).mp. OR exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or systemic lupus.mp. OR arthritis, rheumatoid/ OR rheumatoid arthritis.mp. OR thromboembolism$.mp. OR exp myocardial ischemia/ OR ischemic heart disease or "heart attack" or myocardial infarction or angina OR crohn$ OR ulcerative colitis.mp. OR reiter$,mp. OR fibromyalgia/ or fibromyalg$.mp. or fibrositis.mp. or fibrositides.mp. or "myofascial pain syndrome".mp. OR (uveitis or narcoleps$ or stillbirth or stillborn or still-born or "systemic allergic reaction" or "polyarteritis nodosa" or stroke or strokes or "cerebrovascular accident" or "cerebrovascular accidents" or vasculitis).mp. OR ("ankylosing spondylitis" or "polymyalgia rheumatica" or "sudden infant death").mp. or sudden infant death/ or sids.mp. or "cot death".mp. or "unexpected infant death".mp. or "serum sickness".mp.
NOT

editorials

PNEUMOCOCCAL:
pneumococcal vaccines/ OR (pneumonia/ OR pneumonia.ti,ab. OR pneumococ$) AND (vaccine$ OR vaccinate$ OR vaccination$ OR immuniz$ OR immunis$)) OR prevnar OR pneumovax OR “pnu-imune” OR “pnu imune” OR “pneumococcal polysaccharide$”
AND
safe$ OR harm$ OR adverse OR toxic OR toxicity OR toxicities OR "side effect" OR "side effects" OR
death OR mortality/ OR anaphylaxis/ OR anaphylactic shock/ OR anaphyla$ OR exp ataxia/ OR ataxia$ OR “coordination impairment$” OR dyssynergia OR “gait adj3 disturb$” OR allergic OR allergy OR allergies OR ((edema OR oedema) adj3 peripheral) OR exp urticaria/ OR urticaria$ OR hives OR angioedema OR seizures/ OR seizures, febrile/ OR convulsion/ OR exp epilepsies, myoclonic/ OR spasms, infantile/ OR myoclonus epilepsy/ OR myoclonus seizure/ OR myoclonus/ OR convulsion$.ti,ab. OR epileps$ OR myoclon$ OR spasm$ OR convulsion$ OR seizure$ OR dyskinesia$ OR “gaze palsy” OR hematochezia OR haematochezia OR hypotonia OR intussuscept$ OR sudden infant death/ OR “sudden infant death” OR SIDS OR “cot death” OR“unexpected infant death” OR tremor OR exp syncope/ OR syncope OR syncopes OR syncopal OR fainting OR (vasovagal adj (collapse OR attack OR shock OR reaction)) OR wheez$ OR asthma/ OR status asthmaticus/ OR asthma$ OR exp arthritis/ OR arthropathy, neurogenic/ OR exp arthropathy/ OR arthritis OR arthropath$ OR chronic fatigue syndrome/ OR fatigue syndrome, chronic/ OR “fatigue syndrome$” OR “chronic fatigue” OR “fatigue disorder” OR asthenia OR hyperhidrosis OR hypoaesthesia$ OR hypoesthesia$ OR paraesthesia$ OR paresthesia$ OR “spontaneous abort$” OR “congenital abnormal$” OR abnormalities, congenital/ OR exp guillainbarre syndrome/ OR “guillain barre” OR myelitis, transverse/ OR “transverse myelitis” OR fibromyalgia/ OR fibromyalgia$ OR fibrositis OR fibrositides OR thrombocytopenia$ OR thrombopenia$ OR serum sickness/ OR “serum sickness$” OR “serum disease” OR “plasma sensitivity” OR encephalomyelitis, acute disseminated/ OR “acute disseminated encephalomyelitis” OR exp diabetes mellitus, type 1/ OR “insulin dependent diabetes” OR “insulin-dependent diabetes” OR “type1 diabetes” OR “juvenile onset diabetes” OR “sudden-onset diabetes” OR IDDM OR “brittle diabetes” OR “autoimmune diabetes” OR “ketosis-prone diabetes” OR Idiopathic thrombocytopenic purpura OR thrombocytopenic purpura, idiopathic/ OR Purpura, Thrombocytopenic, Idiopathic/ OR (tic OR tics).mp. OR uveitis OR narcolep$.mp. OR Fisher$ adj syndrome.mp. OR ankylosing spondylitis.mp. OR polymyalgia rheumatica.mp. OR exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or systemic lupus.mp. OR exp polyarteritis nodosa/ or polyarteritis nodosa.mp. or periarteritis nodosa.mp. or essential polyarteritis.mp. or necrotizing arteritis.mp. OR rheumatoid arthritis.mp. OR thrombocytopen$.mp. OR exp brain disease/ or encephal$.ti,ab. or encephalopath$.mp. or brain inflammation.mp. OR exp multiple sclerosis/ OR multiple sclerosis.mp. OR vasculitis OR exp stroke/ or exp death, sudden/ or cerebrovascular accident$.mp. OR thromboembolism$.mp. OR exp myocardial ischemia/ OR ischemic heart disease or "heart attack" or myocardial infarction or angina
NOT
editorials

POLIOVIRUS:
poliovirus Vaccine, Inactivated/ OR (polio$AND (vaccine$ OR vaccinate$ OR vaccination$ OR immuniz$ OR immunis$)) OR ipol OR poliovax OR hexavax OR “quatro virelon” OR pediarix OR kinrix OR pentacel OR orimune
AND
safe$ OR harm$ OR adverse OR toxic OR toxicity OR toxicities OR "side effect" OR "side effects" OR
death OR mortality/ OR anaphylaxis/ OR anaphylactic shock/ OR anaphyla$ OR exp ataxia/ OR ataxia$ OR “coordination impairment$” OR dyssynergia OR “rubral tremor” OR “gait adj3 disturb$” OR allergic OR allergy OR allergies OR ((edema OR oedema) adj3 peripheral) OR exp urticaria/ OR urticaria$ OR hives OR angioedema OR seizures/ OR seizures, febrile/ OR convulsion/ OR exp epilepsies, myoclonic/ OR spasms, infantile/ OR myoclonus epilepsy/ OR myoclonus seizure/ OR myoclonus/ OR convulsion$.ti,ab. OR epileps$ OR myoclon$ OR spasm$ OR convulsion$ OR seizure$ OR dyskinesia$ OR “gaze palsy” OR hematochezia OR haematochezia OR hypotonia OR intussuscept$ OR sudden infant death/ OR “sudden infant death” OR SIDS OR “cot death” OR“unexpected infant death” OR tremor OR exp syncope/ OR syncope OR syncopes OR syncopal OR fainting OR (vasovagal adj (collapse OR attack OR shock OR reaction)) OR wheez$ OR asthma/ OR status asthmaticus/ OR asthma$ OR “paralytic polio$” OR “vaccine strain polio viral infection” OR “spontaneous abort$” OR “congenital abnormal$” OR abnormalities, congenital/ OR encephalomyelitis, acute disseminated OR “acute disseminated encephalomyelitis” OR exp guillain barre syndrome/ OR “guillain barre” OR exp guillain-barre syndrome/ OR “guillain-barre” OR myelitis, transverse/ OR “transverse myelitis” OR fibromyalgia/ OR fibromyalgia$ OR fibrositis OR fibrositides OR thrombocytopenia$ OR thrombopenia$ OR diabetes mellitus, type 1/ OR “insulin dependent diabetes” OR “insulin--dependent diabetes” OR “type1 diabetes” OR “juvenile onset diabetes” OR “sudden-onset diabetes” OR IDDM OR “brittle diabetes” OR “autoimmune diabetes” OR “ketosis-prone diabetes” OR Idiopathic thrombocytopenic purpura OR thrombocytopenic purpura, idiopathic/ OR Purpura, Thrombocytopenic, Idiopathic/ OR (tic OR tics).mp. OR exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or systemic lupus.mp. OR polyarteritis nodosa/ or polyarteritis nodosa.mp. or periarteritis nodosa.mp. or essential polyarteritis.mp. or necrotizing arteritis.mp. OR uveitis OR narcolep$.mp. OR Fisher$ adj syndrome.mp. OR ankylosing spondylitis.mp. OR polymyalgia rheumatica.mp. OR “serum sickness”.mp.
NOT
editorials

ROTAVIRUS:
rotavirus vaccines/ OR rotavirus$ C OR rotarix OR rotateq OR rotashield
AND
safe$ OR harm$ OR adverse OR toxic OR toxicity OR toxicities OR "side effect" OR "side effects" OR
death OR mortality/ OR anaphylaxis/ OR anaphylactic shock/ OR anaphyla$ OR urticaria/ OR urticaria$ OR hives OR angioedema OR allergic OR allergy OR allergies OR intussuscept$ OR sudden infant death/ OR “sudden infant death” OR SIDS OR “cot death” OR“unexpected infant death” OR seizures/ OR seizures, febrile/ OR convulsion/ OR exp epilepsies, myoclonic/ OR spasms, infantile/ OR myoclonus epilepsy/ OR myoclonus seizure/ OR myoclonus/ OR

convulsion$.ti,ab. OR epileps$ OR myoclon$ OR spasm$ OR convulsion$ OR seizure$ OR dyskinesia$ OR tremor$ OR exp syncope/ OR syncope OR syncopes OR syncopal OR fainting OR (vasovagal adj (collapse OR attack OR shock OR reaction)) OR "spontaneous abort$" OR "congenital abnormal$" OR abnormalities, congenital/ OR encephalomyelitis, acute disseminated/ OR "acute disseminated encephalomyelitis" OR exp guillainbarre syndrome/ OR "guillain barre" OR myelitis, transverse/ OR "transverse myelitis" OR fibromyalgia/ OR fibromyalgia$ OR fibrositis OR fibrositides OR "kawasaki disease$" OR "kawasaki syndrome$" OR exp meningitis/ OR meningitis OR exp encephalitis, viral/ OR encephalitis or brain inflammation or encephalomyelitis OR exp brain disease/ OR encephal$.ti,ab. OR brain disease$or encephal$ OR myocarditis OR "gram-negative sepsis" OR exp gastrointestinal hemorrhage/ OR "gastrointestinal bleeding" OR exp diabetes mellitus, type 1/ OR "insulin dependent diabetes" OR "insulin-dependent diabetes" OR "type1 diabetes" OR "juvenile onset diabetes" OR "sudden-onset diabetes" OR IDDM OR "brittle diabetes" OR "autoimmune diabetes" OR "ketosis-prone diabetes" OR Idiopathic thrombocytopenic purpura OR thrombocytopenic purpura, idiopathic/ OR Purpura, Thrombocytopenic, Idiopathic/ OR (tic OR tics).mp. OR intussuscept$.mp OR exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or systemic lupus.mp. OR rheumatoid arthritis.mp. OR Fisher$ adj syndrome.mp. OR exp polyarteritis nodosa/ or polyarteritis nodosa.mp. or periarteritis nodosa.mp. or essential polyarteritis.mp. or necrotizing arteritis.mp. OR vasculitis OR ankylosing spondylitis.mp. OR polymyalgia rheumatica.mp. OR "serum sickness".mp.
NOT
editorials

VARICELLA/ZOSTER:
exp chickenpox vaccine/ or ((vaccines/ or vaccination/) and chickenpox/) or chickenpox vaccin$.mp. or varicella vaccin$.mp. or ((vaccin$ or immuniz$ or immunis$).mp. and ((chicken pox or chickenpox or varicella).mp. or exp herpes zoster/ or zoster.mp. or shingles.mp.)) or varivax.mp. or varcel.mp. or varzos.mp. or varilrix.mp. or zostavax.mp.
AND
Safe$.mp. or safety/ or (harm$ or adverse or toxic or toxicity or toxicities).mp. or "side effect$".mp. or death.mp. or mortality/ OR (viral adj3 reactiv$).mp. or anaphylaxis/ or anaphylactic shock/ or anaphyla$.mp. or exp arthralgia/ or exp arthritis/ or arthropathy, neurogenic.mp. or exp arthropathy/ or arthritis.mp. or arthralgia.mp. or arthropath$.mp. or allergic OR allergy OR allergies {Including Related Terms} OR exp cerebellar ataxia/ or spinocerebellar ataxias/ or ataxia telangiectasia/ or machado-joseph disease/ or cerebellar ataxia$.mp. or cerebellar incoordination$.mp. or cerebellar dysmetria$.mp. or hypermetria$.mp. or adiadochokines$.mp. or cerebellar hemiataxia$.mp. or spinocerebellar ataxia$.mp. or spinocerebellar atrophy.mp. or ataxia telangiectasi$.mp. or machado-joseph.mp. or louis-bar syndrome.mp. or azorean disease.mp. OR exp myocardial infarction/ or exp stroke/ or exp death, sudden/ or cerebrovascular accident$.mp. or myocardial infarction$.mp. or heart attack$.mp. or stroke.mp. or sudden death.mp. or Seizures, febrile/ or convulsion/ or exp epilepsies, myoclonic/ or spasms, infantile/ or Myoclonus epilepsy/ or myoclonus seizure/ or myoclonus/ or convulsion$.ti,ab. or epileps$.mp. or spasm$.mp. or myoclon$.mp. or seizure$.mp. OR (((small fiber neuropath$ or oka vzv or oka varicella).mp. or ((varicella zoster virus.mp. or herpesvirus 3, human/) and (immunosuppres$ or immunocompromise$ or immunodeficien$).mp.) or disseminat$.mp.) adj3 oka.mp.) or exp brain disease/ or encephal$.mp. or encephalopath$.mp. or

brain inflammation.mp. or brain disease$.mp. or brain disorder$.mp. or exp encephalitis/ or exp encephalitis, viral/ OR (small fiber neuropath$ or oka vzv or oka varicella).mp. OR (varicella zoster virus.mp. or herpesvirus 3, human/) and (immunosuppres$ or immunocompromise$ or immunodeficien$).mp. OR (disseminat$ adj3 oka).mp. or exp brain disease/ or encephal$.mp. or encephalopath$.mp. or brain inflammation.mp. or brain disease$.mp. or brain disorder$.mp. or exp encephalitis/ or exp encephalitis, viral/ OR (frozen shoulder/ or exp bursitis/ or shoulder impingement syndrome/ or exp synovitis/ or frozen shoulder.mp. or bursitis.mp. or synovitis.mp. or synovitides.mp. or bursitides.mp. or (Adhesive capsulitis or adhesive capsulitides or periarthritis or periarthritides).mp. or (shoulder impingement or subacromial impingement).mp. or varicella.mp.) adj3 hepatitis.mp. OR frozen shoulder/ or exp bursitis/ or shoulder impingement syndrome/ or exp synovitis/ or frozen shoulder.mp. or bursitis.mp. or synovitis.mp. or synovitides.mp. or bursitides.mp.
16-(Adhesive capsulitis or adhesive capsulitides or periarthritis or periarthritides or (shoulder impingement or subacromial impingement)).mp. OR (varicella adj3 hepatitis).mp. OR (Meningitis or meningo$ or meningeal or arachnoiditis or meningitides or pachymeningitis or pachymeningitides).mp. or exp guillain-barre syndrome/ or myelitis, transverse.mp. or transverse myelitis.mp. or encephalomyelitis, acute disseminated/ or acute disseminated encephalomyelitis OR demyelinating.mp. or guillain barre.mp. or guillain-barre.mp. or fisher syndrome.mp. or fishers syndrome.mp. OR herpesvirus 3.mp. OR (vz adj2 virus).mp. OR ((varicella zoster virus or hhv-3 or ocular herpes zoster virus or chickenpox virus or herpesvirus varicellae) and (immunocompromis$ or immunosuppre$ or immunodeficien$)).mp. OR exp pneumonia/ or pneumonia.mp. or lung inflammation.mp. or pulmonary inflammation.mp. OR exp syncope/ or syncop$.mp. or fainting OR (vasovagal adj5 (collapse or attack or shock or reaction$)).mp. OR exp lupus erythematosus, systemic/ or systemic lupus erythematosus.mp. or libman-sacks.mp. or systemic lupus.mp. OR exp thrombocytopenia/ or hemolytic-uremic syndrome/ or jacobsen distal 11q deletion syndrome/ or jacobsen distal 11q deletion.mp. or purpura, thrombocytopenic/ or thrombocytopenia, neonatal alloimmune/ or thrombocytopen$.mp. or thrombopen$.mp. OR (ramsey-hunt or ramsey hunt or (hunt adj3 syndrome)).mp. OR ((bell$ adj2 palsy) or hemolytic-uremic syndrome or (spontaneous abort$ or congenital abnormal$)).mp. or abnormalities, congenital/ OR (Diabetes mellitus, type 1 or insulin dependent diabetes or insulin-dependent diabetes).mp. or (type 1 diabetes or type1 diabetes or juvenile onset diabetes or juvenile-onset diabetes).mp. or (iddm or brittle diabetes or autoimmune diabetes or ketosis-prone diabetes).mp. OR (tic OR tics).mp. OR uveitis OR narcolep$.mp. OR rheumatoid arthritis.mp. OR live adj3 varicella.mp. OR (herpes zoster).mp. OR ataxia OR polyarteritis nodosa/ or polyarteritis nodosa.mp. or periarteritis nodosa.mp. or essential polyarteritis.mp. or necrotizing arteritis.mp. or smallfiber neuropath$.mp. or small fiber neuropath$.mp. OR vasculitis.mp. OR thromboembolism$.mp. OR exp myocardial ischemia/ OR ischemic heart disease or "heart attack" or myocardial infarction or angina OR ankylosing spondylitis.mp. OR polymyalgia rheumatica.mp. OR fibromyalgia/ or fibromyalg$.mp. or fibrositis.mp. or fibrositides.mp. or "myofascial pain syndrome".mp. OR sudden infant death/ or sudden infant death$.mp. or sids.mp. or cot death.mp. or unexpected infant death.mp. OR serum sickness.mp.
NOT
Editorials

Appendix B. Data Abstraction Tools

Order

(vaccine safety study, effectiveness study which may have AE data, systematic review with more potential includes, useful mechanistic study,
useful background paper including vaccines and pregnancy reviews, risk factor study, other source of potential includes, not sure)

☐ Order (Stop)

Exclude- wrong vaccine

(not Influenza, Tetanus, Diphtheria, Pertussis, Varicella, Zoster, Human Papillomavirus / HPV, Measles, Mumps, rubella / MMR, Pneumococcal (polysaccharide), Meningococcal, Hepatitis A, Hepatitis B, Rotavirus, Haemophilus influenza type b / Hib, inactivated Polio vaccine)

☐ Exclude-vaccine

Exclude-no data

(opinion pieces, study with no comparator including case studies and case series, study not on vaccination at all, animal studies)

☐ Exclude-no data

Exclude-other

(not English-language, meeting/conference abstract, other issues)

☐ Exclude-other

Exclude - Article could not be obtained

Background:

- ☐ Very important background paper (REFERENCE MINE BELOW, HIT SUBMIT)
- ☐ Mechanistic study (REFERENCE MINE BELOW, HIT SUBMIT)

Excludes:

- ☐ Exclude-Participants (animal or in-vitro study) -
- ☐ Exclude-Outcome (no information on presence or absence of AE)
- ☐ Exclude-Language (not English)
- ☐ Exclude-Design, (no comparison of interest, case report, case series)
- ☐ Exclude-Other
- ☐ Exclude-Conference Abstract
- ☐ Exclude-Already included in IOM report
- ☐ Exclude- IOM exclusion

Needs Discussion (bring to meeting)

- ☐ ENTER REASON, THEN SUBMIT

- ☐ **Study of vaccine group vs. unvaccinated (or "routine vaccines") group (controlled trials, cohort studies comparing two groups)**
- ☐ **Multivariate risk factor study (simultaneously analyzing more than 1 risk factor), case-control study (people with AE versus not), and self controlled studies**

Vaccines
(Study with human participants)

- ☐ DTaP
- ☐ Haemoph. Influen. type b (Hib)
- ☐ Hepatitis A
- ☐ Hepatitis B

Human papillomavirus (HPV)

Influenza (inactived)

Influenza (live)

Measles, mumps, rubella (MMR)

Meningococcal conjugate

Meningococcal polysaccharide

Pneumococcal conjugate

Pneumococcal polysaccharide

Polio (inactivated only)

Rotavirus

Td

Tdap

Varicella

Zoster

None of the above (REJECT)

Population (check all that apply)
(Study with human participants)

☐ Children (under age 12)

Adolescents (12-18)

Adults

Elderly (65 and up)

Immunocompromised only

Pregnant

Calculated Exclusion (Vaccine and Population Combination)

○ Exclude - No Relevant Groups (STOP SCREENING, HIT SUBMIT)

Include - At least one relevant group

Vague: Vague Study with no information which adverse event was assessed ("safe," "no AE occurred")

☐ Vague

NOTES:

(i.e. where are the safety data if not in the results, special concerns):

Reference Mining:

☐ Which references should be ordered

Author/ Year	**N/ Population**	**Vaccines**	**Study Design**	**Selection bias**	**Attrition or non-response rate**	**Participation / Self-selection bias**	**Ascertainment of vaccination**	**Ascertainment of health outcome**	**Analysis Type**	**Statistical analysis of potential confounders**	**Period data collected**	**Study funder**	**Primary result regarding vaccine (s)**	**Results regarding risk factors**	**Comment**
Instructions	*Include sample size, location, age group, setting*	*List all analyzed*	*Retrospective cohort or Prospective cohort or Case control*	*Entire population? Or random sample? Or selected segment?*	*Lost to f/u, dropped out, etc*	*Do participants differ from non-participants?*	*Self-report, medical record, etc*	*Self-report, medical record, etc*	*cond. logistic regression etc*	*List all variables included in model*		*Usually listed at end of study*	*include 95% Confidence Interval, p value*	*if significant association, include 95% Confidence Interval, p value*	

Study Details & Participation Information

Country

Study Design (CHECK ONE)

- ○ Cohort study (comparing at least 2 cohorts)
- ○ Controlled clinical trial
- ○ Other (please specify)

Sample Size - Total

Length of follow-up

Mean Units

Range from to Units

Year study was conducted

to

Age

Mean Units

Range from to Units

Gender % Female

Pregnant Patients %

yes no

Trimester

First Second Third

Race and ethnicity (CHECK ALL THAT APPLY) %

White

Latino

Asian/PI

Black / African American

Native American

Other

Not reported

Medical Condition

- [ ] Asthma
- Cancer
- HIV
- Inflammatory Bowel Disease
- Lupus
- Multiple Sclerosis
- Premature babies
- Rheumatoid Arthritis
- Sickle Cell Anemia
- Transplant patients (Specific Type) [ ]
- Other 1 (Specify) [ ]
- Other 2 (Specify) [ ]
- None / not reported

Quality Assessment

McMaster Quality Assessment Scale for Harms (McHarm)	**RATING**
1. Were the harms PRE-DEFINED using standardized or precise definitions?	○ Yes No Unsure Clear Response
2. Were SERIOUS events precisely defined?	○ Yes No Unsure Clear Response
3. Were SEVERE events precisely defined?	○ Yes

McMaster Quality Assessment Scale for Harms (McHarm)	RATING
	No Unsure Clear Response
4. Were the number of DEATHS in each study group specified OR were the reason(s) for not specifying them given?	Yes No Unsure Clear Response
5. Was the mode of harms collection specified as ACTIVE?	Yes No Unsure Clear Response
6. Was the mode of harms collection specified as PASSIVE?	Yes No Unsure Clear Response
7. Did the study specify WHO collected the harms?	Yes No Unsure Clear Response
8. Did the study specify the TRAINING or BACKGROUND of who ascertained the harms?	Yes No Unsure Clear Response
9. Did the study specify the TIMING and FREQUENCY of collection of the harms?	Yes No

McMaster Quality Assessment Scale for Harms (McHarm)	RATING
	Unsure Clear Response
10. Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Yes No Unsure Clear Response
11. Did the authors specify if the harms reported encompass ALL the events collected or a selected SAMPLE?	Yes No Unsure Clear Response
12. Was the NUMBER of participants that withdrew or were lost to follow-up specified for each study group?	Yes No Unsure Clear Response
13. Was the TOTAL NUMBER of participants affected by harms specified for each study arm?	Yes No Unsure Clear Response
14. Did the author(s) specify the NUMBER for each TYPE of harmful event for each study group?	Yes No Unsure Clear Response
15. Did the author(s) specify the type of analyses undertaken for harms data?	Yes No

McMaster Quality Assessment Scale for Harms (McHarm) **RATING**

Unsure

Clear Response

Vaccine Group 1

Sample Size

Enter all that apply:

DTap

Haemoph. Influen. type b (Hib) protein conjugate

Hepatitis A

Hepatitis B

Human papillomavirus (HPV)

Influenza (inactived)

Influenza (live)

Influenza - monovalent H1N1

Measles, mumps, rubella (MMR)

Meningococcal conjugate

Meningococcal polysaccharide

Pneumococcal conjugate (PC7 vs PCV13)

Pneumococcal polysaccharide PSV23 – (23-valent polysaccharide vaccines)

Polio (inactivated only)

Rotavirus

RotaTeq (RVS)

Rotarix (RV1) (also known as RIX4414)

Td

Tdap

Varicella

Zoster

Routine Vaccines

Other Vaccine (please specify)

Brand Name(s)

Manufacturer

Age

Units

to

Formulation

Dose 1 *Timing* *Units* *Dosage* *Units*

Dose 2 *Timing* *Units* *Dosage* *Units*

Dose 3 *Timing* *Units* *Dosage* *Units*

Dose 4 *Timing* *Units* *Dosage* *Units*

Dose 5 *Timing* *Units* *Dosage* *Units*

Adjuvants

- ☐ ASO 4
- Aluminum
- Adjuvant Free
- Not reported
- Other

Preservatives

- ☐ Thimerisol
- Phenol
- Preservative Free
- Not reported
- Other

Delivery route

- ☐ Intradermal
- Intramuscular
- Intravenous

☐ Intranasal

Oral

Other (please specify)

Adverse Events

Adverse Event	#	%	System Category	Severity
# of patients with any AE				
Any Severe Adverse Event				

Adverse Event	#	%	System Category	Severity

Vaccine Group 2

Sample Size

Enter all that apply:

- ☐ DTap
- ☐ Haemoph. Influen. type b (Hib) protein conjugate
- ☐ Hepatitis A
- ☐ Hepatitis B
- ☐ Human papillomavirus (HPV)
- ☐ Influenza (inactived)
- ☐ Influenza (live)
- ☐ Influenza - monovalent H1N1
- ☐ Measles, mumps, rubella (MMR)

☐ Meningococcal conjugate

☐ Meningococcal polysaccharide

☐ Pneumococcal conjugate (PC7 vs PCV13)

☐ Pneumococcal polysaccharide PSV23 – (23-valent polysaccharide vaccines)

☐ Polio (inactivated only)

☐ Rotavirus

RotaTeq (RVS)

Rotarix (RV1) (also known as RIX4414)

☐ Td

☐ Tdap

☐ Varicella

☐ Zoster

☐ Routine Vaccines

☐ Other Vaccine (please specify)

Brand Name(s)

Manufacturer

Age

Units

to

Formulation

Dose 1 *Timing* *Units* *Dosage* *Units*

Dose 2 *Timing* *Units* *Dosage* *Units*

Dose 3 *Timing* *Units* *Dosage* *Units*

Dose 4 *Timing* *Units* *Dosage* *Units*

Dose 5 *Timing* *Units* *Dosage* *Units*

Adjuvants

- ☐ ASO 4
- ☐ Aluminum
- ☐ Adjuvant Free
- ☐ No reported
- ☐ Other

Preservatives

- ☐ Thimerisol
- ☐ Phenol
- ☐ Preservative Free

- ☐ Not reported
- ☐ Other

Delivery route

- ☐ Intradermal
- ☐ Intramuscular
- ☐ Intravenous
- ☐ Intranasal
- ☐ Oral
- ☐ Other (please specify) _____

Adverse Events

Adverse Event	#	%	System Category	Severity
# of patients with any AE				
Any Severe Adverse Event				

Adverse Event	#	%	System Category	Severity

Vaccine Group 3

Sample Size

Enter all that apply:

☐ DTap

☐ Haemoph. Influen. type b (Hib) protein conjugate

☐ Hepatitis A

☐ Hepatitis B

☐ Human papillomavirus (HPV)

☐ Influenza (inactived)

☐ Influenza (live)

☐ Influenza - monovalent H1N1

☐ Measles, mumps, rubella (MMR)

☐ Meningococcal conjugate

☐ Meningococcal polysaccharide

☐ Pneumococcal conjugate (PC7 vs PCV13)

☐ Pneumococcal polysaccharide PSV23 – (23-valent polysaccharide vaccines)

☐ Polio (inactivated only)

☐ Rotavirus

RotaTeq (RVS)

Rotarix (RV1) (also known as RIX4414)

☐ Td

☐ Tdap

☐ Varicella

☐ Zoster

☐ Routine Vaccines

☐ Other Vaccine (please specify)

Brand Name(s)

Manufacturer

Age

Units

to

Formulation

Dose 1	*Timing*	*Units*	*Dosage*	*Units*
Dose 2	*Timing*	*Units*	*Dosage*	*Units*
Dose 3	*Timing*	*Units*	*Dosage*	*Units*
Dose 4	*Timing*	*Units*	*Dosage*	*Units*
Dose 5	*Timing*	*Units*	*Dosage*	*Units*

Adjuvants

- ☐ ASO 4
- ☐ Aluminum

- ☐ Adjuvant Free
- ☐ No reported
- ☐ Other

Preservatives

- ☐ Thimerisol
- ☐ Phenol
- ☐ Preservative Free
- ☐ Not reported
- ☐ Other

Delivery route

- ☐ Intradermal
- ☐ Intramuscular
- ☐ Intravenous
- ☐ Intranasal
- ☐ Oral
- ☐ Other (please specify) _____

Adverse Events

Adverse Event	#	%	System Category	Severity
# of patients with any AE				
Any Severe Adverse Event				

Adverse Event	#	%	System Category	Severity

"Unvaccinated" Comparison Group

Sample Size

☐ Placebo

☐ Routine Vaccines

☐ Nothing

☐ Other (please specify)

If Placebo, does it include the same adjuvants, preservatives, formulations as the active group?

☐ Yes

☐ No

(if no, please specify)

☐ Unsure

Adverse Events

Adverse Event	#	%	System Category	Severity
# of patients with any AE				
Any Severe Adverse Event				

Adverse Event	#	%	System Category	Severity

COMMENTS / NOTES:

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Baxter, 2012, Retro-spective cohort[64]	Sample size: 60,996; Location: US; Age: 18-49; Setting: Kaiser Permanente Managed Care Health Plans	Ann Arbor Strain LAIV	Through Kaiser Permanente's immunization registries, approximately 20,000 individuals 18–49 years of age who were immunized from the 2003–2004 to 2007–2008 influenza seasons with LAIV as part of routine clinical practice were identified.	Not discussed	These were partici-pants of a health plan (i.e. insured).	Medical record	Medical records, healthcare utilization database	Cox proportional hazards model	Adjusted for: Matching factors, seasonal changes in background rates.	2003-2008	MedImmune	The rate of hospitalization or death due to any condition within 180 days of vaccination with LAIV was lower than with TIV (1.46 vs 9.10; p < 0.01) or no vaccine (1.46 vs 3.36; p < 0.01). The incidence rate for any serious adverse event (SAE) within 21 days and 42 days of vaccination with LAIV was lower compared to no vaccination.	NR	
Eder et al. 2011, Case-control[89]	N=318 (159 Cases, 159 Controls); Location=Toronto; Age=Case/control, Mean (SD): 44.9 (13.1)/48.4 (13.3); Setting= Cases taken from University of Toronto Psoriatic	Hepatitis A and B, influenza, pneumo-coccus	Cases and controls selected from different populations. Cases were from a clinic-based group (PsA cohort), while controls were from another cohort of non-arthritic	No attrition mentioned. In terms of recruitment, 190 PsA patients (cases) were identified, authors were unable to contact 29 (6 deceased), and 2 were excluded due to poor English	Study did not note whether participants differed from nonparticipants.	Self-report through question-naire.	Clinical data were available from the cohorts' computerized databases.	Logistic regression	Age, sex, duration and severity of psoriasis, and level of education.	Not given	Krembil Foundation, Arthritis Society Spondy-loarthritis Research Consortium of Canada National Research Initiative. Dr. Eder's work was supported by a fellowship	OR (95% CI) of PsA: Hepatitis A: 0.70 (0.14–2.99), p=0.58 Hepatitis B: 1.50 (0.76–2.81), p=0.25 Pneumococcus: 1.40 (0.75–2.72), p=0.28 Flu: 1.0 (0.58–1.57), p=0.87	Not given	Recall bias was a concern; those with arthritis may show higher recall of triggers. By approaching patients with a recent onset of

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	Toronto Psoriasis Cohort		minimize selection bias, psoriasis patients were recruited from several sources: dermatology clinics at Toronto Western Hospital and Women's College Hospital, community dermatologists, family medicine clinics in Toronto, and the general public in the greater Toronto area by advertising in local newspapers. " However there are no details given for the recruitment of the two cohorts to determine if systematic biases resulted in non-comparable populations.	(83.6%) were included in the study. 196 patients with psoriasis (controls) were approached for enrollment, of whom 159 (81.1%) completed the questionnaire.							by an Abbott Psoriatic Arthritis Fellowship. Ms. Law's work was supported by a scholarship from the Canadian Arthritis Network. Dr. Chandran's work was supported by a Canadian Institutes of Health Research and Krembil Foundation.			short interval from the onset of PsA of approximately 3 years. Authors avoided linking environmental exposures and arthritis in the questionnaire, and requested information about events that occurred in the past 10 years. They also assessed recall bias by comparing reported information about exposure to infections and injuries with available data from a computeri

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
														zed database that stores medical records from 6 medical centers and outpatient clinics. The aim was to assess whether there has been underrep orting of events by psoriasis patients. Overall, 3 of 3 patients with psoriasis reported a previous injury and 0 of 2 reported an infection. In the PsA group, only 1 of 3 reported an injury and 1 of 6 reported an infection. Therefore,

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
														although these figures are small, it seems that recall bias is not a threat to the validity of the study, as the rates of reporting were not lower in the psoriasis group."
Yu et al. 2007, Case-control[91]	N=1,875 (355 Graves' disease cases, 418 Hashimoto's thyroiditis cases, 1,102 controls); Location=Vaccine Safety Datalink Project: Group Health Cooperative, Seattle, WA; Northwest Kaiser Permanente, Portland, OR; and Kaiser Permanente of Northern California, Oakland, CA; Age=18–69 years;	Hepatitis B vaccine, influenza, MMR, Hepatitis A, polio	Potential for those with disease to be more likely to receive vaccination or more likely to be assessed for vaccination. Also possible recall bias and exposure mis-classification. Authors noted that case groups may have included some subjects with thyroid conditions other than	None	Not discussed	Vaccine information was collected from administra-tive immunization records, chart review, and telephone interviews with study subjects.	Medical record review. Identified cases of Graves' disease and Hashimoto's thyroiditis on the basis of International Classification of Diseases, Ninth Revision (ICD-9) codes for thyroid disease, associated with inpatient	Logistic regression	Controls were frequency-matched to cases by birth year, sex, and study site (HMO) All models adjusted for frequency-matching variables (age groups, sex, site, and index year), personal and family history of autoimmune disease, smoking status, race, and education.	January 1, 1999 through June 30, 2002	ID Biomedical, Chiron Therapeutics and Vaccines, and Sanofi Pasteur; Study supported by the Vaccine Safety Datalink contract with America's Health Insurance Plans, funded by the CDC.	OR (95% CI) for Graves' disease Main analysis Hepatitis B: 0.90 (0.62–1.32) Influenza: 1.07 (0.80–1.42) MMR: 0.59 (0.29–1.20) Hepatitis A: 0.70 (0.43–1.13) Polio: 1.29 (0.76–2.17) OR (95% CI) for Hashimoto's thyroiditis Main analysis Hepatitis B: 1.23 (0.87–1.73) Influenza: 1.15 (0.89–1.48) MMR: 1.50 (0.79–2.86) Hepatitis A: 0.97 (0.64–1.46)	Not given	

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	Setting= Three health maintenance organizations (HMOs)		Graves' disease or Hashimoto's thyroiditis.				and outpatient medical encounters that were recorded in HMO administrat ive data systems.					Polio: 1.17 (0.73–1.86)		
Duderstadt et al. 2012, Retrospecti ve cohort[90]	N=2,385,102 active military personnel, including 1,074 cases of type 1 diabetes; Location=US; Age=17-35 years;	Hepatitis B, MMR, smallpox, typhoid, yellow fever	Entire population of Defense Medical Surveillance System. A total of 17,874 were excluded; if these exclusions differed systematicall y from those included, bias would be introduced into the study.	Not applicable	Not discussed	Defense Medical Surveillance System	Defense Medical Surveillanc e System	Poisson regression	Receipt of multiple vaccines, age, race, sex, service branch, military grade, occupation, deployment, and calendar year.	January 1 2002 to December 31 2008	Department of Defense	Risk Ratios for Diabetes Type 1 Hepatitis B: 0.83 (0.72, 0.95) MMR: 0.71 (0.61, 0.83)	Not given	
Gwini et al. 2011, Self-controlled case series[58]	N=8,180 cases of first acute myocardial infarction; Location=UK; Age=>=40 years;	Influenza	Population of study may differ from population as a whole in systematic ways that decrease generalizabil ity.	None	Not discussed	General Practice Research Database (GPRD)	General Practice Research Database (GPRD)	Conditional Poisson regression	Seasonality	2002-2007	Research for Patient Benefit Program of the National Institute for Health Research, United Kingdom.	Incidence Rate Ratio Post-vaccination intervals 1-14 days: 0.68 (0.6–0.78) 15-28 days: 0.75 (0.66–0.86) 29-59 days: 0.82 (0.75–0.90) 60-90 days: 0.96 (0.87–1.07) 91-120 days: 0.98 (0.89–1.09)		

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												121-180 days: 1.02 (0.95–1.10)		
Hambidge et al. 2011, Self-controlled case series[60]	N=348 adults with sickle cell disease in 8 MCOs in the US; (Vaccine Safety Datalink (VSD) cohort)	Influenza	Unclear about differences between sites in population selection, case and exposure ascertainment; differences between cases and other populations (e.g., cases may have been more likely to be vaccinated).	Not discussed	Not discussed	Medical record	Medical record	Conditional Poisson regression	Stratification by sex and age, adjustment for month within season.	1991-2006	Centers for Disease Control and Prevention	Incidence rate ratios for sickle cell hospitalization All: 0.92 (0.66, 1.28), p=0.6	Males: 1.00 (0.59, 1.72), p=1.0 Females: 0.87 (0.57, 1.31), p=0.5 18-49 yrs: 0.84 (0.57, 1.22), p=0.8 50-64 yrs: 1.51 (0.72, 3.18), p=0.3 >=65 yrs: 0.94 (0.10, 8.55), p=1.0	
Hurst et al. 2011, Retrospective cohort[62]	N=51,730 adult Medicare patients with renal transplant; Location=US; Age=>=65 years;	Influenza	Entire population	Not discussed	Not discussed	Medicare claims data	US Renal Data System (RDS) record review	Cox non-proportional hazards regression	Factors known to be independently associated with allograft loss (recipient age, black race, PRA 20%, dialysis vintage, diabetes	2000-2006	Not specified	Vaccination in the first year after transplant was associated with lower risk of subsequent allograft loss and death.	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	9,678 had claims for influenza vaccine in the first year post transplant.								mellitus, congestive heart failure, ischemic heart disease, tobacco use, HLA matching, donor age of 50 years, donor black race, deceased-donor transplant, expanded criteria donor, delayed graft function, cold ischemic time of 24 hours, year of transplant, and induction/discharge immunosuppression). Others not specified for the relevant model but could include: older age, diabetes, later year of transplant, and tacrolimus or mycophenolate at discharge.			Adjusted hazard ratio Allograft loss: 0.77 (0.69-0.85), p=0.001 Death: 0.82 (0.76-0.89), p=0.001 Acute rejection in the first year was not associated with vaccination in the first 6 or 12 months after transplant. Adjusted odds ratio Rejection in first 6 mo: 1.00 (0.88-1.14), p=0.965 Rejection in first 12 mo: 0.97 (0.89-1.07), p=0.569		
Ting et al. 2011, Retrospective matched cohort (each pair included 1 vaccinated and 1 non-vaccinated COPD	586 patients with moderate to severe COPD identified in COPD Registers of 6 general practices in North Derbyshire	Influenza	Entire population of COPD patients in these 6-practices.	Not discussed	Not discussed	Medical record	Medical record (spirometry records)	McNemar's test	Controlled for environmental factors (weather, prevalence of respiratory viral pathogens).	10/2005-12/2005	NR	In the 14 days following vaccination, the control group had 21 COPD exacerbations cf. 11 in the vaccinated group (McNemar's p=0.11, not significant; OR		Study did NOT look at exacerbations by COPD stage or other risk factors.

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
patient)[63]	UK. Age range 37-89 (median 68)											0.52 [95% CI 0.29, 1.14]).		
Farez et al. 2012, Self-controlled case series[53]	N=137 Multiple Sclerosis patients; Location=Argentina; Age=37 +/-8 years (mean)	Influenza (monoval-ent Focetria, Novartis SRL, Italy or trivalent Istivac, Sanofi Pasteur, France).	Bias if cases differed from the general population in systematic ways (e.g., more or less likely to be vaccinated, doctors more likely to recommend vaccinations).	161 relapsing–remitting MS patients were identified from the database. 23 patients refused to participate and 2 had received other immunizations, leaving 137.	Study notes patients excluded did not differ significantly from those included.	Self-report	Database review	Poisson regression model	None given	1 January and 31 December 2010	Raul Carrea Institute for Neurological Research	30-day risk period: 0.86 (95% CI 0.20–3.62, p=0.836) 60-day risk period: 0.61 (95% CI 0.18–2.02, p=0.419) 90-day risk period: 0.51 (95% CI 0.18–1.47, p=0.211)	Not given	
Hedlund et al. 2003, Prospective cohort[87]	N=100,242; Location= Stockholm County, Sweden; Age=>=65 years; Setting=All individuals in Stockholm County aged 65 years or older were invited to take part in a vaccination campaign against influenza and pneumococcal infection	Influenza and 23-valent pneumococcal vaccine (PV)	No randomization - vaccinated group may differ systematically in some fashion that makes them more likely to show adverse (or non-adverse) effects that are not related to the vaccine.	Not discussed	Not discussed	Department of Communicable Disease Control and Prevention for Stockholm County Database	Data on discharge diagnoses and mortality were obtained from the administrative database of Stockholm County Council.	Poisson regression	Age and gender	1998-1999	Financial supportfor this study was received from The Stockholm City Council, The Swedish Heart-Lung Foundation, The Swedish Society of Medicine, and Karolinska Institute.	Hospital admissions/100 000 individuals between 1 December 1998 and 30 November 1999 Influenza 0.68 (0.53-0.88), p=0.002 Pneumonia 0.78 (0.71-0.86), p=<0.0001 IPD: 0.46 (0.25-0.87), p=0.007 COPD: 1.04 (0.92-1.17), p=0.55 Cardiac failure: 0.95 (0.87-1.05), p=0.34	None	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	during 3 consecutive years, 1998–2000.											In-hospital mortality due to investigated diagnoses/100 000 individuals between 1 December 1998 and 30 November 1999 Influenza 1.20 (0.39-3.70), p=0.75 Pneumonia 0.55 (0.43-0.71), p=<0.0001 IPD: 0.53 (0.06-5.10), p=0.58 COPD: 0.53 (0.29-0.98), p=0.034 Cardiac failure: 0.72 (0.59-0.87), p=0.0007 Hospital admissions/100 000 individuals per year between 1 December 1998 and 31 May 1999 Influenza: 0.66 (0.52-0.82), p=0.0002 Pneumonia: 0.72 (0.65-0.79), p=<0.0001 IPD: 0.47 (0.24-0.93), p=0.02 COPD: 1.07 (0.94-1.23), p=0.32 Cardiac failure: 0.90 (0.80-1.01), p=0.08 Hospital admissions/100		

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												000 individuals per year between 1 June and 30 November 1999 Influenza: 1.36 (0.58-3.17), p=0.48 Pneumonia: 0.88 (0.77-1.00), p=0.05 IPD: 0.45 (0.15-1.32), p=0.20 COPD: 1.00 (0.87-1.15), p=0.98 Cardiac failure: 1.02 (0.93-1.11), p=0.69		
Garbe et al. 2012, Case-control[59]	N=1,200 (outpatient + inpatient). Influenza results presented just for outpatients where N=861; Location= Berlin, Germany; Age=18-92; Setting=Berlin hospitals, hematological practices, and laboratories.	Influenza vaccine (Pneumococcal and poliomyelitis vaccine also assessed as causing 1 case each but ORs were not given.)	Cases and controls selected from the same hospitals using the same general procedures for interviews reducing the chance of selection bias occurring. Vaccines were not the only drugs study was interested in so diagnostic or surveillance biases lessened. Exposure	None	Study did not address	Self-report through face-to-face interviews and physician-provided information.	Patients with ITP were identified through regular active inquiry in 2- to 3-week intervals in hospitals, hematological practices and laboratories. Diagnosis was additionally based on a face-to-face interview and physician-provided informatio	Unconditional logistic regression	Model 1: age and sex ("single drug assessment"). Model 2: age, sex and all drugs that were significant in the single drug assessment ("joint drug assessment").	October 2000 until March 2009	Cases were collected within the study "Berlin Case–Control Surveillance (FAKOS) of Serious Blood Dyscrasias," which was supported by a grant from the Federal Institute for Drugs and Medical Devices (Bonn, Germany).	OR (95% CI) of ITP Influenza, outpatient cases and controls: Model 1: 3.8 (1.5–9.1) Model 2: 4.0 (1.5–9.6)	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
			misclassification was a minor concern because drug exposures were assessed 1 week before the index date.				n. An advisory board assessed ambiguous cases.							
Grimaldi-Bensouda et al. 2011, Prospective case-control[52]	N=1225; Location=France; Age=Cases/Controls, Mean (SD): 48.6 (18.0)/50.7 (18.1); Setting=Cases drawn from all university and major regional hospital centers in metropolitan France known to have a large neurology clinic and centers treating neurologic disease in children; Controls from registry of general practice patients across France.	Influenza vaccines (seasonal and A/H1N1)	Hospital-based cases and controls from general practitioner lists. Diagnostic and surveillance approaches may differ such that hospital cases may have had better ascertainment of risk factors. Authors note that exposure misclassification may have occurred.	None	Not discussed	Self-report and objective confirmation obtained in a sample of 40% of cases and controls for the seasonal vaccination. The proportion was raised to 100% during the A/H1N1 vaccination program. Confirmation included copies of vaccination sheets, certificates, and other documentation.	A neurologist completed a detailed medical form - cases ascertained using an algorithm considering clinical, electrophysiologic, and cerebrospinal fluid data. Borderline cases were reviewed by independent and blinded experts	Conditional logistic regression	Cases/controls matched by age, gender, index date (calendar month), and region. Receipt of other vaccines during the same time window, receipt of influenza vaccine in the past (before the time window considered), family history of autoimmune diseases, number of physician consultations in the previous year (0–2, 3–6, 7–12, or >=13), antibiotic or antiviral treatment in the previous 2 months, use of antipyretic agents in the previous 2	March 2007 and June 2010. For the influenza A/H1N1 vaccine, analysis was restricted to the GBS cases that had occurred from commencement of the French national vaccination program on October 20, 2009, to 6 weeks after the end of the vaccination campaign on March 31, 2010.	LA-SER, GSK Biologicals, and Sanofi-Pasteur	All influenza vaccines (A/H1N1 + seasonal) First 6 weeks: 1.22 (0.45-3.32) 7 weeks to 3 months: 0.66 (0.27-1.65) 4 months to 6 months: 0.80 (0.34-1.88) Seasonal influenza vaccine only First 6 weeks: 1.30 (0.41-4.12) 7 weeks to 3 months: 0.60 (0.23-1.60) 4 months to 6 months: 0.69 (0.29-1.66) Influenza A/H1N1 vaccine only First 6 weeks: 0.92 (0.11-7.55) 7 weeks to 3 months: 1.08 (0.09-13.15)	Not given	

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
									months.					
Johnstone et al. 2012, Prospective cohort[57]	N=31,546; Location=40 countries; Setting=Participants in the ONTARGET /TRANSCEND trials: at least 55 years old and a history of vascular disease or diabetes with document end-organ damage.	Influenza, pneumococcal	Difficult to determine without more details on the original studies through which population drawn from.	In total, 99.8% of participants were followed up until the primary outcome occurred or the end of study.	Not discussed	Self-report	All study outcomes were prospectively adjudicated by a central committee blinded to study medication allocation and influenza vaccination status with the use of standardized criteria.	Logistic regression	Adjusted by propensity score for influenza vaccination (body mass index, age, sex, ethnicity, education, vitamin use, smoking history, alcohol use, history of pneumococcal vaccination), history of coronary artery disease, diabetes mellitus, hypertension, stroke, admission to a nursing home, or use of aspirin, beta-blocker, lipid-lowering drug, angiotensin-converting enzyme inhibitor, or angiotensin II inhibitor.	2004 to 2007	This study was supported by a grant from Boehringer Ingelheim. Dr Yusuf was supported by the Heart and Stroke Foundation of Ontario and a Senior Scientist Award from the Canadian Institutes of Health Research (CIHR). Dr Johnstone receives salary support from CIHR. Dr Loeb holds the Michael G. DeGroote Chair in Infectious Diseases at McMaster University.	Association Between Influenza Vaccination and Risk of Major Adverse Vascular Events During the Influenza Season. Cohort 2003-2004: 0.96 (0.73–1.27), p=0.79 2004-2005: 0.62 (0.50–0.77), p=<0.0001 2005-2006: 0.69 (0.53–0.91), p=0.009 2006-2007: 0.52 (0.42–0.65), p=<0.0001 Association Between Influenza Vaccination and Risk of the Major Adverse Vascular Events During the Non-influenza Season Cohort 2003-2004: 0.81	Not given	There was no association between pneumococcal vaccination and the primary outcome during any of the influenza seasons.

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												(0.61–1.09), p=0.16 2004-2005: 0.64 (0.50–0.83), p=0.0005 2005-2006: 0.74 (0.56–0.98), p=0.04 2006-2007: 0.50 (0.38–0.67), p=<0.0001 Association Between Influenza Vaccination and Risk of Non-cardiovascular Death During the Influenza Season Cohort 2004-2005 Non-cardiovascular deaths: 0.26 (0.16–0.40), p=<0.0001 Cancer deaths: 0.20 (0.10–0.39), p=<0.0001 Deaths resulting from other causes: 0.33 (0.18–0.60), p=0.0004 2005–2006 Non-cardiovascular deaths: 0.21 (0.10–0.46), p=0.0001 Cancer deaths: 0.27 (0.10–0.69), p=0.0065		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												Deaths resulting from other causes: 0.14 (0.03–0.58), p=0.0070 2006-2007 Non-cardiovascular deaths: 0.27 (0.18–0.41), p=<0.0001 Cancer deaths: 0.17 (0.10–0.31), p=<0.0001 Deaths resulting from other causes: 0.47 (0.25–0.86), p=0.0137		
Smeeth et al. 2004, Self-controlled case-series[55]	N=20,486 adults with first MI and 19,063 with first stroke who received influenza immunization in UK.	Influenza, pneumococcal	Bias if cases differed from the general population in systematic ways (e.g., more or less likely to be vaccinated, doctors more likely to recommend vaccinations).	Aside from initial exclusions, none	Not discussed	General Practice Research Database	General Practice Research Database	Relative incidence estimation	Age	1987 to 2001	A grant from the British Heart Foundation; a Medical Research Council Clinician Scientist Fellowship; and a Wellcome Trust Advanced Fellowship.	Incidence ratios of first disease incidence Influenza Myocardial Infarction 1-3 days: 0.75 (0.60–0.94) 4-7 days: 0.68 (0.56–0.84) 8-14 days: 0.73 (0.63–0.85) 15-28 days: 0.87 (0.79–0.96) 29-91 days: 1.03 (0.98–1.08) Stroke 1-3 days: 0.77 (0.61–0.96) 4-7 days: 0.72 (0.59–0.88) 8-14 days: 0.84 (0.73–0.96) 15-28 days: 0.88 (0.80–0.97)	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												29-91 days: 1.01 (0.96–1.06) Pneumococcal Myocardial Infarction 1-3 days: 0.49 (0.19–1.32) 4-7 days: 1.11 (0.63–1.96) 8-14 days: 1.22 (0.81–1.84) 15-28 days: 1.15 (0.85–1.55) 29-91 days: 1.10 (0.95–1.28) Stroke 1-3 days: 1.29 (0.67–2.49) 4-7 days: 1.08 (0.58–2.01) 8-14 days: 1.18 (0.75–1.85) 15-28 days: 0.90 (0.63–1.30) 29-91 days: 1.15 (0.98–1.35) Incidence ratios recurrent disease event Influenza Myocardial Infarction 1-3 days: 0.34 (0.19–0.61) 4-7 days: 0.77 (0.55–1.09) 8-14 days: 0.93 (0.73–1.18) 15-28 days: 0.97 (0.82–1.16) 29-91 days: 0.97 (0.88–1.06) Stroke 1-3 days: 0.56 (0.35–0.89)		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												4-7 days: 0.74 (0.52–1.05) 8-14 days: 0.72 (0.55–0.94) 15-28 days: 0.69 (0.57–0.85) 29-91 days: 0.79 (0.71–0.87) Pneumococcal Myocardial Infarction 1-3 days: 0.70 (0.18–2.81) 4-7 days: 0.53 (0.13–2.10) 8-14 days: 1.34 (0.69–2.60) 15-28 days: 1.05 (0.62–1.79) 29-91 days: 1.42 (1.12–1.79) Stroke 1-3 days: 1.01 (0.25–4.04) 4-7 days: 1.13 (0.36–3.52) 8-14 days: 0.64 (0.21–2.00) 15-28 days: 1.06 (0.57–2.00) 29-91 days: 0.99 (0.72–1.35)		
Siriwardena et al. 2010, Matched case-control[56]	N=78,706 (16,012 cases of myocardial infarction (MI), 62,964 controls); Location=UK; Age=40 to >=65; Setting=United Kingdom General Practice	Influenza; pneumococcal (study didn't specify types)	Possible biases in that those with risk factor for outcome may be more likely to be vaccinated, but confounders related to this were	Regression analyses dropped some participants due to missing data on risk factors such as smoking.	Not discussed	Data were extracted from the GPRD (assume by researchers). Virtually all patients in the database are registered with a general	Data were extracted from the GPRD (assume by researchers). Cases were at least 40 years at the time of first acute myocardial	Conditional logistic regression	Model 1 adjusted for asthma or chronic obstructive pulmonary disease, chronic heart disease, stroke or transient ischemic attack, diabetes, splenectomy, chronic liver	Cases identified from incident occurring between Nov.1, 2001, to May 31, 2007.	This study was supported by funding from the Research for Patient Benefit Program of the National Institute for Health Research, United	OR (95% CI) of acute MI Influenza vaccination within previous year: Model 1: 0.81 (0.77-0.85), p<0.001 Model 2: 0.83 (0.80–0.88) Pneumococcal	None given, but subgroup results shows for the following categories: Influenz	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	Research Database (GPRD), an extensively validated computerized database, representativ e of and comprising 5% of the population of England and Wales.		controlled for in multivariate analyses.			practitioner, and all health care attendances are recorded in the database. The database contains anonymized patient data that includes demographic information, diagnoses, medication, health-related behaviors, referrals and treatment outcomes. Influenza vaccination was defined as vaccination given in the year preceding the index date. Other exposures to influenza vaccination considered were influenza vaccination within the current vaccination season and early (i.e.,	infarction (fatal or nonfatal) had clinical records for over five and a half years (between Nov. 1, 2001, to May 31, 2007) and were identified using standardize d (Read and Oxford Medical Informatio n Systems [OXMIS]) codes.		disease, chronic renal failure, immunosuppres sion and HIV, hyperlipidemia, family history of acute myocardial infarction, peripheral vascular disease, hypertension, smoking status, treatment with acetylsalicylic acid, treatment with statins, treatment with antihypertensive s, and general practice consultations. Each type of vaccination was adjusted for the other type. Second set of models (Model 2) adjusted for all of the above variables as well as for body mass index, systolic blood pressure and total cholesterol using 10 multiply imputed data sets. (Systolic blood pressure, body mass index, and total cholesterol were not included in the main adjusted		Kingdom.	vaccination within previous year: Model 1: 0.96 (0.91–1.02) Model 2: 0.98 (0.93-1.04) Pneumococcal vaccination results included in Appendix (www.cmaj.ca/cgi/content/full/cmaj.091891/DC1)	a Vaccination in preceding yr: < 65 yr: Model 1: 0.81 (0.73–0.90) Model 2: 0.83 (0.75–0.92) ≥ 65 yr: Model 1: 0.79 (0.75–0.83) Model 2: 0.82 (0.78–0.86) Time since last vaccination at index date, months: 0–3 months: Model 1: 0.80 (0.74–0.86) Model 2: 0.84 (0.80–0.94) 3–6 months: Model 1:	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
						between Sept. 1 and Nov. 15) or late vaccination (i.e., between Nov. 16 and Feb. 28 or 29, depending on the year). Patients were considered to have had a pneumococcal vaccination if they had ever received the pneumococcal vaccine before the index date. Combined vaccination was defined as pneumococcal vaccination ever combined with influenza vaccination in the year preceding the index date.			analyses owing to missing data (63%, 45% and 15% completeness respectively). Matched case-control, matched for: age, sex, general practice attended and calendar time (i.e., month corresponding to index date of acute myocardial infarction).				0.82 (0.76–0.89) Model 2: 0.86 (0.85–0.99) 6–12 months: Model 1: 0.87 (0.81–0.94) Model 2: 0.91 (1.06–1.24) 12–60 months: Model 1: 1.12 (1.03–1.21) Model 2: 1.15 (0.88–1.20) ≥ 60 months: Model 1: 0.96 (0.82–1.13) Model 2: 1.03 Within-season vaccination Yes: Model 1: 0.80 (0.76–0.84)	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
													Model 2: 0.83 (0.79–0.87) Early within-season (Sept. to mid-Nov.): Model 1: 0.79 (0.75–0.83) Model 2: 0.82 (0.78–0.86) Late within-season (mid-Nov. to Feb.): Model 1: 0.88 (0.79–0.97) Model 2: 0.90 (0.82–1.00) Vaccination in previous yr, by month of index date: Sept. to Nov.: Model 1: 0.75 (0.68–0.83)	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
													Model 2: 0.77 (0.70–0.85) Dec. to Mar.: Model 1: 0.86 (0.79–0.93) Model 2: 0.88 (0.82–0.95) Apr. to Aug.: Model 1: 0.80 (0.73–0.86) Model 2: 0.84 (0.77–0.90) Pneumo coccal < 65: Model 1: 0.83 (0.73–0.95) Model 2: 0.91 (0.79–1.05) ≥ 65: Model 1: 0.88 (0.83–0.93) Model 2: 0.97 (0.91–	

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
													1.03)	
Uno et al. 2012, Case-control[88]	N=413 (189 ASD cases, 224 controls); Location=Kanto area, Japan; Age=22.6 years (mean); Setting=Cases were patients of the Yokohama Psycho-Developmental Clinic (YPDC). Controls were volunteers from area schools.	MMR, diphtheria–pertussis–tetanus vaccine (DPT); the polio vaccine. Study did not specify whether DPT was acellular and did not specify whether polio was inactivated. Only MMR was included in controlled analyses.	Selected segment - Kanto, Japan. Also, cases were patients of psycho-developmental clinic (may differ from cases that don't go to clinic).	89 of 1875 cases excluded because missing vaccine records. Additional 3 excluded because received vaccines overseas. 1429 cases born before 3/84 or after 5/92, leaving 354 cases. 189 cases could be matched to a control.	Not reported	Study notes that "vaccination history collected based on the MCH handbook, which was routinely attached to each patient's file, were examined." Study did not note exactly who did the examining, but I assume it was the researchers.	Patients were diagnosed based on the (DSM-IV) and standardized criteria using the Diagnostic Interview for Social and Communication Disorder (DISCO). Another child psychiatrist or clinical psychologist conducted intellectual or developmental tests, such as the Psycho-Educational Profile-Revised and Wechsler Intelligence	Conditional logistic regression	Maternal hypertension, low Apgar score, obstetrical vacuum extraction or forceps delivery. (Table 4 displays results with control variables. Tables 1-3 display crude ORs. Authors only controlled for those risk factors that displayed high crude ORs.) Cases/controls matched by sex and year of birth.	Study doesn't note when researchers collected data, but the universe of eligible participants included patients visiting the clinic between April 1997 (when the clinic opened) and March 2011.	A part of the study is the result of research grants from the Ministry of Health, Labor and Welfare of Japan, and "Integrated research on neuropsychiatric disorders" carried out under the Strategic Research Program for Brain Sciences by the Ministry of Education, Culture, Sports, Science and Technology of Japan.	MMR: 1.10 (0.64–1.90), p=0.72	Maternal hypertension: 4.19 (0.46–38.57), p=0.21 Low Apgar score: 2.06 (0.18–22.12), p=0.57 Obstetrical vacuum extraction or forceps delivery: 0.98 (0.50–1.92), p=0.96	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
							Scale for Children-Third Edition. After the interview and testing, the diagnosis was made by the team according to the DSM-IV criteria.							
Greene et al. 2012, Self-controlled risk interval and case-centered analysis[50]	N=1.48 million doses Monovalent inactivated H1N1 and 1.72 million doses TIV; 8 US MCOs	Monovalent inactivated influenza vaccine (MIV) and seasonal trivalent inactivated influenza vaccine (TIV) during the 2009-2010 season.	Differences across sites in study participants and entry into medical care organizations may be relevant in terms of sampling bias.	Not given	Not given	Electronic data and medical record review	Electronic data and medical chart review	Conditional Poisson regression for self-controlled analysis and logistic regression for case-centered analysis.	Case-centered analyses by stratum of onset date, age, sex, VSD site).	2009–2010	Centers for Disease Control and Prevention	Relative Risk (self-controlled risk analysis) of Guillain-Barré Syndrome (GBS, RR, 95% CI MIV Confirmed GBS 4.4 (1.3, 14.2) TIV Confirmed GBS: 1.3 (0.5, 3.8) Case-centered: The odds ratio for having illness onset inside of the 42-day risk period versus outside of that period was 2.0 (95% CI: 0.5, 8.1).	None	
Dieleman et al. 2011, Case-control[51]	N=1,302 (104 cases, 1198 matched controls); Location=Dat	Pandemic influenza A (H1N1) 2009 vaccines	Study notes: "Because of differences in healthcare structure	None	Not discussed	Data on pandemic influenza vaccination were	Outcomes ascertained from VAESCO databases.	Conditional logistic regression	Influenza-like illness or upper respiratory tract infection, and other	The study period ran between November 1, 2009	This study was funded by the European Centre for Disease	Table 6 Netherlands, UK, Sweden: Pooled OR (95% CI) Guillain-Barré	None given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	abases from centers in Denmark, France, the Netherlands, Sweden, and the UK; Age=50 (22) (mean (SD)); Setting=VAESCO (Vaccine Adverse Events Surveillance and Communication) consortium (network of organizations - public health institutes, regulatory agencies, and academic research centres) in Europe dedicated to improving monitoring of safety of vaccines after licensing.		and availability of registries, the type of source population from which cases and controls were recruited and the type of data sources differed by country." There was an increased awareness of a potential increase in the risk of Guillain-Barré syndrome associated with pandemic influenza vaccination. As a result, people at increased baseline risk might have been less likely to receive the vaccine and there could have been over-reporting or selective inclusion of			obtained from vaccine registries in Denmark and France, from general practitioner records in the UK and the Netherlands, and through structured interviews in Sweden.	Each case (Guillain-Barré syndrome and its variant Miller-Fisher syndrome) was validated according to the Brighton Collaboration definition of Guillain-Barré syndrome, based on information obtained from the reporting neurologist (France, Sweden, and Netherlands) or from data in charts (UK, Denmark). Case verification varied by country (see Table 1).		vaccinations (especially seasonal influenza vaccination). Cases/controls matched on age (plus or minus one year), sex, index date, and GP practice in Netherlands and UK. Adjusted for seasonal influenza vaccination and influenza-like illness or upper respiratory tract infection.	and March 30, 2010.	Prevention and Control.	syndrome H1N1: 1.0 (0.3 to 2.7) Netherlands, UK Pooled OR (95% CI) Guillain-Barré syndrome H1N1: 0.7 (0.2 to 2.5) Restricted to people without ILI/URTI Netherlands, UK, Sweden Pooled OR (95% CI) Guillain-Barré syndrome H1N1: 1.2 (0.4 to 4.0) Netherlands, UK Pooled OR (95% CI) Guillain-Barré syndrome H1N1: 1.2 (0.3 to 5.8)		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
			exposed people with GB syndrome in each country. In the Netherlands there was under-reporting of cases, but authors suggested this was non-differential with regards to exposure. In Sweden and France, there were delays in inclusion of cases, and selectiveness could not be fully assessed as data on non-included patients were not available. In the UK and Denmark, patient consent was not required, which could reduce the likelihood of differential under-reporting.											

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
			Authors assumed that any selection would work in the direction of including more exposed cases as many physicians were aware of the potential risk. The latter would have resulted in an overestimated risk, which does not seem to have affected the study which did not find an increased risk. Misclassification of the timing of H1N1 vaccine was greater in controls, especially in Sweden, resulting in overestimation of risk. There may have been differential											

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
			recording of risk factors, with more complete recording in cases versus controls.											
Tseng et al. 2010, Prospective cohort[66]	N=84,170; Location=CA; Age=45-69 years; Setting=Kaiser Permanente Northern and Southern California health plans (California Men's Health Study).	Pneumococcal	Should be noted, participants who were vaccinated were significantly older than participants who were not vaccinated. Region, race/ethnicity, household income, education, and BMI also were associated significantly with vaccination status.	Study notes the mean (SD) length of follow-up was 4.7 (1.36) years. The unvaccinated group had relatively shorter length of followup.	Not discussed	Immunization records were tracked by the Kaiser Immunization Tracking System.	Electronic health records	Cox proportional hazards regression	Propensity score was created: age, race/ethnicity, region (northern vs southern California Kaiser Permanente), household income, education, BMI, cigarette smoking, physical activity level, sedentary for more than 6.5 hours per day outside of work, alcohol consumption, number of influenza vaccines received, calorie intake, fat intake, fruit and vegetable consumption, history of diabetes, history of high blood pressure, history of high cholesterol, history of peripheral artery disease, history of other heart diseases,	2002-2007	This study was funded by California Cancer Research Program and Kaiser Permanente.	Association of Pneumococcal Vaccination and Incidence of MI and Stroke Acute MI All men: 1.09 (0.98-1.21), p=0.13 Stroke All men: 1.14 (1.00-1.31), p=0.05	Association of Pneumococcal Vaccination and Incidence of MI and Stroke Age, y <65: 1.23 (1.08-1.40), p=0.001 >=65: 0.89 (0.80-1.01), p=0.10 High-risk groups Current smokers: 1.11 (0.83-1.47), p=0.48 Diabetes: 1.04 (0.87-1.24), p=0.51 Hypertension: 1.10	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
									history of stroke, history of acute MI, and the log scale transformed number of outpatient visits during the 5 years before baseline. Cigarette smoking was modeled through smoking status.				(0.97-1.25), p=0.16 Low-risk group: 0.98 (0.35-2.73), p=0.97 Influenza vaccine 0: 1.10 (0.70-1.72), p=0.69 1-10: 1.10 (0.97-1.26), p=0.14 >10: 1.00 (0.83-1.21), p=0.97	
Vila-Corcoles et al. 2012, Prospective cohort[68]	N=27,204 (8,981 vaccinated, 18,223 unvaccinated) Location=Spain; Age=71.7 (mean at study start); Setting=nine primary care centers in the Health Region of Tarragona (a mixed residential-industrial	Pneumococcal (PPV23)	Paper did not provide details on recruitment - referred reader to another paper.	None discussed	Not discussed	Review of the primary care centers' electronic clinical records.	Computerized clinical record system. Outcomes identified bases on ICD-9 codes with physician verification based on medical record review.	Cox proportional hazards models	The following variables were considered in all the initial models: age, sex, number of outpatient visits to family physician in 12-months before study start, influenza vaccination in prior autumn, history of coronary artery disease, history of stroke, history of chronic heart	Cohort members were followed from the start of the study (December 1, 2008) until the occurrence of any event, change in pneumococcal vaccination status, disenrollm	This work was supported by a grant from the "Fondo de Investigación Sanitaria" of the Instituto de Salud Carlos III [FIS 09/00043] of the Spanish Health Ministry	Multivariate hazard ratio (95% CI) CAP: 0.85 (0.62-1.15), p=0.287 AMI: 0.83 (0.56-1.22), p=0.347 Ischemic Stroke: 0.65 (0.42-0.99), p=0.048 Death from any cause: 0.88 (0.75-1.03), p=0.12	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	urban area in the Mediterranean coast of Catalonia, Spain).								disease, chronic pulmonary disease, hypertension, hypercholesterolemia, obesity, diabetes mellitus, smoking status, alcoholism, chronic severe liver disease, chronic severe nephropathy, cancer, dementia and nursing-home residence. Age, sex and influenza vaccine status were judged epidemiologically relevant variables, being included in all the final models. Final Models: CAP: Adjusted for age, sex, number of outpatient visits in prior year, influenza vaccination in prior year, chronic pulmonary disease, chronic heart disease, smoking and nursing-home resident AMI: Adjusted for age, sex, number of outpatient visits	ent from the primary care center, death, or until the end of first 12-month follow-up (November 30, 2009).				

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
									in prior year, influenza vaccination in prior year, history of coronary artery disease, chronic heart disease, diabetes mellitus, hypercholesterol emia, smoking (confounder) and nursing-home resident Ischemic Heart Disease: Adjusted for age, sex, number of outpatient visits in prior year, influenza vaccination in prior year, history of coronary artery disease, history of stroke, smoking (confounder) and nursing-home resident Death from any cause: Adjusted for age, sex, number of outpatient visits in prior year, influenza vaccination in prior year, chronic pulmonary disease, chronic heart disease,					

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
									diabetes mellitus, cancer, chronic nephropathy, dementia, hypertension, hypercholesterolemia, obesity, smoking, and nursing home-resident.					
Eurich et al. 2012, Prospective cohort[67]	N=6171; Location=Edmonton (Alberta, Canada); Age=mean age 59 years; Setting=Population-based cohort of adults presenting with community-acquired pneumonia (CAP) in Edmonton.	Pneumococcal polysaccharide vaccination (PPV)	Authors note a large protective effect against ACS events among patients receiving PPV during the acute pneumonia event was observed. Although this in itself is not improbable, the fact that no ACS events occurred within the first 2-4 weeks post discharge in this group suggests some selection bias was occurring, as PPV generally	Of the 6874 cohort patients with CAP, authors excluded 310 (5%) who had PPV first administered during their initial CAP presentation and 393 (6%) who could not be linked to the administrative databases, resulting in a final study cohort of 6171 patients.	Not discussed	PPV status was collected by trained staff masked to all study hypotheses. Receipt of vaccination was ascertained through multiple avenues including patient and proxy interview, medical record review, contact with primary care physicians and records from regional office of community health.	Research nurses prospectively collected all clinically diagnosed ACS events in the emergency department and during hospitalization. Thereafter, ACS events were ascertained by linking patients to comprehensive provincial healthcare administrative databases.	Multivariable Cox proportional hazard model	Pneumonia severity based on the PSI; comorbidities including chronic obstructive pulmonary disease, diabetes, ischemic heart disease (IHD); functional status, smoking status and cardiovascular and other medications. Authors also completed a propensity (to receive PPV) score analysis.	2000 to 2002	DTE receives salary support from Alberta Heritage Foundation for Medical Research (AHFMR) and the Canadian Institutes for Health Research (CIHR). SRM receives salary support from AHFMR and holds an endowed chair in patient health management. TJM received Grants-in-aid from Capital Health; and unrestricted grants from Abbott Canada, Pfizer Canada and Janssen-Ortho Canada.	Adjusted HRs for fatal and non-fatal ACS events within 90 days according to pneumococcal vaccination status. Primary analysis Death or ACS-related hospitalization: 0.42 (0.27 to 0.66), p=<0.001 Death: 0.92 (0.32 to 2.63), p=0.88 Hospitalization due to ACS: 0.35 (0.21 to 0.57), p=<0.001 Propensity score analysis Death or ACS-related hospitalization: 0.46 (0.28 to 0.73), p=0.001 Death: 1.51 (0.42 to 5.34), p=0.53 Hospitalization due to ACS:	None	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
			requires 2-4 weeks to initiate a reasonable response. Also the majority of the cohort were older and antibody response is known to be poor in older populations with comorbidities. Finally there may have been confounding by the healthy-user or healthy-vaccine effect, whereby more healthy or health-seeking patients are administered PPV compared with non-PPV patients.									0.36 (0.21 to 0.61), p=<0.001		
Tanner et al. 2012, Case-control[54]	N=286; Location=Utah; Age=20.4 to 92.5; Setting=The	Swine flu (Also assessed measles, mumps,	Selected segment - University of Utah Voice Disorders Center.	No details about dropping out over the course of the study, but	Not reported	Self-report through questionnaire. Trained examiners administere	Voice disorder diagnosis was confirmed by a	Logistic regression	Age, sex, race/ethnicity	Not given	The work was supported in part by a University of Utah College of Health	Vacc v. Nonvacc: 2.1 (0.9-5.0) Don't Know v. Nonvacc: 2.3 (1.3-4.1)	Not given	

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	University of Utah Voice Disorders Center.	and rubella separately - unsure if any of these are MMR).		study notes in the recruitment phase: Of the 192 patients approached and invited to participate, 150 individuals with SD completed the study (cases). Of the 160 patients approached and invited to participate, 136 VC individuals completed the study (controls).		d the questionnaire to each participant and were periodically audited to ensure accuracy.	multidisciplinary team of professionals including a laryngologist and one of four speech-language pathologists. Diagnosis was assigned following a thorough evaluation including a detailed case history, auditory-perceptual evaluation, and videolaryngostroboscopy, employing diagnostic criteria previously established and reported.				Research and Creative Grant.			

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Glanz et al. 2011, Self-controlled case series[108]	N=66,283 who received trivalent inactivated influenza vaccine (TIV); Location=US; Age=24-59 months; Setting=Seven US managed care organizations (Vaccine Safety Datalink).	TIV	No info on systematic differences between sites in vaccine or outcome administration or ascertainment.	Not discussed	Not discussed	VSD records review	Medical record review	Conditional Poisson regression	Calendar month (season) and age	2002-2006	Centers for Disease Control and Prevention	Medically Attended Events That Met the Screening Criteria in Risk Windows of 0 to 2, 1 to 14, and 1 to 42 Days After Vaccination. Non-confirmed Cases From Electronic Data Analysis. Potentially serious Nervous system disorder: 6.32 (0.96-41.65), p=0.06 Cardiac event: 3.56 (0.55-22.89), p=0.18 Hypotension: 5.52 (0.71-43.07), p=0.10 Gastrointestinal tract disorder: 2.75 (1.07-7.09), p=0.04 Cellulitis and skin reaction: 3.06 (0.89-10.53), p=0.08 Potentially less serious and common Rash: 2.33 (0.68-7.93), p=0.18 Limb soreness: 3.56 (1.30-9.75), p=0.01 Fever: 1.40 (1.09-1.80), p=0.01 Gastrointestinal	None given	

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												tract symptoms (vomiting and diarrhea): 1.52 (1.18-1.95), p=0.001 Medical Record–Confirmed Cases Potentially serious Gastrointestinal tract disorder: 7.70 (1.11-53.52), p=0.04 Cellulitis and skin reaction: 3.27 (0.36-29.70), p=0.29 Potentially less serious and common Rash: 1.94 (0.44-8.63), p=0.38 Fever: 1.71 (1.64-1.80) Gastrointestinal tract symptoms (vomiting and diarrhea): 1.18 (1.10-1.25)		
Tseng et al. 2012, Case-centered and Self-controlled case series[78]	N=193,083 recipients of zoster vaccine in 8 US MCOs; Age=50 and older;	Zoster	VSD population - might be differences in case and exposure ascertainment across sites.	Not discussed	Not discussed	Medical records	Authors used computerized data to identify any adult with a pre-specified event of interest or death.	Case-centered: logistic regression SCCS: conditional Poisson regression	No additional confounders controlled for in models.	1 January 2007 to 31 December 2008	Contract from the Centers for Disease Control and Prevention.	Relative risk (RR) and 95% confidence interval (CI) of pre-specified adverse events within predefined risk windows following vaccination with a zoster vaccine. Case-centered Day 1-14 Stroke: 1.03	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												(0.83–1.28) Acute myocardial infarction: 1.17 (0.92–1.48) Cardiomyopathy: 0.73 (0.51–1.03) Heart failure: 0.76 (0.46–1.24) Meningitis, encephalitis and encephalopathy: 0.54 (0.19–1.52) Ramsey-Hunt syndromes and Bell's palsy: 0.63 (0.29–1.38) Day 15-28 Stroke: 0.92 (0.73–1.16) Acute myocardial infarction: 1.04 (0.81–1.34) Acute Myocarditis: 8.98 (1.67–46.36) Cardiomyopathy: 1.11 (0.83–1.48) Heart failure: 1.08 (0.70–1.65) Meningitis, encephalitis and encephalopathy: 0.90 (0.40–2.05) Day 29-42 Stroke: 1.06 (0.85–1.31) Acute myocardial infarction: 0.97 (0.75–1.26) Acute pericarditis: 1.04 (0.13–8.05) Acute Myocarditis:		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												17.18 (3.71–79.67) Cardiomyopathy: 1.00 (0.74–1.36) Heart failure: 0.95 (0.60–1.49) Meningitis, encephalitis and encephalopathy: 0.62 (0.23–1.69) Day 1-42 Stroke: 1.00 (0.87–1.15) Acute myocardial infarction: 1.07 (0.92–1.26) Acute pericarditis: 0.27 (0.03–2.22) Acute Myocarditis: 19.44 (3.58–105.68) Cardiomyopathy: 0.94 (0.77–1.14) Heart failure: 0.91 (0.68–1.21) Meningitis, encephalitis and encephalopathy: 0.66 (0.37–1.16) Mortality: 0.31 (0.23–0.40) Day 1-7 Cellulitis and infection: 1.30 (1.18–1.44) Allergic Reaction: 2.13 (1.87–2.40) SCCS Day 1-14 Cerebrovascular diseases: 0.94 (0.70–1.28)		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												Acute myocardial infarction: 1.22 (0.87–1.73) Cardiomyopathy: 0.70 (0.45–1.10) Heart failure: 0.77 (0.41–1.46) Meningitis, encephalitis and encephalopathy: 0.80 (0.21–2.98) Ramsey-Hunt syndromes and Bell's palsy: 0.78 (0.29–2.09) Day 15-28 Cerebrovascular diseases: 1.03 (0.74–1.42) Acute myocardial infarction: 1.24 (0.85–1.79) Cardiomyopathy: 1.05 (0.69–1.59) Heart failure: 0.92 (0.51–1.63) Meningitis, encephalitis and encephalopathy: 0.86 (0.29–2.55) Day 29-42 Cerebrovascular diseases: 0.97 (0.71–1.30) Acute myocardial infarction: 0.97 (0.67–1.39) Acute pericarditis: 1.00 (0.06–15.99) Acute Myocarditis: 3.00 (0.31–28.84) Cardiomyopathy:		

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												0.86 (0.57–1.29) Heart failure: 0.64 (0.36–1.16) Meningitis, encephalitis and encephalopathy: 0.80 (0.21–2.98) Day 1-42 Cerebrovascular diseases: 0.99 (0.83–1.19) Acute myocardial infarction: 1.05 (0.86–1.29) Acute pericarditis: 0.50 (0.05–5.51) Acute Myocarditis: 5.00 (0.58–42.80) Cardiomyopathy: 0.94 (0.73–1.20) Heart failure: 0.88 (0.61–1.25) Meningitis, encephalitis and encephalopathy: 0.78 (0.39–1.56) Day 1-7 Cellulitis and infection: 1.10 (0.95–1.26) Allergic Reaction: 2.32 (1.85–2.91)		
Zhang et al. 2012, Retrospective cohort[77]	N=463,541(4,026 with ankylosing spondylitis, 66,751 with inflammatory bowel disease, 11,030 with psoriatic arthritis,	Zoster Herpes	Could not control for differences between those who received vaccinations and those who did not (e.g., those	Actual vaccine administration dates were unknown for 59% of patients, which resulted in the exclusion	Did not discuss	Database review	Database review (administrative claims from physicians or hospitalizations).	Proportional hazard regression	Sex, race, immune-mediated disease, time varying concurrent medications, and time-varying health care utilization	January 1, 2006, through December 31, 2009	Agency for Healthcare Research and Quality	HR (95% CI) for Herpes Zoster Incidence Using ICD-9-CM diagnosis code+pharmacy claim definition for HZ case (Def 1)	Sex Men Women Def 1: 1.22 (1.17-1.28) Def 2: 1.21 (1.17-	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	89,565 with psoriasis, and 292,169 with RA); Location=US; Age=74 years (mean at study start); Setting=US Medicare beneficiaries.		receiving vaccines may be a healthier population). Misclassification of medication exposure.	of these patients from safety analyses potentially introducing bias.					(hospitalization and physician visits).			HZ vaccination: 0.61 (0.52-0.71) Using ICD-9-CM diagnosis code only for HZ case (Def 2) HZ vaccination: 0.67 (0.59-0.75)	1.26) Race White Black Def 1: 0.67 (0.62-0.73) Def 2: 0.69 (0.64-0.74) Other Def 1: 0.89 (0.81-0.97) Def 2: 0.89 (0.83-0.95) Immune-mediated disease Rheumatoid arthritis Ankylosing spondylitis Def 1: 0.98 (0.77-1.25) Def 2: 0.94 (0.77-1.13) Inflammatory bowel diseases	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
													Def 1: 1.03 (0.97-1.10) Def 2: 1.02 (0.97-1.07) Psoriatic arthritis Def 1: 0.92 (0.80-1.05) Def 2: 0.92 (0.83-1.02) Psoriasis Def 1: 0.99 (0.93-1.05) Def 2: 0.97 (0.93-1.02) Hospitalized in the previous 6 mo No Yes Def 1: 1.00 (0.95-1.05) Def 2: 1.25 (1.20-1.29)	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
													No. of physicia n visits in the previous 6 mo Def 1: 1.04 (1.04-1.04) Def 2: 1.04 (1.04-1.04) DMARDs , exclusive groups Non-biologic DMARDs Anti-TNF biologics Def 1: 1.15 (1.08-1.23) Def 2: 1.10 (1.04-1.16) Non-TNF biologics Def 1: 0.99 (0.86-1.13) Def 2: 1.05 (0.94-1.16) None Def 1:	

Appendix C-1. Evidence Tables – Post-marketing studies
Adults

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
													0.84 (0.80-0.88) Def 2: 0.86 (0.82-0.89) Oral glucocorticoid use No Yes Def 1: 1.79 (1.71-1.86) Def 2: 1.69 (1.64-1.75)	

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Ngan H. Y. S. et al., 2010 Hong Kong[80]	Controlled Clinical Trial	7	Sample size: 300, Age range: 18 - 35, Percent female: 100%	Human papillomavirus (HPV), Cevarix, GlaxoSmithKline, Each dose (0.5 mL) of the HPV-16/18 vaccine contained20 µg each of HPV-16 and -18 L1 (structural protein of HPV) virus-like particle (VLP) and adjuvant with a proprietary AS04 (3-O-desacyl-4'-monophosphoryllipid [50 µg] adsorbed on aluminium hydroxide [Al(OH)3, 500 µg], Adjuvant: ASO 4, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Month Dose2: 1 Month Dose3: 6 Month	Any adverse event: 90% Any SAE: 2% Event: Arthralgia: 8%, Syscat: 15, Sev: 1-3 Event: Fatigue: 42%, Syscat: 8, Sev: 1-3 Event: Fever: 6%, Syscat: 8, Sev: 1-3 Event: GI symptoms: 16%, Syscat: 7, Sev: 1-3 Event: Headache: 24%, Syscat: 8, Sev: 1-3 Event: Myalgia: 35%, Syscat: 8, Sev: 1-3 Event: Rash: 3%, Syscat: 10, Sev: 1-3 Event: Urticaria: 2%, Syscat: 10, Sev: 1-3	Arthralgia: OR 1.362 (0.556-3.336) Fatigue: OR 1.69 (1.049-2.721)** Fever: OR 0.734 (0.3-1.797) GI symptoms: OR 1.714 (0.86-3.415) Headache: OR 1.439 (0.822-2.519) Myalgia: OR 1.705 (1.031-2.82)** Rash: OR 3.062 (0.476-19.708) Urticaria: OR 1 (0.199-5.036)
Bhatla N. et al.,2010 India[81]	Controlled Clinical Trial	7	Sample size: 337, Mean age: 28.4, Age range: 18 - 35, Percent female: 100%	Human papillomavirus (HPV), HPV-16/18 L1 virus-like particle (VLP) cervical ca, GlaxoSmithKline, HPV-16/18 L1 virus-like particle (VLP) cervical cancer vaccine containing the proprietary ASO4 (3-O-desacyl-4(1)-monophosphoryl lipid [MPL] [0 mcg MPL] adsorbed on aluminum [Al] hydroxide [500 mcg AL(+3)]) adjuvant system, Adjuvant: ASO 4-Aluminum, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Month Dose2: 1 Month Dose3: 6 Month	Any adverse event: 7.4% Any SAE: 1.1% Event: Acute appendicitis: 0.6%, Syscat: 7 Event: Lymph node tuberculosis: 0.6%, Syscat: 11 Event: Pain (Grade 3): 20.5%, Syscat: 17, Sev: 3 Event: Redness (>50 mm): 0.6%, Syscat: 23, Sev: 3 Event: Swelling (>50 mm): 2.9%, Syscat: 23, Sev: 3	Pain (Grade 3): OR 6.189 (2.634-14.54)** Redness (>50 mm): OR 1 (0.063-15.882)

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Langley J. M., et al,2011 Canada[42]	Controlled Clinical Trial	4	Sample size: 1348, Mean age: 37.1, Age range: 18 - 64, Percent female: 54.2%	Influenza (inactivated), NR, Contains equal parts of three monovalent egg-grown, formalin-inactivated influenza antigens formulated with OMPs of N. meningitidis serogroup B strain 8047 at an initial ratio of OMP to haemagglutinin (HA) of 4:1. After diafiltration to remove detergents necessary to keep the OMPs in stable solution in the absence of antigen, the overall total protein to HA ratio in the final vaccine product is 2.5 to 5:1. The trivalent vaccine stock contained HA from each of A/New Caledonia/20/99 [H1N1], A/Panama/2007/99 [H3N2] and B/Shangdong/7/97 [H1N1, Adjuvant: Not Reported, Preservative: Thimerisol, Delivery: Intranasal	Dose1: 0 Days Dose2: 14 Days	Any SAE: 0.219%, Syscat: 10, Sev: 3,4 Event: Shortness of breath (Grade 2/3): 0%, Syscat: 22, Sev: 3-5 Event: Lightheadedness/Dizziness (Grade2/3): 0%, Syscat: 17, Sev: 3-5 Event: New rash/itchy rash (Grade 2/3): 0%, Syscat: 10, Sev: 3-5 Event: Feverishness (Grade2/3): 0%, Syscat: 8, Sev: 3-5 Event: Burning/stinging nose (Grade2/3): 0%, Syscat: 8, Sev: 3-5 Event: Burning/stinging throat (Grade 2/3): 0%, Syscat: 8, Sev: 3-5 Event: Itching nose/throat/eyes (Grade 2/3): 0%, Syscat: 8, Sev: 3-5 Event: Temp >39C: 0%, Syscat: 8, Sev: 3-5	

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Barrett P. N. et al, 2011 US[43]	Controlled Clinical Trial	4	Sample size: 7250, Mean age: NR, Age range: 18 - 49	Influenza (inactivated), Baxter, Austria, contain 15 µg of haemagglutinin antigen from each of the three virus strains - A/Brisbane/59/2007 (A/H1N1), A/Uruguay/716/2007(A/Brisbane/10/2007-like) (A/H3N2), and B/Florida/4/2006 (B). The three virus strains were egg-derived wild-type strains provided by the National Institute for Biological Standards and Control (Potters Bar, UK)., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days	Any adverse event: 35% Any SAE: 0.8%, Sev: 3-5 Event: Arthralgia: 6%, Syscat: 15, Sev: 1-3 Event: Chills: 6%, Syscat: 8, Sev: 1-3 Event: Cough: 1%, Syscat: 22, Sev: 1-3 Event: Fatigue: 18%, Syscat: 8, Sev: 1-3 Event: Headache: 18%, Syscat: 8, Sev: 1-3 Event: Hyperhidrosis: 5%, Syscat: 8, Sev: 1-3 Event: Malaise: 14%, Syscat: 8, Sev: 1-3 Event: Myalgia: 18%, Syscat: 8, Sev: 1-3 Event: Oropharyngeal pain: 2%, Syscat: 7, Sev: 1-3 Event: Pyrexia: 2%, Syscat: 8, Sev: 1-3 Event: Death: 0.05%, Sev: 5	Arthralgia: OR 2.103 (1.666-2.655)** Chills: OR 2.239 (1.766-2.838)** Cough: OR 1.427 (0.862-2.361) Fatigue: OR 1.577 (1.382-1.8)** Headache: OR 1.396 (1.229-1.587)** Hyperhidrosis: OR 1.678 (1.306-2.155)** Malaise: OR 2.024 (1.736-2.36)** Myalgia: OR 3.281 (2.799-3.846)** Oropharyngeal pain: OR 1.626 (1.058-2.5)** Pyrexia: OR 2.271 (1.537-3.355)**
Frey S. et al,2010 US, Finland, Poland[44]	Controlled Clinical Trial	4	Sample size: 11404, Mean age: 33, Age range: 18 - 49, Percent female: 55%	Influenza (inactivated), Agrippal, Novartis, 15 mg of hemagglutinin per 0.5-mL dose of each virus strain recommended for the 2007–2008 Northern Hemisphere influenza season: A/Solomon Islands/3/2006 (H1N1)–like, A/Wisconsin/67/2005 (H3N2)–like, and B/Malaysia/2506/2004–like, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intramuscular	Dose1: 1 Days	Any SAE: 0.95% Event: Chills (mild-moderate): 5%, Syscat: 8, Sev: 1-2 Event: Malaise (mild-moderate): 7.5%, Syscat: 8, Sev: 1-2 Event: Myalgia (mild-moderate): 9%, Syscat: 8, Sev: 1-2 Event: Arthralgia (mild-moderate): 2.5%, Syscat: 15, Sev: 1-2 Event: Headache (mild-moderate): 15%, Syscat: 8, Sev: 1-2 Event: Sweating (mild-moderate): 2.5%, Syscat: 8, Sev: 1-2 Event: Fatigue (mild-moderate): 11%, Syscat: 8, Sev: 1-2 Event: Fever (mild-moderate): 1%, Syscat: 8, Sev: 1-2 Event: Withdrawal after AE: 0.03%, Sev: 1-2 Event: Death: 0.03%, Sev: 5	Headache (mild-moderate): OR 1 (0.881-1.134) Arthralgia (mild-moderate): OR 0.961 (0.722-1.279) Chills (mild-moderate): OR 1 (0.813-1.23) Death: OR 1.061 (0.066-16.969) Fatigue (mild-moderate): OR 1.112 (0.96-1.289) Fever (mild-moderate): OR 2.01 (1.159-3.487)** Malaise (mild-moderate): OR 1.27 (1.061-1.521)** Myalgia (mild-moderate): OR 1.314 (1.112-1.553)** Sweating (mild-moderate): OR 1 (0.749-1.335) Withdrawal after AE: OR 1.061 (0.066-16.969)

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Iorio V et al.,2010 Italy[45]	Controlled Clinical Trial	4	Sample size: 104, Mean age: 71, Age range: 18 - NR, Percent female: 45.1%	Influenza (inactivated), Fluad, Novartis, Fujian/411/02 (influenza A[H3N2]),New Caledonia/20/99 (influenza A[H1N1]), and Shanghai/361/02 (influenzaB), Adjuvant: Other adjuvant, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days Dose2: 42 Days	Any SAE: 0%, Syscat: 0 Event: Posttraumatic elbow hematoma: 0.96%, Syscat: 26, Sev: 1-3 Event: Gingival bleeding: 0.96%, Syscat: 7, Sev: 1-3 Event: Nosebleeds: 2.88%, Syscat: 22, Sev: 1-3 Event: Conjunctival hemorrhage: 0.96%, Syscat: 6, Sev: 1-3 Event: Bruising: 0%, Syscat: 12	Nosebleeds: OR 0.743 (0.162-3.403)
Jackson L. A. et al.,2010 US[46]	Controlled Clinical Trial	7	Sample size: 7611, Mean age: 32.7, Age range: 18 - 49, Percent female: 60%, Percent pregnant: Percent Pregnant: 0.7%	Influenza (inactivated), Flulaval, ID Biomedical Corporation of Quebec (trademarked b, 15 ìg of hemagglutinin(HA) antigen of each recommended influenza strain. Antigens for Season 1 (2005-2006) were A/New Caledonia/20/1999 (H1N1), A/New York/55/2004 (H3N2, A/California/7/2004-like), and B/Jiangsu/10/2003 (B/Shanghai/361/2002-like). Antigens for Season 2 (2006-2007) were A/New Caledonia/20/1999 (H1N1) virus, A/Wisconsin/67/2005 (H3N2), and B/Malaysia/2506/2004., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: 0 Days	Any adverse event: 66% Any SAE: 1.1% Event: Fever: 3%, Syscat: 8, Sev: 1-3 Event: Myalgia/arthralgia: 18%, Syscat: 15, Sev: 1-3 Event: Malaise: 9%, Syscat: 8, Sev: 1-3 Event: Swelling of the face: 1%, Syscat: 8, Sev: 1-3 Event: Cough: 8%, Syscat: 22, Sev: 1-3 Event: Chest tightness or difficulty breathing: 3%, Syscat: 22, Sev: 1-3 Event: Sore throat, hoarseness, or pain swallowing: 9%, Syscat: 7, Sev: 1-3 Event: Death: 0%, Sev: 5	Chest tightness or difficulty breathing: OR 1.218 (0.938-1.581) Cough: OR 1.17 (0.982-1.396) Fever: OR 1.786 (1.278-2.496)** Myalgia/arthralgia: OR 1.979 (1.732-2.262)** Sore throat, hoarseness, or pain swallowing: OR 0.949 (0.809-1.112) Swelling of the face: OR 1.4 (0.915-2.143)

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Madhi S. A. e t al.,2011 South Africa[49]	Controlled Clinical Trial	3	Sample size: 189, Mean age: 36.3, Percent female: 84%, Conditions: HIV	Influenza (inactivated), Mutagrip, Sanofi, 15ugm each (per 0.5 ml) A/Solomon Islands/3/2006 (IVR-145), A/Brisbane/10/2007(IVR-147),B/Florida/4/2006, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intramuscular	Dose1: NR Dose2: NR Dose3: NR	Any adverse event: 14.4% Event: Pain: 8.3% Event: Redness: 2.1% Event: Swelling: 2.1% Event: Lump formation: 1.0% Event: Bruising: 0% Event: Itching: 3.1% Event: Rigors (muscle cramp): 0% Event: Fatigue: 1.0% Event: Headache: 3.1% Event: Fits (seizures): 0% Event: Myalgia: 3.1% Event: Arthralgia: 3.1% Event: Fever: 0%	Arthralgia: OR 0.694 (0.151-3.19) Fatigue: OR 0.179 (0.021-1.564) Headache: OR 0.936 (0.184-4.762) Itching: OR 2.872 (0.293-28.127) Lump formation: OR 0.464 (0.041-5.201) Myalgia: OR 1.42 (0.232-8.7) Pain: OR 1.955 (0.568-6.73) Redness: OR 1.895 (0.169-21.26)
Treanor J. J. et al.,2011 USA[47]	Controlled Clinical Trial	3	Sample size: 4648, Mean age: 32.5, Age range: 18 - 55, Percent female: 59%, Percent pregnant: Percent Pregnant: 0.8%	Influenza (inactivated), FluBlok, NR, The trivalent vaccine contained 45 mcg of each purified rHA0 derived from the A/Solomon Islands/3/2006 (H1N1), A/Wisconsin/67/2005 (H3N2), and B/Malaysia/2506/2004 influenza viruses recommended for the 2007–2008 influenza season formulated with 0.005% Tween®-20 in 10mM sodiumphosphate buffer pH 7.0 ± 0.4 without a preservative, Adjuvant: Not Reported, Preservative: Preservative Free, Delivery: Intramuscular	Dose1: 0 Days	Any adverse event: 51.1% Any SAE: 1.5% Event: Fever (=100.4): 0.7%, Syscat: 8, Sev: 1-5 Event: Fatigue or lack of energy: 14.5%, Syscat: 8 Event: Shivering or chills: 3.0%, Syscat: 8 Event: Joint pain: 3.8%, Syscat: 15 Event: Muscle pain: 10.2%, Syscat: 15 Event: Headache: 14.9%, Syscat: 8 Event: Nausea: 5.5%, Syscat: 7 Event: Pain: 36.3%, Syscat: 8 Event: Bruising: 3.2%, Syscat: 12	Bruising: OR 1.258 (0.89-1.778) Fatigue or lack of energy: OR 1.004 (0.853-1.182) Fever (=100.4): OR 1.395 (0.665-2.928) Headache: OR 0.964 (0.821-1.131) Joint pain: OR 1.056 (0.779-1.432) Muscle pain: OR 1.585 (1.283-1.958)** Nausea: OR 1.173 (0.903-1.524) Pain: OR 6.686 (5.62-7.953)** Shivering or chills: OR 0.968 (0.692-1.354)

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Talaat K. R. et al.,2010 United States[48]	Controlled Clinical Trial	5	Sample size: 1313, Mean age: 56.5, Age range: 18 - 93, Percent female: 57.1%	Influenza - monovalent H1N1, CSL Limited, The 7.5-mgdoses were supplied in prefilled syringes that contained 7.5 mg of HA in 0.25 mL of thimerosal-free diluent., Adjuvant: Adjuvant Free, Preservative: Other, Delivery: Intramuscular	Dose1: NR Dose2: 21 Days	Event: Any systemic AE (Dose 1): 26%, Syscat: 8, Sev: 1-3 Event: Any systemic AE (Dose 2): 13%, Syscat: 8, Sev: 1-3 Event: Headache (Dose 1): 15%, Syscat: 8, Sev: 1-3 Event: Headache (Dose 2): 9%, Syscat: 8, Sev: 1-3 Event: Myalgia (Dose 1): 12%, Syscat: 8, Sev: 1-3 Event: Myalgia (Dose 2): 6%, Syscat: 8, Sev: 1-3 Event: Malaise (Dose 1): 8%, Syscat: 8, Sev: 1-3 Event: Malaise (Dose 2): 8%, Syscat: 8, Sev: 1-3 Event: Nausea (Dose 1): 4%, Syscat: 8, Sev: 1-3 Event: Nausea(Dose 2): 3%, Syscat: 8, Sev: 1-3 Event: Chills(Dose 1): 2%, Syscat: 8, Sev: 1-3 Event: Chills(Dose 2): 2%, Syscat: 8, Sev: 1-3 Event: Vomiting(Dose 1): 1%, Syscat: 8, Sev: 1-3 Event: Vomiting(Dose 2): 0.5%, Syscat: 8, Sev: 1-3 Event: Fever (Dose 1): 1%, Syscat: 8, Sev: 1-3 Event: Fever(Dose 2): 0.5%, Syscat: 8, Sev: 1-3	Any systemic AE (Dose 1): OR 1.176 (0.701-1.974) Any systemic AE (Dose 2): OR 0.562 (0.32-0.987)** Chills(Dose 1): OR 1 (0.208-4.801) Fever (Dose 1): OR 0.99 (0.11-8.922) Headache (Dose 1): OR 1.428 (0.719-2.835) Headache (Dose 2): OR 1 (0.464-2.154) Malaise (Dose 1): OR 1 (0.445-2.247) Malaise (Dose 2): OR 0.704 (0.341-1.452) Myalgia (Dose 1): OR 2.136 (0.885-5.159) Myalgia (Dose 2): OR 0.645 (0.29-1.437) Nausea (Dose 1): OR 1 (0.326-3.067) Nausea(Dose 2): OR 3.062 (0.39-24.025) Vomiting(Dose 1): OR 0.495 (0.089-2.744) Vomiting(Dose 2): OR 0.497 (0.045-5.549)
Lee S. et al,2011 Korea[82]	Controlled Clinical Trial	5	Sample size: 20, Mean age: 28.1, Age range: NR, Percent female: 0%	Td, SK Td Vaccine Inj, SK Chemicals, Seongnam, Korea, >= 2 IU of diphtheria toxoid and >=20 IU of tetanus toxoid, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days	Any adverse event: 80% Event: Serious adverse events: 0% Event: Hypoaesthesia: 30%, Syscat: 17 Event: Hypoaesthesia (vaccine-related): 20%, Syscat: 17	Hypoaesthesia: OR 3.857 (0.326-45.572)

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Weinberg A. et al.,2010 US (No direct mentions)[79]	Cohort	1	Sample size: 82, Mean age: NR, Age range: 18 - 65, Percent female: 35.3%, Conditions: HIV	Varicella, Varivax, Merck, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: 0 Weeks Dose2: 12 Weeks	Event: Dose1: Systemic rash (non-zosteriform): 3%, Syscat: 10, Sev: 1,2 Event: Dose 1: Pruritis: 3%, Syscat: 6, Sev: 1,2 Event: Dose 1: Adenopathy: 0%, Syscat: 26, Sev: 1,2 Event: Dose 1: Nose bleed: 0%, Sev: 1,2 Event: Dose 1: Influenza-like illness: 9%, Syscat: 8, Sev: 1,2 Event: Dose 1: Chest pain: 0%, Syscat: 2, Sev: 1,2 Event: Dose 1: Liver enzyme elevation: 0%, Syscat: 9, Sev: 1,2 Event: Dose 2: Systemic rash (non-zosteriform): 3%, Syscat: 10, Sev: 1,2 Event: Dose2: Pruritis: 0%, Syscat: 6, Sev: 1,2 Event: Dose2: Adenopathy: 0%, Syscat: 26, Sev: 1,2 Event: Dose2: Nose bleed: 3%, Sev: 1,2 Event: Dose2: Influenza-like illness: 0%, Syscat: 8, Sev: 1,2 Event: Dose2:Chest pain: 0%, Syscat: 2, Sev: 1,2 Event: Dose2: Liver enzyme elevation: 6%, Syscat: 9, Sev: 1,2	Dose 1: Influenza-like illness: OR 1.55 (0.242-9.94) Dose 1: Pruritis: OR 0.484 (0.042-5.618) Dose1: Systemic rash (non-zosteriform): OR 0.484 (0.042-5.618) Dose2: Liver enzyme elevation: OR 2.065 (0.178-23.943) Dose 2: Systemic rash (non-zosteriform): OR 1 (0.06-16.69)
Schmader K. E. et al.,2012 North America and Europe[70]	Controlled Clinical Trial	4	Sample size: 22439, Mean age: 54.8, Age range: 50 - 59, Percent female: 61.9%	Zoster, Zostavax, Merck, lyophilized ZV with stabilizers, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Subcutaneous	Dose1: 0 (Baseline)	Any adverse event: 72.8% Any SAE: 0.6% Event: 1 or more Injection-site AEs: 63.9% Event: 1 or more Systemic AEs: 35.4% Event: With vaccine-related AEs: 65.0% Event: Vaccine Related Injection site AEs: 63.9% Event: Vaccine relate systemic AEs: 6.7% Event: With vaccine related SAE: 0% Event: SAE with death: 0%	1 or more Injection-site AEs: OR 10.379 (9.722-11.081)** SAE with death: OR 0.334 (0.035-3.209) With vaccine-related AEs: OR 8.385 (7.882-8.922)** Vaccine relate systemic AEs: OR 0.43 (0.393-0.471)** With vaccine related SAE: OR 0.002 (0-0.013)** 1 or more Systemic AEs: OR 1.089 (1.031-1.151)**

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Vermeulen J. N. et al.,2012 US and Netherlands[71]	Controlled Clinical Trial	5	Sample size: 210, Mean age: 68.7 (Tx); 70.7 (Placebo), Age range: 58 - 90, Percent female: 62.85%	Zoster, Zostavax, Merck, lyophilized ZV (~23,000 plaque forming unit [PFU]/0.5 mL), Adjuvant: Not Reported, Preservative: Not reported, Delivery: Subcutaneous	Dose1: 0 Days Dose2: 42 Days	Event: 1 or more AEs (Post Dose 1): 71.2% Event: With vaccine-related AEs (Post Dose 1): 52.9% Event: Systemic AEs (Post Dose 1): 12.5% Event: SAE (Post Dose 1): 0% Event: Discontinued due to a vaccine-related AE (Post dose 1): 1.9% Event: 1 or more AEs (Post dose 2): 76.5% Event: With vaccine-related AEs (Post Dose 2): 63.3% Event: Systemic AEs (Post Dose 2): 5.1% Event: Systemic AEs (PD #2) -Rash: 2.0%, Syscat: 10 Event: SAEs (Post dose 2): 5.1% Event: Discontinued due to vaccine related AE (Dose 2): 0%	1 or more AEs (Post Dose 1): OR 3.062 (1.732-5.412)** Systemic AEs (PD #2) -Rash: OR 2.019 (0.18-22.617) Systemic AEs (Post Dose 2): OR 0.825 (0.244-2.791) Systemic AEs (Post Dose 1): OR 14.696 (1.886-114.525)** 1 or more AEs (Post dose 2): OR 4.063 (2.278-7.243)** With vaccine-related AEs (Post Dose 1): OR 8.525 (4.179-17.389)** With vaccine-related AEs (Post Dose 2): OR 11.174 (5.461-22.867)**

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Murray A. V. et al.,2011 US, Canada, Spain, Germany, UK[74]	Controlled Clinical Trial	4	Sample size: 11999, Mean age: 70.4, Age range: 60 - 99, Percent female: 58.6%	Zoster, Zostovax, Merck, Lyophilized ZV, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Subcutaneous	Dose1: 0	Any SAE: 5.7% Event: Blood/Lymphatic disorders(1-42d): 0%, Syscat: 1 Event: Cardiac disorders(1-42d): 0.3%, Syscat: 2 Event: GI disorders(1-42d): 0.1%, Syscat: 7 Event: Respiratory/Thoracic (1-42d): 0.1%, Syscat: 22 Event: Neoplasms(1-42d): 0.3%, Syscat: 16 Event: Nervous system (1-42d): 0.1%, Syscat: 17 Event: Psychiatric (1-42d): 0.0%, Syscat: 19 Event: Vaccine related SAEs (1-42d): 0.0%, Syscat: 6,15 Event: Death (1-42d): 0.1% Event: Blood/Lymphatic disorders(1-182d): .1%, Syscat: 1 Event: Cardiac disorders (1-182d): 1.2%, Syscat: 2 Event: GI disorders (1-182d): 0.6%, Syscat: 7 Event: Respiratory/Thoracic (1-182d): 0.5%, Syscat: 22 Event: Neoplasms (1-182d): 1.3%, Syscat: 16 Event: Nervous system(1-182d): 0.4%, Syscat: 17 Event: Psychiatric (1-182d): 0.1%, Syscat: 19 Event: Vaccine related SAEs(1-182d): 0.0% Event: Death (1-182d): 0.4%	Blood/Lymphatic disorders(1-182d): OR 1.253 (0.336-4.669) Cardiac disorders (1-182d): OR 1.016 (0.733-1.41) Cardiac disorders(1-42d): OR 1.002 (0.53-1.895) Death (1-182d): OR 1.417 (0.76-2.64) Death (1-42d): OR 1.203 (0.367-3.944) GI disorders (1-182d): OR 1.281 (0.787-2.085) GI disorders(1-42d): OR 1.337 (0.464-3.855) Neoplasms (1-182d): OR 1.317 (0.934-1.858) Neoplasms(1-42d): OR 1.672 (0.731-3.824) Nervous system(1-182d): OR 0.808 (0.476-1.369) Nervous system (1-42d): OR 0.716 (0.227-2.256) Psychiatric (1-182d): OR 60.2 (0.116-31171.904) Psychiatric (1-42d): OR 1.002 (0.141-7.118) Respiratory/Thoracic (1-182d): OR 1.123 (0.654-1.928) Respiratory/Thoracic (1-42d): OR 1.504 (0.424-5.333)

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Mills R. et a.,2010 US[72]	Controlled Clinical Trial	5	Sample size: 101, Mean age: 67.8 (approx.), Age range: 50 - 93, Percent female: 59.4%	Zoster, Zostavax, Merck, Lyophilized zoster vaccine (~89,000 plaque-forming units[PFU]/dose at release), Adjuvant: Not Reported, Preservative: Not reported, Delivery: Subcutaneous	Dose1: 0 Days Dose2: 28 Days	Any adverse event: 52.0%, Syscat: 8 Any SAE: 0%, Sev: 3,4,5 Event: Overall - Injection site AEs: 45.9%, Syscat: 8 Event: Overall - Systemic AEs: 15.3%, Syscat: 8 Event: Overall - Vaccine related AEs: 2.0%, Syscat: 8 Event: Deaths: 0% Event: Stratum 1: 1 or more AEs: 54.4%, Syscat: 8 Event: Stratum 1: Injection site AEs: 47.1%, Syscat: 8 Event: Stratum 1: Systemic AEs: 13.2%, Syscat: 8 Event: Stratum 1: Vaccine related AEs: 1.5%, Syscat: 8 Event: Stratum 2: 1 or more AEs: 46.7%, Syscat: 8 Event: Stratum 2: Injection site AEs: 43.3%, Syscat: 8 Event: Stratum 2: Systemic AEs: 20.0%, Syscat: 8 Event: Stratum 2: Vaccine related AEs: 3.3%, Syscat: 8 Event: 50-59y: 1 or more AE: 47.4%, Syscat: 8 Event: 50-59y: Systemic AE: 5.3%, Syscat: 8 Event: 50-59y: Vaccine related AE: 0%, Syscat: 8 Event: >=60y: 1 or more AE: 53.2%, Syscat: 8 Event: >=60y: Systemic AE: 17.7%, Syscat: 8 Event: >=60y: Vaccine related AE: 2.5%, Syscat: 8	50-59y: Systemic AE: OR 0.245 (0.027-2.231) 50-59y: 1 or more AE: OR 1.899 (0.613-5.88) >=60y: Systemic AE: OR 1.664 (0.685-4.042) >=60y: 1 or more AE: OR 5.371 (2.609-11.054)** Overall - Injection site AEs: OR 19.841 (6.773-58.123)** Overall - Systemic AEs: OR 1.195 (0.537-2.659) Stratum 1: 1 or more AEs: OR 19.185 (5.673-64.881)** Stratum 1: Injection site AEs: OR 3.49 (1.674-7.277)** Stratum 1: Systemic AEs: OR 0.567 (0.236-1.364) Stratum 2: Injection site AEs: OR 14.943 (1.916-116.559)** Stratum 2: Systemic AEs: OR 6.383 (0.754-54.018) Stratum 2: 1 or more AEs: OR 8.058 (1.781-36.46)**

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Simberkoff M. S. et al.,2010 US[75]	Controlled Clinical Trial	7	Sample size: 38546, Mean age: NR, Age range: 60 - NR	Zoster, Merck, Median potency, 24600 plaque-forming units per dose, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Subcutaneous	Dose1: 0 Days	Any adverse event: 1.4%, Sev: 1-5 Any SAE: 1.68%, Sev: 3-5 Event: # of SAE (60-69y): 0.7%, Sev: 3-5 Event: # of SAE (>=70y): 0.98%, Sev: 3-5 Event: # of SAE (70-80y): 0.78%, Sev: 3-5 Event: # of SAE (>=80y): 0.2%, Sev: 3-5 Event: COSTART - Cardiovascular: 0.5%, Syscat: 2, Sev: 3-5 Event: COSTART - Digestive: 0.21%, Syscat: 7, Sev: 3-5 Event: COSTART - Musculoskeletal: 0.08%, Syscat: 15, Sev: 3-5 Event: COSTART - Nervous Sys: 0.18%, Syscat: 17, Sev: 3-5 Event: COSTART - Respiratory: 0.16%, Syscat: 22, Sev: 3-5 Event: COSTART - Sight/Sense: 0.02%, Syscat: 5,6, Sev: 3-5 Event: COSTART - Skin: 0.15%, Syscat: 23, Sev: 3-5 Event: COSTART - Genitourinary: 0.08%, Syscat: 20, Sev: 3-5 Event: COSTART - Endocrine: 0.01%, Syscat: 5, Sev: 3-5 Event: COSTART - Hemic/Lymphatic: 0.03%, Syscat: 1, Sev: 3-5 Event: COSTART - Metabolic/Nutritional: 0.03%, Syscat: 14, Sev: 3-5 Event: Diagnostic grp - Cancer: 0.27%, Syscat: 16, Sev: 3-5 Event: Diagnostic grp - Vascular (pathological)): 0.41%, Syscat: 26, Sev: 3-5 Event: Diagnostic grp - Vascular (functional): .23%, Syscat: 26 Sev: 3-5	# of SAE (60-69y): OR 1.081 (0.847-1.38) # of SAE (70-80y): OR 0.909 (0.728-1.135) # of SAE (>=70y): OR 0.969 (0.793-1.185) # of SAE (>=80y): OR 1.301 (0.808-2.095) COSTART - Cardiovascular: OR 1.117 (0.835-1.496) COSTART - Digestive: OR 0.719 (0.481-1.075) COSTART - Endocrine: OR 0.25 (0.028-2.237) COSTART - Genitourinary: OR 0.941 (0.476-1.864) COSTART - Hemic/Lymphatic: OR 2.501 (0.485-12.894) COSTART - Metabolic/Nutritional: OR 1.667 (0.398-6.978) COSTART - Musculoskeletal: OR 1 (0.489-2.047) COSTART - Nervous Sys: OR 1.03 (0.642-1.652) COSTART - Respiratory: OR 0.973 (0.588-1.609) COSTART - Skin: OR 0.903 (0.542-1.506) Diagnostic grp - Cancer: OR 1.131 (0.76-1.683)
Macaladad N. et al.,2007 Brazil, Costa Rica, Colombia, Mexico, Peru and Venezuela and the Philippines[69]	Controlled Clinical Trial	2	Sample size: 21, Mean age: 38.1, Age range: 27 - 69, Percent female: 66.7%	Zoster, NR, 50,000 PFU/0.5 mL, Adjuvant: Not Reported, Preservative: Not reported, Delivery: injected	Dose1: 0 NR	Any adverse event: 37.5% Any SAE: 0% Event: Injection-site: 25.0%, Syscat: 8 Event: Systemic: 12.5% Event: Vaccine-related (Related to injection-site AE): 25.0%, Syscat: 8 Event: Injection-site (mild burning, erythema and pruritus): 25.0%, Syscat: 8, Sev: 2 Event: Serious vaccine-related AE: 0%	

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Oxman M. N. et al.,2005 USA[73]	Controlled Clinical Trial	3	Mean age: 69 (median), Age range: 60 - >80, Percent female: 41%	Zoster, Merck, Not really addressed. The estimated potency at vaccination of the 12 vaccine lots used in the study ranged from 18,700 to 60,000plaque-forming units per dose. The median potency was 24,600 plaque-forming units, and more than 90 percent of vaccinated subjects received 32,300 plaque-forming units or less., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Subcutaneous	Dose1: 0 NR	Any adverse event: 57.7% Any SAE: 1.4% Event: One or more systemic adverse events: 24.7% Event: One or more vaccine-related systemic adverse events: 6.3% Event: Documented temperature 38.3°C or higher: 0.8%, Syscat: 8 Event: Self-reports of feeling abnormal temperature: 7.2%, Syscat: 8 Event: One or more adverse events at injection site: 48.3%, Syscat: 8 Event: Subjects hospitalized: 34.0% Event: Hospitalization related to herpes zoster: 0.2%	Documented temperature 38.3°C or higher: OR 0.978 (0.572-1.67) One or more adverse events at injection site: OR 4.67 (4.164-5.237)** One or more systemic adverse events: OR 1.058 (0.945-1.185) One or more vaccine-related systemic adverse events: OR 1.296 (1.049-1.601)** Self-reports of feeling abnormal temperature: OR 1.203 (0.987-1.467)
Vermeulen J. N. et al.,2012[76]	Controlled Clinical Trial	4	Sample size: 209, Mean age: 68.7/70.7 (vaccine/placebo), Age range: 58 - 90, Percent female: 63%, Conditions: Arthritis, hyperlipidemia, hypertension,	Zoster, NR, Lyophilized ZV (~23,000 plaque forming unit [PFU]/0.5mL, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Subcutaneous	Dose1: 0 Days Dose2: 42 Days	Any adverse event: 71.2% Any SAE: 0% Event: Vaccine-related AEs: 52.9% Event: Systemic AEs: 12.5% Event: Pruritus: 2.9%, Syscat: 23 Event: # of patients with any AE Dose 2: 76.5% Event: Any Serious Adverse Event Dose 2: 5.1% Event: Vaccine-related AEs Dose 2: 63.3% Event: Systemic AEs Dose 2: 5.1% Event: Rash Dose 2: 2%, Syscat: 23	# of patients with any AE Dose 2: OR 4.203 (2.348-7.522)** Rash Dose 2: OR 2.039 (0.182-22.841) Systemic AEs: OR 14.857 (1.906-115.797)** Systemic AEs Dose 2: OR 0.833 (0.246-2.82) Vaccine-related AEs: OR 8.699 (4.26-17.763)** Vaccine-related AEs Dose 2: OR 11.44 (5.582-23.446)**

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Ngan H. Y. S. et al.,2010 Hong Kong[80]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: 77% Any SAE: 0.67%, Sev: 1-3 Event: Arthralgia: 6%, Syscat: 15, Sev: 1-3 Event: Fatigue: 30%, Syscat: 8, Sev: 1-3 Event: Fever: 8%, Syscat: 8, Sev: 1-3 Event: GI symptoms: 10%, Syscat: 7, Sev: 1-3 Event: Headache: 18%, Syscat: 8, Sev: 1-3 Event: Myalgia: 24%, Syscat: 8, Sev: 1-3 Event: Rash, Syscat: 10, Sev: 1-3 Event: Urticaria: 2%, Syscat: 10, Sev: 1-3

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Bhatla N. et al.,2010 India[81]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Aluminum hydroxide (placebo) Contains only the aluminum hydrozide, no ASO4	Any adverse event: 13.4% Any SAE: 2.2% Event: Miscarriage: 0.6%, Syscat: 18, Sev: 5 Event: Bronchogenic cyst: 0.6%, Syscat: 22 Event: Cataract: 0.6%, Syscat: 6 Event: Pneumothorax of the left lung: 0.6%, Syscat: 22 Event: Pain (Grade 3): 4.0%, Syscat: 17, Sev: 3 Event: Redness (>50 mm): 0.6%, Syscat: 23, Sev: 3 Event: Swelling (>50 mm), Syscat: 23, Sev: 3
Langley J. M. et al.,2011 Canada[42]	Influenza (inactivated), Contains equal parts of three monovalent egg-grown, formalin-inactivated influenza antigens formulated with OMPs of N. meningitidis serogroup B strain 8047 at an initial ratio of OMP to haemagglutinin (HA) of 4:1. After diafiltration to remove detergents necessary to keep the OMPs in stable solution in the absence of antigen, the overall total protein to HA ratio in the final vaccine product is 2.5 to 5:1. The trivalent vaccine stock contained HA from each of A/New Caledonia/20/99 [H1N1], A/Panama/2007/99 [H3N2] and B/Shangdong/7/97 [H1N1, Adjuvant: Not Reported, Preservative: Thimerisol, Delivery: Not Reported	Dose1: 0 Days	Any SAE: 0% Event: Shortness of breath (Grade 2/3): 0%, Syscat: 22, Sev: 3-5 Event: Lightheadedness/Dizziness (Grade2/3): 0%, Syscat: 17, Sev: 3-5 Event: New rash/itchy rash (Grade 2/3): 0%, Syscat: 10, Sev: 3-5 Event: Feverishness (Grade2/3): 0%, Syscat: 8, Sev: 3-5 Event: Burning/stinging nose (Grade2/3): 0%, Sev: 3-5 Event: Burning/stinging throat (Grade 2/3): 0%, Sev: 3-5 Event: Itching nose/throat/eyes (Grade 2/3): 0%, Syscat: 8, Sev: 3-5 Event: Temp >39C: 0%, Syscat: 8, Sev: 3-5 AE: 0% AE: 0% AE: 0%		Event: Shortness of breath (Grade 2/3): 0%, Syscat: 22, Sev: 3-5 Event: Lightheadedness or dizziness (2/3): 0%, Syscat: 17, Sev: 3-5 Event: A new rash or a rash that has become itchy (2/3): 0%, Syscat: 10, Sev: 3-5 Event: Feverishness: 0%, Syscat: 8, Sev: 3-5 Event: Temperature (>39C): 0%, Syscat: 8, Sev: 3-5 Event: Burning or stinging in the nose (2/3): 0%, Syscat: 8, Sev: 3-5 Event: Burning or stinging in the throat (2/3): 0%, Syscat: 8, Sev: 3-5 Event: Itching nose/throat eyes (2/3): 0%, Syscat: 8, Sev: 3-5

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Barrett P. N. et al.,2011 US[43]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Buffered saline	Any adverse event: 22%, Sev: 1-5 Any SAE: 0.7%, Sev: 3-5 Event: Arthralgia: 3%, Syscat: 15, Sev: 1-3 Event: Chills: 3%, Syscat: 8, Sev: 1-3 Event: Cough: 0.7%, Syscat: 22, Sev: 1-3 Event: Fatigue: 12%, Syscat: 8, Sev: 1-3 Event: Headache: 13%, Syscat: 8, Sev: 1-3 Event: Hiperhidrosis: 3%, Syscat: 8, Sev: 1-3 Event: Malaise: 227%, Syscat: 8, Sev: 1-3 Event: Myalgia: 6%, Syscat: 8, Sev: 1-3 Event: Oropharyngeal pain: 0.9%, Syscat: 7, Sev: 1-3 Event: Pyrexia: 1%, Syscat: 8, Sev: 1-3 Event: Death: 0%, Sev: 5 Event: Potentially placebo related SAE: 0.05%, Syscat: 26, Sev: 3
Frey S. et al.,2010 US, Finland, Poland[44]	Influenza (inactivated), Optaflu, Novartis, 15 mg of hemagglutinin per 0.5-mL dose of each virus strain recommended for the 2007–2008 Northern Hemisphere influenza season: A/Solomon Islands/3/2006 (H1N1)–like, A/Wisconsin/67/2005 (H3N2)–like, and B/Malaysia/2506/2004–like, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intramuscular	Dose1: 1 Days	Any SAE: 1.1% Event: Chills (mild-moderate), Syscat: 8, Sev: 1-2 Event: Malaise (mild-moderate): 7.5%, Syscat: 8, Sev: 1-2 Event: Myalgia (mild-moderate), Syscat: 8, Sev: 1-2 Event: Arthralgia (mild-moderate): 3.5%, Syscat: 15, Sev: 1-2 Event: Headache (mild-moderate): 15%, Sev: 1-2 Event: Sweating (mild-moderate), Sev: 1-2 Event: Fatigue (mild-moderate): 10%, Syscat: 8, Sev: 1-2 Event: Fever (mild-moderate): 1%, Syscat: 8, Sev: 1-2 Event: Withdrew after AE: .1%, Sev: 1-2 Event: Death: .1%, Sev: 5 AE: 0%	Placebo Unsure of adjuvants, preservatives and formulations	Any SAE: 0.97% Event: Chills (mild-moderate): 5%, Sev: 1-2 Event: Malaise (mild-moderate): 6%, Sev: 1-2 Event: Myalgia (mild-moderate): 7%, Sev: 1-2 Event: Arthalgia (mild-moderate): 2.6%, Sev: 1-2 Event: Headache (mild-moderate): 15%, Sev: 1-2 Event: Sweating (mild-moderate): 2.5%, Sev: 1-2 Event: Fatigue (mild-moderate), Sev: 1-2 Event: Fever (mild-moderate): 0.5%, Sev: 1-2 Event: Withdrew after AE (mild-moderate): 0.03%, Sev: 1-2 Event: Death (mild-moderate): .03%, Sev: 5
Iorio A. et al.,2010 Italy[45]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo	Any SAE: 0%, Syscat: 0 Event: Nosebleeds: 3.85%, Syscat: 22, Sev: 1-3 Event: Bruising: 0.96%, Syscat: 12, Sev: 1-3 Event: Posttraumatic elbow hematoma: 0%, Syscat: 26 Event: Gingival bleeding: 0%, Syscat: 7 Event: Conjunctival hemorrhage: 0%, Syscat: 6

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Jackson L. A. et al.,2010 US[46]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo saline placebo injection	Any adverse event: 44% Any SAE: 1.0% Event: Fever: 1%, Syscat: 8, Sev: 1-3 Event: Myalgia/arthralgia: 10%, Syscat: 15, Sev: 1-3 Event: Swelling of the face: 1.0%, Syscat: 8, Sev: 1-3 Event: Cough: 7.0%, Syscat: 22, Sev: 1-3 Event: Chest Tightness/Difficulty breathing: 3.0%, Syscat: 22, Sev: 1-3 Event: Sore throat, hoarseness or pain on swallowing: 9.0%, Syscat: 7, Sev: 1-3 Event: Death (road accident): .03%, Sev: 5 AE: 0%
Madhi S. A. et al.,2011 South Africa[49]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Any adverse event: 9.9% Event: Pain: 4.4% Event: Redness: 1.1% Event: Swelling: 0% Event: Lump formation: 2% Event: Bruising: 0% Event: Itching: 1.1% Event: Rigors: 5% Event: Fatigue: 5.5% Event: Headache: 3.3% Event: Fits: 0% Event: Myalgia: 2.2% Event: Arthralgia: 4.4% Event: Fever: 1.1%
Treanor J. J. et al.,2011 USA[47]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Saline injection	Any adverse event: 31.6% Any SAE: 1.3% Event: Fever (=100.4): 0.5%, Syscat: 8, Sev: 1-5 Event: Fatigue or lack of energy: 14.5%, Syscat: 8 Event: Shivering or chills: 3.1%, Syscat: 8 Event: Joint pain: 3.6%, Syscat: 15 Event: Muscle pain: 6.7%, Syscat: 15 Event: Headache: 15.4%, Syscat: 8 Event: Nausea: 181%, Syscat: 7 Event: Pain: 7.9%, Syscat: 8 Event: Bruising: 2.6%, Syscat: 12

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Talaat K. R. et al.,2010 United States[48]	Influenza - monovalent H1N1, CSL Limited, The 15mg dose was supplied in multidose vials of 60 mg of HA per milliliter with thimerosal 0.01% (wt/vol)., Adjuvant: Adjuvant Free, Preservative: Thimerisol, Delivery: Intramuscular	Dose1: NR NR Dose2: 21 Days	Event: Any systemic AE (Dose 1), Syscat: 8, Sev: 1-3 Event: Any systemic AE (Dose 2): 18%, Syscat: 8, Sev: 1-3 Event: Headache (Dose 1), Syscat: 8, Sev: 1-3 Event: Headache(Dose 2): 11%, Syscat: 8, Sev: 1-3 Event: Malaise(Dose 1): 14%, Sev: 1-3 Event: Malaise(Dose 2), Sev: 1-3 Event: Myalgia(Dose 1): 15%, Syscat: 8, Sev: 1-3 Event: Myalgia(Dose 2): 8%, Syscat: 8, Sev: 1-3 Event: Nausea(Dose 1): 5%, Syscat: 8, Sev: 1-3 Event: Nausea(Dose 2): 5%, Syscat: 8, Sev: 1-3 Event: Chills(Dose 1): 3%, Syscat: 8, Sev: 1-3 Event: Chills(Dose 2): 3%, Syscat: 8, Sev: 1-3 Event: Vomiting(Dose 1): 1%, Syscat: 8, Sev: 1-3 Event: Vomiting(Dose 2): 3%, Syscat: 8, Sev: 1-3 Event: Fever(Dose 1): 1%, Syscat: 8, Sev: 1-3 Event: Fever(Dose 2): 1%, Sev: 1-3 AE: 4%	Placebo Placebo was supplied in multidose vials containing vaccine diluent and thimerosal 0.01% (wt/vol). The 7.5microgram vaccine did not have thimerosal.	Event: Any systemic AEs (Dose 1): 23%, Syscat: 8, Sev: 1-3 Event: Any systemic AEs (Dose 2): 21%, Syscat: 8, Sev: 1-3 Event: Headache (Dose 1): 11%, Syscat: 8, Sev: 1-3 Event: Headache (Dose 2): 9%, Syscat: 8, Sev: 1-3 Event: Malaise (Dose 1): 8%, Syscat: 8, Sev: 1-3 Event: Malaise (Dose 2): 11%, Syscat: 8, Sev: 1-3 Event: Myalgia (Dose 1), Syscat: 8, Sev: 1-3 Event: Myalgia (Dose 2): 9%, Syscat: 8, Sev: 1-3 Event: Nausea (Dose 1): 4%, Syscat: 8, Sev: 1-3 Event: Nausea (Dose 2): 2%, Syscat: 8, Sev: 1-3 Event: Chills (Dose 1): 1%, Syscat: 8, Sev: 1-3 Event: Chills (Dose 2): 2%, Syscat: 8, Sev: 1-3 Event: Vomiting (Dose 1): 0%, Syscat: 8, Sev: 1-3 Event: Vomiting (Dose 2): 2%, Syscat: 8, Sev: 1-3 Event: Fever (Dose 1): 1%, Syscat: 8, Sev: 1-3 Event: Fever (Dose 2): 1%, Syscat: 8, Sev: 1-3
Lee S. et al.,2011 Korea[82]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Any adverse event: 40% Event: Serious adverse events (any): 0% Event: Hypoaesthesia (any): 10%, Syscat: 17 Event: Hypoaesthesia (vaccine-related): 0%, Syscat: 17

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Weinberg A. et al.,2010 US (No direct mentions)[79]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Event: Dose 1: Systemic rash (non-zosteriform): 6%, Syscat: 10, Sev: 1,2 Event: Dose 1: Pruritis: 6%, Syscat: 6, Sev: 1,2 Event: Dose 1: Adenopathy: 3%, Syscat: 26, Sev: 1,2 Event: Dose 1: Nose bleed: 0%, Syscat: Not sure, Sev: 1,2 Event: Dose 1: Influenza-like illness: 6%, Syscat: 8, Sev: 1,2 Event: Dose 1: Chest pain: 3%, Syscat: 2, Sev: 1,2 Event: Dose 1: Liver enzyme elevation: 1%, Syscat: 9, Sev: 1,2 Event: Dose 2:Systemic rash (non-zosteriform): 3%, Syscat: 10, Sev: 1,2 Event: Dose 2: Pruritis: 3%, Syscat: 6, Sev: 1,2 Event: Dose 2: Adenopathy: 0%, Syscat: 26, Sev: 1,2 Event: Dose 2: Nose bleed: 0%, Syscat: Not sure, Sev: 1,2 Event: Dose 2: Influenza-like illness: 3%, Syscat: 8, Sev: 1,2 Event: Dose 2: Chest pain: 0%, Syscat: 2, Sev: 1,2 Event: Dose 2: Liver enzyme elevation: 3%, Syscat: 9, Sev: 1,2
Schmader K. E. et al.,2012 North America and Europe[70]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: 41.5% Any SAE: 0.5% Event: With 1 or more injection site AEs: 14.4% Event: With 1 or more systemic AEs: 33.5% Event: Vaccine related AEs: 17.9% Event: Vaccine related injection site AEs: 14.4% Event: Vaccine related systemic AEs: 4.7% Event: Serious vaccine related AEs: 0% Event: SAE with death: .03% AE: 0%

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Vermeulen J. N. et al.,2012 US and Netherlands[71]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Event: 1 or more AE (Dose 1): 43.8% Event: With vaccine-related AEs (Dose 1): 11.4% Event: Systemic AEs (Dose 1): 1.0% Event: SAEs (Dose 1): 0% Event: Discontinued due to vaccine AE (Dose 1): 0% Event: With one or more AE (Dose 2): 39.6% Event: With vaccine-related AEs (Dose 2): 6% Event: Systemic AE (Dose 2): 5.9% Event: Rash: 1%, Syscat: 10 Event: SAEs (Dose 2): 0% Event: Discontinued due to vaccine AE (Dose 2): 0%
Murray A. V. et al.,2011 US, Canada, Spain, Germany, UK[74]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any SAE: 5.0% Event: Blood/Lymphatic (1-42d): 0%, Syscat: 1 Event: Cardiac(1-42d): 0.3%, Syscat: 2 Event: GI(1-42d): 0.1%, Syscat: 7 Event: Neoplasms(1-42d): 0.2%, Syscat: 16 Event: Nervous system(1-42d): 0.1%, Syscat: 17 Event: Psychiatric(1-42d): 0.0%, Syscat: 19 Event: Respiratory(1-42d): 0%, Syscat: 22 Event: Vaccine SAE(1-42d): 0% Event: Death(1-42d): 0.1% Event: Blood/Lymphatic (1-182d): 0.1%, Syscat: 1 Event: Cardiac(1-182d): 1.2%, Syscat: 2 Event: GI(1-182d): 0.5%, Syscat: 7 Event: Neoplasm(1-182d): 1.0%, Syscat: 16 Event: Nervous(1-182d): 0.5%, Syscat: 17 Event: Psychiatric(1-182d): 0.1%, Syscat: 19 Event: Respiratory(1-182d): 0.4%, Syscat: 22 Event: Vaccine SAE(1-182d): 0.0% Event: Death(1-182d): 0.3%

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Mills R. et al.,2010 US[72]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported		Syscat: 8		Any adverse event: 17.7%, Syscat: 8 Any SAE: 0%, Syscat: 8, Sev: 3,4,5 Event: Overall: Injection site AE: 4.3%, Syscat: 8 Event: Overall: Systemic: 13.5%, Syscat: 8 Event: Overall: Vaccine related: 0%, Syscat: 8 Event: Overall: Deaths: 0% Event: Stratum1: With one or more AE: 22.7%, Syscat: 8 Event: Stratum1:Injection AE: 4.5%, Syscat: 8 Event: Stratum1:Systemic AE: 0%, Syscat: 8 Event: Stratum1:Vaccine AE: 0%, Syscat: 8 Event: Stratum2:With one or more AE: 6.7%, Syscat: 8 Event: Stratum2:Injection AE: 3.3%, Syscat: 8 Event: Stratum2:Systemic AE: 3.3%, Syscat: 8 Event: Stratum2:Vaccine AE: 0%, Syscat: 8 Event: 50-59y:With one or more AE: 26.3%, Syscat: 8 Event: 50-59y:Systemic AE: 21.1%, Syscat: 8 Event: 50-59y:Vaccine AE: 0%, Syscat: 8 Event: >=60y:With one or more AE: 15.6%, Syscat: 8 Event: >=60y:Systemic AE: 11.7% Event: >=60y:Vaccine AE: 0%, Syscat: 8

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Simberkoff M. S. et al.,2010 US[75]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported		Syscat: 4	Placebo Unsure of adjuvants, preservatives and formulations	Any adverse event: 1.4%, Sev: 1-5 Any SAE: 1.66%, Sev: 3-5 Event: # of SAE (60-69y): 0.65%, Sev: 3-5 Event: # of SAE (>=70y): 1.01%, Sev: 3-5 Event: # of SAE (70-80y): 0.86%, Sev: 3-5 Event: # of SAE (>=80y): 0.16%, Sev: 3-5 Event: Diagnostic grp - Cancer: 0.24%, Syscat: 16, Sev: 3-5 Event: Diagnostic grp - Vascular (pathological): 0.4%, Syscat: 26, Sev: 3-5 Event: Diagnostic grp - Vascular (functional): 86%, Syscat: 26, Sev: 3-5 Event: COSTART - Cardiovascular: 0.45%, Syscat: 2, Sev: 3-5 Event: COSTART - Digestive: 0.3%, Syscat: 7, Sev: 3-5 Event: COSTART - Endocrine: .02%, Syscat: 5, Sev: 3-5 Event: COSTART - Hemic/Lymphatic: 0.01%, Syscat: 1, Sev: 3-5 Event: COSTART - Metabolic/nutritional: 0.02%, Syscat: 14, Sev: 3-5 Event: COSTART - Musculoskeletal: 0.08%, Syscat: 15, Sev: 3-5 Event: COSTART - Nervous system: 0.18%, Syscat: 17, Sev: 3-5 Event: COSTART - Respiratory, Syscat: 22, Sev: 3-5 Event: COSTART - Skin: 0.16%, Syscat: 23, Sev: 3-5 Event: COSTART - Sight/Sense: 0%, Sev: 3-5 Event: COSTART - Genitourinary: .09%, Syscat: 20, Sev: 3-5
Macaladad N. et al.,2007 Brazil, Costa Rica, Colombia, Mexico, Peru and Venezuela and the Philippines[69]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Any adverse event: 0% Any SAE: 0% Event: Injection-site: 0%, Syscat: 8 Event: Systemic: 0% Event: Vaccine-related (Related to injection-site AE): 0%, Syscat: 8 Event: Injection-site (mild burning, erythema and pruritus): 0%, Syscat: 8, Sev: 2 Event: Serious vaccine-related AE: 0%

Appendix C-2. Evidence Tables – Vaccinated vs Unvaccinated
Adults

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Oxman M. N. et al.,2005 USA[73]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Any adverse event: 34.4% Any SAE: 1.3% Event: One or more systemic adverse events: 23.6% Event: One or more vaccine-related systemic adverse events: 4.9% Event: Documented temperature 38.3°C or higher: 0.9%, Syscat: 8 Event: Self-reports of feeling abnormal temperature: 6.0%, Syscat: 8 Event: One or more adverse events at injection site: 16.6%, Syscat: 8
Vermeulen J. N. et al.,2012[76]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Any adverse event: 43.8% Any SAE: 0% Event: With vaccine-related AEs: 11.4% Event: Systemic AEs: 1% Event: Pruritus: 0%, Syscat: 23 Event: # of patients with any AE Dose 2: 39.6% Event: With vaccine-related AEs Dose 2: 11.9% Event: Systemic AEs Dose 2: 5.9% Event: Rash Dose 2: 0%, Syscat: 23 Event: With serious AEs Dose 2: 0%

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Morgan et al. 2011, Self-controlled case series[109]	N= 169 children with urea cycle disorders (USD); Location= US Age=0-18 years;	A number of vaccines were analyzed but influenza was only specific vaccine reported on.	Self-controls. No details on recruitment and original design of longitudinal Rare Diseases Clinical Research Consortium dataset to assess biases.	Not discussed	169 patients were enrolled and records obtained for 112. There were no statistically significant differences between patients with and without vaccination records in the types of UCDs, onset of hyperammo nemia in first 30 days of life, or hospital where care was provided. Factors associated with unobtainable vaccination records included older mean age of patient at enrollment and the occurrence of HAEs during the study period.	Clinical records	Clinical records	Conditiona l Poisson regression	Age	February 6, 2006, to July 31, 2009	America's Health Insurance Plans under contract from the Centers for Disease Control and Prevention.	Influenza only: Relative Incidences (Table 4) Risk Period: Days After Vaccination 1–7: 2.31 (0.73–7.30) 8–21: 0.78 (0.19–3.12) 1–21: 1.28 (0.52–3.15)	Not given	
Italian Multicenter Study	N=683 children aged 1 month	A-H1N1 Seasonal influenza	Potentially some selective recruitment of	Aside from initial exclusions, no	Not discussed	Parental report	Active surveillance. Both clinically	Logistic regression	Age and chronic diseases; the	November 2009 to August	Italian Medicines Agency	OR of influenza-like illness Any flu vaccine 2.7	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Group for Drug and Vaccine Safety in Children, 2011, Case-control[106]	to 18 years, hospitalized through the emergency departments of eight pediatric hospitals/wards in Italy.		vaccinated children that should have been attenuated by enrolling cases on a specified day of the week.	attrition discussed.			defined and laboratory confirmed hospitalizations for Influenza Like Illness (ILI) were considered. Adverse events ascertained through parental report.		ORs of A-H1N1 and seasonal vaccine were each adjusted for the other influenza vaccine.	2010		(1.6 to 4.7) A-H1N1 1.3 (0.6 to 3.1) Seasonal vaccine 2.1 (1.1 to 4.1)		
Mommers et al. 2004, Case-control[191]	N=510; Location=Dutch-German borderland; Age=7-8 years; Setting=Participants in a longitudinal study on respiratory health in children was conducted in the Dutch-German borderland, involving the Municipal Health Services of Kreis Heinsberg, Germany and of the Westelijke Mijnstreek, the Netherlands.	Bacille Calmette-Guerin (BCG), pertussis, measles/mumps, rubella, and Haemophilus influenza type b (Hib)	Vaccinated and unvaccinated children may differ in other respects than those accounted for in the regression models. Authors note that for instance, atopic parents may be more reluctant to vaccinate their children than nonatopic parents. In the data however, the authors found no evidence of selective avoidance of vaccination of their child by parents with self-reported asthma.	In 1995, parents of all 5,052 children born between November 30, 1989–December 1, 1990 and living in the study area were invited to participate. Parents of 3,871 children (76.6%) returned the completed questionnaire on respiratory symptoms and diagnosis. A second survey was conducted in 1997; 218 children (5.6%) were lost to follow-up because they had moved out of the study area	Not discussed	Data on vaccination status and childhood infections were obtained from the Youth Health Care Department of the participating Municipal Health Services. In the Netherlands, vaccination status was registered during routine checkups of children. In Germany, vaccination status was registered during the checkup of school beginners at	Parental questionnaires were sent for self-completion. In the presence of one or both parents, completeness of the questionnaire was checked by an assistant of the Municipal Health Service, and blood samples were taken for immunological analysis.	Multivariate logistic regression	Gender, birth order, country of residence, socioeconomic status, breastfeeding, exposure to environmental tobacco smoke, home dampness, pets, and childhood infections (measles, mumps, rubella, varicella, and scarlet fever). Analyses stratified according to country of residence or respiratory status were additionally performed.	1995-1997	European Union; Euregio Maas-Rhine; Land Northrhine-Westphalia; Province of Limburg; Counties of Heinsberg, Midden-Limburg, and Westelijke Mijnstreek.	Odds Ratios and 95% Confidence Intervals for Association Between Risk Factors and Atopic Disease Pertussis Respiratory symptoms 0.83 (0.45–1.52) Allergic sensitization 0.89 (0.47–1.70) Sensitized against grasses 0.84 (0.38–1.84) Sensitized against HDM 1.02 (0.46–2.25) Measles Respiratory symptoms 0.93 (0.30–2.90) Allergic sensitization 1.51 (0.43–5.35) Sensitized against grasses 2.85 (0.45–18.08) Sensitized against HDM 1.93 (0.38–9.95)	Gender (male vs. female) Respiratory symptoms 1.68 (1.13–2.49) Allergic sensitization 2.68 (1.76–4.09) Sensitized against grasses 3.44 (2.05–5.76) Sensitized against HDM 2.90 (1.69–4.96) Birth order Only younger siblings Respiratory symptoms 1.06 (0.54–2.08) Allergic sensitization 0.57 (0.29–1.13) Sensitized against grasses 0.52 (0.24–1.12) Sensitized against HDM 0.74 (0.30–1.83) 1 older sibling	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
				or were unlocatable. Of the remaining 3,653 children, 2,884 (78.9%) completed the 1997 questionnaire. Children with respiratory symptoms as well as controls were selected based on the answers given in the first and second surveys. The parents of 775 (76.0%) 7–8-year-old children returned the completed questionnaire.		age 5–6 years.						Rubella Respiratory symptoms 1.17 (0.65–2.10) Allergic sensitization 0.85 (0.46–1.57) Sensitized against grasses 0.75 (0.36–1.56) Sensitized against HDM 0.89 (0.41–1.92) Hib Respiratory symptoms 1.39 (0.60–3.19) Allergic sensitization 0.74 (0.30–1.79) Sensitized against grasses 0.55 (0.19–1.58) Sensitized against HDM 1.14 0.33–3.89 Frequencies of BCG, Pertussis, Measles, Rubella, and Hib Vaccination in Children With Respiratory Symptoms and in Sensitized Children Respiratory symptoms Pertussis: 0.85 (0.60–1.19) Measles: 0.86 (0.36–2.06) Rubella: 0.94 (0.64–1.38) Hib: 1.14 (0.82–1.58) Allergic sensitization Pertussis: 1.04 (0.73–1.47)	Respiratory symptoms 0.91 (0.47–1.76) Allergic sensitization 0.47 (0.24–0.92) Sensitized against grasses 0.44 (0.20–0.95) Sensitized against HDM 0.75 (0.31–1.82) 2 older siblings Respiratory symptoms 1.63 (0.74–3.60) Allergic sensitization 0.40 (0.18–0.91) Sensitized against grasses 0.40 (0.16–1.02) Sensitized against HDM 0.69 (0.24–1.97) >2 older siblings Respiratory symptoms 0.95 (0.30–3.02) Allergic sensitization 0.33 (0.09–1.15) Sensitized against grasses 0.20 (0.04–1.13) Sensitized against HDM 0.29 (0.05–1.71)	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												Measles: 1.59 (0.61–4.17) Rubella: 0.80 (0.54–1.19) Hib: 0.94 (0.67–1.32)		
Hummel et al. 2000, Prospective cohort[202]	N=823; Location=Germany; Age=0-2 years; Setting=German BABYDIAB Study	Bacille Calmette-Guérin [BCG]); haemophilus influenza (HIB); diphtheria, tetanus, and pertussis (DTP); poliomyelitis; tick-born encephalitis (TBE); and measles, mumps, and rubella (MMR)	Study design described in another paper.	From 1989 until the time of analysis (1999), 1,002 of 1,553 offspring recruited at birth had reached the age of 2 years; 823 (82%) participated in the 2-year follow-up visit and were included into this analysis. Completed questionnaires were returned from 626 offspring (76.1%). Information concerning total duration of breast-feeding, exclusive time of breast-feeding, vaccinations, and infections was missing from 110, 137, 56, and 68 offspring, respectively.	Not discussed	Structured questionnaires	Direct measurement	Odds ratios were calculated as the ratio of the proportion of offspring with islet antibodies in those with breast-feeding times greater and less than 3 months and in those with and without a vaccination event.	None mentioned	1989-1999	Work was supported by grants from the Bundesministerium für Forschung, Bildung und Technologie	Figure 2. Risk (odds ratio) for developing islet antibodies with respect to environmental factors. (Estimates from figure) Hib: 1.4 (0.07-4.00) Measles: 1.6 (0.07-7.00) Mumps: 1.2 (0.08-3.50) Rubella: 1.3 (0.07-4.00)	None given	Ziegler AG, Hummel M, Schenker M, Bonifacio E: Antibody appearance and risk for the development of childhood diabetes in offspring of parents with type 1 diabetes: the German BABYDIAB Study. Diabetes 48:460–468, 1999

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Gruber et al. 2008, Retrospective cohort[190]	N=2173 (cases with atopic dermatitis and family history of allergy); Location=12 countries, Australia, Austria, Belgium, Czech Republic, France, Germany, Italy, the Netherlands, Poland, South Africa, Spain, and the UK; Age=1-2 years; Setting=97 study centers in 10 European countries, South Africa and Australia	Diphtheria, tetanus, pertussis, polio, Haemophilus influenza Type B, hepatitis B, mumps, measles, rubella, varicella, BCG, meningococci and pneumococci	Participants recruited into a randomized clinical trial but no real details given. Results for this paper taken from screening population before randomization occurred.	Eleven children with all immunization data missing were excluded from further analyses but no differences discussed.	Not discussed	Recorded from immunization cards	Scoring atopic dermatitis (SCORAD) tool administered by trained investigators for atopic dermatitis severity. All IgE measurements were performed in three central laboratories with the Pharmacia ImmunoCAP fluorescence enzyme immunoassay technology.	Logistic regression	Total assessed: country, age, gender, birth weight, maternal age, family history of atopy, presence of siblings, breastfeeding, parental smoking, day care, exposure to pet animals and SCORAD total index.	March 2002 and March 2004	UCB Pharma, Brussels, Belgium	OR (95% CI) for IgE-sensitivity to aeroallergens Infants immunized against hepatitis B at birth were less likely to be IgE-sensitized to aeroallergens (adjusted Hepatitis B at birth: 0.54 (0.32, 0.90), p = 0.018 No effect was seen for hepatitis B immunization later on in life. OR (95% CI) for sensitivity to food allergens Newborns immunized against polio: 2.60 (1.08–6.25,) p = 0.032 Immunization against polio later in life: NS OR (95% CI) for elevated total IgE hepatitis B vaccine (first 6 months): R 1.48 (1.03–2.13), p = 0.034 OR (95% CI) for elevated total IgE varicella immunization in the first year: 0.27 (0.08–0.87), p = 0.028 varicella immunization in the 3 months before screening: 0.28 (0.14–	Not given	ORs are also presented in figure 2.

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												0.56), p = 0.0003 varicella immunization since birth: 0.37 (0.21–0.65), p = 0.0005 rubella immunization since birth: 0.79 (0.63–0.99), p = 0.043 pneumococci immunization since birth: 0.49 (0.27–0.92), p = 0.027 No significant association of vaccination status and atopy (as defined by any positive IgE test) was found. OR (95%CI) for a moderate to severe SCORAD index immunization against polio in the first 6 months: 0.66 (0.45–0.97), p = 0.034 pertussis immunization in the first year: 0.30 (0.10–0.89), p = 0.027 OR (95% CI) for eczema severity varicella immunization in the first year: 0.34 (0.12–0.93), p = 0.036 varicella immunization since birth: 0.56 (0.33–0.93), p = 0.026		

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Ma et al. 2005, Case-control[199]	N=732; Location=California; Age=0-14 years; Setting=Northern California Childhood Leukemia Study (major pediatric clinical centers)	DPT, polio, MMR, Hib, Hepatitis B	Details given in other papers, but there is a detailed protocol for control selection. Only issue is with hospital case selection if the hospital cases differed systematically from the general population controls.	Approximately 85% of the eligible cases consented to participate. 82.5% of controls were eligible.	Did not discuss	Records obtained from parents or physicians.	Ascertainment from pediatric clinical centers within 72 hours of diagnosis.	Conditional logistic regression	Matched on date of birth, sex, mother's race and Hispanic status. Adjusted for maternal education and annual household income.	1995-2002	National Institute of Environmental Health Sciences	Table 4: Vaccinations and the risk of childhood leukemia—adjusted odds ratios Each dose before the reference date DPT Leukemia: 0.97 (0.74, 1.28) ALL: 0.96 (0.72, 1.28) Polio Leukemia: 1.14 (0.88, 1.47) ALL: 1.08 (0.82, 1.41) MMR Leukemia: 1.06 (0.69, 1.63) ALL: 0.87 (0.55, 1.37) Hib Leukemia: 0.81 (0.68, 0.96) ALL: 0.81 (0.66, 0.98) Hepatitis B Leukemia: 0.97 (0.77, 1.23) ALL: 1.01 (0.78, 1.31)	Not given	
Pagaoa et al. 2011, Case-control[201]	N=14,000(2800 cancer cases, 11,200 controls); Location= Texas; Age=2 to 17 years; Setting= Texas Cancer Registry combined with birth certificate	DTaP, IPV, MMR, Hib, Hepatitis B, Varicella Zoster, 4-3-1 (Four doses of DTaP, 3 doses of IPV, 1 dose of MMR), 4-3-1-3 (Four doses of DTaP, 3 doses of IPV, 1 dose of MMR, 3 doses of	Cancer patients may differ from the general population in certain ways that make them systematically different (e.g., more likely to be vaccinated).	3871 cancer cases assessed originally, a total of 2800 were included.	Not discussed	Rates from the Texas Department of State Health Services, validated with vaccination records; also data gotten from state's active surveillance systems.	Texas Cancer Registry	Multilevel mixed-effects regression model	Stratified analyses with infant sex, race/ethnicity, maternal age at birth, birth weight, and parity. Subjects matched on sex and birth year. Adjusted for	1995 to 2006	Not listed	OR (95% CI) for total cancer cases DTaP: 0.92 (0.80-1.07), p=0.28 IPV: 0.93 (0.81-1.07), p=0.30 MMR: 0.92 (0.82-1.02), p=0.11 Hib: 0.84 (0.70-1.00), p=0.05 4-3-1: 0.90 (0.80-1.03), p=0.13 4-3-1-3: 0.98 (0.87-1.11), p=0.78	None reported	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	data to identify eligible participants	Hib), 4-3-1-3-3, 4-3-1-3-3-1.							sex, child's birth year, child's ethnicity, child's birth weight, mother's age at child's birth.			OR (95% CI) for acute lymphoblastic leukemia DTaP: 0.82 (0.63-1.06), p=0.12 IPV: 0.83 (0.63-1.09), p=0.17 MMR: 0.87 (0.71-1.08), p=0.21 Hib: 0.58 (0.42-0.82), p=0.002 4-3-1: 0.77 (0.60-1.00), p=0.05 4-3-1-3: 1.04 (0.74-1.47), p=0.80 OR (95% CI) for Non-Hodgkin Lymphoma DTaP: 0.88 (0.58-1.32), p=0.53 IPV: 1.01 (0.59-1.74), p=0.98 MMR: 0.99 (0.63-1.55), p=0.96 Hib: 0.65 (0.26-1.59), p=0.34 4-3-1: 0.98 (0.59-1.64), p=0.95 4-3-1-3: 1.18 (0.70-1.98), p=0.54 OR (95% CI) for Medulloblastoma DTaP: 1.11 (0.71-1.73), p=0.65 IPV: 1.49 (0.89-2.52), p=0.13 MMR: 1.10 (0.70-1.72), p=0.68 Hib: 1.45 (0.75-2.80), p=0.28 4-3-1: 1.39 (0.85-2.27), p=0.19 4-3-1-3: 1.46 (0.90-2.36), p=0.12 County-level vaccination rates:		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												OR (95% CI) for total cancer cases DTaP: 1.20 (0.90-1.60), p=0.21 IPV: 0.88 (0.74-1.05), p=0.17 MMR: 1.10 (0.84-1.45), p=0.48 Hib: 0.92 (0.82-1.04), p=0.18 Hepatitis B: 0.81 (0.67-0.98), p=0.03 Varicella Zoster: 1.03 (0.92-1.16), p=0.60 4-3-1: 1.00 (0.89-1.11), p=0.93 4-3-1-3-3: 0.90 (0.74-1.09), p=0.28 4-3-1-3-3-1: 0.98 (0.88-1.10), p=0.77 OR (95% CI) for acute lymphoblastic leukemia DTaP: 1.02 (0.61-1.72), p=0.92 IPV: 0.67 (0.49-0.92), p=0.01 MMR: 0.84 (0.51-1.39), p=0.49 Hib: 0.76 (0.54-1.08), p=0.13 Hepatitis B: 0.63 (0.46-0.88), p=0.006 Varicella Zoster: 1.07 (0.78-1.47), p=0.67 4-3-1: 0.73 (0.51-1.06), p=0.10 4-3-1-3-3: 0.62 (0.44-0.87), p=0.007 4-3-1-3-3-1: 0.77 (0.50-1.17), p=0.22 OR (95% CI) for Non-Hodgkin Lymphoma DTaP: 2.34 (0.93-5.90), p=0.07		

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												IPV: 0.73 (0.31-1.72), p=0.47 MMR: 2.81 (1.27-6.22), p=0.01 Hib: 0.98 (0.59-1.64), p=0.94 Hepatitis B: 0.77 (0.32-1.81), p=0.54 Varicella Zoster: 0.97 (0.58-1.62), p=0.91 4-3-1: 1.13 (0.71-1.82), p=0.60 4-3-1-3-3: 1.22 (0.40-3.69), p=0.72 4-3-1-3-3-1: 0.84 (0.51-1.38), p=0.49 OR (95% CI) for Medulloblastoma DTaP: 1.43 (0.44-4.63), p=0.55 IPV: 1.47 (0.73-2.96), p=0.28 MMR: 1.20 (0.37-3.88), p=0.76 Hib: 1.62 (1.00-2.62), p=0.05 Hepatitis B: 1.39 (0.67-2.91), p=0.38 Varicella Zoster: 0.90 (0.54-1.51), p=0.70 4-3-1: 1.14 (0.60-2.18), p=0.69 4-3-1-3-3: 1.58 (0.76-3.30), p=0.22 4-3-1-3-3-1: 1.12 (0.58-2.17), p=0.74		

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Sun et al. 2012, Prospective cohort study and self-controlled case series[194]	N=378,834 (cohort study), 7811 children with febrile seizures (cases); Location=Denmark; Age=0-7 years; Cohort was identified by using information from the Danish Civil Registry	DTaP-IPV-Hib	Both inpatients and outpatients were included in the register system lessening chance of selection bias. Children with missing values on vaccination remained in the reference cohort and tended to bias the association toward the null hypothesis. Authors note, "Any misclassification of febrile seizures or epilepsy is likely to be non-differential and cause a bias of the HR toward the null hypothesis, but we expect this bias to be small."	Study had almost complete follow-up of all children born in Denmark during a 6-year period due to nationwide registries.	Study indicated there should be little difference.	Information on vaccinations was obtained from reports submitted from general practitioners (GPs) to the Danish Health Insurance Registry.	Information on febrile seizures and epilepsy was obtained from the Danish National Hospital Register.	Cohort study: Cox proportional hazard SCCS: conditional Poisson regression	Cohort: child's sex, multiple births, calendar year of birth, season, gestational age, birth weight, parity of the mother, parental history of epilepsy, maternal education, and family income at the time of birth. Season was included as a time-varying variable. SCCS: age of the child (1-week interval) and the season of the observation period.	2003-2009	Lundbeck Foundation. Dr Sun also received support from the Lennart Grams Memorial Foundation. The data recruitment was supported by grants from the Danish Medical Research Council, NordForsk, and Seventh Framework Programme (FP7) grant from the European Research Council.	Cohort analysis - Adjusted HR Time After DTaP-IPV-Hib Vaccination First Vaccination 0 days: 6.02 (2.86-12.65) 1-3 days: 1.38 (0.58-3.31) 4-7 days: 0.41 (0.10-1.69) 0-7 days: 1.64 (0.93-2.88) Second Vaccination 0 days: 3.94 (2.18-7.10) 1-3 days: 1.57 (0.91-2.72) 4-7 days: 0.52 (0.23-1.18) 0-7 days: 1.36 (0.93-1.98) Third Vaccination 0 days: 1.07 (0.73-1.57) 1-3 days: 0.89 (0.70-1.14) 4-7 days: 1.06 (0.87-1.28) 0-7 days: 0.99 (0.86-1.15) SCCS analysis Relative IR Time After DTaP-IPV-Hib Vaccination First Vaccination 0 days: 6.49 (3.10-13.61) 1-3 days: 1.47 (0.62-3.50) 4-7 days: 0.44 (0.11-1.81) 0-7 days: 1.65 (0.94-2.90) Second Vaccination	Differences between boys and girls not significant.	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												0 days: 3.97 (2.20-7.16) 1-3 days: 1.52 (0.88-2.64) 4-7 days: 0.49 (0.22-1.11) 0-7 days: 1.32 (0.90-1.92) Third Vaccination 0 days: 1.07 (0.73-1.57) 1-3 days: 0.89 (0.70-1.14) 4-7 days: 1.06 (0.87-1.28) 0-7 days: 0.99 (0.86-1.15)		
Mullooly et al. 2007, Case-control[192]	N=1074 (844 atopy cases, 230 controls); Location=West Coast; Age=6-16 years; Setting=Kaiser Permanente Northwest (KPNW) HMO	DTP, MMR, HBV, IPV, HIB	Cases and controls drawn from same population and underwent same allergen test. Some tests were incomplete so there may have been some outcome misclassification.	Of the 1287 continuously eligible children referred to allergy clinics during 1987–2001, 1150 (89%) had records of skin tests. We excluded 14 patients with a skin test because of serious chronic conditions or treatments, which left 1136 study-eligible patients. Eight hundred forty-four (74%) had a positive skin test for at least one	Not discussed	Vaccinations were abstracted from electronic medical records (EMR) and from paper-based medical charts.	Atopy or atopic predisposition in early childhood was determined according to skin-prick test results from ages 6–16 years.	Logistic regression	Covariates associated with atopy at $p < 0.20$ in bivariate analyses were included in the regression models. Controls for age at skin test, gender, race, maternal/family history of atopy, low birth weight, maternal age at birth, breast feeding at 2 months, household smoking, dogs in home, calendar period of skin test (1978–	Study participants eligible if skin tested for inhalant allergens during 1987-2001 and enrolled in KPNW since birth.	Supported in part by CDC through a subcontract with America's Health Insurance Plans (AHIP).	OR (95% CI) for atopy All cases versus all controls No. of pertussis doses 1.06 (0.89–1.27) No. of measles doses 0.85 (0.56–1.29) No. of HIB doses 0.93 (0.81–1.08) No. of HBV doses 1.15 (0.88–1.49) All cases versus asthma controls No. of pertussis doses 0.98 (0.74–1.29) No. of measles doses 0.80 (0.42–1.53) No. of HIB doses 0.88 (0.73–1.07) No. of HBV doses 1.04 (0.75–1.45) Asthma cases versus asthma controls No. of pertussis doses 0.95 (0.71–1.29) No. of measles doses	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
				allergen and were classified as atopy cases. Sixty-two of the 292 with no positive skin tests were tested for two or fewer allergens and were excluded from the study as having indeterminate atopy status, leaving 230 non-atopic controls. Atopy cases accounted for 79% (844) of the 1074 eligible study subjects.					93, 1994–99, 2000–01).			0.69 (0.36–1.35) No. of HIB doses 0.88 (0.72–1.08) No. of HBV doses 1.05 (0.73–1.50)		
Chen et al. 1997, Prospective cohort[195]	N=~242,000 (MMR, DTP, though I'm unsure on this) 12,626 and 3,379 for 10-12 year olds and 14-16 year olds respectively for Td); Location=US; Age=0-6 years; Setting=Vaccine Safety Datalink (VSD) project (4 HMOs, Group Health	DTP, MMR, Td, Hib (example analytic studies)	Entire population of VSD, but no detail of potential differences between sites in ascertainment or vaccination procedures.	Not discussed	Not discussed	VSD record review	International Classification of Diseases (ICD)-9 codes for all hospitalizations and emergency department visits are compiled for the VSD study cohort.	Cox regression model (DTP and MMR and seizures)	MMR/DTP - stratified by HMO and birth date, adjusted for other vaccines. Age (Td)	1991-1994	Not given (assume CDC)	Relative risk and 95% confidence interval of seizures and persistent seizure disorders following DTP and MMR vaccinations in the Vaccine Safety Datalink Project (estimates from figure). DTP Interval (days post vaccination) 0 days: 2.20 (1.50-3.40) 1-3 days: 1.00 (0.70-1.40) 4-7 days: 0.80 (0.50-	Not given	Article discusses the VSD generally and then gives a couple examples of the analytic capabilitie which are abstracted here.

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	Cooperative (GHC) of Puget Sound in Washington, Northwest Kaiser Permanente (NWK) in Oregon, Northern California Kaiser (NCK), and Southern California Kaiser (SCK) Permanente											1.00) 8-14 days: 0.85 (0.60-0.90) 15-30 days: 0.84 (0.70-0.90) MMR Interval (days post vaccination) 0 days: 0.80 (0.30-1.90) 1-3 days: 0.50 (0.20-1.00) 4-7 days: 1.80 (1.20-2.70) 8-14 days: 2.50 (2.20-3.30) 15-30 days: 1.00 (0.90-1.20) On crude analysis, a possible association was found 8 to 14 days after vaccination with both Hib (1.40 (1.2-1.8)) and MMR (2.30 (1.9-2.9)) vaccines. After adjustment there was no association between Hib and seizures (0.90 (0.7-1.2)), whereas the association with MMR persisted (2.42 (1.8-3.2)). Rates of Hospitalization and Emergency Department Visits After Tetanus-Diphtheria (Td) Toxoid Vaccination by Age: Vaccine Safety		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												Datalink Project Within 7 days of Td Hospitalization: 1.53 (0.65–3.48), p=0.38 Emergency department visit: 1.49 (0.98–2.23), p=0 .06 Emergency department visit: 0.93 (0.40–2.11), p=0.99 Within 14 days of Td Hospitalization: 1.47 (0.74–2.90), p=0.31 Emergency department visit: 1.46 (1.05–2.01), p=0.03 Emergency department visit: 1.42 (0.80–2.47), p=0.25 Within 30 days of Td Hospitalization: 1.53 (0.85–2.72), p=0.18 Emergency department visit: 1.23 (0.96–1.58), p=0.11 Emergency department visit: 1.03 (0.66–1.60), p=0.96		
Bernsen et al. 2006,[189] Study says observational cross-sectional study - they are collecting information on exposures and outcomes at the same	N=1875; Location=Netherlands; Age=8-12 years; Setting=Orthodox Reformed (Protestant) primary schools	DTP-IPV (diphtheria-tetanus-pertussis-(inactivated) poliomyelitis vaccination)	Information biases based on self-reported data. Physician-diagnosed outcomes introduce bias due to populations systematically differing between those who see doctors versus those who do	A total of 1875 children returned the questionnaire (a response rate of 42%), of which three questionnaires were excluded because of missing vaccination status).	Did not discuss	Self-report (questionnaires)	Self-report (questionnaires) Blood samples were taken for objective assessment of outcome. 72% of the participants gave informed consent for a blood sample (73.6% of the vaccinated, and	Logistic regression	A variable was included in the multivariate model if it changed the univariate point estimate by at least 10%. Following confounders were assessed: Season of	Autumn 2003–Spring 2004	Not given	OR (95% CI) for Atopic disorders Asthma: 1.04 (0.76–1.42) Hay fever: 0.79 (0.55–1.12) Eczema: 0.87 (0.66–1.14) Food allergy: 1.13 (0.71–1.81) Any atopic disorder: 1.00 (0.80–1.24) OR (95% CI) for Physician diagnosed	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
time, but assessing childhood vaccination in the first year of life and "ever had" diseases but also current adverse events so study is prospective in some cases but difficult to tease apart			not. Study assessed the possibility of selection bias due to low response rates of schools and children and determined that the chances were small.				70.3% of the unvaccinated children). From these children a random stratified sample of 100 children were selected. On the basis of the objective allergy data of 100 children and other relevant variables, authors imputed the objective allergy for the remaining 1773 children.		birth; Birth order; Gender; Gestational age; Birth weight; Age of the mother at the time of delivery; Exposure to smoking (prenatally, during the first year of life and currently); Breast feeding for four months or more (yes/no); Housing in the first year of life (rural and living on a farm with livestock/rural, other/city); Pet keeping (furry pets or birds yes/no) during the first year of life and currently; Day care starting at age 6 months or less (yes/no); Current age; Asthma and/or allergy of the parents and/or siblings;			atopic disorders Asthma: 1.03 (0.72–1.46) Hay fever: 1.06 (0.59–1.90) Eczema: 0.96 (0.73–1.25) Food allergy: 1.13 (0.71–1.81) Any atopic disorder: 1.04 (0.82–1.31)		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
									Highest educational level of the parents; Family income; Current level of urbanization (five levels); Living on a farm with livestock (yes/no); Sibship size; Mold in the child's bedroom in the past year; Frequent (more than 5 days/week) consumption of fruit (yes/no) (raw or cooked) vegetables (yes/no) anti-oxidants (yes/no) unskimmed dairy products (yes/no) whole meal bread (yes/no); Frequent (at least 1 day/week) consumption of fish; Frequent exercise (school gym					

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
									at least once a week and playing games with physical activity for at least half an hour a day and either being a member of a sporting club or walking or cycling from home to school vice versa for at least 1 h a day); Body mass index; Hib vaccination. In all models family size, education and atopic history of parents or siblings proved to be confounders.					
Klein et al. 2011, Case-control[209]	N= 1,617, including 77 cases with inborn metabolic disorders and 1,540 controls; Age= <=18 years; Setting=Northern California Kaiser Permanente (KPNC)	Dtwp, Dtap, MMR, oral poliovirus vaccine, inactivated poliovirus vaccine, hepatitis B, and Haemophilus influenza type B vaccine (study lumps together).	Entire HMO population. Possible biases if cases treated differently in regards to vaccination versus those without Inborn Error of Metabolism (IEM).	We identified 249 individuals with a single IEM ICD-9 code from 1990 to 2007 who were born at KPNC and had continuous membership until 2 years of age, which decreased to 131 when	Not discussed	Medical records	Medical records	Poisson regression	None beyond matching variables (gender, birth month and year, and birth facility).	1990 to 2007	Contract with America's Health Insurance Plans from the Centers for Disease Control and Prevention.	There were few differences in percentage of children with IEM who were up to date at 2 years of age for receipt of vaccines according to recommended schedule when compared to matched health controls. One exception was that children with "chronic" IEM were less likely to have received all	None	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
				requiring 2 separate IEM ICD-9 codes. We excluded an additional 54 individuals after medical record review for a final immunization rates study population of 77 IEM subjects and 1,540 matched control subjects.								recommended dose of polio, hepatitis B, and MMR by age two. Risk of hospitalization during post vaccination days 0 to 14 was elevated among 1 to 4 year old children in the "sickest" group of IEM cases RR 4.2, 95% CI 1.2 - 15.1.		
Aljadhey et al. 2012, Prospective cohort[105]	N=359 (169 vaccinated group, 190 control); Location= Riyadh, Saudi Arabia; Age=6-18 years; Setting= Schools	H1N1 vaccine (Pandemrix)	Populations drawn from same schools and similar age groups, but differed by having parents who agreed or didn't agree to vaccination. No mention if there might be systematic differences between the groups (e.g., children of parents who declined vaccinations tended to be sicker or received less medical care overall).	Response rate was 97% (372 initially contacted, 359 responded and included).	No assessment of differences between responders and non-responders.	Research team visited schools and offered vaccine to students.	Self-report - a pharmacist was trained to conduct phone interviews.	Logistic regression	Age, sex, education, use of medications	Not given	Support from the Medication Safety Research Chair at King Saud University, National Plan for Science and Technology, Data Safety Managemen t Board, lead author is employee of Drug Safety Research Unit which receives grants from pharmaceuti cal companies.	OR (95% CI) for Hospitalization or ED H1N1: 1.25 (0.47-3.35) OR (95% CI) for Flu-like symptoms H1N1: 0.63 (0.41-0.99)	Not given	Recall bias a potential concern as well.

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Gallagher and Goodman 2010, Cross-sectional[170]	N=7074 (30 with autism, 7044 without autism); Location= US; Age=boys 3 through 17 years born prior to 1999; Setting= National Health Interview Survey	Hepatitis B	Study notes, a greater proportion of children without autism diagnosis had vaccination records. (Observations without a vaccination record were excluded so autism diagnosis prevalence may be underestimated.) Incomplete and missing data may introduce bias in the analysis.	Patients with missing values for outcome, exposure, or risk factor variables were excluded from analyses.	Study did not discuss	Self-report with trained interviewers	Self-report with trained interviewers	Logistic regression	Race/ethnicity, two-parent household, maternal education	1997 through 2002	Unfunded	OR (95% CI) of autism diagnosis Received first dose of hepatitis B vaccine during first month of life OR=3.00 (1.11-8.13), p=0.031	Non-Hispanic white: 0.36 (0.15-0.88), p=0.025 Two-parent household 0.30 (0.12-0.75), p=0.010 Maternal education, high school or higher 2.32 (0.85-6.30), p=0.099	
Mullooly et al. 2011, Self-controlled case series[210]	N=18,628; Location= US; Age=0-16 months; Setting= Infants born at five health maintenance organizations	Hepatitus B, DTaP, HiB, IPV, MMR, Varicella, PCV7, TIV	HMO study population, possible generalizability issues if population differed from general.	Authors note ascertainment of infants with complex medical condition indicator ICD-9 codes was likely incomplete (e.g., omitted renal failure), however misclassification does not threaten the validity of results since there was no evidence of	Not discussed	HMO database record review	Database record review: ICD-9 coded database records. Random samples of medical charts of non-fragile premature infants with wheezing lower respiratory diseases (WLRD) ICD-9-CM codes were abstracted to assess the	Cox proportional hazard regression	age, seasonal circulation of respiratory viruses (RSV, Rhinovirus), and frequency of well-baby visits (WBV), and linear and quadratic age effects.	The study population of premature infants born into the HMOs during 1997–2002 was followed for the first 16 months of life.	Subcontract with America's Health Insurance Plans (AHIP)from the Centers for Disease Control and Prevention (CDC).	Adj HR of WLRD, non-fragile 1–7 days HBV: 0.59 (0.49–0.72) DTaP: 0.68 (0.58–0.81) HiB: 0.68 (0.58–0.8) IPV: 0.61 (0.5–0.75) MMR: 0.55 (0.41–0.74) Varicella: 0.61 (0.45–0.83) PCV7: 0.72 (0.59–0.87) TIV: 0.47 (0.29–0.78) 8–14 days HBV: 0.84 (0.72–0.98) DTaP: 0.97 (0.85–1.11)	None	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
				increased wheezing lower respiratory diseases (WLRD) risk in either population.			positive predictive value (PPV) of diagnosis codes and the accuracy of medical-care encounter sequences as proxies for WLRD onsets.					HiB: 0.96 (0.84–1.09) IPV: 0.91 (0.78–1.07) MMR: 0.68 (0.52–0.88) Varicella: 0.71 (0.53–0.94) PCV7: 0.95 (0.8–1.12) TIV: 0.73 (0.48–1.09) 15–30 days HBV: 0.95 (0.85–1.05) DTaP: 1.08 (0.99–1.19) HiB: 1.05 (0.96–1.15) IPV: 1.04 (0.93–1.16) MMR: 0.83 (0.69–1.00) Varicella: 0.92 (0.76–1.11) PCV7: 1.09 (0.98–1.23) TIV: 0.94 (0.71–1.25) 31–44 days HBV: 0.88 (0.78–0.98) DTaP: 0.96 (0.87–1.06) HiB: 0.95 (0.86–1.05) IPV: 0.89 (0.79–1) MMR: 0.86 (0.71–1.05) Varicella: 0.90 (0.74–1.11) PCV7: 0.95 (0.84–1.07) TIV: 0.75 (0.53–1.06) Adj HR fragile 1–7 days HBV: 0.73 (0.62–0.86) DTaP: 0.66 (0.56–0.77) HIB: 0.65 (0.55–0.76) IPV: 0.67 (0.56–0.81) MMR: 0.58 (0.43–		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												0.79) Varicella: 0.55 (0.39–0.77) PCV7: 0.61 (0.5–0.75) TIV: 0.87 (0.63–1.21) 8–14 days HBV: 0.87 (0.74–1.01) DTaP: 0.82 (0.71–0.95) HIB: 0.83 (0.73–0.96) IPV: 0.88 (0.74–1.03) MMR: 0.82 (0.63–1.07) Varicella: 0.84 (0.64–1.11) PCV7: 0.84 (0.7–1.00) TIV: 1.05 (0.78–1.41) 15–30 days HBV: 0.97 (0.87–1.07) DTaP: 0.97 (0.89–1.07) HIB: 0.99 (0.9–1.09) IPV: 0.96 (0.86–1.08) MMR: 0.90 (0.74–1.08) Varicella: 0.86 (0.7–1.05) PCV7: 0.99 (0.88–1.12) TIV: 1.00 (0.79–1.26) 31–44 days HBV: 0.93 (0.83–1.04) DTaP: 0.96 (0.87–1.06) HIB: 0.97 (0.88–1.07) IPV: 0.99 (0.88–1.11) MMR: 0.92 (0.76–1.13) Varicella: 1.01 (0.82–1.23) PCV7: 1.01 (0.89–1.14) TIV: 0.98 (0.75–1.27)		

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Chao et al. 2012, Prospective cohort[180]	N=189,629 females who received HPV Age=9–26 years; Setting=Two managed care organizations in California	HPV4	Women receiving HPV vaccines may differ systematically from women who do not in susceptibility to outcome or likelihood of having outcome causing bias. Or there might be diagnoses biases where doctors look for adverse events more closely following vaccinations.	Not discussed	Not discussed	Health records review	MCO record review. Review of all safety data emerging from this study was carried out by an independent scientific committee, the Safety Review Committee (SRC). Cases were identified through electronic health records and then In-depth case review by a panel of experts.	Incidence rate ratio estimation	None	08/2006 and 03/2008	Merck & Co.	Incidence rate ratio (IRR) and 95% confidence interval (CI) of select autoimmune conditions in the vaccinated vs. non-vaccinated female populations of similar age in Kaiser Permanente Southern California. Rheumatologic / autoimmune Immune thrombocytopenia: 1.24 (0.91–2.02) Systemic lupus erythematosus: 1.10 (0.71–1.66) Rheumatoid arthritis: 0.70 (0.41–1.60) Juvenile rheumatoid arthritis: 0.36 (0.14–0.71) Autoimmune haemolytic anaemia - excluded Endocrine Type 1 diabetes: 0.54 (0.45–0.70) Hashimoto's disease: 2.02 (1.65–2.60) Graves' disease: 0.76 (0.42–1.10) Neurological / ophthalmic Multiple sclerosis: 1.37 (0.74–3.20) Other demyelinating diseases of central nervous system: 0.71	None	Cluster of disease onset in relation to vaccinatio n timing, dose sequence or age was found for any autoimmu ne condition. None of the estimated IRR was significant y elevated except Hashimoto 's disease [IRR=1.29, 95% confidence interval: 1.08-1.56] Further investigati on of temporal relationsh p and biological plausibility revealed no consistent evidence for a safety signal for autoimmu ne thyroid conditions

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												(0.38–2.13) Optic neuritis: 1.45 (1.00–2.91) Uveitis: 1.28 (0.53–6.39)		The SRC and the investigato rs identified no autoimmu ne safety concerns in this study.
Gee et al. 2011, Prospective cohort[181]	N=600,558 doses of HPV4; Females age 9-26 years in7 large managed care organizations (MCOs)in US	HPV4	Entire population of females in 7 MCOs meeting certain requirements. Unsure how generalizable to larger population outside of the 7 MCOs. Also unknown how sites differ from one another in patient population. For unexposed cohort - possible ascertainment biases where those who got vaccinated might have been monitored more closely for adverse events.	Not discussed	Not discussed	Weekly standardized data files from participating MCOs.	Weekly standardized data files from participating MCOs. Case ascertainment was limited to the first episode in a particular time period.	Poisson based maximized sequential probability ratio test (maxSPRT). Logistic regression (appendicitis only).	Logistic regression: sex, age, and seasonality	Between August 2006 and October 2009	Centers for Disease Control and Prevention	No statistically significant increased risk for any of the pre-specified adverse events (Appendicitis, Guillain–Barré Syndrome, Seizures, Stroke, Syncope, Venus Thromboembolism) after vaccination was detected.	None	
Kelly et al. 2012, Retrospective cohort[211]	N=104,076 children presenting to Perth hospitals	Influenza	Entire population was assessed though unknown if	Not discussed	Not discussed	Unknown	Emergency Department Information from 9 Perth hospitals	Risk estimation	None	March to April 2010	No funding to disclose	The 49-day risk of emergency department presentation for a febrile convulsion	None given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	with febrile convulsion		hospital cases differed systematically in the 9 hospitals assessed from other area hospitals									following Fluvax was 38/11,963 = 32/10,000. The risk in those who had not received Fluvax was 61/92,113 = 7/10,000. The VAR, calculated as the risk difference, is thus estimated as 25/10,000 children		
Gilbertson et al. 2011, Prospective cohort[61]	N=118,533 Medicare patients who initiated hemodialysis before August 1, 2003 and were alive through October 31, 2005; Location= US Age=>=18 years;	Influenza, pneumococcal	Vaccinated may be healthier cohort than unvaccinated or may reflect population with better quality of care.	Not discussed	Not discussed	Claims records	Unclear - patients were followed up, but unclear if claims records were searched.	Cox proportional hazards	Patient demographics, doesn't specify but variables assessed include age, sex, race, primary cause of end-stage renal disease, dialysis duration, comorbid conditions. Also controlled for influenza vaccination.	Patients identified from 2003-2005, followed from 2005-2006	Fresenius Medical Care	Relative risk of mortality (Table 2) Pneumococcal vacc: 0.94 (0.90–0.98), p=0.005 Influenza vacc (both seasons): 0.77 (0.73–0.81), p=<0.0001	Vaccine associated with lower mortality. Higher risk of mortality if older, longer on dialysis, have comorbid conditions.	
Baxter, 2012, Retrospective cohort[107]	43,702 LAIV recipients, 53,366 matched unvaccinated controls, 43,702 TIV recipients Age: 5 to 17 years, Setting: Kaiser Permanente	LAIV, TIV, unvaccinated comparison group	Included all LAIV vaccine recipients in database	Not discussed	Not discussed	Medical record	Medical record	Cox proportional hazards model	Relative risks (RR) were calculated as the ratio of the incidence rates of the two comparison groups without adjustment for any covariate.	October 2003 to March 2008	MedImmune	The incidence rates of serious adverse events (SAEs) overall and by specific diagnosis were not significantly higher or lower in the LAIV recipients relative to control groups in any comparison.	Children aged 5 to 8 vaccinated with LAIV had higher risk of acute GI event in 21 days (HR 1.36, 10.05 - 1.76) and 42 days (HR 1.30, 1.08 - 1.78) than unvaccinated cohort same age. Children aged 5 to 8 also had higher	

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	health system								Hazard ratios (HR) were also calculated adjusting for matching factors and seasonal changes in background rates.				risk of acute respiratory tract event in 21 days (HR 1.12, 1.00 - 1.25) and 42 days (HR 1.15, 1.06 - 1.24) than unvaccinated cohort same age.	
Wilson et al. 2011, Self-controlled case series[133]	N=413,957; Location=Ontario, Canada; Age=12 and 18 months;	Live MMR	Newborn Screening Ontario dataset captures over 99% of births	Not discussed	Not discussed	Database record review: pediatric vaccination was identified using the Ontario Health Insurance Plan (OHIP) database.	The Canadian Institute for Health Information's (CIHI) Discharge Abstract Database (DAD) was used to ascertain hospital admission. CIHI's National Ambulatory Care Registration System (NACRS) was used to ascertain ER visits, the Canadian Triage and Acuity Score (CTAS) rating and the diagnosis made by the most responsible physician for the visit. The Registered Persons	Fixed effects Poisson regression	None in the model	2006-2009	Canadian Foundation for Innovation, the Population Health Improvement Research Network (PHIRN), and by the Institute for Clinical Evaluative Sciences (ICES), which is funded by an annual grant from the Ontario Ministry of Health and Long-Term Care (MOHLTC)	Relative incidence of combined endpoint (hospital admission or emergency room visit) following 12 month vaccination. Risk interval: Relative Incidence (95% CI), P value Day 4: 1.15 (1.06–1.25), p=0.0008 Day 5: 1.19 (1.10–1.29), p=0.0001 Day 6: 1.20 (1.11–1.31), p=0.0001 Day 7: 1.20 (1.10–1.30), p=0.0001 Day 8: 1.62 (1.50–1.74), p=0.0001 Day 9: 2.04 (1.91–2.17), p=0.0001 Day 10: 1.84 (1.72–1.97), p=0.0001 Day 11: 1.72 (1.60–1.84)), p=0.0001 Day 12: 1.32 (1.22–1.43), p=0.0001 Days 4 to 12** (Combined risk interval): 1.33(1.29–1.38), p=0.0001 Relative incidences of	None given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
							Database was used to ascertain cases of death.					individual endpoints (emergency room visit, hospital admission, death) during highest risk interval compared to control period. 12 months Emergency visits: 1.34 (1.29–1.39) Admissions: 1.08 (0.93–1.25) 18 months Emergency visits: 1.25 (1.18–1.34) Admissions: 1.23 (0.94–1.59) Relative incidence of combined endpoint (hospital admission or emergency room visit) following 18 month vaccination Risk interval: Relative Incidence (95% CI), P value Days 10: 1.31 (1.19–1.45), p=0.0001 Days 11: 1.26 (1.14–1.39), p=0.0001 Days 12: 1.34 (1.21–1.47), p=0.0001 Days 10 to 12 (Combined risk interval): 1.25 (1.17-1.33), p=0.0001		
Pahud et al. 2012, Case-centered method[203]	N=110 encephalitis cases; Location=CA; Age= 6 months to 18 years	Many analyzed, measles virus-containing vaccines and pertussis antigen	Of 1,434 cases, immunization records were requested for over 800 and received for only 246. 136	Not discussed	Not discussed	Immunizatio n records request	Medical record review	Logistic regression	None reported	Between July 1998 and December 2008	America's Health Insurance Plans (AHIP) Vaccine Safety	Association with pre-defined risk windows Measles virus-containing vaccines 5–15 days: OR=1.31 (0.30–5.77)	None reported	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
		containing vaccines reported	were excluded due to incomplete immunization records or because no vaccines were given in the 1 year observation period, leaving 110 for analysis. If nonparticipants differed in systematic ways then bias will be introduced though we do not know which direction the bias would go.								Fellowship program under contract from the Centers for Disease Control and Prevention (CDC)	Pertussis antigen-containing vaccines 0–3 days: OR=1.37 (0.33–5.78)		
MacArthur et al. 2008, Case-control[200]	N=798; Location=Canada; Age=0-15 years; Setting=Canadian pediatric oncology centers and population-based cancer registries	Measles, mumps, and rubella (MMR), diphtheria, tetanus, and pertussis (DTP), poliomyelitis, hepatitis, or Bacillus Calmette-Guerin (BCG)	Cases from pediatric oncology treatment centers in each of the five provinces. And population-based cancer registries. Controls were area residents. Study notes, "Inherent in our case-control study is the possibility of selection or recall bias, as well as	Initial contact with potential controls was by letter, followed by telephone contact. In total, 449 cases and 675 controls were identified as possible subjects. Of these, 445 cases and 526 controls eligible for inclusion in the study were	Study notes, "Because controls were of a higher socioeconomic status than cases, it is possible that control participation bias may have influenced these results."	Standardized, personal interviews conducted in the home with the child's parents or guardians. Immunization data were recorded from the child's vaccination record if available at the time of interview. Otherwise, parents were	Participants meeting these criteria were ascertained through pediatric oncology treatment centers in each of the five provinces. Population-based cancer registries were also used for case ascertainment in all provinces except Quebec.	Conditional logistic regression	Maternal education, annual household income, ethnicity, maternal age at birth, and number of residences since birth. Multivariate models relied on strata formed by the following matching factors: province,	1990-1994	Funding for this study was provided by the National Health Research and Development Program of Health Canada and the Canadian Electricity Association. Additional funding for one of the authors (A. C. M.) was	Vaccinations in childhood and risk of childhood leukemia, the Cross-Canada Childhood Leukemia Study, 1990–1994 Mumps: 0.83 (0.39-1.75) Measles 0.88 (0.41-1.90) Rubella 0.85 (0.42-1.70) Diphtheria 0.85 (0.29-2.49) Pertussis 0.71 (0.27-1.85) Tetanus 0.74 (0.27-2.03) Polio 0.90 (0.35-2.29)	None given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
			exposure misclassificatio n, since information was not always corroborated with the index child's vaccination or medical records."	successfully contacted. A total of 399 case-control pairs agreed to participate, resulting in contact participation rates of 90 percent for eligible cases and 76 percent for eligible controls.		asked to recall their child's immunization history.			gender, and age.		provided by a research unit infrastructu re grant from the Michael Smith Foundation for Health Research	Hepatitis 1.09 (0.34-3.52) Other vaccine 0.81 (0.58-1.13)		
Bertuola et al. 2010, Case-control[131]	N=2,311 (387 cases, 1924 controls); Location=Ital y; Age=Mean (SD) case/control: 4.9 (3.5) / 5.7 (4.9); Setting=Four pediatric hospitals: Department of Pediatrics, University of Padua; Giannina Gaslini Pediatric Hospital, Genova; Bambino Gesu Hospital, Rome; Santobono-Pausilipon Pediatric	MMR	Both cases and controls chosen from a population of hospitalized children lessening the chance of selection bias.	Not discussed	Not discussed	Physician interview (self-report)	Information on the reason for hospital admission came from pediatric emergency department records. Final diagnosis was retrieved from the clinical records after discharge.	Logistic regression	Age and use of drugs	November 1999 to December 2007	Italian Medicines Agency	OR 95% CI for ITP: MMR 2.4 (1.2-4.7)	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	Hospital, Naples													
Andrews et al. 2012, Prospective cohort, also analyzed as self-controlled case series[130]	N=343 cases of thrombocyto penic purpura (TP); Location=Eng land, Denmark; Age=12–23 months;	MMR	In England, regional immunization registers, where ethical and data custodian permissions had been obtained for linkage, were used which cover a birth cohort of about 60,000. No discussion of whether those who gave permission may have systematically differed from those who did not.	Not discussed	Not discussed	Database review: immunization registry data	Database review: national TP coded hospital discharge data	Cohort: Poisson regression	Age Cohort study: Models were fitted just adjusting for age (1-month intervals) and calendar period (1 year intervals), and also adjusting for other covariates: child's gender, place of birth (classified according to degree of urbanization), ethnicity of mother (Danish or not), mother's age at birth (using age categories: ≤19, 20–24, 25–29, 30–34, 35–39, ≥40).	England: 1996-2007 Denmark: 1990-2007	The VAESCO consortium is funded by the European Centre for Disease Prevention and Control	Relative incidence of TP after MMR vaccination in children aged 12–23 months in England using the self-controlled case series method (SCCS) and in Denmark using the SCCS and cohort methods Self Controlled Case Series Period after MMR (days) 0–13 England: 1.10 (0.33–3.71) Denmark: 1.38 (0.68–2.78) 14–27 England: 3.13 (1.44–6.79) Denmark: 2.75 (1.61–4.69) 28–42 England: 1.53 (0.58–4.03) Denmark: 1.94 (1.04–3.62) 0–42 England: 1.92 (1.02–3.59) Denmark: 2.01 (1.34–	None	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												2.99) Cohort (Denmark) Period after MMR (days) 0–13: 1.32 (0.65–2.68) 14–27: 2.54 (1.47–4.37) 28–42: 1.72 (0.92–3.22) 0–42: 1.85 (1.23–2.78)		
Gold et al. 2010, Self-Controlled Case Series[196]	N= 323 cases of febrile seizures Location=South Australia; Age=0-7 years;	MMR, DTP	Approximately 98% of all newborns are registered on the immunization database within 12 months. Outcomes from hospital data (2 major hospitals). No indication if patients were more or less representative of the general population.	Amongst the 174,136 hospital admissions, there were 35,590 admissions (20.4%) without any ICD-codes or Complaint Codes. However adverse events were carefully identified from the admission description text field using broad criteria for inclusion. Authors note "it is unlikely that we either underestimated or overestimated the number of true adverse	Not discussed	Australian Childhood Immunization Register (ACIR)	Database review: data were derived from two sources; the Open Architecture Clinical Information System Clinical Reporting Repository (OACIS CRR), which contains hospital admissions data and emergency department data and the Women and Children's Hospital (WCH) database and Flinders Medical Center.	Within-subjects Poisson regression	SCCS method accounted for exposure period and age	1997-2002	Department of Health, South Australia, under the Human Services Research and Innovation Programme	IRR for febrile seizures MMR vaccine Exposure period −1 to −14 days: 0.58 (0.33–1.02), p=0.06 Exposure period 6 to 11 days: 2.11 (1.43–3.10), p=<0.001 Exposure period 15 to 35 days: 0.90 (0.65–1.25), p=0.54 DTP vaccine Exposure period −1 to −14 days: 0.56 (0.33–0.94), p=0.03 Exposure period 0 to 3 days: 0.59 (0.24–1.45), p=0.25 Exposure period 4 to 7 days: 0.94 (0.46–1.91), p=0.86 Exposure period 8 to 14 days: 0.93 (0.54–1.62), p=0.80	None given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
				events."										
O'Leary et al. 2012, Retrospective cohort[132]	N=1.8 million from 5 managed care organizations; Location=Colorado, Hawaii, Georgia, Northern CA, Massachusetts; Age=6 weeks	MMR, Hepatitis A, varicella, Tdap, Hib	Study did not discuss if any biases may have existed in the populations included in the managed care databases versus those who were not o differences in diagnosing practices across	Not discussed	Not discussed	Medical record	Potential ITP cases were identified by using diagnostic codes and platelet counts. All cases were verified by chart review.	Self-controlled care series	None reported	2000 to 2009	Kaiser Permanente with funds provided by the Food and Drug Administration	IRR for immune thrombocytopenic purpura (ITP) 6 wk to 11 mo Hib: 0.53 (0.14, 1.94), p=0.33 PCV: 0.58 (0.15, 2.18), p=0.42 6 to 23 mo TIV: 2.69 (0.81, 8.88), p=0.11 12 to 19 mo MMR: 5.48 (1.61,	None reported	Authors: ITP is unlikely after early childhood vaccines other than MMR. Because of the small number of exposed cases and

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	to 17 years;		the five sites.									18.64), p=0.006 MMRV: 2.87 (0.78, 10.56), p=0.11 DTaP: 1.00 (0.21, 4.81), p=0.99 Hib: 0.75 (0.16, 3.63), p=0.72 PCV: 0.72 (0.14, 3.97), p=0.70 12 to 23 mo Hep A: 0.22 (0.03, 1.82), p=0.16 2 to 6 years TIV: 1.86 (0.41, 8.38), p=0.42 Hep A: 1.14 (0.34, 3.86), p=0.83 4 to 6 years MMR: 3.06 (0.42, 22.30), p=0.27 VAR: 4.39 (0.46, 41.65), p=0.20 DTaP: 2.57 (0.53, 12.37) p=0.24 IPV: 1.37 (0.23, 8.32), p=0.73 7 to 17 years Hep A: 23.14 (3.59, 149.30), p=0.001 TIV: 5.95 (0.54, 65.96), p=0.15 11 to 17 years VAR: 12.14 (1.10, 133.96), p=0.04 HPV: 9.71 (0.87, 108.92), p=0.07 MCV: 6.02 (0.64, 56.18), p=0.12 Tdap: 20.29 (3.12, 131.83), p=0.002		potential confoundin g, the possible associatior of ITP with hepatitis A varicella, and tetanus-diphtheria acellular pertussis vaccines in older children requires further investigati on.

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Stowe et al. 2011, Self-controlled case series[104]	N=2,366 cases of convulsions; Location=UK; Age=Under 10 years; Used General Practice Research Database (GPRD)	Monovalent H1N1 influenza vaccine during the 2009/10 influenza season or seasonal TIV	Data from General Practitioners, bias may occur if population differs from general (e.g., more likely to get vaccinations or diagnoses or better care).	The children were followed up for an average of 5.1 years each (range 0.3–10.0 years) but attrition not discussed.	Not discussed	Medical records	Medical records	Conditional Poisson regression	Age, period and season	May 2000 to April 2010	Not specified, study notes J. Stowe is funded from a grant from the Department of Health Policy Research Programs.	Incidence rate ratio (IRR) estimates for the onset of a convulsion episode in relation to the timing of influenza vaccination and type of vaccine administered Vaccine, Period, IRR TIV 2 Weeks pre-vaccine: 1.00 (0.70–1.42) Day of vaccination: 1.23 (0.39–3.83) 1–3 Day post vaccine: 0.98 (0.47–2.07) 4–7 Days post vaccine: 0.96 (0.50–1.86) 0–7 Days post vaccine: 1.00 (0.64–1.59) Monovalent H1N1 vaccine 2 Weeks pre-vaccine 0.44 (0.25–0.76) Day of vaccination 1.83 (0.68–4.90) 1–3 Day post vaccine 1.08 (0.51–2.28) 4–7 Days post vaccine 0.70 (0.31–1.57) 0–7 Days post vaccine 0.99 (0.61–1.60) Incidence rate ratio (IRR) estimates for the onset of a convulsion episode in relation to the timing of monovalent H1N1 vaccine Dose 1 2 Weeks pre-vaccine: 0.37 (0.20–0.68) Day of vaccination: 1.52 (0.49–4.73)	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												1–3 Day post vaccine: 0.85 (0.35–2.04) 4–7 Days post vaccine: 0.77 (0.34–1.72) 0–7 Days post vaccine: 0.89 (0.53–1.52) Dose 2 2 Weeks pre-vaccine: 1.24 (0.40–3.88) Day of vaccination: 5.24 (0.73–37.41) 1–3 Day post vaccine: 3.48 (0.86–14.07) 4–7 Days post vaccine: 0 0–7 Days post vaccine: 1.96 (0.62–6.14)		
Groves et al. 1999, Case-control[198]	N=878; Location=nine Midwestern and Mid-Atlantic states; Age=0-14 years; Setting=Patients with ALL, diagnosed between 1989 and 1993, were enrolled in the study. Subjects who resided in Illinois, Indiana, Iowa, Michigan, Minnesota, New Jersey, Ohio, Pennsylvania, or Wisconsin at the time of	Oral or injected poliovirus vaccine, trivalent diphtheria–tetanus–pertussis vaccine, bivalent diphtheria–tetanus vaccine, bivalent tetanus–diphtheria vaccine, monovalent tetanus vaccine, trivalent measles–mumps–rubella vaccine, Haemophilus influenza group b (Hib)	Author notes, controls selected using random-digit dialing were more likely to be offspring of parents with higher education and/or family income compared with cases. However, while this may explain the tendency of the controls to have more vaccinations, the association between conjugate Hib vaccine and ALL persisted after statistical adjustment for family	Mothers of 96% of eligible cases and 75% of eligible controls from the nine states completed an initial telephone interview, and mothers of 788 (98%) and 699 (97%) eligible cases and controls, respectively, participated in a subsequent in-person interview. In the third component, vaccination data were provided by	Not discussed	Data collection forms were completed by the mothers using vaccination records from physicians or by the physicians themselves.	Case ascertainment described in another study	Conditional logistic regression	Age at censoring, year of birth, sex, race, family income, parental education and attendance at day-care and/or preschool	Patient diagnosis between 1989 and 1993. Unsure when data was collected. After 1993, before 1999 when study was published.	Not given	Effect of vaccination (ever vs never) on subsequent risk of childhood acute lymphoblastic leukemia (439 matched pairs) Measles–mumps–rubella: 1.19 (0.67–2.10) Oral poliovirus: 1.05 (0.41–2.67) Diphtheria–tetanus–pertussis: 0.66 (0.27–1.65) Tetanus (all): 0.75 (0.26–2.16) Diphtheria (all): 0.75 (0.26–2.16) Haemophilus influenza b (Hib): 0.73 (0.50–1.06) (Presumptive) polysaccharide vaccine: 1.13 (0.64–1.98) (Presumptive)	Not given	Kleinerman et al, 1997. Kleinerman RA, Linet MS, Hatch EE, Wacholder S, Tarone RE, Severson RK, Kaune WT, Friedman DR, Haines CM, Muirhead CR, Boice JD and Robison LL (1997) Magnetic field exposure assessmen in a case-control study of

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	diagnosis were eligible for the vaccination component of the study.	vaccines, hepatitis B virus vaccine and other vaccines	income and parental education, and no such inverse association was observed for any other vaccine.	mothers (based on vaccination records from physicians) or obtained directly from the physicians of 630 (79.9%) cases and 550 (78.7%) controls, representing overall participation rates of 70.1% for cases and 50.4% for controls.								conjugate vaccine: 0.57 (0.36–0.89)		childhood leukemia. Epidemiol gy 8: 575–583. Details case ascertainm ent.
Klein et al. 2008, Prospective cohort[212]	N=497; Location=CA; Age=27.3 weeks (mean gestational age); Setting=NICU database in the Northern California Kaiser Permanente Medical Care Program	Polio vaccines (IPV and oral poliovirus vaccine), diphtheria/tetanus/pertussis vaccine (either DTP or DTaP vaccine), Hib vaccine, HBV vaccine, Streptococcus pneumonia vaccine (pneumococcal conjugate vaccine), and trivalent influenza vaccine. Infants born earlier in the study period might have	Study notes that the apnea observed in the post immunization period may not reflect an adverse response to immunization but may be attributable to normal variations in apnea occurrence in this NICU population. Clinicians may not have vaccinated infants perceived to be at risk for a	557 (74.4%) received 1 vaccine and were eligible for chart abstraction. Sixty of those 557 eligible infants (10.7%) were not reviewed, for the following reasons: missing charts (n 15), charts missing significant data (n 7), infants not at KPMCP on day 53 (n 37), and significant congenital	Not discussed	Database record review	Neonatal Minimum Data Set, medical records review. To evaluate apnea after discharge from the NICU, we examined hospital and emergency department visits for apnea diagnoses captured within the KPMCP electronic medical record during the 2 weeks after hospital discharge.	Multivariate logistic regression	Desaturations and/or bradycardia, SNAP-II of >10, Receiving caffeine, Gestational age, Weight of 2000 g, Age of 67 d, Female gender.	1997-2003	Vaccine Safety Datalink contract with America's Health Insurance Plans, funded by the Centers for Disease Control and Prevention	Multivariate Model Predicting Apnea During the 48-Hour Period After Immunization With Pre-immunization Apnea Apnea: 25.5 (9.0–71.9), p=0.0001 Desaturations and/or bradycardia: 1.4 (0.7–2.7), p=0.33 SNAP-II of >10: 3.4 (1.2–9.3), p=0.02 Receiving caffeine: 1.7 (0.8–3.3), p=0.15 Gestational age: 1.1 (0.9–1.2), p=0.40 Weight of 2000 g: 2.0 (0.98–4.1), p=0.06 Age of 67 d: 2.2 (1.1–4.4), p=0.03 Female gender: 1.0	None	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
		received the combination DTP/Hib or DTaP/Hib vaccines, whereas those born later might have received DTaP/IPV/HBV vaccine"	vaccine-related adverse event until the infants were without apnea for a period of time. This bias, similar to the healthy vaccine phenomenon, would result in a healthier pre immunization population, compared with a similar, unvaccinated, NICU population.	anomalies (n 1).								(0.6–1.8),p=0.96 Without Pre-immunization Apnea Desaturations and/or bradycardia: 1.4 (0.7–2.7), p=0.30 SNAP-II of >10: 4.2 (1.2–14.3), p=0.02 Receiving caffeine: 1.5 (0.7–3.2), p=0.25 Gestational age: 1.1 (0.9–1.2), p=0.38 Weight of 2000 g: 2.1 (1.0–4.5), p=0.05 Age of 67 d: 2.3 (1.1–4.8), p=0.03 Female gender: 1.1 (0.6–2.0), p=0.85		
Velázquez et al. 2012, Self-controlled case-series[167]	N=698 infants < 1 year old in Mexico with intussusception Active surveillance across hospitals in Mexico from the Mexican Institute of Social Security	Rotarix	Bias if cases differed from the general population in systematic ways (e.g., more or less likely to be vaccinated, doctors more likely to recommend vaccinations).	None	Total of 751 infants enrolled and 698 included. No discussion of differences between participants and non-participants.	Review of records, confirmed by review of Expanded Program on Immunization cards. If direct review of Expanded Program on Immunization cards was not possible, vaccination history was confirmed from available clinical files (medical charts or the IMSS database). If this was not possible,	Review of hospital admission and discharge logs, and emergency department, pediatric ward, surgery and radiology files. Episodes of intussusception were classified as definite according to the case definition developed by the Brighton Collaboration Working Group for Intussusception, and were confirmed by radiography,	Conditional Poisson regression	Age	January 2008 and October 2010	Not listed, many authors were GlaxoSmithKline employees.	Relative Incidence Dose and risk period (days after vaccination) Dose 1, 0-30 days: 1.75 (1.24–2.48), p=0.001 Dose 2, 0-30 days: 1.06 (0.75–1.48), p=0.75 Dose 1, 0-15 days: 3.24 (2.15–4.87), p=<0.001 Dose 2, 0-15 days: 1.06 (0.69–1.61), p=0.79 Dose 1, 0-6 days: 6.49 (4.17–10.09), p=<0.001 Dose 2, 0-6 days: 1.29 (0.80–2.11), p=0.29	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
						vaccination history was confirmed through parent/guardian recall.	surgery or postmortem examination.							
Patel et al. 2011, Case-control (also did self-controlled case-series)[168]	N=2665 (615 cases of intussusception, 2050 controls); Location=Mexico, Brazil; Age=45-245 days; Setting=53 hospitals in 7 states in Brazil and at 16 hospitals in 10 states in Mexico	RV1, Rotarix	Neighborhood controls - possible differences in risk factors or exposure ascertainment between cases and controls. Possible misclassification; Case and control status was not concealed from the interviewers so there may have been some differences in the effort made by the interviewers with respect to ascertaining vaccination history (misclassification).	A total of 615 infants with intussusception (285 in Mexico and 330 in Brazil) and 2050 controls (739 in Mexico and 1311 in Brazil) were enrolled. Of these, 594 case patients (97%) and 2033 controls (99%) had a history of vaccination as confirmed by a vaccination card.	Not discussed	Medical records review	Clinical record review	Conditional logistic regression	Matched by date of birth, also controlled for age, sex	August 2008 through August 2010	GAVI Alliance under a collaborative agreement with the Program for Appropriate Technology in Health (PATH) and in part by the U.S. Department of Health and Human Services.	OR (95% CI) for intussusception (Case-control) Rotavirus vaccination Mexico Either dose, any time before reference date 1.0 (0.6–1.7) First dose 1–7 days: 5.8 (2.6–13.0) 8–14 days: 1.0 (0.4–2.9) 15–21 days: 0.8 (0.3–2.1) Second dose 1–7 days: 1.1 (0.6–2.2) 8–14 days: 2.3 (1.2–4.4) 15–21 days: 2.0 (1.0–3.8) Brazil Either dose, any time before reference date 1.7 (0.9–2.9) First dose 1–7 days: 1.4 (0.4–4.8) 8–14 days: 1.6 (0.5–4.7) 15–21 days: 0.6 (0.1–	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												2.2) Second dose 1–7 days: 1.9 (1.1–3.4) 8–14 days: 0.9 (0.5–1.8) 15–21 days: 0.8 (0.4–1.6) OR (95% CI) for intussusception (Case-series) Rotavirus vaccination Mexico First dose 1–7 days: 5.3 (3.0–9.3) 8–14 days: 1.1 (0.5–2.7) 15–21 days: 0.9 (0.3–2.2) Second dose 1–7 days: 1.8 (0.9–3.8) 8–14 days: 2.2 (1.1–4.2) 15–21 days: 2.2 (1.2–4.0) Brazil First dose 1–7 days: 1.1 (0.3–3.3) 8–14 days: 1.3 (0.5–3.4) 15–21 days: 0.2 (0.0–1.4) Second dose 1–7 days: 2.6 (1.3–5.2) 8–14 days: 1.4 (0.7–3.0)		

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												15–21 days: 0.9 (0.4–2.0)		
Hambidge et al. 2011, Matched case-control (and self-controlled case series)[213]	N=1294 (269 cases of hospitalization of sickle cell crisis, 1025 controls); Location=United States; Age=6 months to 17 years; Setting=8 managed care organizations that comprise the Vaccine Safety Datalink	TIV (trivalent inactivated influenza)	For the case-control study possible bias in that children hospitalized for SCA, might be more likely to get vaccine (did not seem to be a factor in this study because of self-controlled case series results). Authors note that children classified as not receiving vaccine may have received vaccine outside of their MCO. Attempt to retrieve outside records varied by MCO. Decrease in temperatures during flu season is known trigger for pain crisis. This could possibly introduce a temporal bias in the analysis."	Analysis was limited to periods when most TIV was administered, between October 1 and January 31 of each influenza season. This resulted in the removal of 3 TIV-exposed children who were vaccinated in the months of February or March. Two cases could not be matched to a control and were removed for analysis.	Not discussed	Record review from Vaccine Safety Datalink dataset	Medical records of potential cases were reviewed to confirm hospitalization for sickle cell crises.	Conditional logistic regression	Cases/controls matched on age category, gender, Vaccine Safety Datalink site, and season.	1999 to 2006	Centers for Disease Control and Prevention through America's Health Insurance Plans	Case-control study OR (95% CI) of hospitalization TIV: 1.3 (0.8–2.2) Self-controlled All children: 1.21 (0.75–1.95), p=0.43 Boys: 1.07 (0.50–2.28), p=0.86 Girls: 1.33 (0.72–2.44), p=0.36 6-23 months: 1.23 (0.25–6.04), p=0.80 60 mo to 17 yr: 1.38 (0.83–2.29), p=0.22	Not given	

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Rowhani-Rahbar et al. 2012, Case-centered[197]	N=233 cases of Bell's Palsy; Age=<=18 years; Setting=Kaiser Permanente Northern California population	TIV, Hepatitis B	Bias if cases differed from the general population in systematic ways (e.g., more or less likely to be vaccinated, doctors more likely to recommend vaccinations).	977 children originally identified, after exclusions 233 included in final sample.	Not discussed	Database review	Database record review, reviewed and adjudicated by an otolaryngologist.	Logistic regression	None	2001 through 2006	Centers for Disease Control and Prevention	OR, 95% CI TIV Days 1-14: 1.0 (0.2, 5.0) Days 1-28: 0.7 (0.2, 2.8) Days 29-56: 1.2 (0.3, 4.8) Hep B Days 1-14: 1.3 (0.4, 4.5) Days 1-28: 0.8 (0.2, 2.4) Days 29-56: 0.9 (0.3, 2.6)	None	
Tse et al. 2012, Self-controlled risk interval, current vs. historical vaccine design[214]	N=206,174 children vaccinated with TIV in 8 US MCOs ; Age=6-59 months;	TIV, PCV13	Bias if cases differed from the general population in systematic ways (e.g., more or less likely to be vaccinated, doctors more likely to recommend vaccinations).	Not discussed	Not discussed	Database record review	Medical record review	Maximized sequential probability ratio test (MaxSPRT) for the self-controlled risk interval design; Poisson-based conditional MaxSPRT (CMaxSPRT) for the current vs. historical design.	Adjustment for TIV or PCV13	2010-2011	Centers for Disease Control and Prevention	Incidence rate ratios, self-controlled risk interval design First dose TIV IRR: 4.0 (2.1-6.2) First dose TIV, any dose PCV13 TIV IRR: 2.4 (1.2-4.7) PCV13 IRR: 2.5 (1.3-4.7)	None	
Thomson et al. 2010, Prospective cohort[193]	N=488; Location=Australia; Age=2-6 years (outcomes ascertained	Triple antigen [diphtheria, tetanus and pertussis (DTP)], combined diphtheria and	Study notes, "Loss to follow-up is a potential issue for prospective studies as selective loss to	By 6 yr of age, 488 (79%) of the original birth cohort of 620 remained, representing a cumulative	Not assessed	Parental report	Parental report of consistent symptoms and/or physician/doctor	Linear regression	Parental socio-demographics, allergic disease, parental smoking	The MACS recruited 620 infants born between February 1990 and	MACS was initially supported by Nestle´ Australia, while the Asthma	RR (95% CI) for Asthma Triple antigen (DTP) 1st year: 4.75 (0.88, 25.58) 2nd year: 0.74 (0.56, 0.96)	RR (95% CI) for Asthma Socio-demographics child Gender (male) 1.61 (1.21, 2.14)	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
	at 6 years); Setting=Melbourne Atopy Cohort Study (MACS), an ongoing prospective cohort study initiated in 1989	tetanus (CDT), measles mumps rubella (MMR)	follow-up may bias the results. It is not possible to test whether loss to follow-up has influenced the associations reported as information on outcomes in those lost to follow-up is not available. However, it seems unlikely that selective attrition has had a major impact as the rate of follow-up was relatively high being almost 80% by 6 yr which is the strength of the study."	loss to follow-up of 21%. At initial recruitment, 19 of the 620 were loss to follow up. 24 were loss to follow up at 1 year old data collection and another 89 were loss to follow up at the two year old data collection. Reason for loss to follow up were not provided.			diagnosis		history; parental education; gender of child and older siblings, pet ownership of at least one dog and/or cat.	November 1994	Foundation of Victoria supported the 10-yr follow-up.	Combined diphtheria and tetanus 1st year 1.88 (1.28, 2.77) 2nd year 1.00 (0.57, 1.74) Measles mumps rubella 2nd year 0.78 (0.61, 1.00)	Older siblings (at least 1) 1.27 (1.17, 1.38) Characteristics mother Education (tertiary) 0.94 (0.67, 1.31) Marital status (married) 0.75 (0.45, 1.24) Smoking (never) 0.70 (0.47, 1.03) Asthma 1.43 (1.07, 1.90) Eczema 1.32 (1.02, 1.72) Allergic rhinitis 0.87 (0.65, 1.17) Food allergy 1.14 (0.84, 1.53) Drug allergy 1.33 (1.02, 1.74) Characteristics father Education (tertiary) 1.11 (0.78, 1.58) Smoking (never) 0.99 (0.71, 1.40) Asthma 1.34 (1.01, 1.79) Eczema 1.16 (0.84, 1.61) Allergic rhinitis 1.37 (1.04, 1.81) Food allergy 0.73 (0.50, 1.08) Drug allergy 0.89 (0.44, 1.81) Pet ownership Dog 0.84 (0.61, 1.14) Cat 1.05 (0.78, 1.42)	

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Buttery et al. 2011, Observed/expected analysis[166]	Children under 24 months old receiving RotaTeq (N=296,023) or, Rotarix (302,455)in Australia; Active surveillance mechanisms	Two states used RotaTeq, two states used Rotarix	Rotavirus vaccination was introduced under the Australian National Immunization Program (NIP) in July 2007 and has a high coverage rate (90–95% for most infant vaccines. The eligible population for the study covers nearly all infants. Study notes, "there is potential for bias in the estimation of both the observed cases and the background incidence rate due to limitations in the data sources used in the calculations. It is important to consider the size and direction of these possible biases but we consider them unlikely to account for the	None - study depended on active ascertainment of cases	Not discussed	Records from the Australian Childhood Immunization Register (ACIR). Vaccination status was confirmed from written records and/or by linkage to a national vaccination registry (ACIR) in PAEDS cases.	Active surveillance through the Australian Pediatric Surveillance Unit (APSU) and Pediatric Active Enhanced Disease Surveillance (PAEDS) study. Surveillance of registered pediatricians and surgeons across Australia (APSU) and surveillance of four major tertiary pediatric hospitals across Australia.	Relative risk estimation	No control for confounders	1st July 2007 to 31st December 2008	National Health and Medical Research Council; the Department of Health and Ageing, Commonwealth Government of Australia; the Sydney Medical School, University of Sydney; CSL Limited (CSL) and GlaxoSmith Kline. The PAEDS pilot study is funded by the Department of Health and Ageing, Commonwealth Government of Australia.	Observed and expected cases of intussusception by age in months in jurisdictions delivering RotaTeq 1–7 days post-vaccine Dose 1: 5.26 (1.09, 15.4) Dose 2: 1.33 (0.16, 4.82) Dose 3: 0.00 (0.00, 2.16) Total: 1.15 (0.37, 2.68) 1–21 days post-vaccine Dose 1: 3.51 (1.29, 7.64) Dose 2: 0.67 (0.14, 1.94) Dose 3: 0.00 (0.00, 0.89) Total: 0.77 (0.37, 1.41) Observed and expected cases of intussusception by age in months in jurisdictions delivering Rotarix 1–7 days post-vaccine Dose 1: 3.45 (0.71, 10.1) Dose 2: 1.05 (0.13, 3.80) Total: 1.58 (0.51, 3.69) 1–21 days post-vaccine Dose 1: 1.53 (0.42, 3.92)	None	

Appendix C-3. Evidence Tables – Post-marketing studies
Children-Adolescents

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Partici-pation bias	Ascertain-ment of vaccination status	Ascertain-ment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
			observed excess cases." Differences in surveillance methods between the two mechanisms may have led to biases in estimation of exposure and outcome (underestimates). There may have been overestimation of incidence rate.									Dose 2: 0.88 (0.29, 2.05) Total: 1.37 (0.73, 2.34)		

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Kong B. P. et al.,2008[215]		NC	Sample size: NR	NR, Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not reported			
Andrews N. et al.,2010 UK[216]	Cohort	1	Sample size: 118200, Mean age: NR, Age range: 1 - 12	Haemoph. Influenza. type b (Hib) protein conjugate, DTwP, NR, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: NR	Any adverse event: 29.6% Event: Crying: 3.7%, Syscat: 8 Event: Diarrhea: 17.9%, Syscat: 7 Event: Feeding problem: 2.3%, Syscat: 7 Event: Fever: 6.8%, Syscat: 8 Event: Vaccine reaction: 0.3%, Syscat: 10 Event: Vomiting: 11.9%, Syscat: 8 Event: Convulsion/fit/seizure: 0.6%, Syscat: 17 Event: Apnea/collapse/cyanosis/pallor: 0.2%, Syscat: 17,8	
Santosham M. et al.,1991 United States[102]	Controlled Clinical Trial	4	Sample size: 5190, Mean age: 54.6, Age range: 35 - 196, Percent female: 49.4%	Haemoph. influenza. type b (Hib) protein conjugate, Routine Vaccines, PedvaxHIB, Merck, OMPC lots 1072,1080, and 1085. After reconstitution with 0.1ml of dilutent, each 0.5m of vaccine contained 15 micrograms of H. influenza polysaccharide and 131 to 272 micrograms of group B meningococcal OMPC., Adjuvant: Aluminum, Preservative: Thimerisol, Delivery: Intramuscular	Dose1: 42-90 Days Dose2: 70-146 Days	Event: Viral infections: 0.5%, Syscat: 11 Event: Conjunctivitis: 2%, Syscat: 6 Event: Areas of redness measuring less than 2.54 cm in diameter: 3.3%, Syscat: 8 Event: Areas if swelling measuring less than 2.54 cm: 6.2%, Syscat: 8 Event: Hospitalizations 30 days after vaccination: 4.02% Event: Fever above 38.9 C: 1.63%, Syscat: 8	Areas of redness measuring less than 2.54 cm in diameter: OR 2.713 (1.574-4.676)** Areas if swelling measuring less than 2.54 cm: OR 9.446 (4.905-18.19)** Conjunctivitis: OR 0.628 (0.408-0.968)** Fever above 38.9 C: OR 1.059 (0.685-1.638) Hospitalizations 30 days after vaccination: OR 0.986 (0.748-1.299) Viral infections: OR 0.285 (0.13-0.627)**
Capeding M. R. Z. et al.,1996 Philippines[103]	Controlled Clinical Trial	3	Sample size: 174, Mean age: 6.9, Age range: 5 - 8, Percent female: 37%	Haemoph. influenza. type b (Hib) protein conjugate, Routine Vaccines, Pedvax-Hib, Merck, PRP-OMP polysaccharide coupled to an outer membrane protein of Neisseria meningitidis group B. Lot 0957V., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intramuscular	Dose1: 6-8 Weeks Dose2: 10-12 Weeks Dose3: 14-16 Weeks	Event: Serious adverse reactions: 0% Event: Fever greater than or equal to 38 C: 26%, Syscat: 8	Fever greater than or equal to 38 C: OR 1.246 (0.467-3.323)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
De Carvalho N. et al.,2010 Brazil[178]	NA	3	Sample size: 433, Mean age: 26.5, Percent female: 100%, Percent pregnant: Percent Pregnant: 9.5%	Human papillomavirus (HPV), Cervarix, GlaxoSmithKline, 20 µg of HPV-16 L1 virus-like particle and 20 µg of HPV-18 L1 virus-like particle. Each type of virus-like particle was produced on Spodoptera frugiperda Sf-9 and Trichoplusia ni Hi-5 cell substrate with AS04 adjuvant containing 500 µg aluminum hydroxide and 50 µg 3-deacylated monophosphoryl lipid A (MPL, Corixa, Montana, USA) provided in a monodose vial., Adjuvant: ASO 4-Aluminum, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Month Dose2: 1 Month Dose3: 6 Month	Any SAE: 1.8% Event: Medically significant adverse event (any): 8.1% Event: New onset chronic disease: 0% Event: New onset autoimmune disease: 0%	Medically significant adverse event (any): OR 1.344 (0.641-2.816)
Giuliano A. R. et al.,2011 18 countries[177]	Controlled Clinical Trial	4	Sample size: 3895, Mean age: 20.5, Age range: 15 - 27, Percent female: 0%	Human papillomavirus (HPV), Gardasil or Silgard, Merck, Quadrivalent HPV types 6, 11, 16, 18. Low-dose contained 20 ug type 6, 40 ug type 11, 40 ug type 16, 20 ug type 18, with 225 ug aluminum adjuvant. (from reference for Villa, 2005, which is study ID 20223), Adjuvant: Aluminum, Preservative: Not reported, Delivery: Intramuscular	Dose1: 1 Days Dose2: 2 Month Dose3: 6 Month	Any adverse event: 69.2% Event: Serious vaccine-related events (entire study period): 0% Event: Death (entire study period): 0.2%, Sev: 5 Event: Serious vaccine-related events (first 15 days): 0% Event: Death (first 15 days): 0%	Death (entire study period): OR 0.3 (0.082-1.091)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Khatun S. et al.,2012 Bangladesh[176]	Controlled Clinical Trial	2	Sample size: 67, Mean age: 12, Age range: 9 - 13, Percent female: 100%	Human papillomavirus (HPV), Cervarix, GlaxoSmithKline, HPV16/18 ASO4-adjuvanted cervical cancer vaccine. Purified L1 VLPs of HPV16/18 at 20/20-g per dose formulated on ASO4 adjuvant comprising 500 gm of aluminum hydroxide and 50 gm of 3-deacylated monopods phage lipid A, Adjuvant: ASO 4, Preservative: Not reported, Delivery: Not reported	Dose1: 0 Days Dose2: 1 Month Dose3: 6 Month	Any SAE: 0% Event: Any AE, 1st dose: 80% Event: Any AE, 2nd dose: 88% Event: Any AE, 3rd dose: 90%	
Kim, S. C. et al.,2011 Korea[175]	Controlled Clinical Trial	8	Sample size: 208, Mean age: 22, Age range: 15 - 25, Percent female: 100%	Human papillomavirus (HPV), Cervarix, GlaxoSmithKline, HPV-16/18 contained 20 mcg each of HPV-16 and -18 L1 (structural protein of HPV) virus like particle, adjuvanted with the proprietary immunostimulant ASO4 adjuvant system (comprising 3-O desacyl-4(1)-MPL [50 mcg] adsorbed on aluminium hydroxide [AI(OH)3, 500 mcg]), Adjuvant: ASO 4-Aluminum, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Month Dose2: 1 Month Dose3: 6 Month	Event: Unsolicited - Infections and infestations, Syscat: 11 Event: Unsolicited - Breast and reproductive system, Syscat: 21 Event: Unsolicited - any AE (Grade 3), Sev: 3 Event: Medical significant adverse condition Event: New onset chronic diseases Event: Solicited - Arthralgias (Grade 3): 10.7%, Syscat: 15, Sev: 3 Event: Solicited - Fatigue (Grade 3): 49.0%, Syscat: 8, Sev: 3 Event: Solicited - Fevers (Grade 3): 1.6%, Syscat: 8, Sev: 3 Event: Solicited - GI symptoms (Grade 3): 17.5%, Syscat: 7, Sev: 3 Event: Solicited - Headache (Grade 3): 29.6%, Syscat: 17, Sev: 3 Event: Solicited - Myalgia (Grade 3): 44.1%, Syscat: 15, Sev: 3 Event: Solicited - Rash (Grade 3): 9.6%, Syscat: 23, Sev: 3 Event: Solicited - Urticaria (Grade 3): 3.0%, Syscat: 23, Sev: 3	Medical significant adverse condition: OR 1.892 (0.846-4.233) New onset chronic diseases: OR 0.374 (0.11-1.272) Solicited - Arthralgias (Grade 3): OR 3.12 (1.423-6.845)** Solicited - Fevers (Grade 3): OR 1.698 (0.343-8.402) Solicited - GI symptoms (Grade 3): OR 3.342 (1.759-6.352)** Solicited - Headache (Grade 3): OR 5.063 (2.405-10.658)** Solicited - Rash (Grade 3): OR 3.024 (1.328-6.886)** Solicited - Urticaria (Grade 3): OR 2.167 (0.596-7.877) Unsolicited - Breast and reproductive system: OR 2.731 (0.767-9.718) Unsolicited - Infections and infestations: OR 2.317 (0.96-5.589) Unsolicited - any AE (Grade 3): OR 0.06 (0.02-0.183)**

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Levin M. J. et al.,2010 US (not stated explicitly)[174]	Controlled Clinical Trial	7	Sample size: 126, Mean age: NR, Age range: 7 - 12, Conditions: HIV	Human papillomavirus (HPV), Gardasil, Merck, Quadrivalent human papillomavirus (QHPV) (types 6, 11, 16, 18) recombinant vaccine, 0.5 mL, intramuscular, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Weeks Dose2: 8 Weeks Dose3: 24 Weeks	Any adverse event: 29% Any SAE: 2%, Sev: 4 Event: Ear and eye and respiratory system: 1%, Syscat: 4, 5, 22 Event: Laboratory abnormality: 3%, Syscat: 13 Event: Systemic reactions: 2% Event: (Injection site reactions) Event: (Other)	Ear and eye and respiratory system: OR 0.305 (0.019-5.034) Laboratory abnormality: OR 0.935 (0.094-9.343) Systemic reactions: OR 0.617 (0.054-7.053)
Li R. et al.,2012 China[173]	Controlled Clinical Trial	4	Sample size: 600, Mean age: 24.6, Age range: 9.0 - 45.8, Percent female: 83.3%	Human papillomavirus (HPV), Gardasil/Silgard, Merck, Says to see ref 19. But ref 19 is of a different trial where multiple formulations were used. Cannot ascertain useful information., Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Intramuscular	Dose1: 1 Days Dose2: 2 Month Dose3: 6 Month	Any adverse event: 50.7% Event: Serious AE (any): 0% Event: Serious AE (vaccine-related): 0% Event: Severe pruritius: 0%, Syscat: 23, Sev: Serious Event: Systemic AE (any): 42.7% Event: Systemic AE (vaccine-related): 28.7%	Systemic AE (any): OR 1.122 (0.81-1.553) Systemic AE (vaccine-related): OR 1.066 (0.747-1.522)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Block S. L. et al.,2010 Asia, Europe, Latin America, North America[172]	Controlled Clinical Trial	7	Sample size: 21480, Mean age: NR, Age range: 9 - 26, Percent female: 94%	Human papillomavirus (HPV), Gardasil/Silgard, Merck, HPV-6/11/16/18, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: 1 Days Dose2: 2 Month Dose3: 6 Month	Event: Blood/lymphatic system: 0.03%, Syscat: 1, Sev: 3,4,5 Event: Cardiac: 0.03%, Syscat: 2, Sev: 3,4,5 Event: Gastrointestinal: 0.03%, Syscat: 7, Sev: 3,4,5 Event: Hepatobiliary: 0.02%, Syscat: 9, Sev: 3,4,5 Event: Infections/infestations: 0.2%, Syscat: 11, Sev: 3,4,5 Event: Injury/poisoning/procedural: 0.2%, Syscat: 12, Sev: 3,4,5 Event: Musculoskeletal/connective tissue: 0.01%, Syscat: 15, Sev: 3,4,5 Event: Neoplasms benign malignant, unspecified: 0.01%, Syscat: 16, Sev: 3,4,5 Event: Nervous system: 0.04%, Syscat: 17, Sev: 3,4,5 Event: Pregnancy/puerperium/perinatal: 0.3%, Syscat: 18, Sev: 3,4,5 Event: Psychiatric: 0.03%, Syscat: 19, Sev: 3,4,5 Event: Renal/urinary: 0.02%, Syscat: 20, Sev: 3,4,5 Event: Reproductive system/breast: 0.03%, Syscat: 21, Sev: 3,4,5 Event: Respiratory/thoracic/mediastinal: 0.04%, Syscat: 22, Sev: 3,4,5 Event: Vascular: 0.03%, Syscat: 26, Sev: 3,4,5 Event: Serious systemic AE: 0.9% Event: Death: 0.1%, Sev: 5 Event: Discontinuation due to AE: 0.2%	Cardiac: OR 2.472 (0.257-23.766) Death: OR 1.295 (0.502-3.341) Discontinuation due to AE: OR 1.099 (0.596-2.025) Gastrointestinal: OR 1.648 (0.302-8.998) Infections/infestations: OR 1.295 (0.662-2.532) Injury/poisoning/procedural: OR 0.669 (0.398-1.123) Musculoskeletal/connective tissue: OR 0.412 (0.037-4.543) Neoplasms benign malignant, unspecified: OR 0.824 (0.052-13.172) Nervous system: OR 0.824 (0.238-2.846) Pregnancy/puerperium/perinatal: OR 0.736 (0.463-1.17) Psychiatric: OR 1.236 (0.206-7.397) Renal/urinary: OR 0.824 (0.116-5.849) Reproductive system/breast: OR 0.824 (0.206-3.294) Respiratory/thoracic/mediastinal: OR 1.03 (0.276-3.836) Vascular: OR 164.803 (0-178246427.81)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Moreira Jr E. D. et al.,2011 18 countries including Brazil, Germany, Mexico, US, South Africa, Australia, Canada[171]	Controlled Clinical Trial	7	Sample size: 4065, Mean age: NR, Age range: 16 - 26, Percent female: 0%	Human papillomavirus (HPV), Gardasil/Silgard, Merck, Quadrivalent HPV (type6/11/16/18) L1 VLP vaccine with amorphous aluminum hydroxyphosphatesulfate (AAHS) adjuvant, Adjuvant: Aluminum, Preservative: Not reported, Delivery: Intramuscular	Dose1: 1 Days Dose2: 2 Month Dose3: 6 Month	Any adverse event: 69.2% Any SAE: 0.4%, Sev: 3-5 Event: Death (entire study period): 0.2%, Sev: 5 Event: Discontinuation due to AE (entire study period): 0.3%, Sev: 1-5 Event: Discontinuation due to SAE (entire study period): 0.2%, Sev: 3-5 Event: 1 or more systemic AE (1-15 days): 31.7%, Sev: 1-3 Event: Influenza (1-15 days): 2.2%, Syscat: 11, Sev: 1-3 Event: Nasopharyngitis(1-15 days): 2.3%, Syscat: 11, Sev: 1-3 Event: Pharyngitis(1-15 days): 1.1%, Syscat: 11, Sev: 1-3 Event: Upper respiratory tract infection(1-15 days): 1.4%, Syscat: 11, Sev: 1-3 Event: Injury, Poisoning and Procedural Complications(1-15 days): 1.5%, Syscat: 12, Sev: 1-3 Event: Musculoskeletal and Connective Tissue Disorders(1-15 days): 3.1%, Syscat: 15, Sev: 1-3 Event: Nervous System Disorders(1-15 days): 10.6%, Syscat: 17, Sev: 1-3 Event: Dizziness(1-15 days): 1.0%, Syscat: 17, Sev: 1-3 Event: Respiratory, Thoracic And Mediastinal Disorders(1-15 days): 3.6%, Syscat: 22, Sev: 1-3 Event: Oropharyngeal pain(1-15 days): 2.0%, Syscat: 22, Sev: 1-3 Event: Gastrointestinal Disorders(1-15 days): 6.4%, Syscat: 7, Sev: 1-3 Event: General Disorders(1-15 days): 8.3%, Sev: 1-3 Event: Skin And Subcutaneous Tissue Disorders(1-15 days): 1.3%, Sev: 1-3	Death (entire study period): OR 0.3 (0.083-1.093) Dizziness(1-15 days): OR 1.061 (0.555-2.027) Gastrointestinal Disorders(1-15 days): OR 1.049 (0.81-1.359) General Disorders(1-15 days): OR 0.953 (0.761-1.194) Influenza (1-15 days): OR 0.958 (0.625-1.469) Injury, Poisoning and Procedural Complications(1-15 days): OR 1.259 (0.734-2.162) Musculoskeletal and Connective Tissue Disorders(1-15 days): OR 1.232 (0.844-1.801) Nasopharyngitis(1-15 days): OR 0.881 (0.585-1.328) Nervous System Disorders(1-15 days): OR 0.889 (0.729-1.084) Oropharyngeal pain(1-15 days): OR 1.032 (0.654-1.63) Pharyngitis(1-15 days): OR 1.106 (0.602-2.033) Respiratory, Thoracic And Mediastinal Disorders(1-15 days): OR 20.774 (7.088-60.889)** Skin And Subcutaneous Tissue Disorders(1-15 days): OR 0.84 (0.497-1.421) Upper respiratory tract infection(1-15 days): OR 1.361 (0.761-2.434) Discontinuation due to SAE (entire study period): OR 0.3 (0.083-1.093)
Roteli-Martins C. M. et al.,2012 Brazil[179]	#10119 f/u	NC	Sample size: 436, Mean age: 26.5, Age range: 15 - 25, Percent female: 100%, Percent pregnant: Percent Pregnant: 17%	Human papillomavirus (HPV), HPV-16/18, GlaxoSmithKline, Described in another study, Adjuvant: ASO 4, Preservative: Not reported, Delivery: Reported in previous study	Dose1: 0 Month Dose2: 1 Month Dose3: 6 Month	Event: New Onset Chronic Disease: 2.2% Event: New Onset Autoimmune Disease, Syscat: 10 Event: Serious Adverse Events: 4.5% Event: Medically Significant Adverse Events: 17.9%	Medically Significant Adverse Events: OR 1.721 (0.998-2.97) New Onset Autoimmune Disease: OR 0.955 (0.133-6.84) New Onset Chronic Disease: OR 2.42 (0.464-12.609) Serious Adverse Events: OR 1.382 (0.516-3.699)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Englund J. A. et al.2010 US[98]	Controlled Clinical Trial	6	Sample size: 1375, Mean age: 9.1, Age range: 2 - 7	Influenza (inactivated), Fluzone, Sanofi, 0.25 mL dose contained 7.5 g hemagglutinin (HA) of A/New Caledonia/20/99(H1N1); A/New York/55/2004 (H3N2), and B/Jiangsu/10/2003, Adjuvant: Not Reported, Preservative: Preservative Free, Delivery: Intramuscular	Dose1: 0 Days Dose2: 1 Month	Any adverse event: 93.4%, Sev: 1-3 Any SAE: 1.9%, Sev: 2-3 Event: Fever >=38C (Dose 1): 11.2%, Syscat: 8, Sev: 1-3 Event: Any irritability (Dose 1): 80%, Syscat: 8, Sev: 1-3 Event: Decreased appetite (Dose 1): 39%, Syscat: 8, Sev: 1-3 Event: Any emesis (Dose 1): 15%, Syscat: 8, Sev: 1-3 Event: Abnormal crying (Dose 1): 62%, Syscat: 8, Sev: 1-3 Event: Any drowsiness (Dose 1): 67%, Syscat: 8, Sev: 1-3 Event: Fever >=38C (Dose 2): 2.3%, Syscat: 8, Sev: 1-3 Event: Any irritability (Dose 2): 55%, Syscat: 8, Sev: 1-3 Event: Decreased appetite (Dose 2): 22%, Syscat: 8, Sev: 1-3 Event: Any emesis (Dose 2): 11%, Syscat: 8, Sev: 1-3 Event: Abnormal crying (Dose 2): 41%, Syscat: 8, Sev: 1-3 Event: Any drowsiness (Dose 2): 41%, Syscat: 8, Sev: 1-3 Event: Death: 0.1%, Sev: 5	Abnormal crying (Dose 1): OR 1 (0.794-1.26) Abnormal crying (Dose 2): OR 1.042 (0.83-1.31) Any drowsiness (Dose 1): OR 1.093 (0.863-1.384) Any emesis (Dose 1): OR 1.294 (0.926-1.808) Any emesis (Dose 2): OR 0.193 (0.146-0.256)** Any irritability (Dose 1): OR 1.128 (0.858-1.483) Any irritability (Dose 2): OR 0.922 (0.736-1.156) Decreased appetite (Dose 1): OR 0.883 (0.703-1.109) Decreased appetite (Dose 2): OR 0.944 (0.723-1.234) Fever >=38C (Dose 1): OR 0.952 (0.67-1.352) Fever >=38C (Dose 2): OR 0.596 (0.313-1.135)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Gotoh K. et al.,2011 Japan[101]	Cohort	1	Sample size: 101, Mean age: 9.8, Percent female: 51.5%, Conditions: Transplant	Influenza (inactivated), NR, 15 lg hemagglutinin per 0.5 mLof each of the following influenza strains: A/New Caledonia/20/99 (H1N1), A/Hiroshima/52/2005 (H3N2), and B/Malaysia/2506/2004 in the 2006–2007 season; A/SolomonIslands/3/2006 (H1N1), A/Hiroshima/52/2005 (H3N2), and B/Malaysia/2506/2004 in the 2007–2008 season; and A/Brisbane/59/2007 (H1N1), A/Uruguay/716/2007 (H3N2),and B/Florida/4/2006 in the 2008–2009 season. These inactivated vaccines did not contain adjuvant., Adjuvant: Adjuvant Free, Preservative: Not reported, Delivery: Not reported	Dose1: 0 Days	Any SAE: 0% Event: Acute allograft rejection: 0%, Syscat: 10 Event: Acute febrile illness: 21.2%, Syscat: 8 Event: Flu virus infection: 6.1%, Syscat: 10	Acute febrile illness: OR 0.421 (0.16-1.11) Flu virus infection: OR 0.819 (0.143-4.703)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Halasa N. et al.,2011 US[99]	Controlled Clinical Trial	2	Sample size: 20, Mean age: 12.2, Age range: 5 - 17, Percent female: 45%, Conditions: Cancer	Influenza (live), MedImmune, 2005-2005 prep: 106.5-7.5 TCID50per dose for each of the following strains: A/New Caledonia/20/99 (A/NC/20/99; A/H1N1), A/Wyoming/3/2003(A/Fujian/411/02-like, A/Fuj/411/02; A/H3N2), and B/Jilin/20/2003(B/Shanghai/361/2002-like, Yam88 lineage; B/Yam/166/98; B2005-2006: contained an identical A/H1N1 strain, but the A/H3N2 isolate was updated to A/California/7/2004(A/Cal/7/04) and the B strain was replaced with B/Jiangsu/10/2003(B/Shanghai/361/2002-like, Yam88 lineage; B/Yam/166/98; B, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intranasal	Dose1: 0 Days	Any adverse event: 88.9% Any SAE: 0% Event: Fever >=100C (0-42 days): 22.2%, Syscat: 8, Sev: 1-3 Event: Runny nose: 77.8%, Syscat: 22, Sev: 1-3 Event: Sore throat: 22.2%, Syscat: 22, Sev: 1-3 Event: Cough: 11.1%, Syscat: 22, Sev: 1-3 Event: Vomiting: 44.4%, Syscat: 8, Sev: 1-3 Event: Headache: 44.4%, Syscat: 8, Sev: 1-3 Event: Muscle ache: 0%, Syscat: 15, Sev: 1-3 Event: Chills: 11.1%, Syscat: 8, Sev: 1-3 Event: Tiredness: 44.4%, Syscat: 8, Sev: 1-3 Event: Irritability: 0%, Syscat: 8, Sev: 1-3 Event: Rash: 0%, Syscat: 10, Sev: 1-3 Event: Febrile neutropenia: 0%, Syscat: 1, Sev: 1-3	Chills: OR 0.259 (0.022-3.063) Cough: OR 0.259 (0.022-3.063) Fever >=100C (0-42 days): OR 0.375 (0.051-2.772) Headache: OR 0.286 (0.045-1.821) Runny nose: OR 1.556 (0.244-9.913) Sore throat: OR 0.25 (0.034-1.819) Tiredness: OR 0.444 (0.074-2.66) Vomiting: OR 1.556 (0.244-9.913)
Steele A. D. et al.,2010 South Africa[155]	Controlled Clinical Trial	4	Sample size: 475, Mean age: 6.3	Rotavirus, Rotarix, GlaxoSmithKline, RIX4414 developed from 89-12 parent vaccine strain which was cloned and passaged on Vero cells. Viral concentration of 1 dose contained at least 1x10e6.0 medial cell culture infective dose and lyophilised vaccine was reconstituted with calcium carbonate as buffer, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 10 Weeks Dose2: 14 Weeks	Any adverse event: 70% Event: Serious adverse events (any): 5.3% Event: Serious adverse events (vaccine-related): 0% Event: Deaths (vaccine-related): 0% Event: Deaths (any): 1.1% Event: Intussusception: 0%	Serious adverse events (any): OR 1.011 (0.336-3.046)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Zaman K. et al.,2010 Bangladesh and Vietnam[164]	Controlled Clinical Trial	8	Sample size: 2035, Mean age: 8.9, Age range: 5.9 - 25.9, Percent female: 47%	Rotavirus, RotaTeq, Merck, Pentavalent rotavirus vaccine containing 5 human-bovine reassortant rotaviruses with the WC3 bovine strain as backbone and viral surface proteins corresponding to human rotavirus serotypes G1, G2 G3, G4, P1A[8], Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 6 Weeks Dose2: 10 Weeks Dose3: 14 Weeks	Any SAE: 2.5% Event: Death: 0.3%, Sev: 5 Event: Serious adverse events (vaccine-related): 0%	Death: OR 0.75 (0.167-3.36)
Laserson K. F. et al.,2012 Kenya[145]	Controlled Clinical Trial	7	Sample size: 297, Age range: 0 - 12, Percent female: 51.8%, Conditions: HIV	Rotavirus, RotaTeq, Merck, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 6 Weeks Dose2: 10 Weeks Dose3: 14 Weeks	Any adverse event: 93.2% Event: One of more serious adverse events: 9.5%, Sev: Serious Event: Infections: 9.5%, Syscat: 11, Sev: Serious Event: Respiratory, thoracic and mediastinal disorders: 0%, Syscat: 22, Sev: Serious Event: General disorders and administration site conditions: 0%, Syscat: 8, Sev: Serious Event: Death: 0%, Syscat: 8 Event: Infections: 71.4%, Syscat: 11, Sev: Serious Event: Respiratory, thoracic and mediastinal disorders: 69.4%, Syscat: 22, Sev: Serious Event: General disorders and administration site conditions: 66%, Syscat: 8, Sev: Serious Event: Gastrointestinal disorders: 60.5%, Syscat: 7, Sev: Serious Event: Nervous system disorders: 0%, Syscat: 17, Sev: Serious Event: Reproductive system and breast disorders: 0.7%, Syscat: 21, Sev: Serious	Gastrointestinal disorders: OR 1.534 (0.968-2.431) General disorders and administration site conditions: OR 0.97 (0.599-1.57) Infections: OR 0.684 (0.332-1.412) Infections: OR 0.524 (0.301-0.912)** One of more serious adverse events: OR 0.581 (0.286-1.179) Respiratory, thoracic and mediastinal disorders: OR 337.733 (45.817-2489.554)**
Vesikari T. et al.,2006 Finland[159]	Controlled Clinical Trial	5	Sample size: 1946, Age range: 2 - 8	Rotavirus, NR, Low-potency pentavalent G1, G2, G3, G4, P1A 2.41×106., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Weeks Dose2: 4-8 Weeks Dose3: 8-16 Weeks	Event: Post-vaccination fever greater than or equal to 38.1 C rectally after dose 1: 27%, Syscat: 8 Event: Post-vaccination fever greater than or equal to 38.1 C rectally after dose 2: 27%, Syscat: 8 Event: Post-vaccination fever greater than or equal to 38.1 C rectally after dose 3: 30%, Syscat: 8 Event: Intussusception: 0.4%, Syscat: 7 Event: Deaths: 0%	Post-vaccination fever greater than or equal to 38.1 C rectally after dose 1: OR 1.479 (0.982-2.229) Post-vaccination fever greater than or equal to 38.1 C rectally after dose 2: OR 1.171 (0.788-1.74) Post-vaccination fever greater than or equal to 38.1 C rectally after dose 3: OR 1.286 (0.873-1.894)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Grant L. R et al.,2012 United States[140]	Controlled Clinical Trial	5	Sample size: 1003, Age range: 6 - 12	Rotavirus, RotaTeq, Merck, PRV is a live, pentavalent, vaccine that contains humanbovine (WC3 strain) reassortant rotaviruses expressing the G1, G2, G3, G4, and P[8] human rotavirus antigens, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Weeks Dose2: 4-10 Weeks Dose3: 8-20 Weeks	Event: Vomiting, vaccine related: 11.4%, Syscat: 7 Event: Diarrhea, vaccine related: 31.8%, Syscat: 7 Event: Fever, vaccine related: 33.2%, Syscat: 8 Event: Intussusception: 0%, Syscat: 7 Event: Deaths, (Were outside of 42 day safety window and not associated with vaccine): 0.39% Event: Vomiting, all events: 17.5%, Syscat: 7 Event: Diarrhea, all events: 43.0%, Syscat: 7 Event: Fever, all events: 54.2%, Syscat: 8	Deaths, (Were outside of 42 day safety window and not associated with vaccine): OR 1.945 (0.176-21.517) Diarrhea, all events: OR 1.208 (0.939-1.555) Diarrhea, vaccine related: OR 1.113 (0.851-1.456) Fever, all events: OR 0.943 (0.736-1.21) Fever, vaccine related: OR 1.047 (0.804-1.364) Vomiting, all events: OR 1.097 (0.788-1.527) Vomiting, vaccine related: OR 1.384 (0.911-2.102)
Armah G. E. et al.,2010 Ghana, Kenya, Mali[134]	Controlled Clinical Trial	5	Sample size: 5560, Age range: 4 - 12, Conditions: HIV	Rotavirus, RotaTeq, Merck, 2×107infectious units per reassortant rotavirus, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 6 Weeks Dose2: 10 Weeks Dose3: 14 Weeks	Event: One or more serious adverse event: 1.5% Event: Death: 0%, Syscat: 8 Event: Pyrexia: <0.1%, Syscat: 8 Event: Sudden infant death syndrome: 0%, Syscat: 8 Event: Bronchiolitis: <0.1%, Syscat: 11 Event: Bronchopneumonia: 0.2%, Syscat: 11 Event: Gastroenteritis: 0.6%, Syscat: 11 Event: Otis media acute: 0%, Syscat: 11 Event: Pneumonia: 0.5%, Syscat: 11 Event: Respiratory tract infection: 0.1%, Syscat: 11 Event: Upper respiratory tract infection: <0.1%, Syscat: 11 Event: Other: 0.2% Event: Vomiting: <0.1%, Syscat: 7	Bronchiolitis: OR 1 (0.063-16.002) Bronchopneumonia: OR 1.669 (0.398-6.989) Gastroenteritis: OR 1 (0.51-1.964) One or more serious adverse event: OR 0.933 (0.61-1.425) Other: OR 0.714 (0.226-2.253) Pneumonia: OR 1.302 (0.57-2.974) Respiratory tract infection: OR 0.6 (0.143-2.512) Upper respiratory tract infection: OR 0.5 (0.045-5.518)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Vesikari T. et al.,2004 Finland[158]	Controlled Clinical Trial	5	Sample size: 405, Mean age: 8.3, Age range: 6 - 12	Rotavirus, Rotarix, GlaxoSmithKline, The vaccine was a lyophilized product; it was reconstituted with a diluent containing calcium carbonate as buffer. Each reconstituted vaccine dose contained 104.7 focus forming units of the RIX4414 strain rotavirus vaccine, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: 2 Month Dose2: 4 Month	Event: Fever greater than or equal to 38.0°C, Dose 1: 12%, Syscat: 8 Event: Diarrhea, Dose 1: 8%, Syscat: 7 Event: Vomiting, Dose 1: 9%, Syscat: 7 Event: Irritability, Dose 1: 62%, Syscat: 8 Event: Loss of appetite, Dose 1: 24%, Syscat: 14 Event: Fever greater than or equal to 38.0°C, Dose 2: 27%, Syscat: 8 Event: Diarrhea: 4%, Syscat: 7 Event: Vomiting: 6%, Syscat: 7 Event: Irritability: 59%, Syscat: 8 Event: Loss of appetite: 24%, Syscat: 14 Event: Intussusception, Syscat: 7	Diarrhea, Dose 1: OR 1.652 (0.685-3.984) Diarrhea: OR 2.042 (0.538-7.745) Fever greater than or equal to 38.0°C, Dose 2: OR 1.11 (0.694-1.773) Fever greater than or equal to 38.0°C, Dose 1: OR 1.103 (0.578-2.105) Irritability, Dose 1: OR 1.088 (0.715-1.654) Irritability: OR 1.276 (0.845-1.928) Loss of appetite, Dose 1: OR 1.542 (0.914-2.602) Vomiting, Dose 1: OR 1.879 (0.788-4.48) Vomiting: OR 0.645 (0.299-1.393)
Sow S. O. et al.,2012 Vietnam, Bangledash, Ghana, Kenya, Mali[154]	Controlled Clinical Trial	5	Sample size: 1960, Mean age: NR, Age range: 6 - 14, Percent female: 48.3%	Rotavirus, RotaTeq, Merck, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 6 Weeks Dose2: 10 Weeks Dose3: 14 Weeks	Event: One or more serious adverse events: 0.5% Event: Serious vaccine-related adverse events: 0% Event: Deaths: 0.3%, Syscat: 8 Event: Bronchiolitis: 0.1%, Syscat: 11 Event: Meningitis: 0.1%, Syscat: 11 Event: Meningitis pneumococcal: 0.1%, Syscat: 11 Event: Pneumonia: 0.2%, Syscat: 11	Bronchiolitis: OR 1.002 (0.063-16.044) Deaths: OR 0.6 (0.143-2.518) One or more serious adverse events: OR 0.834 (0.254-2.742) Pneumonia: OR 0.667 (0.111-4.003)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Block S. L. et al.,2007 United States, Finland[135]	Controlled Clinical Trial	5	Sample size: 1312, Age range: 6 - 13, Percent female: 47.8%	Rotavirus, RotaTeq, Merck, ©1.1X10 infectious U per dose. Pentavalent (G1–G4, and P[8]) humanbovine(WC3) reassortant rotavirus vaccine (PRV), Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Weeks Dose2: 4-10 Weeks Dose3: 8-20 Weeks	Any adverse event: 88.3% Event: Serious Adverse Event: .03% Event: Gastrointestinal system: 0.46%, Syscat: 7 Event: Abdominal pain: 0%, Syscat: 7 Event: Constipation: 0%, Syscat: 7 Event: Decreased appetite: 0.15%, Syscat: 14 Event: Dehydration: 0.15%, Syscat: 14 Event: Gastroenteritis: 0.15%, Syscat: 7 Event: Hematochezia: 0%, Syscat: 7 Event: General Body: 0.46%, Syscat: 8 Event: Fever, greater than or equal to 102.5 F: 0.31%, Syscat: 8 Event: SIDS: 0.15%, Syscat: 8 Event: Nervous system: 0.31%, Syscat: 17 Event: Meningitis: 0.15%, Syscat: 11 Event: Partial seizures: 0.15%, Syscat: 17 Event: Respiratory: 2%, Syscat: 22 Event: Bronchiolitis/bronchitis/bronchospasm: 1.23%, Syscat: 22 Event: Influenza: 0.15%, Syscat: 22 Event: Pertussis: 0%, Syscat: 22 AE: 3%, Syscat: 22 Event: Respiratory syncytial virus infection: 1%, Syscat: 22 Event: Upper respiratory tract infection: 0%, Syscat: 22	Bronchiolitis/bronchitis/bronchospasm: OR 1.162 (0.419-3.224) Decreased appetite: OR 1.015 (0.063-16.269) Dehydration: OR 0.253 (0.028-2.267) Gastroenteritis: OR 0.507 (0.046-5.605) Gastrointestinal system: OR 0.301 (0.083-1.1) Influenza: OR 0.507 (0.046-5.605) Respiratory syncytial virus infection: OR 6.778 (0.03-1543.45) Respiratory: OR 1.905 (0.755-4.806) Serious Adverse Event: OR 0.783 (0.438-1.399)
Chang C.-C. et al.,2009 Taiwan[136]	Controlled Clinical Trial	NC	Sample size: 189, Age range: 6 - 12, Percent female: 47.6%	Rotavirus, RotaTeq, Merck, five human-bovine reassortant rotaviruses, each of which contained the WC3 bovine strain backbone with different human viral surface proteins G1, G2, G3, G4 and P[8}. An estimated final concentration of 6.5 × 107 IU to 1.2 × 108 IU was included in a 2 mL dose solution, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Weeks Dose2: 4-10 Weeks Dose3: 8-20 Weeks	Event: Fever, rectal temperature > 38.0°C: 53.7%, Syscat: 8 Event: Intussusception: 0%, Syscat: 7 Event: Diarrhea: 26.3%, Syscat: 7 Event: Vomiting: 8.4%, Syscat: 7 Event: Irritable crying: 1.1%, Syscat: 8	Diarrhea: OR 2.015 (0.972-4.178) Fever, rectal temperature > 38.0°C: OR 0.875 (0.492-1.555) Irritable crying: OR 0.979 (0.06-15.882) Vomiting: OR 1.13 (0.392-3.252)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Kim D. S. et al.,2008 Korea[143]	Controlled Clinical Trial	3	Sample size: 178, Age range: 6 - 12, Percent female: 42.7%	Rotavirus, RotaTeq, Merck, PRV contained 5 WC3 reassortant rotaviruses, each consisting of the WC3 bovine strain with viral surface proteins corresponding to human rotavirus serotypes G1, G2, G3, G4, and P1A_8 suspended in a liquid sodium citrate and phosphate buffer at an aggregate viral titer of approximately 6.9 _ 107 to 8.6 _ 107 infectious units per dose., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Weeks Dose2: 4-10 Weeks Dose3: 8-20 Weeks	Event: One or more serious adverse events: 5.3% Event: Intussusception: 0%, Syscat: 7 Event: Vaccine-related serious adverse event: 0.87%	One or more serious adverse events: OR 0.44 (0.141-1.373)
Shui I. M. et al.,2012 US[169]	Cohort	1	Sample size: 117575, Mean age: NR, Age range: 4 - 34	Rotavirus, RotaTeq, Merck, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 2 Month Dose3: 2 Month	Event: Intussusception - All doses (1-30d risk period), Syscat: 7 Event: Intussusception - All doses (1-7d risk period), Syscat: 7 Event: Intussusception - 1 dose (1-30d risk period), Syscat: 7 Event: Intussusception - 1 dose (1-7d risk period), Syscat: 7 Event: Intussusception - 2 dose (1-30d risk period), Syscat: 7 Event: Intussusception - 2 dose (1-7d risk period), Syscat: 7 Event: Intussusception - 3 dose (1-30d risk period), Syscat: 7 Event: Intussusception - 3 dose (1-7d risk period), Syscat: 7	Intussusception - 2 dose (1-30d risk period): OR 0.396 (0.106-1.473) Intussusception - 3 dose (1-30d risk period): OR 0.989 (0.247-3.954) Intussusception - 3 dose (1-7d risk period): OR 0.989 (0.09-10.907) Intussusception - All doses (1-30d risk period): OR 0.865 (0.363-2.063) Intussusception - All doses (1-7d risk period): OR 0.742 (0.124-4.439)
Vesikari T. et al.,2006 11 countries[160]	Controlled Clinical Trial	8	Sample size: 69274, Mean age: 9.8, Age range: 6 - 12, Percent female: 49.3%	Rotavirus, RotaTeq, Merck, Pentavalent, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 4-10 Weeks Dose3: 4-10 Weeks	Any SAE: 2.4%, Syscat: 3-4 Event: Intussusception (total): 0.03%, Syscat: 7 Event: Intussusception (within 42 day of any dose): 0.02%, Syscat: 7 Event: Intussusception related Death: 0%, Syscat: 7 Event: Total deaths: 0.07%, Sev: 5 Event: Death due to SIDS: 0.02%, Sev: 5	

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Goveia M. G. et al.,2007 11 countries[139]	Controlled Clinical Trial	8	Sample size: 2074, Mean age: NR, Age range: 6 - 12, Conditions: Premature babies	Rotavirus, RotaTeq, Merck, vaccine contained 5live human-bovine reassortant rotaviruses, each consisting of the WC3 bovine strain expressing a viral surface protein corresponding to human rotavirus serotypes G1, G2, G3, G4,or P1A, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 4-10 Weeks Dose3: 4-10 Weeks	Any SAE: 5.5% Event: Bronchiolitis (all subjects, most frequent AE): 1.4%, Syscat: 22, Sev: 3-4 Event: Intussusception (all subjects, confirmed): 0%, Syscat: 7, Sev: 3-4 Event: hematochezia (all subjects): 0%, Syscat: 1, Sev: 3-4 Event: Deaths (total, all subjects): 0.2%, Sev: 5 Event: Death due to SIDS (all subjects): 0.1%, Sev: 5 Event: At least one SAE (extreme preemie): 8.1%, Sev: 3-4 Event: Bronchiolitis (extreme preemie): 2.7%, Syscat: 22, Sev: 3-4 Event: Pneumonia (extreme preemie): 2.7%, Syscat: 22, Sev: 3-4 Event: Apneic attack (extreme preemie): 1.4%, Syscat: 22, Sev: 3-4	Apneic attack (extreme preemie): OR 1.056 (0.066-16.901) At least one SAE (extreme preemie): OR 0.702 (0.249-1.979) Bronchiolitis (all subjects, most frequent AE): OR 0.7 (0.354-1.383) Bronchiolitis (extreme preemie): OR 1.056 (0.148-7.509) Deaths (total, all subjects): OR 1.056 (0.148-7.509) Death due to SIDS (all subjects): OR 1.056 (0.066-16.901) Pneumonia (extreme preemie): OR 2.113 (0.191-23.345)
Omenaca F. et al.,2012 France, Portugal, Poland and Spain[148]	Controlled Clinical Trial	6	Sample size: 1009, Mean age: 8.5, Age range: 5 - 14, Percent female: 49%, Conditions: Premature babies	Rotavirus, Rotarix, GlaxoSmithKline, A single dose of RIX4414 vaccine contained at least 106.0 median cell culture infective dose of the live-attenuated RIX4414 human rotavirus strain., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 30-83 Days	Any SAE: 5.1% Event: At least 1 unsolicited symptom: 29.3% Event: At least 1 unsolicited symptom (grade 3): 1.9%, Syscat: 8,7 Event: At least 1 unsolicited symptom (vaccine-related): 8.5% Event: Intussusception: 0%, Syscat: 7 Event: Death: 0%, Sev: 5 Event: infection - Gastroenteritis: 2.4%, Syscat: 11 Event: infection - Upper resp infection: 2.1%, Syscat: 11	At least 1 unsolicited symptom: OR 0.602 (0.458-0.792)** At least 1 unsolicited symptom (grade 3): OR 0.285 (0.142-0.573)** At least 1 unsolicited symptom (vaccine-related): OR 0.608 (0.401-0.92)** infection - Gastroenteritis: OR 0.744 (0.341-1.625) infection - Upper resp infection: OR 0.649 (0.291-1.448)
Tregnaghi M. W. et al.,2011 Argentina, Brazil, Colombia, Dominican Republic, Honduras, and Panama[157]	Controlled Clinical Trial	4	Sample size: 6568, Mean age: 8.6, Age range: 6 - 12	Rotavirus, Rotatix, GlaxoSmithKline, Contained at least 106.0 median Cell Culture Infective Dose (CCID50) of live attenuated human rotavirus RIX4414 strain. The lyophilized vaccine was reconstituted with the supplied buffer before oral administration., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 1-2 Month	Any SAE: 11.5%, Sev: 3-5 Event: Bronchiolitis: 3.4%, Syscat: 22, Sev: 3-4 Event: Gastroenteritis: 2.2%, Syscat: 7, Sev: 3-4 Event: Pneumonia: 2.1%, Syscat: 22, Sev: 3-4 Event: Intussusception: 0.1%, Syscat: 7, Sev: 3-4 Event: Death: 0.2%, Sev: 5	Bronchiolitis: OR 1.178 (0.874-1.588) Intussusception: OR 1 (0.183-5.464) Death: OR 2.503 (0.548-11.436) Gastroenteritis: OR 0.727 (0.529-1)** Pneumonia: OR 1 (0.699-1.43)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Kawamura N. et al.,2011 Japan[141]	Controlled Clinical Trial	4	Sample size: 764, Mean age: 7.7, Age range: 6 - 14, Percent female: 50%	Rotavirus, Rotarix, GlaxoSmithKline, Each dose (1ml) of the lyophilized RIX4414 vaccine (Rotarix TM) contained at least 10-6.0 median Cell Culture Infective Dose (CCID50) of live attenuated human rotavirus RIX4414 strain, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Month Dose2: 1 Month	Any adverse event: 75.8% Any SAE: 14.2% Event: # of patients with any AE (31-day post vacc): 54.9% Event: Eczema: 14.2%, Syscat: 23 Event: Upper respiratory tract infection: 9.8%, Syscat: 22 Event: Cough/runny nose: 35%, Syscat: 22, Sev: 1 Event: Diarrhea: 8%, Syscat: 7 Event: Fever: 11%, Syscat: 8 Event: Irritability: 53%, Syscat: 8 Event: Loss of appetite: 16%, Syscat: 8 Event: Vomiting: 15%, Syscat: 7	# of patients with any AE (31-day post vacc): OR 0.96 (0.71-1.299) Cough/runny nose: OR 1.045 (0.762-1.434) Diarrhea: OR 1.652 (0.866-3.153) Eczema: OR 1.299 (0.82-2.057) Fever: OR 1.421 (0.837-2.414) Irritability: OR 1.128 (0.835-1.523) Loss of appetite: OR 1.397 (0.895-2.179) Upper respiratory tract infection: OR 1.011 (0.61-1.678) Vomiting: OR 1.084 (0.706-1.664)
Vesikari T. et al.,2011 Finland[161]	Controlled Clinical Trial	3	Mean age: 9.1, Age range: 6 - 12, Percent female: 50%	Rotavirus, Rotarix, GlaxoSmithKline, RIX4414 oral suspension (liquid formulation). Contained at least 10-6median cell culture infective dose (CCID50) of live attenuated RIX4414 human rotavirus strain. The liquid formulation of RIX4414 contained sucrose as excipient and the content of sucrose in the liquid formulation is higher than one in the lyophilized formulation., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 1 Month	Event: Cough/runny nose: 39%, Syscat: 22 Event: Diarrhea: 2%, Syscat: 7 Event: Fever: 8%, Syscat: 8 Event: Irritability: 69%, Syscat: 8 Event: Loss of appetite: 18%, Syscat: 8 Event: Vomiting: 14.2%, Syscat: 7	Cough/runny nose: OR 0.959 (0.477-1.927) Diarrhea: OR 0.49 (0.066-3.639) Fever: OR 1.652 (0.381-7.173) Irritability: OR 1.199 (0.582-2.47) Loss of appetite: OR 0.778 (0.334-1.814) Vomiting: OR 1.098 (0.404-2.984)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Dennehy P. H. et al.,2005 United States, Canada[138]	Controlled Clinical Trial	6	Sample size: 529, Mean age: 8.7, Age range: 5 - 15, Percent female: 51%	Rotavirus, Routine Vaccines, RIX4414, GlaxoSmithKline, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Month Dose2: 2 Month	Any adverse event: 4.72% Event: Fever: 0%, Syscat: 8 Event: Hypovolemia/dehydration: 0.47%, Syscat: 14, Sev: Serious Event: Meningitis: 0%, Syscat: 11, Sev: Serious Event: Petit mal seizures: 0%, Syscat: 17, Sev: Serious Event: Leukocytosis: 0%, Syscat: 1, Sev: Serious Event: Pyelonephritis: 0.94%, Syscat: 20, Sev: Serious Event: Kidney cyst: 0.47%, Syscat: 20, Sev: Serious Event: Bronchiolitis: 1.42%, Syscat: 22, Sev: Serious Event: Wheezing: 0%, Syscat: 22, Sev: Serious Event: Pneumonia: 0%, Syscat: 22, Sev: Serious Event: Asthma: 0.47%, Syscat: 22, Sev: Serious Event: Other respiratory illness: 0%, Syscat: 22, Sev: Serious Event: Gastroenteritis: 0.94%, Syscat: 7, Sev: Serious Event: GERD: 0%, Syscat: 7, Sev: Serious Event: Mesenteric adenitis: 0%, Syscat: 7, Sev: Serious	Bronchiolitis: OR 0.502 (0.1-2.532) Hypovolemia/dehydration: OR 0.507 (0.031-8.187)
Madhi S. A. et al.,2010 South Africa and Malawi[146]	Controlled Clinical Trial	3	Sample size: 4939, Mean age: 6.4 in placebo and rotarix gro, Percent female: 49.6%, Conditions: HIV	Rotavirus, Routine Vaccines, Rotarix, GlaxoSmithKline, Calcium carbonate buffer, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 6 Weeks Dose2: 10 Weeks Dose3: 14 Weeks	Event: Overall SAE: 9.7% Event: Gastroenteritis: 3.8%, Syscat: 7, Sev: Serious Event: Pneumonia: 2.3%, Syscat: 22, Sev: Serious Event: Bronchopneumonia: 1.4%, Syscat: 22, Sev: Serious Event: Bronchiolitis: 1%, Syscat: 22, Sev: Serious Event: Sepsis: 1.4%, Syscat: 11, Sev: Serious Event: Deaths: 2.5% Event: Intussception: 0.03%, Syscat: 7 Event: Vaccine-related AEs: 0.1%	Bronchiolitis: OR 1.027 (0.563-1.871) Bronchopneumonia: OR 0.995 (0.601-1.647) Deaths: OR 0.959 (0.661-1.393) Gastroenteritis: OR 0.779 (0.584-1.039) Overall SAE: OR 0.823 (0.68-0.995)** Pneumonia: OR 0.818 (0.564-1.185) Sepsis: OR 1.234 (0.722-2.11)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Narang A. et al.,2009 India[147]	Controlled Clinical Trial	5	Sample size: 363, Mean age: 8.7, Age range: 8 - 10, Percent female: 47.1%	Rotavirus, Routine Vaccines, Rotarix, GlaxoSmithKline, Vaccine contained at least 106.0 median cell culture infectious dose (CCID50) of the vaccine strain per dose. The placebo contained the same constituents as the study vaccine but without the virus component. The lyophilized vaccine and placebo were reconstituted with a diluent containing Calcium Carbonate as a buffer., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Month Dose2: 1 Month	Event: Serious adverse event: 2.61% Event: SAE, lower respiratory tract infection: 1.74%, Syscat: 11 Event: SAE, pneumonia: 0.87%, Syscat: 11 Event: GE episodes from dose 1 to one month post-dose 2: 12.6%, Syscat: 7 Event: Cough/runny nose: 3%, Syscat: 22, Sev: 3 Event: Diarrhea: 3%, Syscat: 7, Sev: 3 Event: Fever: 1%, Syscat: 8, Sev: 3 Event: Irritability: 1%, Syscat: 8, Sev: 3 Event: Loss of appetite: 1%, Syscat: 14, Sev: 3 Event: Vomiting: 4%, Syscat: 7, Sev: 3 Event: Cough/runny nose: 28%, Syscat: 22, Sev: 1-5 Event: Diarrhea: 9%, Syscat: 7, Sev: 1-5 Event: Fever: 16%, Syscat: 8, Sev: 1-5 Event: Irritability: 24%, Syscat: 8, Sev: 1-5 Event: Loss of appetite: 12%, Syscat: 14, Sev: 1-5 Event: Vomiting: 16%, Syscat: 7, Sev: 1-5	Cough/runny nose: OR 1.515 (0.276-8.315) Cough/runny nose: OR 4.472 (2.02-9.902)** Diarrhea: OR 1 (0.218-4.597) Diarrhea: OR 0.89 (0.366-2.164) Fever: OR 0.675 (0.346-1.319) GE episodes from dose 1 to one month post-dose 2: OR 0.94 (0.433-2.04) Irritability: OR 0.242 (0.031-1.913) Irritability: OR 2.316 (1.135-4.723)** Loss of appetite: OR 1.136 (0.5-2.584) Serious adverse event: OR 1.473 (0.241-8.988) Vomiting: OR 0.093 (0.034-0.256)**
Zaman K. et al.,2012 Bangladesh[165]	Controlled Clinical Trial	5	Sample size: 1136, Mean age: 8.2, Percent female: 48.6%	Rotavirus, Routine Vaccines, RotaTeq, GlaxoSmithKline, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 6 Weeks Dose2: 10 Weeks Dose3: 14 Weeks	Event: Acute diarrhea: 0.18%, Syscat: 7, Sev: Serious Event: Bronchiolitis: 0.53%, Syscat: 11, Sev: Serious Event: Umbilical infection: 0%, Syscat: 11, Sev: Serious Event: Pneumonia: 1.94%, Syscat: 11, Sev: Serious Event: Head injury: 0.18%, Syscat: 12, Sev: Serious Event: All Serious Adverse Events: 2.82%, Sev: Serious Event: Death, All causes: 0.53%, Syscat: 8, Sev: 5 Event: Death, CMV infection: 0.18%, Sev: 5 Event: Death, Pneumonia: 0.18%, Sev: 5 Event: Death, Hepatoblastoma: 0%, Sev: 5 Event: Death, UTI and sepsis: 0% Event: Accidental drowning: 0.18%, Sev: 5	Acute diarrhea: OR 1 (0.062-16.027) All Serious Adverse Events: OR 0.939 (0.47-1.878) Death, All causes: OR 1 (0.201-4.976) Pneumonia: OR 0.728 (0.331-1.599)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Christie C. D. C. et al.,2010 Jamaica[137]	Controlled Clinical Trial	4	Sample size: 1804, Mean age: 7.7, Age range: 6 - 12, Percent female: 48.4%	Rotavirus, Routine Vaccines, RotaTeq, Merck, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Month Dose2: 2 Month Dose3: 2 Month	Any SAE: 4.8%, Sev: 4-5 Event: Death: 0.11%, Sev: 5 Event: Bronchiolitis: 1.3%, Syscat: 22, Sev: 1-3 Event: Urinary Tract Infection: 0.8%, Syscat: 20, Sev: 1-3 Event: Otitis media: 0.4%, Syscat: 4, Sev: 1-3 Event: Gastroenteritis: 0.3%, Syscat: 7, Sev: 1-3 Event: Bronchopneumonia: 0.6%, Syscat: 22, Sev: 1-3 Event: Viral infections: 0.4%, Syscat: 11, Sev: 1-3 Event: Convulsions: 0.2%, Syscat: 17, Sev: 1-3 Event: Anemia: 0.2%, Syscat: 1, Sev: 1-3 Event: Anal fissure: 0.2%, Syscat: 7, Sev: 1-3 Event: Asthma: 0.2%, Syscat: 22, Sev: 1-3 Event: Upper resp infection: 0.2%, Syscat: 22, Sev: 1-3 Event: Femur fracture: 0.1%, Syscat: 12, Sev: 1-3 Event: Intussusception: 0%, Syscat: 22, Sev: 1-3	Bronchiolitis: OR 1.081 (0.475-2.463) Convulsions: OR 0.99 (0.139-7.044) Death: OR 0.329 (0.034-3.172) Femur fracture: OR 0.99 (0.062-15.854) Gastroenteritis: OR 0.99 (0.199-4.918) Otitis media: OR 1.322 (0.295-5.922) Urinary Tract Infection: OR 1.389 (0.439-4.393) Viral infections: OR 3.973 (0.443-35.62)
Ruiz-Palacios G. M. et al.,2006 Finland, Argentina, Brazil, Chile, Colombia, the Dominican Republic, Honduras, Mexico, Nicaragua, Panama, Peru, Venezuela[153]	Controlled Clinical Trial	6	Sample size: 63225, Mean age: 8.2, Percent female: 49%	Rotavirus, Routine Vaccines, Rotarix, GlaxoSmithKline, Contained 10.5 median cell-culture infective doses of the RIX4414 vaccine strain. Vaccine was reconstituted with 1.3 ml of liquid calcium carbonate buffer., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 2 Month Dose2: 4 Month	Event: Serious adverse events: 2.93% Event: Death: 0.18%, Syscat: 8, Sev: 5 Event: Hospitalization: 2.8% Event: Definite intussusception, 31 days or less after either dose: 0.02%, Syscat: 7 Event: Definite intussusception, 31 days or less after dose 1: 0%, Syscat: 7 Event: Definite intussusception, 31 days or less after dose 2: 0.02%, Syscat: 7 Event: Definite intussusception, between dose 1 and visit 3: 0.03%, Syscat: 7	Death: OR 1.298 (0.872-1.932) Definite intussusception, 31 days or less after dose 1: OR 0.498 (0.045-5.493) Definite intussusception, 31 days or less after dose 2: OR 0.996 (0.288-3.441) Definite intussusception, 31 days or less after either dose: OR 0.854 (0.287-2.541) Definite intussusception, between dose 1 and visit 3: OR 0.56 (0.248-1.268) Hospitalization: OR 0.877 (0.8-0.961)** Serious adverse events: OR 0.879 (0.804-0.962)**

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Phua K. B. et al.,2009 Hong Kong, Singapore, Thailand[150]	Controlled Clinical Trial	8	Sample size: 10708, Mean age: 11.6, Age range: 5 - 20, Percent female: 49.1%	Rotavirus, Routine Vaccines, Rotarix, GlaxoSmithKline, contained at least 106.0 median cell culture infectious dose (CCID50) of the vaccine strain per dose, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Dose2: 1-2 Month	Event: Intussusception (within 31 days post vaccination): 0%, Syscat: 7, Sev: 1-4 Event: Intussusception (from Dose 1 to age 2): 0.15%, Syscat: 7, Sev: 1-4 Event: Death: 0.02%, Sev: 5 Event: Withdrawal due to AE: 0.13%	Death: OR 0.332 (0.035-3.195) Intussusception (from Dose 1 to age 2): OR 1.996 (0.601-6.632) Withdrawal due to AE: OR 0.581 (0.229-1.477)
Rodriguez Z. M. et al.,2007 United States[152]	Controlled Clinical Trial	1	Sample size: 1358, Mean age: 9.35, Age range: 6 - 13, Percent female: 51.1%	Rotavirus, Routine Vaccines, RotaTeq, Merck, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 28-70 Days Dose3: 56-140 Days	Any adverse event: 82.3% Event: Diarrhea: 14.7%, Syscat: 7 Event: Vomiting: 9.4%, Syscat: 7 Event: Fever: 46.5%, Syscat: 8 Event: Upper respiratory infection: 23.6%, Syscat: 11 Event: Nasopharyngitis: 14.7%, Syscat: 11 Event: Otitis media: 10.1%, Syscat: 11 Event: Cough: 13.1%, Syscat: 22 Event: Nasal congestion: 13.0%, Syscat: 22 Event: Intussusception: 0.15%, Syscat: 7	Cough: OR 1.027 (0.748-1.41) Diarrhea: OR 0.711 (0.535-0.946)** Fever: OR 0.901 (0.728-1.115) Nasal congestion: OR 0.957 (0.699-1.311) Nasopharyngitis: OR 0.891 (0.664-1.197) Otitis media: OR 0.786 (0.561-1.103) Upper respiratory infection: OR 0.827 (0.647-1.056) Vomiting: OR 0.747 (0.528-1.055)
Zaman K. et al.,2009 Bangladesh[163]	Controlled Clinical Trial	7	Sample size: 294, Mean age: 6.1, Age range: 6 - 7, Percent female: 53.4%	Rotavirus, Routine Vaccines, Rotarix, GlaxoSmithKline, 10.5 median cell culture infective dose of the G1P strain., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 6 Weeks Dose2: 10 Weeks Dose3: 14 Weeks	Event: Unsolicited symptoms: 67% Event: Death due to severe pneumonia and cardi respiratory and renal failure 16 days after dose 1: 1.03%, Syscat: 8 Event: Gastroenteritis: 1.03%, Syscat: 7 Event: Any diarrhea: =6/day: 2%, Syscat: 7, Sev: 3 Event: fever: rectal temperature =38 ?C: 15%, Sysc at: 8, Sev: 3 Event: fever: rectal temperature >39.5 ?C: 3%, Sysc at: 8, Sev: 1-5 Event: Irritability: 48%, Syscat: 8, Sev: 1-5 Event: Irritability: ying that could not be comforted/prevented normal activity: 2%, Syscat: 8, Sev: 3 Event: Loss of appetite: 38%, Syscat: 14, Sev: 1-5 Event: Vomiting: =1 episode of forceful emptying of partially digested stomach contents =1 h after feeding within a day: 22%, Syscat: 7, Sev: 1-5 Event: Vomiting: =3 episodes/day: 7%, Syscat: 7, Sev: 1-5	fever: rectal temperature =38 ?C OR 0.3 (0.134-0.675)** Any diarrhea: =6/day: OR 0.66 (0.074-5.862) Gastroenteritis: OR 0.49 (0.03-8.001) Loss of appetite: OR 1.138 (0.553-2.341) Unsolicited symptoms: OR 0.603 (0.272-1.336) Vomiting: =1 episode of forceful emptying of partially digested stomach contents =1 h after feeding within a day: OR 1.377 (0.564-3.364)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Phua K. B. et al.,2012 Singapore, Hong Kong, Taiwan[151]	Controlled Clinical Trial	1	Sample size: 8407, Mean age: 35.3, Age range: 23 - 44, Percent female: 49%, Percent pregnant: Percent Pregnant: 0%	Rotavirus, Routine Vaccines, Rotarix, GlaxoSmithKline, reconstitution of lyophilized vaccine in calcium carbonate buffer to a concentration of at least 10*6.0 cell culture infective dose (CCID50) of live-attenuated virus (median), Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: NR Dose2: 1-2 Month	Any adverse event: 0.24% Event: Intussusception: 7% Event: gastroenteritis (failed treatment?): 7% Event: Kawasaki disease: 1%	Intussusception: OR 1.983 (0.18-21.878) gastroenteritis (failed treatment?): OR 1.487 (0.248-8.905)
Kim J. S. et al.,2012 South Korea[144]	Controlled Clinical Trial	5	Sample size: 684, Mean age: 8.8, Percent female: 45.3%	Rotavirus, Routine Vaccines, RIX4414, NR, >=10*6.0 median Cell Culture Infective Dose per ml, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 8 Weeks Dose2: 16 Weeks	Any adverse event: 72.6% Any SAE: 3.3% Event: Patients with unsolicited AE over 31d: 29.1% Event: nasopharygitis (unsolicited/31d): 5.7%, Syscat: 22 Event: URI (unsolicited/31d): 3.9%, Syscat: 22 Event: Bronchiolitis (unsolicited/31d): 3.5%, Syscat: 22 Event: gastroenteritis (unsolicited/31d): 8.3%, Syscat: 7 Event: Bronchiolitis (total study period): 1.2%, Syscat: 22 Event: Gastroenteritis (total study period): 1.0%, Syscat: 7	Bronchiolitis (total study period): OR 0.409 (0.123-1.356) Bronchiolitis (unsolicited/31d): OR 0.77 (0.327-1.811) Gastroenteritis (total study period): OR 0.427 (0.113-1.61) Patients with unsolicited AE over 31d: OR 0.815 (0.565-1.176) URI (unsolicited/31d): OR 0.861 (0.371-2) gastroenteritis (unsolicited/31d): OR 0.843 (0.467-1.521) nasopharygitis (unsolicited/31d): OR 0.563 (0.301-1.051)

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Kerdpanich A. et al.,2010 Thailand[142]	Controlled Clinical Trial	9	Sample size: 400, Age range: 6 - 12	Rotavirus, Routine Vaccines, Rotarix, GlaxoSmithKline, RIX4414 vaccine contained at least 106.0 cell culture infective dose 50 (CCID50) of the RIX4414 strain. CaCO3 buffer based reconstitution., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Month Dose2: 2 Month	Any adverse event: <4% Any SAE: 2.3%, Syscat: 7,8,20,26, Sev: 3-4 Event: SAE - Gastroenteritis: 0.57%, Syscat: 7, Sev: 3-4 Event: SAE - UTI: 0.57%, Syscat: 20, Sev: 3-4 Event: SAE- Neonatal hypertension: 0.57%, Syscat: 26, Sev: 3-4 Event: SAE - Escherischia UTI: 0.57%, Syscat: 20, Sev: 3-4 Event: Loss of appetite: 23%, Syscat: 8, Sev: 3-4 Event: Fatality: 0%, Sev: 5	Loss of appetite: OR 0.487 (0.205-1.16) SAE - UTI: OR 0.145 (0.009-2.384)
Phua K. B. et al.,2005 Singapore[149]	Controlled Clinical Trial	3	Sample size: 2464, Mean age: 13.3, Age range: 11 - 17, Percent female: 50.2%	Rotavirus, Routine Vaccines, Rotarix, GlaxoSmithKline, 10.7 ffu group. To produce RIX4414, the parent 89–12vaccine strain was further passaged in Vero cells and cloned [18,20]. The vaccine was a lyophilized preparation supplied in single-dose vials with calcium carbonate buffer for reconstitution., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 1 Month	Any SAE: 6.27% Event: SAE - Intussusception: 0%, Syscat: 7, Sev: 2-4 Event: Severe Fever (Dose 1): 0%, Syscat: 8, Sev: 2-4 Event: Severe Fever (Dose 2): 0%, Syscat: 8, Sev: 2-4 Event: Severe Vomiting (Dose 1): 1%, Syscat: 7, Sev: 2-4 Event: Severe Vomiting (Dose 2): 1%, Syscat: 7, Sev: 2-4 Event: Severe Diarrhea (Dose 1): 0%, Syscat: 7, Sev: 2-4 Event: Severe Diarrhea (Dose 2): 0%, Syscat: 7, Sev: 2-4	Severe Vomiting (Dose 1): OR 1 (0.312-3.203) Severe Vomiting (Dose 2): OR 1 (0.312-3.203)

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Kong B. P. et al.,2008[215]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported				

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Andrews N. et al.,2010 UK[216]	Haemoph. influenza. type b (Hib) protein conjugate, Polio (inactivated only), Tdap, Pediacel, Sanofi, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not Reported	Dose1: NR	Any adverse event: 30.4% Event: Crying: 2223%, Syscat: 8 Event: Diarrhea: 18.4%, Syscat: 7 Event: Feeding Problem: 2.55%, Syscat: 7 Event: Fever: 7.2%, Syscat: 8 Event: Vaccine reaction: 0.1% Event: Vomiting: 11.88% Event: Convulsion/fit/seizure: 0.4%, Syscat: 17 Event: Apnea/collapse/cyanosis/pallor: 0.2%, Syscat: 17,8 AE: 0% AE: 0% AE: 0%		
Santosham M. et al.1991 United States[102]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo, Routine Vaccines Unsure of adjuvants, preservatives and formulations	Event: Viral infections: 1.6%, Syscat: 11 Event: Conjunctivitis: 3.1%, Syscat: 6 Event: Areas of redness measuring less than 2.54 cm in diameter: 1.2%, Syscat: 8 Event: Areas of swelling measuring less than 2.54 cm in diameter: 0.7%, Syscat: 8 Event: Hospitalizations 30 days after vaccination: 4.07% Event: Fever above 38.9 C: 1.54%, Syscat: 8
Capeding M. R. Z. et ak.,1996 Philippines[103]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Routine Vaccines	Event: Serious adverse reactions: 0% Event: Irritability: 22%, Syscat: 8 Event: Fever: 22%, Syscat: 8
De Carvalho N. et al.,2010 Brazil[178]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any SAE: 2.4% Event: Medically significant adverse event (any): 6.2% Event: New onset chronic disease: 0% Event: New onset autoimmune disease: 0%
Giuliano A. R. et al.,2011 18 countries[177]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: 64.2% Event: Serious vaccine-related events (entire study period): 0% Event: Death (entire study period): 0.5%, Sev: 5 Event: Serious vaccine-related events (first 15 days): 0% Event: Death (first 15 days): 0%
Khatun S. et al.,2012 Bangladesh[176]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Nothing	Any SAE: 0%

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Kim S. C. et al.,2011 Korea[175]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Event: Unsolicited - Infections and infestations: 10.5%, Syscat: 11 Event: Unsolicited - Breast and reproductive system: 4.48%, Syscat: 21 Event: Unsolicited -any AE (Grade 3): 32.8%, Sev: 3 Event: Medical significant adverse condition: 13.4% Event: New onset chronic diseases: 8.96% Event: Solicited - Arthralgias (Grade 3): 13.4%, Syscat: 15, Sev: 3 Event: Solicited - Fatigue (Grade 3): 2%, Syscat: 8, Sev: 3 Event: Solicited - Fever (Grade 3): 2.99%, Syscat: 8, Sev: 3 Event: Solicited - GI Symptoms (Grade 3): 25.4%, Syscat: 7, Sev: 3 Event: Solicited - Headache (Grade 3): 64%, Syscat: 17, Sev: 3 Event: Solicited - Myalgia (Grade 3): 80.6%, Syscat: 15, Sev: 3 Event: Solicited - Rash (Grade 3): 11.9%, Syscat: 23, Sev: 3 Event: Solicited - Urticaria (Grade 3): 4.48%, Syscat: 23, Sev: 3
Levin M. J. et al.,2010 US (not stated explicitly)[174]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: 23% Any SAE: 0% Event: Ear and eye and respiratory system: 3%, Syscat: 4, 6, 22 Event: Laboratory abnormality: 3%, Syscat: 13 Event: Systemic reactions: 3% Event: (Injection site reactions) Event: (Other)
Li R. et al.,2012 China[173]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: 44.0% Event: Serious AE (any): 0.3% Event: Serious AE (vaccine-related): 0% Event: Severe pruritius: 0%, Syscat: 23 Event: Systemic AE (any): 39.9% Event: Systemic AE (vaccine-related): 27.5%

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Block S. L. et al.,2010 Asia, Europe, Latin America, North America[172]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo There was an aluminum and a non-aluminum containing placebo.	Event: Blood/lymphatic system: 0%, Syscat: 1, Sev: 3,4,5 Event: Cardiac: 0.1%, Syscat: 2, Sev: 3,4,5 Event: Gastrointestinal: 0.2%, Syscat: 7, Sev: 3,4,5 Event: Hepatobiliary: 0%, Syscat: 9, Sev: 3,4,5 Event: Infections/infestations: 0.1%, Syscat: 11, Sev: 3,4,5 Event: Injury/poisoning/procedural: 0.3%, Syscat: 12, Sev: 3,4,5 Event: Musculoskeletal/connective tissue: 1%, Syscat: 15, Sev: 3,4,5 Event: Neoplasms benign malignant, unspecified: 0.01%, Syscat: 16, Sev: 3,4,5 Event: Nervous system: 0.05%, Syscat: 17, Sev: 3,4,5 Event: Pregnancy/puerperium/perinatal: 0.4%, Syscat: 18, Sev: 3,4,5 Event: Psychiatric: 0.02%, Syscat: 19, Sev: 3,4,5 Event: Renal/urinary: 0.02%, Syscat: 20, Sev: 3,4,5 Event: Reproductive system/breast: 0.04%, Syscat: 21, Sev: 3,4,5 Event: Respiratory/thoracic/mediastinal: 0.04%, Syscat: 22, Sev: 3,4,5 Event: Vascular: 0.02%, Syscat: 26, Sev: 3,4,5 Event: serious systemic AE: 1.1%, Sev: 3,4,5 Event: Death: 0.1%, Sev: 5 Event: Discontinuation due to AE: 0.2%

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Moreira Jr E. D. et al.,2011 18 countries including Brazil, Germany, Mexico, US, South Africa, Australia, Canada[171]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported		Syscat: 2	Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: 64.2% Any SAE: 0.6% Event: Death (entire study): 0.5%, Sev: 5 Event: discontinued due to an adverse experience (entire study): 0.7%, Sev: 1-5 Event: discontinued due to SAE(entire study): 0.5%, Sev: 3-5 Event: Gastrointestinal Disorders (1-15 days): 6.2%, Syscat: 7, Sev: 1-5 Event: General Disorders (1-15 days): 8.7%, Syscat: 8, Sev: 1-5 Event: Infections and Infestations (1-15 days): 9.6%, Syscat: 11, Sev: 1-5 Event: Influenza (1-15 days): 50%, Syscat: 11, Sev: 1-5 Event: Nasopharyngitis (1-15 days): 2.6%, Syscat: 11, Sev: 1-5 Event: Pharyngitis (1-15 days): 1.0%, Syscat: 11, Sev: 1-5 Event: Upper respiratory tract infection (1-15 days): 1.0%, Syscat: 11, Sev: 1-5 Event: Injury, Poisoning and Procedural (1-15 days) Complications: 1.2%, Syscat: 12, Sev: 1-5 Event: Musculoskeletal and Connective Tissue Disorders (1-15 days): 2.6%, Syscat: 15, Sev: 1-5 Event: Nervous System Disorders (1-15 days): 11.8%, Syscat: 17, Sev: 1-5 Event: Dizziness (1-15 days): 0.9%, Syscat: 17, Sev: 1-5 Event: Respiratory, Thoracic And Mediastinal Disorders (1-15 days): 3.5%, Syscat: 22, Sev: 1-5 Event: Oropharyngeal pain (1-15 days): 1.9%, Syscat: 22, Sev: 1-5 Event: Skin And Subcutaneous Tissue Disorders (1-15 days): 1.6%, Sev: 1-5
Roteli-Martins C. M et al.,2012 Brazil[179]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Event: New Onset Chronic Disease: 0.9% Event: New Onset Autoimmune Disease, Syscat: 10 Event: Serious Adverse Events: 3.3% Event: Medically Significant Adverse Events: 11.3%

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Englund J. A. et al.,2010 US,[98]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo 0.25 mL sterile with 0.9% sodium chloride	Any adverse event: 92.7%, Sev: 1-3 Any SAE: 1.5%, Sev: 2-3 Event: Fever >=38C (Dose 1): 11.7%, Syscat: 8, Sev: 1-3 Event: Any irritability (Dose 1): 78%, Syscat: 8, Sev: 1-3 Event: Decreased appetite (Dose 1): 42%, Syscat: 8, Sev: 1-3 Event: Any emesis (Dose 1): 12%, Syscat: 8, Sev: 1-3 Event: Abnormal crying (Dose 1): 62%, Syscat: 8, Sev: 1-3 Event: Any drowsiness (Dose 1): 65%, Syscat: 8, Sev: 1-3 Event: Fever >=38C (Dose 2), Syscat: 8, Sev: 1-3 Event: Any irritability (Dose 2): 57%, Syscat: 8, Sev: 1-3 Event: Decreased appetite (Dose 2): 23%, Syscat: 8, Sev: 1-3 Event: Any emesis (Dose 2): 9.4%, Syscat: 8, Sev: 1-3 Event: Abnormal crying (Dose 2): 39%, Syscat: 8, Sev: 1-3 Event: Any drowsiness (Dose 2): 40%, Syscat: 8, Sev: 1-3 Event: Death: 0%, Sev: 5
Gotoh K. et al.,2011 Japan[101]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Nothing	Any SAE: 0% Event: Acute allograft rejection: 2.8%, Syscat: 10 Event: Acute febrile illness: 31.0%, Syscat: 8 Event: Influenza virus infection: 5.6%, Syscat: 10

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Halasa N. et al.,2011 US[99]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Any adverse event: 90% Any SAE: 0% Event: Fever >100C: 40%, Syscat: 8, Sev: 1-3 Event: Runny nose: 30%, Syscat: 22, Sev: 1-3 Event: Sore throat: 10%, Syscat: 22, Sev: 1-3 Event: Cough: 30%, Syscat: 22, Sev: 1-3 Event: Vomiting: 30%, Syscat: 8, Sev: 1-3 Event: Headache: 70%, Syscat: 8, Sev: 1-3 Event: Muscle aches: 3%, Syscat: 15, Sev: 1-3 Event: Chills: 30%, Syscat: 8, Sev: 1-3 Event: Tiredness: 60%, Syscat: 8, Sev: 1-3 Event: Irritability: 10%, Syscat: 8, Sev: 1-3 Event: Rash: 20%, Syscat: 10, Sev: 1-3 Event: Febrile neutropenia: 20%, Syscat: 1, Sev: 1-3
Steele A. D. et al.,2010 South Africa[155]	Rotavirus, Rotarix, GlaxoSmithKline, RIX4414 developed from 89-12 parent vaccine strain which was cloned and passaged on Vero cells. Viral concentration of 1 dose contained at least 1x10e6.0 medial cell culture infective dose and lyophilized vaccine was reconstituted with calcium carbonate as buffer, Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported	Dose1: 6 Weeks Dose2: 10 Weeks Dose3: 14 Weeks	Any adverse event: 54%, Sev: N,N Event: Serious adverse events (any): 9% Event: Serious adverse events (vaccine-related): 0% Event: Death (vaccine-related): 0% Event: Death (any): 0.5% Event: Intussusception: 0% AE: 0% AE: 0% AE: 0%	Placebo, Routine Vaccines Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: 59% Event: Serious adverse events (any): 5.2% Event: Serious adverse-events (vaccine-related): 1%, Syscat: 7, Sev: Serious Event: Death (vaccine-related): 0% Event: Death (any): 0% Event: Intussusception: 0%
Zaman K. et al.,2010 Bangladesh and Vietnam[164]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo, Routine Vaccines Placebo includes same adjuvants, preservatives, formulations as the active group	Any SAE: 0.2% Event: Death: 0.4% Event: Serious adverse event (vaccine-related): 0%

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Laserson K. F. et al.,2012 Kenya[145]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo, Routine Vaccines Unsure of adjuvants, preservatives and formulations	Any adverse event: 98% Event: One or more serious adverse event: 15.3% Event: Infections: 13.3%, Syscat: 11, Sev: Serious Event: Respiratory, thoracic and mediastinal disorders: 0.7%, Syscat: 22, Sev: Serious Event: General disorders and administration site conditions: 0.7%, Syscat: 8, Sev: Serious Event: Death: 0.7% Event: Infections: 82.7%, Syscat: 11, Sev: Serious Event: Respiratory, thoracic, and mediastinal disorders: 100%, Syscat: 22, Sev: Serious Event: General disorders and administration site conditions: 66.7%, Syscat: 8, Sev: Serious Event: Gastrointestinal disorders: 50.0%, Syscat: 7, Sev: Serious Event: Nervous system disorders: 2.7%, Syscat: 17, Sev: Serious Event: Reproductive system and breast disorders: 0%, Syscat: 22, Sev: Serious
Vesikari T. et al.,2006 Finland[159]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Event: Post-vaccination fever greater than or equal to 38.1 C rectally after dose 1, Syscat: 8 Event: Post-vaccination fever greater than or equal to 38.1 C rectally after dose 2, Syscat: 8 Event: Post-vaccination fever greater than or equal to 38.1 C rectally after dose 3, Syscat: 8
Grant L. R. et al.,2012 United States[140]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Event: Vomiting, vaccine related: 8.5%, Syscat: 7 Event: Diarrhea, vaccine related: 29.7%, Syscat: 7 Event: Fever, vaccine related: 32.3%, Syscat: 8 Event: Intussusception: 0%, Syscat: 7 Event: Deaths (outside of 42 day follow-up safety window and not assoc with vaccine): 0.2% Event: Vomiting, all events: 16.3%, Syscat: 7 Event: Diarrhea, all events: 275%, Syscat: 7 Event: Fever, all events: 55.9%, Syscat: 8

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Armah G. E. et al.,2010 Ghana, Kenya, Mali[134]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo, Routine Vaccines Placebo includes same adjuvants, preservatives, formulations as the active group	Event: One or more serious adverse event: 1.7% Event: Vomiting: 0%, Syscat: 7 Event: Death: 0.1%, Syscat: 8 Event: Pyrexia: 0%, Syscat: 8 Event: Sudden infant death syndrome: <0.1%, Syscat: 8 Event: Bronchiolitis: <0.1%, Syscat: 11 Event: Bronchopneumonia: 17%, Syscat: 11 Event: Gastroenteritis: 0.6%, Syscat: 11 Event: Otitis media acute: <0.1%, Syscat: 11 Event: Pneumonia: 0.4%, Syscat: 11 Event: Respiratory tract infection: 0.2%, Syscat: 11 Event: Upper respiratory tract infection: 0.1%, Syscat: 11 Event: Other: 0.3%
Vesikari T. et al.,2004 Finland[158]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Event: Fever greater than or equal to 38.0°C, Dose 1: 11%, Syscat: 8 Event: Diarrhea, Dose 1: 5%, Syscat: 7 Event: Vomiting, Dose 1: 5%, Syscat: 7 Event: Irritability, Dose 1: 60%, Syscat: 8 Event: Loss of appetite, Dose 1: 17%, Syscat: 14 Event: Fever greater than or equal to 38.0°C: 25%, Syscat: 8 Event: Diarrhea, Dose 2, Syscat: 7 Event: Vomiting, Dose 2: 9%, Syscat: 7 Event: Irritability, Dose 2: 53%, Syscat: 8 Event: Loss of appetite, Dose 2: 20%, Syscat: 14 Event: Intussusception: 0%, Syscat: 7
Sow S. O. et al.,2012 Vietnam, Bangledash, Ghana, Kenya, Mali[154]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Event: One or more serious adverse events: 0.6% Event: Serious vaccine-related adverse events: 0.2% Event: Deaths: 0.5%, Syscat: 8 Event: Bronchiolitis: 0.1%, Syscat: 11 Event: Meningitis: 0%, Syscat: 11 Event: Meningitis pneumococcal: 3%, Syscat: 11 Event: Pneumonia: 3%, Syscat: 11

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Block S. L. et al.,2007 United States, Finland[135]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported		Syscat: 2	Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: 89.8% Event: Serious Adverse Event: .04% Event: Gastrointestinal system: 1.52%, Syscat: 7 Event: Abdominal pain: 0.15%, Syscat: 7 Event: Constipation: 0.15%, Syscat: 7 Event: Decreased Appetite: 0.15%, Syscat: 14 Event: Dehydration: 0.61%, Syscat: 14 Event: Gastroenteritis: 1%, Syscat: 7 Event: Hematochezia: 0.15%, Syscat: 7 Event: General body: 0%, Syscat: 8 Event: Fever, greater than or equal to 102.5 F: 0%, Syscat: 8 Event: SIDS: 0%, Syscat: 8 Event: Nervous system: 0%, Syscat: 17 Event: Mengitis: 0%, Syscat: 11 Event: Partial Seizures: 0%, Syscat: 17 Event: Respiratory system, Syscat: 22 Event: Bronchiolitis/bronchitis/bronchospasm: 1.06%, Syscat: 22 Event: Influenza: 0.3% Event: Pertussis: .45%, Syscat: 22 Event: Pneumonia: 0.15%, Syscat: 22 Event: Respiratory syncytial virus infection: 1%, Syscat: 22 Event: Upper respiratory tract infection: 1%, Syscat: 22 AE: 0% AE: 0% AE: 0% AE: 0% AE: 0% AE: 0% AE: 0% AE: 0%
Chang C.-C. et al.,2009 Taiwan[136]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Event: Fever, rectal temperature > 38.0°C: 57%, Syscat: 8 Event: Intussusception: 0%, Syscat: 7 Event: Diarrhea: 15.1%, Syscat: 7 Event: Vomiting: 7.5%, Syscat: 7 Event: Irritable crying: 1.1%, Syscat: 8
Kim D. S. et al.,2008 Korea[143]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Event: One or more serious adverse event: 11.1% Event: Intussusception: 0%, Syscat: 7

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Shui I. M. et al.,2012 US[169]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Routine Vaccines	Event: Intussusception - All doses (1-30d risk period), Syscat: 7 Event: Intussusception - All doses (1-7d risk period), Syscat: 7 Event: Intussusception - 1 dose (1-30d risk period), Syscat: 7 Event: Intussusception - 1 dose (1-7d risk period), Syscat: 7 Event: Intussusception - 2 dose (1-30d risk period), Syscat: 7 Event: Intussusception - 2 dose (1-7d risk period), Syscat: 7 Event: Intussusception - 3 dose (1-30d risk period): 1%, Syscat: 7 Event: Intussusception - 3 dose (1-7d risk period), Syscat: 7
Vesikari T. et al.,2006 11 countries[160]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Any SAE: 2.5% Event: Intussusception (total) Event: Intussusception w/in 42 days of any dose Event: Intussusception related death: 0%, Sev: 5 Event: Deaths (all): 0.1%, Sev: 5 Event: Death due to SIDS, Sev: 5
Goveia M. G. et al.,2007 11 countries[139]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any SAE: 5.8%, Sev: 3-4 Event: Bronchiolitis: 2.0%, Syscat: 22, Sev: 3-4 Event: Intussusception (confirmed): 0%, Syscat: 7, Sev: 3-4 Event: hematochezia: 0.09%, Syscat: 1, Sev: 3-4 Event: Deaths (total): 0.19%, Sev: 5 Event: Deaths due to SIDS: 0.09%, Sev: 5 Event: At least 1 SAE (extreme preemie): 9.8%, Sev: 3-4 Event: Bronchiolitis (extreme preemie): 1%, Syscat: 22, Sev: 3-4 Event: Pneumonia (extreme preemie): 1.1%, Syscat: 22, Sev: 3-4 Event: Apneic attack (extreme preemie): 1.1%, Syscat: 22, Sev: 3-4

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Omenaca F. et al.,2012 France, Portugal, Poland and Spain[148]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo includes same adjuvants, preservatives, formulations as the active group	Event: At least 1 SAE: 6.2% Event: At least 1 unsolicited symptom: 40.7% Event: At least 1 unsolicited symptom (Grade 3): 6.5%, Syscat: 8,7, Sev: 3 Event: At least 1 unsolicited symptom (vaccine related): 13.3% Event: Death - Bronchiolitis: 0.29%, Sev: 5 Event: Intussception: 0%, Syscat: 7 Event: infection - Gastroenteritis, Syscat: 11 Event: infection - upper resp infection: 3.2%, Syscat: 11
Tregnaghi M. W. et al.,2011 Argentina, Brazil, Colombia, Dominican Republic, Honduras, and Panama[157]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any SAE: 12.1%, Sev: 3-5 Event: Bronchiolitis: 2.9%, Syscat: 22, Sev: 3-4 Event: Gastroenteritis: 3.0%, Syscat: 7, Sev: 3-4 Event: Pneumonia: 2.1%, Syscat: 22, Sev: 3-4 Event: Intussusception: 0.1%, Syscat: 7, Sev: 3-4 Event: Death: 0.1%, Sev: 5
Kawamura N . et al.,2011 Japan[141]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Any adverse event: 73.5(8-daypostvacc)% Any SAE: 17.1% Event: # of patients with any AE (31-day post vacc): 56.0% Event: Eczema: 11.3%, Syscat: 23 Event: Upper respiratory tract infection: 9.7%, Syscat: 22 Event: Cough/runny nose (8-day post vacc): 34%, Syscat: 22, Sev: 1 Event: Diarrhea (8-day post vacc): 5%, Syscat: 7 Event: Fever (8-day post vacc): 8%, Syscat: 8 Event: Irritability (8-day post vacc), Syscat: 8 Event: Loss of appetite (8-day post vacc): 12%, Syscat: 8 Event: Vomiting (8-day post vacc): 14%, Syscat: 7

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Vesikari T. et al.,2011 Finland[161]	Rotavirus, Rotarix, GlaxoSmithKline, lyophilized formulation (1 ml after reconstitution with calcium carbonate buffer). Contained at least 10-6median cell culture infective dose (CCID50) of live attenuated RIX4414 human rotavirus strain, Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported	Dose1: 0 Days Dose2: 1 Month	Event: Cough/runny nose, Syscat: 22 Event: Diarrhea: 5.5%, Syscat: 7 Event: Fever, Syscat: 8 Event: Irritability: 66%, Syscat: 8 Event: Loss of appetite: 20% Event: Vomiting AE: 6%	Placebo Unsure of adjuvants, preservatives and formulations	Event: Cough/runny nose: 40%, Syscat: 22 Event: Diarrhea: 4%, Syscat: 7 Event: Fever: 5%, Syscat: 8 Event: Irritability: 65%, Syscat: 8 Event: Loss of appetite: 22%, Syscat: 8 Event: Vomiting: 13.1%, Syscat: 7
Dennehy P. H. et al.,2005 United States, Canada[138]	Rotavirus, Routine Vaccines, RIX4414, GlaxoSmithKline, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not Reported	Dose1: 0 Month Dose2: 2 Month	Any adverse event: 3.83% Event: Fever: 0%, Syscat: 8, Sev: Serious Event: Hypovolemia/dehydration: 0%, Syscat: 14, Sev: Serious Event: Meningitis: 0.48%, Syscat: 11, Sev: Serious Event: Petit mal seizures: .48%, Syscat: 17, Sev: Serious Event: Leukocytosis: 0%, Sev: Serious Event: Pyelonephritis: 0%, Sev: Serious Event: Kidney cyst: 0%, Syscat: 20, Sev: Serious Event: Bronchiolitis: .48%, Syscat: 22, Sev: Serious Event: Wheezing: 0%, Syscat: 22, Sev: Serious Event: Pneumonia: .5%, Syscat: 22, Sev: Serious Event: Asthma: 0%, Syscat: 22, Sev: Serious Event: Other respiratory illness: 0%, Syscat: 22, Sev: Serious Event: Gastroenteritis: 0%, Syscat: 7, Sev: Serious Event: GERD: 0%, Syscat: 7, Sev: Serious Event: Mesenteric adenitis: 1%, Syscat: 7, Sev: Serious AE: 0% AE: 0% AE: 0%	Placebo, Routine Vaccines Unsure of adjuvants, preservatives and formulations	Any adverse event: 9.26% Event: Fever: 0.93%, Syscat: 8, Sev: Serious Event: Hypovolemia/dehydration: 0.93%, Syscat: 14, Sev: Serious Event: Meningitis: 0%, Syscat: 11, Sev: Serious Event: Petit mal seizures: 0%, Syscat: 17, Sev: Serious Event: Leukocytosis: 1.85%, Syscat: 1, Sev: Serious Event: Pyelonephritis: 0%, Syscat: 20, Sev: Serious Event: Kidney cyst: 3%, Syscat: 20, Sev: Serious Event: Bronchiolitis: 2.78%, Syscat: 22, Sev: Serious Event: Wheezing: 0.93%, Syscat: 22, Sev: Serious Event: Pneumonia: .93%, Syscat: 22, Sev: Serious Event: Asthma: 0%, Syscat: 22, Sev: Serious Event: Other respiratory illness: 0.93%, Syscat: 22, Sev: Serious Event: Gastroenteritis: 0%, Syscat: 7, Sev: Serious Event: GERD: 0%, Syscat: 7, Sev: Serious Event: Mesenteric adenitis, Syscat: 7, Sev: Serious

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Madhi S. A. et al.,2010 South Africa and Malawi[146]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Event: Overall SAE: 11.5%, Sev: Serious Event: Gastroenteritis: 4.8%, Syscat: 7, Sev: Serious Event: Pneumonia: 2.8%, Syscat: 22, Sev: Serious Event: Sepsis: 1.2%, Syscat: 11, Sev: Serious Event: Bronchopneumonia: 1.4%, Syscat: 22, Sev: Serious Event: Bronchiolitis: 1%, Syscat: 22, Sev: Serious Event: Vaccine-related AEs: 43% Event: Deaths: 2.6%
Narang A. et al.,2009 India[147]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo, Routine Vaccines Unsure of adjuvants, preservatives and formulations	Event: Serious adverse events: 1.79% Event: SAE, bronchiolitis: 0.89%, Syscat: 22 Event: SAE, parotitis: 0.89%, Syscat: 11 Event: GE episodes from dose 1 to one month post-dose 2: 13.3%, Syscat: 7 Event: Cough/runny nose: 2%, Syscat: 22, Sev: 3 Event: Diarrhea: 3%, Syscat: 7, Sev: 3 Event: Fever, Syscat: 8, Sev: 3 Event: Irritability: 4%, Syscat: 8, Sev: 3 Event: Loss of appetite: 0%, Syscat: 14, Sev: 3 Event: Vomiting: 5%, Syscat: 7, Sev: 3 Event: Cough/runny nose: 31%, Syscat: 22, Sev: 1-5 Event: Diarrhea: 8%, Syscat: 7, Sev: 1-5 Event: Fever: 10%, Syscat: 8, Sev: 1-5 Event: Irritability: 22%, Syscat: 8, Sev: 1-5 Event: Loss of appetite: 12%, Syscat: 14, Sev: 1-5 Event: Vomiting: 7.5%, Syscat: 7, Sev: 1-5
Zaman K. et al.,2012 Bangladesh[165]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo, Routine Vaccines Unsure of adjuvants, preservatives and formulations	Event: Acute diarrhea: 0.18%, Syscat: 7, Sev: Serious Event: Bronchiolitis: 0%, Syscat: 11, Sev: Serious Event: Umbilical infection: 0.18%, Syscat: 11, Sev: Serious Event: Pneumonia: 2.64%, Syscat: 11, Sev: Serious Event: Head injury: 0%, Syscat: 12, Sev: Serious Event: All Serious adverse events: 2.99%, Sev: Serious Event: Death, all causes: 0%, Syscat: 8, Sev: 5 Event: Death, CMV infection: 0%, Sev: 5 Event: Death, Pneumonia: 0%, Sev: 5 Event: Death, Hepatoblastoma: .18%, Sev: 5 Event: Death, UTI sepsis: 0.18%, Sev: 5 Event: Death, Accidental drowning: 0.18%, Sev: 5

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Christie C. D. C. et al.,2010 Jamaica[137]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Unsure of adjuvants, preservatives and formulations	Any SAE: 3.5%, Sev: 4-5 Event: Death: 0.33%, Sev: 5 Event: Bronchiolitis: 1.2%, Syscat: 22, Sev: 1-3 Event: UTI: 0.6%, Syscat: 20, Sev: 1-3 Event: Otitis media: 0.3%, Syscat: 4, Sev: 1-3 Event: Gastroenteritis: 0.3%, Syscat: 7, Sev: 1-3 Event: Bronchopneumonia: 0%, Syscat: 22, Sev: 1-3 Event: Viral infections: 2%, Syscat: 11, Sev: 1-3 Event: Convulsions: 0.2%, Syscat: 17, Sev: 1-3 Event: Anemia: 0%, Syscat: 1, Sev: 1-3 Event: Anal fissure: 0%, Syscat: 7, Sev: 1-3 Event: Asthma: 0%, Syscat: 22, Sev: 1-3 Event: URI: 0%, Syscat: 22, Sev: 1-3 Event: Femur fracture: 0.1%, Syscat: 12, Sev: 1-3 Event: Intussusception: 0.2%, Syscat: 7, Sev: 1-3
Ruiz-Palacios G. M. et al.,2006 Finland, Argentina, Brazil, Chile, Colombia, the Dominican Republic, Honduras, Mexico, Nicaragua, Panama, Peru, Venezuela[153]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo, Routine Vaccines Placebo includes same adjuvants, preservatives, formulations as the active group	Event: Serious adverse event between dose 1 and visit 3: 3.32% Event: Hospitalization: 3.18%, Sev: 3, 4 Event: Death: 0.14%, Syscat: 8, Sev: 5 Event: Deinite intussusception, 31 days or less after either dose: 0.02%, Syscat: 7 Event: Deinite intussusception, 31 days or less after dose 1: 0.01%, Syscat: 7 Event: Deinite intussusception, 31 days or less after dose 2: 0.02%, Syscat: 7 Event: Deinite intussusception, between dose 1 and visit 3: .05%, Syscat: 7 AE: 0%
Phua K. B. et al.,2009 Hong Kong, Singapore, Thailand[150]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Sev: 3-5 Event: Intussusception (w/in 31 days post vaccination): 0%, Syscat: 7, Sev: 1-4 Event: Intussusception (Dose 1 to age 2): 0.07%, Syscat: 7, Sev: 1-4 Event: Death (entire study period): 0.06%, Sev: 5 Event: Withdrawal due to AE: 0.22%

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Rodriguez, Z. M. et al. 2007[152] United States	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo, Routine Vaccines Unsure of adjuvants, preservatives and formulations	Any adverse event: 87.1% Event: Diarrhea: 19.5%, Syscat: 7 Event: Vomiting: 12.2%, Syscat: 7 Event: Fever: 49.1%, Syscat: 8 Event: Upper respiratory infection: 27.2%, Syscat: 11 Event: Nasopharyngitis: 16.2%, Syscat: 11 Event: Otitis media: 12.5%, Syscat: 11 Event: Cough, Syscat: 22 Event: Nasal congestion: 13.5%, Syscat: 22
Zaman K., et al.,2009 Bangladesh[163]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo, Routine Vaccines Unsure of adjuvants, preservatives and formulations	Event: Unsolicited symptoms: 77.1% Event: Gastroenteritis: 2.08%, Syscat: 7 Event: Any diarrhea: =6/day: 3%, Syscat: 7, Sev: 3 Event: Fever: rectal temperature =38 ? C: 37%, Syscat: 8, Sev: 1-5 Event: Loss of appetite: 35%, Syscat: 14, Sev: 1-5 Event: Vomiting: =1 episode of forceful emptying of partially digested stomach contents =1 h after feeding within a day: 17%, Syscat: 7, Sev: 1-5
Phua K. B. et al.,2012 Singapore, Hong Kong, Taiwan[151]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo, Routine Vaccines Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: 0.26% Event: Intussusception: 0.02% Event: gastroenteritis: 0.05%
Kim J. S. et al.,2012 South Korea[144]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported			Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: 76.7% Any SAE: 7.4% Event: Patients with unsolicited AE over 31d: 33.5% Event: nasopharygitis (unsolicited/31d): 9.7%, Syscat: 22 Event: URI (unsolicited/31d): 4.5%, Syscat: 22 Event: Bronchiolitis (unsolicited/31d): 4.5%, Syscat: 22 Event: gastroenteritis (unsolicited/31d): 9.7%, Syscat: 7 Event: Bronchiolitis (total study period): 2.8%, Syscat: 22 Event: Gastroenteritis (total study period): 2.3%, Syscat: 7 AE: 1.31%

Appendix C-4. Evidence Tables – Vaccinated vs Unvaccinated
Children-Adolescents

Author- Year-Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Kerdpanich A. et al.,2010 Thailand[142]	Rotavirus, Routine Vaccines, Rotarix, GlaxoSmithKline, RIX4414 vaccine contained at least 106.0 cell culture infective dose 50 (CCID50) of the RIX4414 strain. Water base reconstitution., Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported	Dose1: 0 Month Dose2: 2 Month	Any adverse event: <4% Any SAE: 2.87%, Syscat: 8,22,23, Sev: 3-4 Event: SAE- infantile colic: 1%, Syscat: 8, Sev: 3-4 Event: SAE- pneumonia: 1.15%, Syscat: 22, Sev: 3-4 Event: SAE -pharygotonsilitis: 0.57%, Syscat: 22, Sev: 3-4 Event: SAE- cellulitis: .57%, Syscat: 23, Sev: 3-4 Event: Loss of appetite: 2%, Sev: 3-4 Event: Fatality: 0%, Sev: 5 AE: 1% AE: 0% AE: 0%	Placebo, Routine Vaccines, Water Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event: <4%, Sev: 3 Any SAE: 7.69%, Syscat: 22,20,8, Sev: 3-4 Event: SAE - Bronchiolitis: 3.85%, Syscat: 22, Sev: 3-4 Event: SAE - UTI: 3.85%, Syscat: 20, Sev: 3-4 Event: Loss of appetite: 38%, Syscat: 8 Event: Fatality: 0%, Sev: 5
Phua K. B. et al.,2005 Singapore[149]	Rotavirus, Routine Vaccines, Rotarix, GlaxoSmithKline, 10.2 ffu group. To produce RIX4414, the parent 89–12vaccine strain was further passaged in Vero cells and cloned [18,20]. The vaccine was a lyophilized preparation supplied in single-dose vials with calcium carbonate buffer for reconstitution., Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported	Dose1: 0 Days Dose2: 1 Month	Any SAE: 8.33% Event: SAE - Intussception (likely related to vaccine), Syscat: 7, Sev: 2-4 Event: Severe Fever (Dose 1): 1%, Syscat: 8, Sev: 2-4 Event: Severe Fever (Dose 2), Syscat: 8, Sev: 2-4 Event: Severe Vomiting (Dose 1): 2%, Syscat: 7, Sev: 2-4 Event: Severe Vomiting (Dose 2): 2%, Sev: 2-4 Event: Severe Diarrhea (Dose 1), Sev: 2-4 Event: Severe Diarrhea (Dose 2): 0%, Syscat: 7, Sev: 2-4 AE: 0%	Placebo, Routine Vaccines Unsure of adjuvants, preservatives and formulations	Any SAE: 6.12% Event: SAE- Intussusception (likely unrelated to vaccine): 1%, Syscat: 7, Sev: 2-4 Event: Severe Fever (Dose 1): 0%, Syscat: 8, Sev: 2-4 Event: Severe Fever (Dose 2): 1%, Syscat: 8, Sev: 2-4 Event: Severe Vomiting (Dose 1): 1%, Syscat: 7, Sev: 2-4 Event: Severe Vomiting (Dose 2): 1%, Syscat: 7, Sev: 2-4 Event: Severe Diarrhea (Dose 1): 0%, Syscat: 7, Sev: 2-4 Event: Severe Diarrhea (Dose 2), Syscat: 7, Sev: 2-4

Appendix C-5. Evidence Tables – Post-marketing studies
Mixed Population

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Nakajima et al. 2007, Prospective cohort[217]	N=8443; Location=Tasmania; Age=7-30 years; Setting=Primary schools (Tasmanian Asthma Study, a prospective population-based cohort study which started in 1968)	Diphtheria, tetanus, pertussis, polio (Study notes in Australia, there were two forms of polio vaccine—the Salk (injected polio vaccine) which was commonly used before the introduction of Sabin (oral polio vaccine) in 1966.	Children born in the UK, US, New Zealand, Canada or South Africa were more likely to have been immunized against diphtheria, pertussis and polio than those born in Tasmania. Study notes parental health attitudes might have affected both seeking a diagnosis of an atopic condition and having their children vaccinated, which might have contributed to the risk of atopic conditions being associated with vaccination. Such a detection bias is more likely with eczema, given that eczema is more likely to develop in early	Subjects were lost to follow-up at each stage of the study. In 1968 99% response rate; In 1974 87.2% response rate; In 1991 74.7% response rate.	Not discussed	School medical records filled out by parents.	Parental report	Multiple logistic regression	Sex, birthplace, history of bacterial infection, parental smoking, parental asthma, history of viral infection, birth order and history of pneumonia. Asthma after 13 years: Sex, parental asthma. Eczema after 7 years: Age 7 years asthma status, sex, parental asthma, parental smoking. Food allergy after 7 years: Age 7 years asthma status, sex, parental smoking. Hay fever after 7 years: Age 7 years asthma status, sex, parental smoking, feeding in 1st 3 months.	Authors collected information from the 1968 survey and the 1974 and 1991 follow-up studies.	The 1968 and 1974 studies were funded by the Tasmanian Asthma Foundation and the 1991 study was funded by the National Health Medical Research Council. Computerization of the 1974 study was funded by the Victorian Asthma Foundation.	OR (95% CI) for asthma by age 7 years Diphtheria: 1.33 (1.06-1.68), p=0.01 Tetanus: 1.16 (0.94-1.43), p=0.16 Pertussis: 1.19 (0.96-1.47), p=0.11 Polio: 1.05 (0.83-1.32), p=0.69 OR (95% CI) for asthma by age 13 years Diphtheria: 1.28 (0.98-1.66), p=0.07 Tetanus: 1.18 (0.89-1.55), p=0.24 Pertussis: 1.11 (0.91-1.37), p=0.31 Polio: 1.03 (0.79-1.35), p=0.84 OR (95% CI) for eczema by age 7 years Diphtheria: 1.53 (1.13-2.07), p=0.01 Tetanus: 1.53 (1.15- 2.04), p=0.01 Pertussis: 1.46 (1.10-1.93), p=0.01 Polio: 1.36 (1.00-1.87), p=0.05 OR (95% CI) for food allergy by age 7 years Diphtheria: 1.47 (1.04-2.07), p=0.03 Tetanus: 1.26 (0.93-1.71), p=0.14 Pertussis: 1.39 (1.01-1.91), p=0.04	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
			childhood, during which timeframe childhood immunizations are given. The observed associations may also suggest that there is a higher likelihood of childhood immunizations in those already at greater risk of atopic disease. However the authors did not believe this to be the case. Potential recall biases and differential misclassification of exposure.									Polio: 1.44 (1.00-2.07), p=0.05 OR (95% CI) for hay fever by age 7 years Diphtheria: 1.20 (0.94-1.53), p=0.15 Tetanus: 1.05 (0.84-1.31), p=0.67 Pertussis: 1.10 (0.88-1.38), p=0.42 Polio: 0.88 (0.69-1.12), p=0.30 OR (95% CI) for asthma after age 13 years Diphtheria: 0.58 (0.26-1.27), p=0.17 Tetanus: 0.79 (0.32-1.96), p=0.61 Pertussis: 0.57 (0.30-1.09), p=0.09 Polio: 0.50 (0.22-1.10), p=0.08 OR (95% CI) for eczema after age 7 years Diphtheria: 0.68 (0.36-1.29), p=0.24 Tetanus: 0.76 (0.38-1.52), p=0.44 Pertussis: 0.57 (0.35-0.93), p=0.03 Polio: 0.76 (0.39-1.48), p=0.43 OR (95% CI) for food allergy after age 7 years Diphtheria: 1.50 (0.81-2.79), p=0.20 Tetanus: 0.98 (0.54-1.75), p=0.94 Pertussis: 0.88 (0.57-1.35), p=0.55 Polio: 1.02 (0.57-		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												1.83), p=0.94 OR (95% CI) for hay fever after age 7 years Diphtheria: 1.19 (0.75-1.89), p=0.45 Tetanus: 1.09 (0.67-1.78), p=0.72 Pertussis: 0.96 (0.67-1.38), p=0.83 Polio: 0.78 (0.47-1.28), p=0.32		
Matheson et al. 2010, Prospective cohort[218]	N=5,556 members of Tasmanian Longitudinal Health Study, Age=7 to 44 yrs;	Diphtheria, Tetanus, Pertussis, Polio, Smallpox	Representative sample of Tasmania residents	At this follow-up, 88.1% (n = 7,562) were traced. A postal survey was sent to all traced participants and a response rate of 78.4% (n = 5,729) was achieved. This analysis is based on questionnaire data collected in 1968 and follow-up in 2004. School medical record data were available for 5,556 (97%) of 5,729.	Not discussed	School medical records which contained parent reported immunization history.	Questionnaire - self-report	Multivariable regression models were used to estimate relative risks while adjusting for confounders. Cox regression was used to estimate the association between childhood immunizations and asthma developing after the age of 7 yrs.	Multivariate: Sex, birthplace and history of bacterial infection, parental smoking, and parental asthma, history of viral infection, birth order and social class in 2004. We also investigated any effect modification related to having childhood asthma by age 7 yrs. Cox: sex, bacterial infections, birth order and social class in 1968. The Cox model with	2004	National Health and Medical Research Council of Australia, Clifford Craig Foundation of Tasmania and Victorian & Tasmanian Asthma Foundations	Associations with immunization (Adjusted RR) Current asthma at age 44 Diphtheria: 0.93 (0.71, 1.22) Tetanus: 1.05 (0.81, 1.38) Pertussis: 0.87 (0.68, 1.12) Polio: 0.92 (0.69, 1.24) DTP: 0.92 (0.73, 1.16) Eczema by age 44 Diphtheria: 1.05 (0.92, 1.20) Tetanus: 1.07 (0.94, 1.21) Pertussis: 0.99 (0.88, 1.12) Polio: 1.03 (0.89, 1.18) DTP: 1.04 (0.93, 1.16) Food allergy by age 44 Diphtheria: 1.09 (0.81, 1.47) Tetanus: 1.03 (0.78, 1.35) Pertussis: 1.11	None	Giles GG, Lickiss N, Gibson HB. Respiratory symptoms in Tasmanian adolescents: a follow up of the 1961 birth cohort. Aust N Z J Med 1984: 14: 631–7. Jenkins MA, Hopper JL, Bowes G, Carlin JB, Flander LB, Giles GG. Factors in childhood as predictors of asthma in adult life. BMJ 1994: 309: 90–3.

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
									asthma onset after the age of 21 yrs as the outcome was also adjusted for adult smoking, and socio-economic status in adult life.			(0.84, 1.47) Polio: 1.11 (0.80, 1.53) DTP: 1.02 (0.80, 1.30) Hay fever by age 44 Diphtheria: 1.02 (0.92, 1.12) Tetanus: 1.03 (0.94, 1.13) Pertussis: 1.03 (0.93, 1.13) Polio: 1.04 (0.93, 1.16) DTP: 1.05 (0.97, 1.15) Association between immunization and incident asthma from age 8 to age 44 (Adjusted HR, 8-44 years) Diphtheria: 1.07 (0.83,1.39) Tetanus: 1.13 (0.88,1.45) Pertussis: 1.04 (0.82,1.32) Polio: 1.19 (0.89,1.60) DTP: 1.05 (0.85,1.31)		
Lee et al. 2011, Self-controlled design or a current versus historical comparison[2 19]	N=4,512,366 flu doses in eight U.S. managed care organizations; Age=6 mos to >=65 years;	H1N1 monovalent inactivated (MIV) and live, attenuated (LAMV) vaccines separate from	Comprehensive population group	Not discussed	Not discussed	Medical record review	Medical record review. For Guillain–Barré syndrome (GBS), all cases were adjudicated by at least two neurologists.	SCRI: maximized sequential probability ratio test (MaxSPRT) Current versus historical comparison: Either the	Case-centered logistic regression: case date, age group, gender, and site.	2009-2010	Centers for Disease Control	No significant associations were noted during sequential analyses for Guillain-Barré syndrome, most other neurologic outcomes, and allergic and cardiac events. For MIV, a statistical signal	None	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
		seasonal trivalent inactivated (TIV) and live, attenuated (LAIV) influenza vaccines						Poisson-based MaxSPRT or the Poisson-based conditional MaxSPRT (CMaxSPRT) was used logistic regression.				was observed for Bell's palsy for adults aged >=25 years on March 31, 2010, using the self-controlled approach. Subsequent analyses revealed no significant temporal cluster. Case-centered logistic regression adjusting for seasonality demonstrated an OR for Bell's palsy of 1.26 (95% CI=0.97, 1.63).		
Tokars et al. 2012, Self-controlled analyses[220]	N= 379 Guillain-Barré Syndrome (GBS) patients; Location=10 US states/metro areas; Age=1-84 years; From Centers for Disease Control and Prevention Emerging Infections Program active, population-based surveillance dataset.	H1N1 vaccines	Biases if cases differed from the general population in terms of for example being more likely to be vaccinated.	None	Not given	Self-report or medical record	Active ascertainment through network of neurologists, hospital discharge data and review of medical charts.	Conditional Poisson regression	Tested interactions: age group, sex, mode of administration (injected, intra-nasal, or unknown), whether seasonal influenza vaccine had been received in the 42 days prior to H1N1 vaccine receipt, and the EIP site reporting the data.	2009-2010	Not given	Relative risk Overall: 2.1 (1.2, 3.5)	RRs Age (years) 0.5–24: 3.0 (1.0, 9.1) 25–49: 2.0 (0.7, 5.5) 50–64: 2.1 (0.8, 5.6) ≥65: 1.5 (0.5, 4.3) Sex Male: 2.3 (1.2, 4.7) Female: 1.8 (0.8, 3.9) Vaccine type Inactivated: 2.2 (1.3, 3.9) Live attenuated: 1.3 (0.1, 14.1)	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
													Unknown: 1.4 (0.2, 9.0) Seasonal vaccine within 42 days before H1N1 vaccine No: 2.4 (1.3, 4.5) Yes: 1.6 (0.6, 4.0)	
Ray et al. 2011, Prospective cohort and case-control[221]	N=1,660 (415 Rheumatoid arthritis cases, 1245 controls) Location=CA; Age=15-59 years; Setting=Kaiser Permanente Northern CA members	Hepatitis B, influenza	Cases and controls from the same HMO population. Cases more likely to be African American or Latino than controls. Controls more likely to have missing data for race.	None noted	Not discussed	Database record review and medical record review	Medical record review	Cohort study: Poisson regression. Case control: conditional logistic regression.	Cohort study: adjusted for age, sex, race, number of health care visits within 1 year. Case-control: sex, race, number of utilization visits. Matched on age and utilization.	1997 to 1999	Centers for Disease Control and Prevention Vaccine Safety Datalink Project	RR from cohort study 90 Day Exposure Interval Hepatitis B: 1.44 (0.46, 4.51), p=0.53 Influenza: 0.72 (0.45, 114), p=0.16 180 Day Exposure Interval Hepatitis B: 1.67 (0.74, 3.77), p=0.22 Influenza: 1.36 (1.03, 1.80), p=0.03 365 Day Exposure Interval Hepatitis B: 1.23 (0.58, 2.63), p=0.59 Influenza: 1.34 (1.06, 1.69), p=0.01 OR from case-control study 90 Day Exposure Interval Hepatitis B: 1.5 (0.4, 5.2), p=0.55 Influenza: 0.7 (0.4, 1.2), p=0.14 180 Day Exposure Interval Hepatitis B: 2.0	Not given	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												(0.8, 5.1), p=0.14 Influenza: 1.1 (0.8, 1.6), p=0.57 365 Day Exposure Interval Hepatitis B: 1.4 (0.6, 3.1), p=0.39 Influenza: 1.1 (0.9, 1.5), p=0.43 730 Day Exposure Interval Hepatitis B: 1.0 (0.5, 2.1), p=0.91 Influenza: 1.1 (0.8, 1.4), p=0.59		
Wise et al. 2012, Retrospective cohort[222]	N=408 Guillain–Barré syndrome (GBS) cases; Location=US; Age=0-65+ (no average measures given); Setting=10 sites of the Emerging Infections Program (EIP): California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee	Inactivated and live attenuated influenza A (H1N1) 2009 monovalent vaccines (in study referred to collectively as pH1N1 vaccine)	No details on recruitment for EIP, but study focused on entire population. Possible misclassification of exposure and outcome.	707 suspected GBS cases 282 did not meet Brighton criteria (40%) Of the remaining 425, 14 were excluded due to GBS onset prior to 10/1/09 Medical records reviewed for 411 GBS cases 408 vaccinated.	Not discussed	Dates of receipt of pH1N1 vaccine and 2009–2010 seasonal influenza vaccine (hereafter referred to as seasonal vaccine) were recorded from vaccination cards, vaccine registries, or providers administering the vaccine, or via self-report (as recorded in the medical record or telephone interview) if a documented source was not available.	Active, population-based surveillance for GBS cases. Trained surveillance officers reviewed medical records to gather standardized information on patient characteristics, clinical presentation, and medical history for every suspected GBS case.	Estimation of incidence rate ratios using Mantel-Haenszel method.	Age (stratification) Age specific RR were adjusted for sex	October 1, 2009, and May 31, 2010	Not given	RR (95% CI) of GBS (confirmed and probable) pH1N1 vaccine <25: 1.67 (0.58-3.22) 25+: 1.54 (0.90-2.25) Overall: 1.57 (1.02-2.21) Seasonal vaccine <25: 1.78 (0.59-3.48) 25+: 1.36 (0.84-1.91) Total: 1.43 (0.94-1.89)	Not given	

Appendix C-5. Evidence Tables – Post-marketing studies
Mixed Population

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Siberry et al. 2010,[223] Phase I/II open label safety and immunogenicity trial with no control group	N=305 HIV positive adolescents; Age=11–24 years; Setting=27 US sites of the IMPAACT network	MCV4	Eligibility criteria for were: (1) age of 11 to 24 years; (2) on stable antiretroviral therapy (ART) or not receiving ART for at least 90 days prior to vaccination; (3) no personal or family history of Guillain–Barré Syndrome (GBS); and (4) no meningococcal polysaccharide vaccine within last 2 years and no MCV4 at any time.	324 original participants, 305 final	Subjects included in the immunogenicity analysis (n = 305) were similar to those not included except that those not included were less likely to be receiving HAART.	Vaccines were administered by authors	Observation and self-report	Multivariable logistic regression	Not given	Between July and October of 2007	National Institute of Allergy and Infectious Diseases cooperative agreement #5 U01 AI41110 with the Pediatric AIDS Clinical Trials Group (PACTG) and #1 U01 AI068616 with the IMPAACT Group.	No subjects had GBS. Two subjects had AEs grade >= 3 or higher. Authors ruled out any possible association with MCV4 vaccine.	Lower CD4 count more likely to experience AEs.	
Yih et al. 2012,[224] Self-controlled risk interval, case-centered, and current-vs.-historical comparison. For GBS and most other outcomes, the SCRI design was used. Case-centered approach was used to adjust for seasonality.	N=3,040,363 doses; Location=US; Age=2–49 years; Setting=Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system. Five health insurance and associated companies with 38 million	Monovalent pandemic 2009 H1N1 influenza vaccine	Comprehensive set of data from health insurance companies. No control group	To avoid bias related to time lag in the accrual of health insurance claims data, authors used outcome data only for vaccinations given up to dates in January or February, ensuring nearly complete follow-up through both the risk and	Not discussed	Insurance company records	Data on outcomes came from insurance claims. For GBS, there was GBS medical record review by experts.	SCRI: conditional Poisson regression. Case-centered method for GBS: Logistic regression. Current-vs.-historical: logistic regression.	Case-centered: data partner, sex, and age group. Current v historical: data partner, sex, and age group.	2009-2010	Food and Drug Administration through America's Health Insurance Plans under Centers for Disease Control and Prevention contract	Risks of Health Outcomes of Interest Occurring After Receipt of a First Dose of Inactivated or Not-Otherwise-Specified 2009 H1N1 Influenza Vaccine: A 95% CI was used for anaphylaxis; 99% CIs were used for all other outcomes shown in the table, to account for multiple testing SCRI analysis Demyelinating disease: 1.01 (0.86-	None	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
For selected rare outcomes, current vs.-historical comparison methods were used	members and 9 state/city immunization registries contributed records.			control periods.								1.20), 0.84 Peripheral nervous system disorders 6 months–24 years: 1.17 (0.84-1.63), 0.24 >=25 years: 0.99 (0.92-1.05), 0.61 Bell's palsy 6 months–24 years: 1.21 (0.54-2.69), 0.54 >=25 years: 1.23 (0.88-1.73), 0.12 Other cranial nerve disorders >=25 years: 1.07 (0.89-1.28), 0.35 Allergic reactions >=6 months: 1.17 (0.92-1.49), 0.10 Hemorrhagic stroke 6 months–24 years: 1.13 (0.46-2.82), 0.72 >=25 years: 0.85 (0.62-1.16), 0.18 Ischemic stroke 6 months–24 years: 2.17 (0.61-7.73), 0.12 >=25 years: 0.92 (0.77-1.10), 0.23 Seizures 6 months–24 years: 0.55 (0.22-1.37), 0.09 >=25 years: 0.50 (0.15-1.65), 0.13 Current-vs.-historical analysis Demyelinating disease 6 months–24 years:		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												0.95 (0.54-1.68), 0.82 Encephalitis/myelitis/encephalomyelitis >=6 months: 0.85 (0.28-2.54), 0.69 Other cranial nerve disorders 6 months–24 years: 0.85 (0.55-1.32), 0.35 Ataxia >=6 months: 0.72 (0.41-1.28), 0.14 Anaphylaxis >= 6 months: 0.75 (0.29-1.90), 0.54 2009 H1N1 Vaccines Without Proximate Seasonal Influenza Vaccine SCRI analysis Demyelinating disease >=25 years: 1.00 (0.79-1.28), 0.98 Peripheral nervous system disorders 6 months–24 years: 0.88 (0.50-1.55), 0.57 >=25 years: 1.12 (1.01-1.23), 0.003 Bell's palsy 6 months–24 years: 1.25 (0.37-4.24), 0.64 >=25 years: 1.65 (1.03-2.64), 0.006 Other cranial nerve disorders		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												>=25 years: 1.07 (0.82-1.40), 0.51 Allergic reactions >=6 months: 1.06 (0.71-1.60), 0.69 Hemorrhagic stroke 6 months–24 years: 1.00 (0.23-4.42), 1.00 >=25 years: 0.93 (0.59-1.45), 0.66 Ischemic stroke 6 months–24 years: 2.50 (0.29-21.6), 0.27 >=25 years: 0.88 (0.69-1.13), 0.18 Seizures 6 months–24 years: 0.25 (0.03-1.92), 0.08 >= 25 years: 0.44 (0.09-2.09), 0.18 Current-vs.-historical analysis Demyelinating disease 6 months–24 years: 0.82 (0.40-1.68), 0.47 Encephalitis/myelitis/encephalomyelitis >= 6 months: 0.62 (0.15-2.49), 0.37 Other cranial nerve disorders 6 months–24 years: 0.87 (0.51-1.49), 0.52 Ataxia >=6 months: 0.67 (0.35-1.29), 0.12		

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												Anaphylaxis >=6 months: 0.67 (0.22-2.00), 0.47 2009 H1N1 Vaccines With Concomitantly Administered Seasonal Influenza Vaccine SCRI analysis Demyelinating disease >=25 years: 1.48 (0.80-2.72), 0.10 Peripheral nervous system disorders 6 months–24 years: 1.50 (0.56-4.01), 0.29 >=25 years: 1.12 (0.88-1.43), 0.22 Bell's palsy 6 months–24 years: 4.00 (0.22-71.2), 0.21 >=25 years: 1.33 (0.43-4.15), 0.51 Other cranial nerve disorders >=25 years: 1.72 (0.97-3.07), 0.02 Allergic reactions >= 6 months: 2.41 (1.15-5.07), 0.002 Hemorrhagic stroke 6 months–24 years: 2.00 (0.21-18.6), 0.42 >=25 years: 1.13 (0.32-3.93), 0.81 Ischemic stroke 6 months–24 years:		

Appendix C-5. Evidence Tables – Post-marketing studies
Mixed Population

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												2.00 (0.09-46.9), 0.57 >=25 years: 1.05 (0.49-2.25), 0.88 Seizures 6 months–24 years: 1.00 (0.12-8.19), 1.00 Current-vs.-historical analysis Demyelinating disease 6 months–24 years: 1.04 (0.31-3.45), 0.93 Encephalitis/myelitis/encephalomyelitis >=6 months: 3.45 (0.70-17.0), 0.05 Other cranial nerve disorders 6 months–24 years: 0.86 (0.32-2.34), 0.70 Ataxia >= 6 months: 1.01 (0.22-4.60), 0.98 Anaphylaxis >=6 months: 1.20 (0.16-9.04), 0.86		

Appendix C-6. Evidence Tables – Vaccinated vs Unvaccinated
Mixed Population

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Mallory R. M et al,2010 US[100]	Controlled Clinical Trial	3	Mean age: 9, Age range: 2 - 17, Percent female: 51%	Influenza - monovalent H1N1, not reported, MedImmune, derived by genetic reassortment of the hemagglutinin and neuraminidase genes from the wild-type A/California/7/2009virus and the remaining 6 gene segments from an attenuated master donor virus (in sucrose phosphate buffer and egg allantoic fluid, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intranasal	Dose1: 1 Days Dose2: 29 Days	Event: # with any AE Dose 1: 18.1% Event: # with any AE Dose 2: 13.7% Event: Blood and lymphatic system Dose 1, Syscat: 1 Event: Blood and lymphatic system Dose 2, Syscat: 1 Event: Ear and labyrinth Dose 1, Syscat: 4 Event: Ear and labyrinth Dose 2, Syscat: 4 Event: Eye Dose 1, Syscat: 6 Event: Eye Dose 2, Syscat: 6 Event: GI Dose 1, Syscat: 7 Event: GI Dose 2, Syscat: 7 Event: General disorders and administration site conditions Dose 1, Syscat: 8 Event: General disorders and administration site conditions Dose 2, Syscat: 8 Event: Immune system Dose 1, Syscat: 10 Event: Immune system Dose 2, Syscat: 10 Event: Infections and infestations Dose 1, Syscat: 11 Event: Infections and infestations Dose 2, Syscat: 11 Event: Injury, poisoning, procedural complications Dose 1, Syscat: 12 Event: Injury, poisoning, procedural complications Dose 2, Syscat: 12	# with any AE Dose 1: OR 1.103 (0.537-2.267) # with any AE Dose 2: OR 0.985 (0.448-2.167) Ear and labyrinth Dose 2: OR 0.251 (0.015-4.066) GI Dose 1: OR 1.017 (0.367-2.818) GI Dose 2: OR 0.882 (0.281-2.774) Infections and infestations Dose 1: OR 0.756 (0.149-3.834) Infections and infestations Dose 2: OR 1.821 (0.404-8.219) Injury, poisoning, procedural complications Dose 2: OR 0.759 (0.078-7.414)
Vesikari T. et al.,2004 Belgium, Germany[162]	Controlled Clinical Trial	5	Sample size: 59, Age range: 1 - 44	Rotavirus, Rotarix, GlaxoSmithKline, Derived from the parent strain 89-12single dose of a minimum of 10(6.1) focus forming unit (ffu) of RIX4414 or placebo, with prior administration of Mylanta® as buffer, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days	Any adverse event: 0% Any SAE: 0%	

Appendix C-6. Evidence Tables – Vaccinated vs Unvaccinated
Mixed Population

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Mallory R. M. et akl.,2010 US[100]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported		Event: Musculoskeletal and connective tissue Dose 1: 2%, Syscat: 15 Event: Musculoskeletal and connective tissue Dose 2, Syscat: 15 Event: Nervous System Dose 1, Syscat: 17 Event: Nervous System Dose 2, Syscat: 17 Event: Respiratory, thoracic, and mediastinal Dose 1 Event: Respiratory, thoracic, and mediastinal Dose 2 Event: Skin and subcutaneous tissue Dose 1, Syscat: 23 Event: Skin and subcutaneous tissue Dose 2, Syscat: 23 Syscat: 1		Event: # with any AE Dose 1: 16.7% Event: # with any AE Dose 2: 13.6% Event: Blood and lymphatic system Dose 1, Syscat: 1 Event: Blood and lymphatic system: 0%, Syscat: 1 Event: Ear and labyrinth Dose 1: 0%, Syscat: 4 Event: Ear and labyrinth Dose 2: 1.52%, Syscat: 4 Event: Eye Dose 1: 0%, Syscat: 6 Event: Eye Dose 2: 0%, Syscat: 6 Event: GI Dose 1: 7.58%, Syscat: 7 Event: GI Dose 2: 6.1%, Syscat: 7 Event: General disorders and administration site conditions Dose 1: 0%, Syscat: 8 Event: General disorders and administration site conditions Dose 2: 0%, Syscat: 8 Event: Immune System Dose 1: 0%, Syscat: 10 Event: Immune System Dose 2: 0%, Syscat: 10 Event: Infections and infestations Dose 1, Syscat: 11 Event: Infections and infestations Dose 2: 3.03%, Syscat: 11 Event: Injury, poisoning, procedural complications Dose 1: 0% Event: Injury, poisoning, procedural complications Dose 2***: 1.5%, Syscat: 12
Vesikari T. et al.,2004 Belgium, Germany[162]	Rotavirus, Rotarix, GlaxoSmithKline, Derived from the parent strain 89-12. 10.7 ffu or 10.4 ffu of RIX4414 or placebo administered with prior administration of Maalox® as buffer., Adjuvant: Not Reported, Preservative: Not Reported, Delivery: Not Reported	Dose1: 0 Days	Event: At least 1 solicited AE (10.7 ffu group) Event: At least 1 solicited AE (10.4 ffu group): 0% AE: 0%	Placebo Unsure of adjuvants, preservatives and formulations	Event: at least 1 solicitied SAE (1-3 yr): 100% Event: Any SAE (18-44 yr): 0%

Appendix C-7. Evidence Tables – Post-marketing studies
Pregnant Women

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
Omer,2011, Retrospective cohort[207]	4,168 pregnant women and their newborns enrolled in Georgia Pregnancy Risk Assessment Monitoring System (PRAMS), mean age not reported but 11.5% were <19, 12.5% were >35, and 76% were 19-35. Recruitment occurred in the flu seasons of 2004-2006.	Inactivated influenza	PRAMS is a selected segment intended to oversample black women and women who gave birth to Small for Gestational Age (SGA) babies; within PRAMS, black women are significantly less likely to get influenza vaccine.	Not applicable	Yes, see selection bias	Self-report	Self-report	Logistic regression	Influenza activity period (pre-influenza activity period, periods of least local/regional influenza activity, period of widespread influenza activity) maternal variables (age, multiple births, medical risk factors, labor/delivery complications, birth defects, smoking during pregnancy, hypertension, insurance coverage, maternal diabetes, use of multivitamins, alcohol use during pregnancy, black race, education, marital status) Covariates were tested for the separate	Following 2004-2005 and 2005-2006 influenza seasons	Emory University, National Foundation for Infectious Diseases	Prematurity was defined as birth < 37 weeks gestation; SGA was defined as birth weight <10th percentile for gestational age. Infants born during the putative vaccine season to women who were vaccinated were less likely to be premature compared to infants born in the same period to unvaccinated mothers (adjusted OR 0.60, 95% CI 0.38 to 0.94) During the period of local influenza activity, this relationship increased (adjusted OR 0.44, 95% CI 0.26 to 0.73)) During the widespread influenza activity period, this relationship was greatest: adjusted OR 0.80, 95% CI 0.11. to 0.74) Also during the widespread influenza activity period, compared with newborns of unvaccinated mothers, newborns of vaccinated	NA	Maternal immunization is associated with reduced likelihood of prematurity and SGA except during the pre-influenza activity period.

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
									multivariate models by testing which potential confounders moved the relationship between immunization and birth outcome closer to 1.			mothers had 69% lower odds of being SGA (adjusted OR 0.31, 0.13 to 0.75).		
Xu et al. 2012, retrospective cohort[208]	n=198 pregnant women who enrolled before 20 weeks gestation; US/Vaccine and Medication in Pregnancy Surveillance System study.	H1N1	Self-selected population (women who contacted the system).	Not dicussed	Participants were all pregnant women	Not reported	Not reported	Time-independent (naive) and time-dependent covariate Cox models to account for left-truncation (due to possible enrollment later than conception) and vaccine exposure timing.	Vaccine exposure (1st or 2nd trimester) Previous spontaneous abortion (SAB) events (0, 1, 2, >=3) smoking maternal age asthma. Dependent variable: SAB	Not reported	DHHS	Controls (n=40, no vaccine) No. SAB: 4 SAB rate: 34% Vaccination between LMP and date of conception(n=5) No. SAB: 1 SAB rate: 25% RR (time-independent): 1.13(0.13, 10.24) RR (time-dependent): 1.13(0.13, 10.24) Vaccination during 1st trimester (n=119) No. SAB: 4 SAB rate: 18.6% RR (time-independent): 0.48(0.08, 2.70) RR (time-dependent): 0.79(0.19, 3.23) Vaccination during 2nd trimester (by definition, fetal	Data not shown, although none of the confounders was associated with enrollment time.	Aim of this study was not to assess effect of H1N1 on SAB rate but to illustrate use of survival analysis methods to study effects of vaccines on SAB.

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
												loss>20weeks is still-birth, not SAB)(n=34) No. SAB: 0 Vaccination during 1st or 2nd trimester (n=153) No. SAB: 4 SAB rate: 16.5% RR (time-independent): 0.58(0.10, 3.24) RR (time-dependent): 0.97(0.24, 3.94)		
Whitehouse et al. 2011, Prospective cohort[225]	N=804 participants from the Western Australian Pregnancy Cohort; Location=Australia; Age=infants followed up to 20 years;	MMR	Study assessed autism scores in low and high income groups and found no differences (because those in the study tended to be more socially advantaged). Authors note, "our inclusion criterion for the gastrointestinal group – presentation to hospital, general practitioner, or clinic with gastrointestinal symptoms – may have biased this sample towards families more	Data available for 37.6% of the 2,138 children whose whereabouts were still know (2,868 in original cohort).	Study noted that participants differed from birth cohort in that they were: more likely to have mothers who had completed secondary school at the time of pregnancy and to come from families who lived above the income 'poverty' threshold.	Parental report	Self-report (questionnaire)	Bivariate analyses	Primary purpose was to study association of early GI problems and ASD.	Recruitment from 1989 to 1992, followed for 20 years	National Health and Medical Research Council, Raine Medical Research Foundation, University of Western Australia, the University of Western Australia Faculty of Medicine, Dentistry and Health Sciences, Tele- thon Institute for Child Health Research, and the Women's and Infants Research	Mean autism quotient (AQ) did not differ between those who had received MMR, those who had received measles and mumps vaccine, and those who had received neither. p =0.65.	None	

Author, Year, Study Design	Population studied	Vaccines included	Selection Bias	Attrition, non-response	Participation bias	Ascertainment of vaccination status	Ascertainment of health outcome	Analysis conducted	Adjusted for these potential confounders	Period data collected	Study funder	Primary results regarding vaccine	Any risk factor findings	Comment
			inclined to seek health services rather than children in actual need of assistance."								Foundation			

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Lin T. H. et al.,2012 Taiwan[204]	Cohort	7	Sample size: 396, Mean age: 32.4 (exposed), Percent female: 100%	Influenza (inactivated), AdimFlu-S®, Adimmune Corporation, Taichung, Taiwan, The vaccine evaluated in this study was produced by Adimmune Corporation (Taichung, Taiwan) using standard techniques for the production of seasonal inactivated influuenza vaccines. The vaccine is a monovalent, unadjuvanted, inactivated, split-virus vaccine. One shot (0.5ml) of AdimFlu-S®influenza A (H1N1) vaccine contains 15 ®g of New York Medical College X-179A reassortant of the A/California/7/2009 (H1N1) like strain. Adjuvant: Adjuvant Free, Preservative: Not reported, Delivery: Intradermal	Dose1: 0 Days	Any adverse event: 35.6% Event: Infant: Hyperbilirubinemia neonatal: 2.5%, Syscat: 13 Event: Infant: Dermatitis contact: 5.4%, Syscat: 23 Event: Infant: Upper respiratory tract infection: 3.0%, Syscat: 22 Event: Infant: Seborrheic dermatitis: 4.0%, Syscat: 23 Event: Infant: Respiratory distress: 2.0%, Syscat: 22 Event: Maternal: Fever, cough, runny nose, nasal congestion, and skin itching: 2.0%, Syscat: 8 Event: Maternal: At least one adverse event: 8.6% Event: Maternal: Severe adverse event: 0%	Infant: Dermatitis contact: OR 1.882 (0.682-5.194) Infant: Hyperbilirubinemia neonatal: OR 0.083 (0.032-0.214)** Infant: Respiratory distress: OR 0.66 (0.183-2.375) Infant: Seborrheic dermatitis: OR 2.042 (0.605-6.895) Infant: Upper respiratory tract infection: OR 0.742 (0.253-2.18) Maternal: At least one adverse event: OR 0.371 (0.202-0.68)**

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	Adverse Event	OR, 95% CI, versus unvaccinated group
Fell D. B. et al.,2012 Canada[205]	Cohort	4	Sample size: 55570, Mean age: NR, Age range: <18 - 40+, Percent female: 100%	Influenza - monovalent H1N1, NR, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: NR	Event: Preterm birth (<37w): 5.9%, Syscat: 18, Sev: 1 Event: Very preterm (<32w): 0.6%, Syscat: 18, Sev: 2 Event: Small for gestational age: <10th percentile: 8.3%, Syscat: 18, Sev: 2 Event: Small for gestational age: <3rd percentile: 2%, Syscat: 18, Sev: 3-4 Event: 5min APGAR score <7: 1.19%, Syscat: 18 Event: Fetal Death: 0.26%, Syscat: 18, Sev: 5	5min APGAR score <7: OR 0.925 (0.794-1.078) Fetal Death: OR 0.595 (0.439-0.806)** Preterm birth (<37w): OR 0.915 (0.853-0.981)** Small for gestational age: <10th percentile: OR 0.836 (0.788-0.887)** Small for gestational age: <3rd percentile: OR 0.74 (0.66-0.829)** Very preterm (<32w): OR 0.717 (0.584-0.879)**
Mackenzie I. S. et al.,2012 Scotland[206]	Cohort	2	Sample size: 4066, Mean age: 53.6, Percent female: 57.9 (>=16 years))%, Percent pregnant: Percent Pregnant: 3.2%, Conditions: multiple	Influenza - monovalent H1N1, Celvapan /Pandemrix, see above, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: NR Dose2: NR Dose3: NR	Event: Chest infection: 1.41%, Syscat: 22 Event: Coryza: 0.64%, Syscat: 22 Event: Malaise: 0.56%, Syscat: 8 Event: Cough: 0.51%, Syscat: 22 Event: allergy: 0.32%, Syscat: 10 Event: Flu-like symptoms: 0.32%, Syscat: 11 Event: Pyrexia: 0.32%, Syscat: 8 Event: Dyspnea: 0.29%, Syscat: 22 Event: Pharyngitis: 0.29%, Syscat: 22 Event: Limb pain: 0.27%, Syscat: 15 Event: Headache: 0.24%, Syscat: 17 Event: Myalgia: 0.21%, Syscat: 15 Event: Rash: 0.21%, Syscat: 23 Event: Diarrhea: 0.19%, Syscat: 7 Event: Chest pain: 0.19%, Syscat: 2 Event: sinusitis: 0.19%, Syscat: 2,22 Event: Nausea, Influenza, Pain, viral infection, Syscat: 7,11,8,11 Event: Death: .16%	Chest infection: OR 0.879 (0.349-2.216) Coryza: OR 0.997 (0.235-4.24) Chest pain: OR 0.581 (0.071-4.738) Death: OR 0.498 (0.06-4.149) Dyspnea: OR 0.914 (0.118-7.103)

Author- Year- Country	Vaccine	Timing	Adverse Event	Control group	Adverse Events Control
Lin T. H. et al.,2012 Taiwan[204]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery:			Nothing	Any adverse event: 49% Event: Infant: Hyperbilirubinemia neonatal: 22.8%, Syscat: 13 Event: Infant: Dermatitis contact: 2.9%, Syscat: 23 Event: Infant: Upper respiratory tract infection: 3.9%, Syscat: 22 Event: Infant: Seborrheic dermatitis: 1.9%, Syscat: 23 Event: Infant: Respiratory distress: 2.9%, Syscat: 22 Event: Maternal: At least one adverse event: 20.2% Event: Maternal: Severe adverse event: 0% AE: 0%
Fell D. B. et al.2012 Canada[205]	Adjuvant: Not Reported, Preservative: Not Reported, Delivery:			Nothing	Event: Preterm birth (<37w): 6.41%, Syscat: 18, Sev: 1 Event: Very preterm (<32w): 0.84%, Syscat: 18, Sev: 2 Event: Small for gest age: <10th percentile: 9.77%, Syscat: 18, Sev: 2 Event: Small for gest age: <3rd percentile: 2.68%, Syscat: 18, Sev: 3-4 Event: 5min APGAR score <7: 1.28%, Syscat: 18 Event: Fetal death: 0.43%, Syscat: 18, Sev: 5
Mackenzie I. S. et al.,2012 Scotland[206]	Influenza - monovalent H1N1, Adjuvant: Not Reported, Preservative: Not reported, Delivery:	Dose1: NR Dose2: NR Dose3: NR	Event: Hypospadias: 1%, Syscat: 3 Event: skin tag on finger: 0.78%, Syscat: 3 Event: Downs: 0.78%, Syscat: 3 Event: Hydrocephalus: .78%, Syscat: 3 Event: umbilical hernia: .78% Event: cleft palate: 0.78% Event: miscarriage: 3.1%, Syscat: 18 AE: 1% AE: 1% AE: 1%	Nothing	Event: Chest infection: 1.6%, Syscat: 22 Event: Coryza: 0.64%, Syscat: 22 Event: Angina: 0.32%, Syscat: 2 Event: Asthma worsening: 0.32%, Syscat: 22 Event: Carcinoma stomach: 0.32%, Syscat: 16 Event: cardiac failure: 0.32%, Syscat: 2 Event: cardiovascular system unspecified: 1%, Syscat: 2 Event: constipation: 0.32%, Syscat: 7 Event: dyspnea: 0.32%, Syscat: 22 Event: fracture: .32%, Syscat: 15 Event: death: 0.32%

Appendix D. List of Excluded Studies and Backgrou
Papers

Rejected for Participants (animal or in-vitro study) – 20

1. Abraham E. Intranasal Immunization with Bacterial Polysaccharide Containing Liposomes Enhances Antigen-Specific Pulmonary Secretory Antibody-Response. Vaccine. 1992;10 (7):461-8. PMID WOS:A1992HV88400007.

2. Bellinzoni RC, Blackhall J, Baro N, et al. Efficacy of an inactivated oil-adjuvanted rotavirus vaccine in the control of calf diarrhoea in beef herds in Argentina. Vaccine. 1989 1989;7 (3):263-8. PMID 1989174507 MEDLINE PMID 2551102 (http://www.ncbi.nlm.nih.gov/pubmed/2551102).

3. Bucardo F, Rippinger CM, Svensson L, Patton JT. Vaccine-derived NSP2 segment in rotaviruses from vaccinated children with gastroenteritis in Nicaragua. Infection, Genetics and Evolution. 2012 August;12 (6):1282-94. PMID 2012327099.

4. Choi NW, Estes MK, Langridge WHR. Mucosal immunization with a ricin toxin B subunit-rotavirus NSP4 fusion protein stimulates a Th1 lymphocyte response. Journal of Biotechnology. 2006 24;121 (2):272-83. PMID 2006012524 MEDLINE PMID 16181698 (http://www.ncbi.nlm.nih.gov/pubmed/16181698).

5. Cui YL, Zhang XM, Gong Y, et al. Immunization with DnaJ (hsp40) could elicit protection against nasopharyngeal colonization and invasive infection caused by different strains of Streptococcus pneumoniae. Vaccine. 2011 Feb;29 (9):1736-44. PMID WOS:000288058500003.

6. Dorea JG. Integrating experimental (in vitro and in vivo) neurotoxicity studies of low-dose thimerosal relevant to vaccines. Neurochemical Research. 2011 June;36 (6):927-38. PMID 2011250772 MEDLINE PMID 21350943 (http://www.ncbi.nlm.nih.gov/pubmed/21350943).

7. Gotschlich EC, Goldschneider I, Artenstein MS. Human immunity to the meningococcus. IV. Immunogenicity of group A and group C meningococcal polysaccharides in human volunteers. Journal of Experimental Medicine. 1969 Jun 1;129 (6):1367-84. PMID 4977283.

8. Hainisch EK, Brandt S, Shafti-Keramat S, Van den Hoven R, Kirnbauer R. Safety and immunogenicity of BPV-1 L1 virus-like particles in a dose-escalation vaccination trial in horses. Equine Veterinary Journal. 2012 Jan;44 (1):107-11. PMID 21895749.

9. Iosef C, Van Nguyen T, Jeong KI, et al. Systemic and intestinal antibody secreting cell responses and protection in gnotobiotic pigs immunized orally with attenuated Wa human rotavirus and Wa 2/6-rotavirus-like-particles associated with immunostimulating complexes. Vaccine. 2002 15;20 (13 14):1741-53. PMID 2002110438 MEDLINE PMID 11906761 (http://www.ncbi.nlm.nih.gov/pubmed/11906761).

10. Koyama S, Aoshi T, Tanimoto T, et al. Plasmacytoid dendritic cells delineate immunogenicity of influenza vaccine subtypes. Science Translational Medicine. 2010 2010;2 (25):25ra4. PMID 2010309645 MEDLINE PMID 20424013 (http://www.ncbi.nlm.nih.gov/pubmed/20424013).

11. Neeper CA, Seastone CV. Mechanisms of Immunologic Paralysis by Pneumococcal Polysaccharide. Iv. Comparison of Polysaccharide and Whole Organisms. Journal of Immunology. 1964 Nov;93:867-71. PMID 14239947.

12. Ranheim T, Mathis PK, Joelsson DB, et al. Development and application of a quantitative RT-PCR potency assay for a pentavalent rotavirus vaccine (RotaTeq (R)). Journal of Virological Methods. 2006 Feb;131 (2):193-201. PMID WOS:000235264500012.

13. Roldao A, Vieira HLA, Charpilienne A, et al. Modeling rotavirus-like particles production in a baculovirus expression vector system: Infection kinetics, baculovirus DNA replication, mRNA synthesis and protein production. Journal of Biotechnology. 2007 10;128 (4):875-94. PMID 2007113507 MEDLINE PMID 17289202 (http://www.ncbi.nlm.nih.gov/pubmed/17289202).

14. Rubin SA, Afzal MA. Neurovirulence safety testing of mumps vaccines--historical perspective and current status. Vaccine. 2011 Apr 5;29 (16):2850-5. PMID 21334386.

15. Shen Z, Lei H. Expression of hBD-2 induced by 23-valent pneumococcal polysaccharide vaccine, Haemophilus influenzae type b vaccine and split influenza virus vaccine. Molecular Medicine Reports. 2012 October;6 (4):733-8. PMID 2012488666.

16. Soto PC, Stein LL, Hurtado-Ziola N, Hedrick SM, Varki A. Relative Over-Reactivity of Human versus Chimpanzee Lymphocytes: Implications for the Human Diseases Associated with Immune Activation. Journal of Immunology. 2010 Apr;184 (8):4185-95. PMID WOS:000276625800020.

17. Spadaccini A, Virnik K, Ni YS, Prutzman K, Berkower I. Stable expression of a foreign protein by a replication-competent rubella viral vector. Vaccine. 2010 Feb;28 (5):1181-7. PMID WOS:000275122200008.

18. Thiele S, Borschewski A, Kuchler J, Bieberbach M, Voigt S, Ehlers B. Molecular analysis of varicella vaccines and varicella-zoster virus from vaccine-related skin lesions. Clinical & Vaccine Immunology: CVI. 2011 Jul;18 (7):1058-66. PMID 21562115.

19. Wise RP, Iskander J, Pratt RD, et al. Postlicensure safety surveillance for 7-valent pneumococcal conjugate vaccine. JAMA. 2004 Oct 13;292 (14):1702-10. PMID 15479935.

20. Xu PL, Iwata M, Leong S, Sequeira L. Highly virulent strains of Pseudomonas solanacearum that are defective in extracellular-polysaccharide production. Journal of Bacteriology. 1990 Jul;172 (7):3946-51. PMID 2163393.

Rejected for Language (not English) – 9

1. Benefits and risks of vaccination against papillomavirus human ORIGINAL (NON-ENGLISH) TITLE Beneficios y riesgos de la vacunacion contra el virus del papiloma humano. Ginecologia y Obstetricia de Mexico. 2011 December;79 (12):803-7. PMID 2012155624 MEDLINE PMID 22384535 (http://www.ncbi.nlm.nih.gov/pubmed/22384535).

2. Akazawa M. Economic analysis of vaccine programs. Japanese Journal of Clinical Pharmacology and Therapeutics. 2010 September;41 (5):245-52. PMID 2010626428.

3. Autret E, Jonville-Bera AP, Galy-Eyraud C, Hessel L. [Thrombocytopenic purpura after isolated or combined vaccination against measles, mumps and rubella]. Therapie. 1996 Nov-Dec;51 (6):677-80. PMID 9164004.

4. Forster J. Current rotavirus vaccines. Efficacy and cost-effectiveness. Monatsschrift Kinderheilkunde. 2005 Sep;153 (9):831-+. PMID WOS:000232710300003.

5. Li YP, Zhang SM, Ye Q. Safety and immunogenicity of the diphtheria, tetanus, accellular pertussis plus hemophilus influenza type b combined vaccine (DTaP-Hib) to Chinese infants. Zhongguo ji hua mian yi = Chinese journal of vaccines and immunization. 2010 Apr;16 (2):97-104.

6. Minodier P, Noel G, Blanc P, Uters M, Retomaz K, Garnier JM. Rotavirus vaccines and the risk of intussusception. Archives de Pediatrie. 2007 Jun;14 (6):618-20. PMID WOS:000247302100035.

7. Mrozek-Budzyn D, Majewska R, Kieltyka A, Augustyniak M. [Lack of association between thimerosal-containing vaccines and autism]. ORIGINAL (NON-ENGLISH) TITLE Brak zwiazku miedzy ekspozycja na szczepionki zawierajace tiomersal i rozwojem autyzmu u dzieci. Przeglad Epidemiologiczny. 2011 2011;65 (3):491-5.

8. Yang SP, Li JY, Yan XX, Yang KH, Liu YL. A review on adverse events following immunization of meningococcal vaccines. Chinese Journal of Evidence-Based Medicine. 2011 2011;11 (12):1468-70. PMID 2012080945.

9. Zahedpasha Y, Ahmadpour Kacho M, Pour Nasrollah M, Bijani A, Saadat H, Mazloumi A. Immune response in preterm infants to hepatitis B vaccine. Journal of Babol University of Medical Sciences. 2011;13 (4) PMID 2011408656.

Rejected for Conference Abstract – 191

1. Global Advisory Committee on Vaccine Safety, 6-7 June 2006. Weekly Epidemiological Record. 2006 Jul 14;81 (28):273-8. PMID 16841398.

2. Global Advisory Committee on Vaccine Safety, 12-13 June 2007. Weekly Epidemiological Record. 2007 Jul 20;82 (28-29):252-9. PMID 17642098.

3. Global Advisory Committee on Vaccine Safety, 12-13 December 2007. Weekly Epidemiological Record. 2008 Jan 25;83 (4):37-44. PMID 18219807.

4. Global Advisory Committee on Vaccine Safety, 17-18 December 2008. Weekly Epidemiological Record. 2009 Jan 30;84 (5):37-40. PMID 19180768.

5. Global Advisory Committee on Vaccine Safety, report of meeting held 17-18 June 2009. Weekly Epidemiological Record. 2009 Aug 7;84 (32):325-32. PMID 19860024.

6. Canadian Society of Allergy and Clinical Immunology Annual Scientific Meeting 2010. Allergy, Asthma and Clinical Immunology. 2010;6 (2):2010-11.

7. Pneumococcal immunization in older adults. Clinical Geriatrics. 2010 June;18 (6):13-4. PMID 2010389740.

8. Ackerman K, Cohen DC, Erickson RA. Hepatitis B Vaccination Induced Idiopathic Thrombocytopenic Purpura. Gastroenterology. 2011 May;140 (5):S976-S. PMID WOS:000290167304500.

9. Ahmed S, Perveen I. Safety, Immunogenicity and reactogenicity of recombinant hepatitis B vaccine Engerix(trademark)-B. Immunology. 2011 December;135 SUPPL. 1:81.

10. Al Qudah Z, Abukwaik W, Souayah N. Stroke after vaccination in United States. A report from the CDC/FDA vaccine adverse event reporting system. [1990-2010. Neurology. 2012;78 (1):2012-04.

11. Ali AK. Vaccine-associated guillain-barre syndrome: A pharmacovigilance analysis of data in the United States' vaccine adverse event reporting system (1990-2009). Value in Health. 2011 May;14 (3):A113-A4.

12. Allwin R, Gauer S, Roessel, et al. Eficacy and side effects of H1N1 vaccination in renal transplant and dialysis patients. Transplant International. 2011 September;24 SUPPL. 2:289.

13. Alvarez MM, Fernandez CG, Exposito AG. Antibody response to the standard hepatitis B vaccination in patients with rheumatoid arthritis and ankylosign spondylitis treated with infliximab. Arthritis and Rheumatism. 2011;63 (10):1316.

14. Alvarez-Soria MJ, Hernandez-Gonzalez A, Carrasco-Garcia de Leon S, Dominguez-Bertalo

J, Gallardo-Alcaniz MJ, Del Real-Francia MA. Demyelinating disease and papillomavirus vaccine: Report of three cases. Journal of Neurology. 2010 June;257 SUPPL. 1:S119.

15. Andreas J, Jenke A, Weckelmann A, et al. Incidence, management and protective factors of intussusception in children: Results from a nationwide german surveillance. Journal of Pediatric Gastroenterology and Nutrition. 2009 May;48 SUPPL. 3:E52-E3.

16. Anh DD, Thiem VD, Hutagalung Y, et al. Immunogenicity, Reactogenicity and Safety of the Oral Live Attenuated Human Rotavirus Vaccine RIX4414(Rotarix (TM)) Oral Suspension (Liquid Formulation) in Vietnamese Infants. International Journal of Infectious Diseases. 2008 Dec;12:E147-E. PMID WOS:000263287800365.

17. Aqua KA, Basu P, Petit RG. ADXS11-001 immunotherapy targeting HPV-E7: Preliminary safety data from two phase 2 studies in women with CIN 2/3 and with recurrent/refractory cervical cancer. Journal of Immunotherapy. 2011 November-December;34 (9):700.

18. Autret-Leca E, Daubin C, Poggi P, Collignon AE, Bensouda-Grimaldi L, Jonville-Bera AP. Pneumococcal conjugate vaccine: national monitoring of serious adverse effects. Fundamental & Clinical Pharmacology. 2009 Jun;23:88-. PMID WOS:000268185600444.

19. Baluch A, Humar A, Egli A, et al. A randomized controlled trial of high-dose intradermal vs. standard intramuscular influenza vaccine in solid organ transplant recipients. American Journal of Transplantation. 2012 May;12 SUPPL. 3:53-4.

20. Benoit B, Claire PN, Vincent M, et al. Safety and Efficacy of an Inactivated, Unadjuvanted Vaccine Against the Novel Influenza A Variant (H1N1v) in Renal Transplant Recipients (INSERM C09-32, Transfluvac Study). American Journal of Transplantation. 2011 Apr;11:78-. PMID WOS:000289318400160.

21. Bermal N, Alberto E, Hernandez M, et al. Safety and Reactogenicity of a 10-Valent Pneumococcal Non-Typeable Haemophilus influenzae Protein D-Conjugate Vaccine (PHiD-CV) in Filipino Infants. International Journal of Infectious Diseases. 2008 Dec;12:E153-E. PMID WOS:000263287800379.

22. Bharadwaj AS, Rathod A, Badheka A, Veeranna V, Jacob S, Afonso L. Vaccination Serology Status (Non-Pneumococcal and Non-Influenza) and Cardiovascular Mortality: Insights from Nhanes Iii. Journal of the American College of Cardiology. 2011 Apr;57 (14):E556-E. PMID WOS:000291695100557.

23. Black S, Shinefield H, Ray P, et al. Safety and immunogenicity of heptavalent pneumococcal conjugate vaccine (Wyeth-Lederle) in infancy. Pediatric Research. 1996 Apr;39 (4):986-. PMID WOS:A1996UD23800986.

24. Black SB, Shinefield HR, Hiatt RH, et al. Safety and Efficacy of Hboc Conjugate Haemophilus Influenzae Type-B Vaccine in 61,000 Infants. Pediatric Research. 1991 Jan;29 (1):116-. PMID WOS:A1991EP11000024.

25. Boen M, DeLeon D, Bennett CL, Samaras AT, McKoy JM. Gardasil: A false sense of immunity? Journal of Clinical Oncology. 2010;28 (15):2010-06.

26. Borba EF, Saad CGS, Calich ALG, et al. The novel pandemic influenza A (H1N1) 2009 vaccine: Low rate of Seroconversion after vaccination in systemic lupus erythematosus. Arthritis and Rheumatism. 2010 2010;62 SUPPL. 10:481.

27. Brauner S, Kvarnstom M, Gorgen S, et al. Vaccination of patients with primary Sjogren's syndrome reveals hyperreactive B cell compartment with a skewed maturation pattern. Annals of the Rheumatic Diseases. 2011 March;70 SUPPL. 2:A67.

28. Broder K, Haber P, Miller E, DeStefano F, Vellozzi C. Detecting signals in the vaccine adverse event reporting system. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S358.

29. Brookhart SMA, Li J, Paeglow C, et al. Characterizing vaccine-associated risk using natural smoothing. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S260-S1.

30. Callejo D, Lopez-Polin A, Blasco JA. Cost utility of human papiloma virus vaccine in Spain. Value in Health. 2010 November;13 (7):A258.

31. Camacho LH, Betts RF, Wertheim MS, et al. Safety and immunogenicity of heat-treated zoster vaccine (ZV(HT)) in adults with hematologic malignancy (HM). Blood. 2010;116 (21):2010-12.

32. Ceschi A, Ingram K, Curkovic I, et al. Adverse drug reactions: The most commonly involved drugs and organ systems in pharmacovigilance reports at the University Hospital Zurich. British Journal of Clinical Pharmacology. 2009 October;68 SUPPL. 1:50.

33. Chambers CD, Johnson DL, Xu R, et al. Challenges and design of a prospective, observational cohort study to assess the risk of spontaneous abortion following administration of human papillomavirus (HPV) bivalent (Types 16 and 18) recombinant vaccine. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S358.

34. Chambers CD, Schatz M, Mitchell AA, Louik C, Jones KL. The vaccines and medications in pregnancy surveillance system (VAMPSS): Launch of a new system for post-marketing surveillance. Birth Defects Research Part A - Clinical and Molecular Teratology. 2010 May;88 (5):406.

35. Chenaf C, Zenut M, Eschalier A. Thrombocytopenic Purpura and vaccination: Where do we stand? Fundamental and Clinical Pharmacology. 2010 April;24 SUPPL. 1:73.

36. Chioato A, Noseda E, Stevens M, Picaud H, Gaitatzis N, Kleinschmidt A. Efficacy of influenza and meningococcal vaccinations in healthy subjects exposed to secukinumab 150 mg: Preliminary study results. Arthritis and Rheumatism. 2011;63 (10):1822.

37. Chlebna-Sokol D, Szynczewska E. Immunogenicity and Safety of Heptavalent Pneumococcal Conjugate Vaccine in Very Preterm Infants - Draft Report. Acta Paediatrica. 2009 Oct;98:101-2. PMID WOS:000269862100263.

38. Cordero E, Perez-Ordonez A, Aydillo T, et al. Immunogenicity, efficacy, and safety of the pandemic influenza A/H1N1 vaccine in solid organ transplant recipients. Clinical Microbiology and Infection. 2011 May;17 SUPPL. 4:S48.

39. Cowan ML, Chon WJ, Josephson M, et al. Impaired response to influenza vaccination in kidney transplant recipients. American Journal of Transplantation. 2012 May;12 SUPPL. 3:55.

40. Crespo M, Collado S, Mir M, et al. Renal patients showed a poor response to the 2009 pandemic new influenza a H1N1 virus vaccine. Transplant International. 2011 September;24 SUPPL. 2:42.

41. Dagan R, Kassis I, Sarov B, Midthun K, Sarov I. Safety and Immunogenicity of Oral Rhesus Rotavirus Tetravalent Vaccine (Orrtv) in Neonates. Pediatric Research. 1991 Jan;29 (1):117-. PMID WOS:A1991EP11000026.

42. Daniel BS, Venugopal SS, Murrell DF. Complete resolution of chronic multiple verruca vulgaris treated with quadrivalent human papilloma virus (HPV) vaccine. Australasian Journal of Dermatology. 2011 May;52 SUPPL. 1:21.

43. Davies EG, Ashton L, McDermott E, Core C, Taylor AMR, Goldblatt D. Immunogenicity of conjugate pneumococcal vaccine (Prevenar) in ataxia telangiectasia: evidence of a genotype/phenotype correlation. Clinical and Experimental Immunology. 2008 Nov;154:115-6. PMID WOS:000262727500218.

44. de Boer AW, McNeil S, Halperin SA, et al. Safety and Immunogenicity of a Novel Hepatitis B Vaccine Adjuvanted with Immunostimulatory Sequence (Iss) in Renal Predialysis and Dialyis Patients. American Journal of Kidney Diseases. 2010 Apr;55 (4):A51-A. PMID WOS:000276054500100.

45. De La Hoz F, Alvis N, Gamboa O, Castaneda C, Paternina A. Cost-effectiveness analysis of the introduction of the varicellavaccine in Colombia. Value in Health. 2011 May;14 (3):A118.

46. De Lavallade H, Garland PL, Sekine T, et al. 2009 pandemic influenza A H1N1 vaccination in the patients with hematologic malignancies: Requirement for repeated dosing to optimize seroprotection. Blood. 2010;116 (21):2010-12.

47. Del Pozo Garcia G, Gallego C, Gomez JJ, Hilatrio HA, De Orbe GG, Arevalo J. Possible indicators of intussusception post-rotavirus vaccine. Pediatric Radiology. 2011 May;41 SUPPL. 1:S337-S8.

48. Dieleman J, Lecomte C, Schuemie M, et al. Safety of adjuvanted pandemic influenza

vaccines: Background rate of narcolepsy in Europe. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S260.

49. Dieleman JP, Romio SS, de Vries CS, et al. Guillain-Barre Syndrome and Adjuvanted Pandemic Influenza A (H1N1) 2009 Vaccines - A Multinational Case Control Study in Europe. Pharmacoepidemiology and Drug Safety. 2011 Aug;20:S258-S9. PMID WOS:000294946600573.

50. Dodds L, McNeil S, Scott J, Allen VM, Spencer A, MacDonald N. Influenza vaccination in pregnancy. American Journal of Epidemiology. 2011 1;173 SUPPL. 11:S40.

51. Doran I, Shaharabani H, Kariv R, et al. Influenza A H1N1 Vaccine is Safe and Effective in Patients With Inflammatory Bowel Disease (IBD) Treated With Thiopurines and TNF-alpha Blockers. Gastroenterology. 2011 May;140 (5):S771-S2. PMID WOS:000290167303427.

52. Doug BR, Xu Y, Zhang YL, Yue JR. Efficacy and safety of 23-valent pneumococcal polysaccharide vaccine in prevention of lower respiratory tract infections in the Chinese elderly: A prospective concurrent controlled trial. Chest. 2005 Oct;128 (4):148S-S. PMID WOS:000232800300060.

53. Duan ZP, Zou HB, Chen Y, et al. Efficacy and Safety of Double Vs. Standard Dose Recombinant Hepatitis B Vaccine in Infants Born to Hbsag-Positive Mothers:An Interim Report of a Multi-Center, Randomized and Controlled Trial. Hepatology. 2011 Oct;54:884A-5A. PMID WOS:000295578003329.

54. Farez MF, Ysrraelit MC, Fiol M, Correale J. H1N1 vaccination does not increase risk of exacerbation in MS: A self-controlled case-series study. Multiple Sclerosis. 2011 October;17 (10 SUPPL. 1):S133-S4.

55. Farinas-Alvarez C, Nunez-Viejo MA, Ansorena-Pool L, et al. Impact of pneumococcal vaccination in preventing invasive pneumococcal disease in Cantabria (SPAIN). Clinical Microbiology and Infection. 2011 May;17 SUPPL. 4:S243-S4.

56. Faure C, Koller A, Hartmann K, et al. Development of a large safety database using studies conducted during the clinical development and post-marketing of a virosomal aluminium-free hepatitis a vaccine. Value in Health. 2011 November;14 (7):A285-A6.

57. Ferreira GLC, Almeida JM, Alena K. Implementation of panenza A(H1N1) 2009 pandemic vaccine pharmacovigilance plan. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S356-S7.

58. Fontaine H, Chazallon C, Mancini-Bourgine M, et al. Relapse after analogues treatment discontinuation is not prevented by DNA vaccination in chronic hepatitis B (ANRS HB 02 VAC-ADN). Hepatology. 2011 October;54 SUPPL. 1:1064A.

59. Franca ILA, Ribeiro ACM, Aikawa NE, et al. Influenza a H1N1/2009 vaccine in rheumatic

disease patients under anti-TNF therapy: Safety and response. Arthritis and Rheumatism. 2011;63 (10):2619.

60. Fremond ML, Duchamp M, Guerin V, et al. CD4 T-cell response to pandemic H1N1 specific vaccine after HSCT in pediatric recipients. Blood. 2010;116 (21):2010-12.

61. Galindo CM, Rosillon D, Holick CN, et al. Post-marketing study of autoimmune diseases following vaccination with human papillomavirus bivalent (types 16 and 18) recombinant vaccine in females in the US: Rationale and design. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S359.

62. Garbe E, Andersohn F, Bronder E, Klimpel A, Thomae M, Kurtal H. Association between drug use and acute immune thrombocytopenia in adults: Results from the berlin case-control surveillance study. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S147.

63. Geier DA, Young HA, Geier MR. Thimerosal exposure & increasing trends of premature puberty in the vaccine safety datalink. Indian Journal of Medical Research. 2010 April;131 (4):500-7. PMID 2010231604 MEDLINE PMID 20424300 (http://www.ncbi.nlm.nih.gov/pubmed/20424300).

64. George C, Taylor DN, Cathaud O. Electronic data capture (EDC) with digital pen and paper in a phase I clinical trial of a new influenza vaccine. Journal of Clinical Pharmacology. 2011 September;51 (9):1332.

65. Gilbert CL, Klopfer SO, Schodel FP, Bhuyan PK. Immunogenicity and Safety of a Hepatitis B Vaccine Manufactured by a Modified Process in Healthy Adults 50-64 years of age and >= 65 years of age. Journal of the American Geriatrics Society. 2011 Apr;59:S171-S2. PMID WOS:000289524600500.

66. Goldstone S. Efficacy of the quadrivalent hpv vaccine to prevent anal intraepithelial neoplasia among young men who have sex with men. Sexually Transmitted Infections. 2011 July;87 SUPPL. 1:A352.

67. Goss MA, Lievano F, Seminack M, Buchanan K, Dana A. No adverse signals observed after exposure to human papillomavirus type 6/11/16/18 vaccine during pregnancy: Five year pregnancy registry data. Birth Defects Research Part A - Clinical and Molecular Teratology. 2012 May;94 (5):367.

68. Gregg M, Blackhouse G, Loeb M, Goeree R. Economic evaluation of a cluster randomized controlled trial of an influenza immunization program directed at healthy children. Value in Health. 2012 June;15 (4):A242.

69. Grimaldi-Bensouda L, Alperovitch A, Besson G, et al. Guillain-barre syndrome, influenza-like illnesses and influenza vaccination during seasons with and without circulating a/H1N1 viruses. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S259-S60.

70. Grimaldi-Bensouda L, Michel M, Viallard JF, et al. A multicenter case-control prospective study to assess the risk of immune thrombocytopenia (ITP) associated with vaccines in adults using the PGRx-ITP registry. Blood. 2011;118 (21):2011-12.

71. Guissa VR, Aikawa NE, Sallum AM, et al. Influenza a H1N1/2009 vaccine in juvenile dermatomyositis: Rreduced response in patients under immunosuppressive agents. Arthritis and Rheumatism. 2011;63 (10):2020.

72. Haber P, Izurieta H, Patel M, Baggs J, Umesh P. Intussusception reports following RotaTeq (TM) vaccination: Vaccine adverse event reporting system (VAERS), 3/2006-02/2007. Pharmacoepidemiology and Drug Safety. 2007 Aug;16:S61-S2. PMID WOS:000248820200129.

73. Halperin SA, Gupta A, Jeanfreau R, et al. Clinical immunogenicity and reactogenicity of menveo(registered trademark) (MenACWY-CRM) versus menactra(registered trademark) (MCV4) in healthy 2-to-10-year-old children. Canadian Journal of Infectious Diseases and Medical Microbiology. 2010 Winter;21 (4):184.

74. Han GR, Pan C, Jiang HX, Zhao W, Cao MK. A PROSPECTIVE STUDY FOR THE EFFICACY AND SAFETY OF THE COMBINATION WITH 200 IU HBIG AND 20 UG RECOMBINANT HBV VACCINE FOR THE PREVENTION OF PERINATAL TRANSMISSION OF HEPATITIS B VIRUS (HBV) IN THE INFANTS BORN TO HBEAG plus AND HIGHLY VIREMIC MOTHERS. Hepatology. 2010 Oct;52 (4):531A-2A. PMID WOS:000288775600430.

75. Hansen J, Black S, Shinefield H, Lewis E, Malinoski F, Laufer D. Lack of association of seizures with receipt of seven valent pneumococcal conjugate vaccine (Prevnar (c), Wyeth). Clinical Infectious Diseases. 2001 Oct;33 (7):1149-. PMID WOS:000171226900381.

76. Harandi AA, Pakdaman H, Sahraian MA, Hosseini SK. Infectious diseases, related vaccinations, and risk of multiple sclerosis later in life: A case-control study. Neurology. 2012;78 (1):2012-04.

77. Harandi AM, Medaglini D, Shattock RJ. Vaccine adjuvants: A priority for vaccine research. Vaccine. 2010 11;28 (12):2363-6. PMID 2010132270 MEDLINE PMID 20064476 (http://www.ncbi.nlm.nih.gov/pubmed/20064476).

78. Harris K. A retrospective study of adverse drug reactions following the administration of influenza, pneumococcal and/or tetanus vaccines to geriatric nursing facility patients. Journal of the American Geriatrics Society. 2000 Aug;48 (8):S129-S. PMID WOS:000088887000538.

79. Harris MA, Shen H, Marion S, Tsui J, Teschke K. Associations between viral infections and Parkinson's disease in a case-control study. Movement Disorders. 2011 May;26 SUPPL. 2:S51-S2.

80. Heijstek MW, Heijstek M, Ott De Bruin L, et al. Vaccinations in pediatric autoimmune and autoinflammatory diseases: A systematic literature review. Clinical and Experimental

Rheumatology. 2011 March-April;29 (2):453.

81. Hitchon CA, Peschken CA, Mailley T, Dooley J, Nickerson P, El-Gabalawy HS. Environmental and genetic contributions to disease severity in north american natives with early inflammatory arthritis. Arthritis and Rheumatism. 2011;63 (10):2139.

82. Hua W, Tiernan R, Steffey A, Martin D, Wise R. Postmarketing safety review for rotarix1: Data from the vaccine adverse event reporting system (VAERS), April 2008-October 2009. Pharmacoepidemiology and Drug Safety. 2010 August;19 SUPPL. 1:S326-S7.

83. Huang WT, Chang S, Miller ER, et al. Safety assessment after recall of haemophilus influenzae type B (Hib) vaccine - United States, 2007-2008. Pharmacoepidemiology and Drug Safety. 2008 Aug;17:S116-S. PMID WOS:000258420100265.

84. Huu TN, Phuong NTM, Toan NT, et al. Assessment of the immunogenicity and safety of Quinvaxem(registered trademark) (DTwP-HepB- Hib) against diphtheria, pertussis, tetanus, hepatitis B and diseases caused by H. influenzae among healthy Vietnamese children. International Journal of Infectious Diseases. 2012 June;16 SUPPL.1:e304-e5.

85. Huu TN, Toan NT, Tuan HM, et al. Safety and reactogenicity of the 10-valent pneumococcal non-typeable Haemophilus influenzae protein D conjugate vaccine (PHiD-CV) co-administered with DTPa-HBV-IPV/Hib in Vietnamese infants. International Journal of Infectious Diseases. 2012 Jun;16:E304-E. PMID WOS:000308353101314.

86. Huu TN, Toan NT, Tuan HM, et al. Safety and reactogenicity of the 10-valent pneumococcal nontypeable Haemophilus influenzae protein D conjugate vaccine (PHiD-CV) co-administered with DTPa-HBV-IPV/Hib in Vietnamese infants. International Journal of Infectious Diseases. 2012 June;16 SUPPL.1:e304.

87. Jessen H. HPV-Impfung bei Mannern. JDDG - Journal of the German Society of Dermatology. 2012 June;10 SUPPL. 3:30.

88. Kang HY, Kim KH, Kim HM, Kim JK, El Khoury AC, Kim DS. Public heath and economic impact of rotavirus vaccination in Korea. Value in Health. 2010 November;13 (7):A549.

89. Kemmeren JM, Timmer SS, Van Der Maas NAT, De Melker HE. Comparing the tolerability of a fifth dose of an acellular pertussis-containing booster vaccination in differently primed children. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S360-S1.

90. King J, Vink P, Farley J, et al. Safety and immunogenicity of 3 doses of a 5-valent pneumococcal conjugate vaccine (PCV) in HIV and non-HIV-infected children <2 yrs of age. Pediatric Research. 1996 Apr;39 (4):1037-. PMID WOS:A1996UD23801037.

91. Kivitz A, Schechtman J, Texter M, Fichtner A, Chartash E. Assessment of immune responses to pneumococcal and influenza vaccines in patients with rheumatoid arthritis receiving certolizumab pegol. Arthritis and Rheumatism. 2011;63 (10):2011-11.

92. Koksal B, Ozbek O. Evaluation of the effects of influenza vaccination on asthma control in schoolage children. Allergy: European Journal of Allergy and Clinical Immunology. 2011 June;66 SUPPL. 94:665.

93. Kombo LA, Gerber MA, Pickering LK, Atreya CD, Breiman RF. Intussusception, infection, and immunization: summary of a workshop on rotavirus. Pediatrics. 2001 Aug;108 (2):E37. PMID 11483847.

94. Kumar D, Lien D, Campbell P, et al. Safety and immunogenicity of quadrivalent human papillomavirus vaccine in solid organ transplant recipients. American Journal of Transplantation. 2010 April;10 SUPPL. 4:206.

95. Lapeyre-Mestre M, Saussier C, Dumolard C, et al. Guillain Barre Syndrome and A(H1N1) 2009 vaccination: A French case-control study. Fundamental and Clinical Pharmacology. 2011 April;25 SUPPL. 1:104.

96. Lawrence J, He S, Hille D, et al. A study of RotaTeqTM (pentavalent rotavirus vaccine) in Chinese healthy adults, children and infants. International Journal of Infectious Diseases. 2012 June;16 SUPPL.1:e307.

97. Le NM, Ontaneda D, Moodley M, Worley S, Rensel M. Neuromyelitis optica: Disease onset in relationship with infections and vaccinations. Journal of Neurology. 2009 June;256 SUPPL. 2:S54.

98. Lepage AK, McIntyre RC, Kennedy SE, Pussell BA, Mackie FE. Safety and reactogenicity of the human papilloma virus vaccine in kidney transplant patients. Immunology and Cell Biology. 2011 October;89 (7):A22.

99. Li J, Daniel GW, Paeglow C, et al. Use of self-controlled risk-interval design in childhood vaccine safety. SOURCE Pharmacoepidemiology and Drug Safety (2011) 20 SUPPL. 1 (S242-S243). Date of Publication: August 2011 CONFERENCE NAME 27th International Conference on Pharmacoepidemiology and Therapeutic Risk Management CONFERENCE LOCATION Chicago, IL, United States CONFERENCE DATE 2011-08-14 to 2011-08-17. 2011.

100. Liu IF, Huang CC, Chan WL, Chen JW, Leu HB. Effect of annual influenza vaccination on mortality and hospitalization in patients with chronic heart disease. Journal of the American College of Cardiology. 2011 5;57 (14 SUPPL. 1):E598.

101. Loughlin J, Christopher Mast T, Wang FT, Doherty M, Seeger JD. A general safety evaluation of the pentavalent rotavirus vaccine. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S362.

102. Loughlin J, Florence W, Eng PM, Mast TC, Seeger JD. A post-marketing surveillance program for pentavalent rotavirus vaccine. Pharmacoepidemiology and Drug Safety. 2009 August;(2009) 18 (S1):S27.

103. Loulergue P, Rousseau B, Mir O, et al. Immunogenicity and safety of two doses of AS03Aadjuvanted influenza A/H1N1 2009 vaccine in cancer patients on chemotherapy - VACANCE study. Clinical Microbiology and Infection. 2011 May;17 SUPPL. 4:S320.

104. Lu Y, Ashworth LA, Bousvaros A, Carey R, Renna HD, Jacobson DL. Immune response to human papillomavirus vaccine (Gardasil) in girls and young women with inflammatory bowel disease. Gastroenterology. 2011 May;140 (5 SUPPL. 1):S158-S9.

105. Makris M, Polyzos K, Mavros M, Athanasiou S, Rafailidis P, Falagas M. Safety of hepatitis B, pneumococcal, and meningococcal vaccines in pregnancy: Evaluation of the published evidence. Clinical Microbiology and Infection. 2011 May;17 SUPPL. 4:S405.

106. Manoff S, McFetridge R, Liss C, et al. Antibody Persistence 10 Years after 1st and 2nd Doses of 23-Valent Pneumococcal Polysaccharide Vaccine (PN23), and Immunogenicity and Safety of 2nd and 3rd Doses in Older Adults. Journal of the American Geriatrics Society. 2010 Apr;58:25-6. PMID WOS:000276247100071.

107. Marman SE, Yousef E. Adverse reactions to Pneumovax pneumococcal vaccine-cases of hyperimmunization? Journal of Allergy and Clinical Immunology. 2007 Jan;119 (1):S96-S. PMID WOS:000251460400378.

108. Mehling M, Hilbert P, Fritz S, et al. Viral antigen-specific adaptive immune responses in fingolimod-treated MS patients. Multiple Sclerosis. 2010 October;16 (10 SUPPL. 1):S28-S9.

109. Menschik VD, Martin D. Empirical bayesian data mining as an FDA tool for prospective early detection of novel safety signals in the vaccine adverse events reporting system (VAERS): A case study of febrile seizures after an influenza virus. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S241.

110. Miossi R, Fuller R, Moraes JCB, et al. Influenza H1N1 vaccination in mixed connective tissue disease: Effectiveness and safety independent of disease or therapy. Arthritis and Rheumatism. 2011;63 (10):2011-11.

111. Mohty B, Bel M, Vukicevic M, et al. Immunogenicity and safety of the ASO3-adjuvanted A/09/H1N1 influenza vaccine in adult allogeneic haematopoietic stem cell transplantation recipients. Bone Marrow Transplantation. 2011 Apr;46:S21-S2. PMID WOS:000289195400046.

112. Moro PL, Arana J, Cano M, et al. Clinical patterns of adverse events after high-dose influenza vaccine reported to the vaccine adverse event reporting system. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S362.

113. Mullane KM, Mullane MR, Wong BMY, et al. Safety and immunogenicity of heat-treated zoster vaccine (ZVHT) in adults with solid tumor malignancy (STM). Journal of Clinical Oncology. 2011;29 (15):2011-06.

114. Mundt AJ. Overall efficacy of HPV-16/18 AS04-adjuvanted vaccine against grade 3 or greater cervical intraepithelial neoplasia: 4-Year End-of-study analysis of the randomised, double-blind PATRICIA trial. International Journal of Radiation Oncology Biology Physics. 2012 1;82 (3):1039-40. PMID 2012064415.

115. Naleway A, Weintraub E, Riedlinger K, et al. CC5-02: A Descriptive Study of Vaccinations Occurring During Pregnancy, 2002-2006. Clinical Medicine & Research. 2012 Aug;10 (3):187. PMID 22904519.

116. Namkoong JM, Park GC, Hwang S, Lee SG. Retransplantation for recurrent hepatitis A virus infection following liver transplantation for fulminant hepatitis A infection. Liver Transplantation. 2011 June;17 SUPPL. 1:S177-S8.

117. Nath K, Burel J, Pritchard AL, et al. Impaired immune response to influenza vaccination in chronic obstructive pulmonary disease. Internal Medicine Journal. 2011 September;41 SUPPL. 4:13.

118. Nkanza J, Lafleche J, Anyoti H, Ahmadipour N, Pless R, Law B. Adverse events following immunization (AEFI) with human papillomavirus vaccine and hepatitis B vaccines in females aged 9 to 26 Years in Canada, 2006-2010. Canadian Journal of Infectious Diseases and Medical Microbiology. 2010 Winter;21 (4):186.

119. Omenaca F, Merino JM, Tejedor JC, et al. Immunogenicity and Safety of the 10-Valent Pneumococcal Non-Typeable Haemophilus Influenzae Protein D Conjugate Vaccine (Phid-Cv) Following Primary and Booster Vaccination in Preterm-Born Children. Child Care Health and Development. 2010 Jan;36:78-9. PMID WOS:000273636500169.

120. Oude Bruin LM, Heijstek M, Bijl M, et al. Vaccinations in pediatric patients receiving DMARDs, glucocorti-costeroids or biological therapy: A systematic literature review. Clinical and Experimental Rheumatology. 2011 March-April;29 (2):444.

121. Ouwens M, Littlewood K, Sauboin C, et al. Impact of mmrv mass vaccination with or without a catch up program on the incidence of varicella complications in France. Value in Health. 2010 November;13 (7):A430.

122. Parisi CAS, Maspero JF, Gervasoni ME, Smaldini P, Docena G. Anaphylaxis to oral poliovirus vaccine in children with cow milk protein allergy. Journal of Allergy and Clinical Immunology. 2011 February;127 (2 SUPPL. 1):AB248.

123. Parrino J, Marquez F, Fisher CL, et al. Safety, tolerability, and immunogenicity of zoster vaccine in patients on chronic/maintenance corticosteroids. Arthritis and Rheumatism. 2011;63 (10):2011-11.

124. Pasoto SG, Calich ALG, Aikawa NE, et al. Antimalarials: A window of opportunity to improve the influenza A/H1N1 vaccine response in lupus patients under immunosuppressive agents. Arthritis and Rheumatism. 2011;63 (10):2011-11.

125. Perez-Lloret S, Rey MV, Bondon-Guitton E, Rascol O, Montastruc JL. Drugs related to Tourette-like syndrome: A case/non-case study in the French Pharmacovigilance database. Movement Disorders. 2012 June;27 SUPPL. 1:S440.

126. Prelog M, Schonlaub J, Zlamy M, Zimmerhackl L, Wurzner R. Reduced IgG antibody avidity in organ transplant recipients after varicella-zoster-virus vaccination. Clinical Microbiology and Infection. 2010 April;16 SUPPL. 2:S57.

127. Rahbar H, Abreu-Lanfrranco O, Singh A, et al. Risk factors for readmissions in patients 65 or older admitted for pneumonia. Journal of the American Geriatrics Society. 2012 April;60 SUPPL. 4:S84-S5.

128. Rajeshwari K. Prevention of rotavirus gastroenteritis. Indian Pediatrics. 2006 November;43 (11):1018. PMID 2007132628.

129. Rennels MB, Edwards KM, Keyserling HL, et al. Immunogenicity and safety of 7-valent pneumococcal-CRM(197) conjugate vaccine. Pediatric Research. 1996 Apr;39 (4):1082-. PMID WOS:A1996UD23801082.

130. Riaz H, Denyer M. The efficacy of bivalent and tetravalent HPV vaccination against cervical intraepithelial neoplasia and persistent HPV 16 and 18 infection. BJOG: An International Journal of Obstetrics and Gynaecology. 2012 June;119 SUPPL. 1:176-7.

131. Rohde KA, Moran JJM, Hayney MS. Effectiveness and safety of influenza vaccine in first six months post-lung transplant. Pharmacotherapy. 2011 October;31 (10):439e.

132. Rossi JF, Caumes B, Cymbalista F, et al. Immunogenicity and safety of one dose of influenza A H1N1v 2009 adjuvanted vaccine for unpreviously treated patients with binet-stage a chronic lymphoid leukaemia of B-cell type (B-CLL): Result of a prospective study conducted in 9 French centers by the intergroupe Francnullais GOELAMS/GFLLC-MW. Blood. 2010;116 (21):2010-12.

133. Rothberg M. Herpes zoster: is there a role for vaccination? Clinical Microbiology and Infection. 2010 April;16 SUPPL. 2:S52.

134. Rothova A, De Groot JDF, Mudrikova T. Reactivation of acute retinal necrosis after flu H1N1 vaccination. British Journal of Ophthalmology. 2011 February;95 (2):291. PMID 2011056354 MEDLINE PMID 20733030 (http://www.ncbi.nlm.nih.gov/pubmed/20733030).

135. Rousseau BJ, Loulergue P, Mir O, et al. Immunogenicity and Safety of Two Doses of As03a-Adjuvanted Influenza a H1n1v 2009 Vaccine in Cancer Patients on Chemotherapy - Vacance Study. Annals of Oncology. 2010 Oct;21:399-400. PMID WOS:000284592300521.

136. Rowhani-Rahbar A, Fireman B, Lewis N, Klein N, Baxter R. Use of the case-centered analytic method in epidemiologic studies of immunization safety. American Journal of

Epidemiology. 2011 1;173 SUPPL. 11:S159.

137. Rowhani-Rahbar A, Klein NP, Dekker CL, et al. Biologically plausible risk intervals to assess febrile seizure following immunization with influenza and pneumococcal conjugate vaccines. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S243.

138. Saah A. An evaluation of the long-term effectiveness, immunogenicity, and safety of gardasil in previously vaccinated women. Sexually Transmitted Infections. 2011 July;87 SUPPL. 1:A357-A8.

139. Saddier P, Tran T, Ackerson B, et al. Importance of medical record review for database studies: Example of Febrile Convulsion (FC). Pharmacoepidemiology and Drug Safety. 2010 August;19 SUPPL. 1:S322.

140. Samad L, Bashir HE, Marven S, et al. Intussusception in the first year of life: A UK national surveillance study. Archives of Disease in Childhood. 2010 April;95 SUPPL. 1:A1.

141. Sambatakou H. Adverse effect of influenza A/H1N1 vaccination on endothelial function of HIV infected patients. Clinical Microbiology and Infection. 2011 May;17 SUPPL. 4:S647.

142. Sammon CJ, McGrogan A, Snowball J, De Vries CS. Swine flu vaccination in pregnancy and associated miscarriage risk. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S58-S9.

143. Santanello NC, Mast C, Loughlin J, Seeger J. Cautionary example of potential exposure-based differential misclassification in a post-marketing vaccine safety study. Pharmacoepidemiology and Drug Safety. 2009 August;(2009) 18 (S1):S26.

144. Sargsyan N, Balyan AY. Retrospective study of pentavalent vaccine administration in children. New Armenian Medical Journal. 2010 September;4 (3):58.

145. Saussier CS, Hill CH, Castot AC. Number of Spontaneous Reports of Guillain-Barre Syndrome after Flu A(H1N1) Vaccination versus Expected Number in France. Drug Safety. 2010;33 (10):920-. PMID WOS:000282559300072.

146. Schilling A, Morgan T. High grade cervical dysplasia in young women after HPV vaccination. Reproductive Sciences. 2011 March;18 (3 SUPPL. 1):87A-8A.

147. Schwarz TF, Pauksens K, Juergens C, et al. An Open-label Trial to Assess the Safety of 13-Valent Pneumococcal Conjugate Vaccine in Older Adults, Previously Vaccinated With 23-Valent Pneumococcal Polysaccharide Vaccine. Journal of the American Geriatrics Society. 2011 Apr;59:S30-S. PMID WOS:000289524600086.

148. Scott P, Moss WJ, Gilani Z, Low N. Safety and immunogenicity of measles vaccine in HIV-infected children: Systematic review and meta-analysis. International Journal of Infectious Diseases. 2010 Mar;14:E70-E1. PMID WOS:000276298200166.

149. Shaikh AG, Termsarasab P, Nwankwo C, Katirji B. Guillain-Barre Syndrome Following Swine Influenza Vaccination. Muscle & Nerve. 2011 Oct;44 (4):656-. PMID WOS:000295402000120.

150. Sheikh Z, Abukwaik W, Souayah N. Ataxia after vaccination in united states, a report from the CDC/FDA vaccine adverse event reporting system [1990-2010]. Neurology. 2012;78 (1):2012-04.

151. Sheikh Z, Abukwaik W, Souayah N. Meningitis after vaccination in United States, a report from the CDC/FDA vaccine adverse event reporting system [1990-2010]. Neurology. 2012;78 (1):2012-04.

152. Shinjo SK, Neto ML, Silva CA, et al. Pandemic unadjuvanted influenza a 2009 vaccine in adult dermatomyositis and polymyositis: Immunogenicity independent of therapy and no harmful effect in disease. Arthritis and Rheumatism. 2011;63 (10):2011-11.

153. Sibunruang S. Two-site intradermal influenza vaccination in elderly. Clinical Microbiology and Infection. 2011 May;17 SUPPL. 4:S425-S6.

154. Small TN, Iovino CS, Abboud M, et al. Vaccine response in recipients of HLA mismatched unrelated double unit cord blood transplantation (CBT). Blood. 2010;116 (21):2010-12.

155. Small TN, Jakubowski AA, Barker JN, et al. Safety and immunogenicity of the 13-valent protein-conjugated pneumococcal vaccine(PCV13) following related and unrelated hematopoietic stem cell transplantation (HCT). Blood. 2011;118 (21):2011-12.

156. Smith K, Muther J, Duke A, McKee E, Wilson PC, James JA. Antibody secreting cells arising after vaccination from anti-cardiolipin positive individuals can produce antibodies which are bi-specific and bind to both cardiolipin and the vaccinating antigen. Arthritis and Rheumatism. 2011;63 (10):2011-11.

157. Smith LM, Srighanthan J, Poon KKY, Levesque LE. Quality of reporting of harms in randomized controlled trials: An example using human papillomavirus (HPV) vaccines. Pharmacoepidemiology and Drug Safety. 2010 August;19 SUPPL. 1:S82.

158. Sonmezer M, Tuncer Ertem G, Ucal Bakkal S, Bulut C, Kinikli S, Tulek N. The side effects of H1N1 pandemic vaccine in pregnant women and comparison to other healthcare workers. Clinical Microbiology and Infection. 2011 May;17 SUPPL. 4:S830.

159. Steffey A, Lizewski R, Sutherland A, Roberts J, Miller N, Wise RP. Acute pancreatitis after quadrivalent human papillomavirus vaccination: Reports to a post-marketing passive surveillance system, 2006-2009. Pharmacoepidemiology and Drug Safety. 2010 August;19 SUPPL. 1:S186.

160. Suryakiran PV, Vinals C, Vanfraechem K, Han HH, Guerra Y, Buyse H. The human

rotavirus vaccine rix4414 in infants: An integrated safety summary (ISS). Acta Paediatrica, International Journal of Paediatrics. 2011 December;100 SUPPL. 463:56-7.

161. Swamy GK. Phase II Study To Assess the Safety and Immunogenicity of Two Dose Levels of 2009 H1N1 Influenza Vaccine in Pregnant Women. Reproductive Sciences. 2011 Mar;18 (3):235A-A. PMID WOS:000291721701143.

162. Tan SJ, Chean R, Hurt A, et al. Follow-up response of renal transplant recipients to booster influenza a H1N1 vaccine. Nephrology. 2011 September;16 SUPPL. 1:78.

163. Trabert B, Graubard BI, Erickson RL, McGlynn KA. Mumps, orchitis and testicular germ cell tumors: A cause for concern? SOURCE American Journal of Epidemiology (2011) 173 SUPPL. 11 (S165). Date of Publication: 1 Jun 2011 CONFERENCE NAME 3rd North American Congress of Epidemiology CONFERENCE LOCATION Montreal, QC, Canada CONFERENCE DATE 2011-06-21 to 2011-06-24. 2011.

164. Tran GMK, Gerbaud L, Caprani A. Auto-immune thrombocytopenia after Measles Mumps Rubella MMR vaccination: molecular mimicry of measles virus phosphoprotein with platelet gpIIb. Retrovirology. 2010 May;7:66-7. PMID WOS:000278329600210.

165. Tricotel A, Fagot J, Tubert-Bitter P, Escolano S, Weill A, Castot A. Human papillomavirus vaccine and autoimmune disorders: A cohort study of 5.8 millions of adolescents and young women. Two years follow-up results. Fundamental and Clinical Pharmacology. 2011 April;25 SUPPL. 1:101.

166. Tseng YR, Chen HL, Hu FC, et al. Symptomatic and fulminant hepatitis B in infancy after universal hepatitis B vaccination: Clinical outcome and risk factors. Hepatology. 2011 October;54 SUPPL. 1:703A.

167. Ulanova M, Hawdon N, Nix E, Ferroni G, McCready W. Risk of invasive haemophilus influenzae type B (Hib) disease and response to Hib vaccine in patients with chronic renal failure. Canadian Journal of Infectious Diseases and Medical Microbiology. 2011 Spring;22 SUPPL. SA:20A.

168. Umapathi T. International collaborative safety monitoring for pandemic 2009 H1N1 vaccines: Estimation of the risk of Guillain-Barre syndrome-Singapore experience. Journal of the Peripheral Nervous System. 2011 September;16 SUPPL. 3:S137-S8.

169. Van Besouw NM, Zuijderwijk JM, Noorlander I, De Leeuw Van Weenen NJ, Verjans GMGM, Weimar W. Varicella zoster virus vaccination induces virus-specific class II restricted memory responses in seronegative kidney transplant recipients. American Journal of Transplantation. 2012 May;12 SUPPL. 3:193.

170. Van Der Maas N, Wesselo C, Phaff T, Vermeer-de Bondt P, Oostvogels B. Adverse events following bivalent human papillomavirus vaccination reported to the enhanced passive surveillance system of the Netherlands. Pharmacoepidemiology and Drug Safety. 2010

August;19 SUPPL. 1:S324.

171. Van Der Maas N, Zonnenberg-Hoff I, Kemmeren J, De Melker H. Immediate occurring adverse events following bivalent human papillomavirus vaccination in the Netherlands. Pharmacoepidemiology and Drug Safety. 2010 August;19 SUPPL. 1:S329-S30.

172. Van Praet S, Puertolas PA, Alvarez SZ. Study on Pandemrix pharmacovigilance at CHU St. Pierre. International Journal of Clinical Pharmacy. 2011 April;33 (2):379-80.

173. Vardeny O, Hermanson MP, Moran JM, Johnson MR, Sweitzer NK. A randomized study of double-dose versus single-dose influenza vaccination in patients with heart failure. Circulation. 2011;124 (21):2011-11.

174. Velazquez FR, Colindres R, Grajales C, et al. Postmarketing surveillance of intussusception following mass introduction of the human rotavirus vaccine in Mexico: An interim analysis. Acta Paediatrica, International Journal of Paediatrics. 2010 December;99 SUPPL. 462:92.

175. Verity C, Stellitano L, Winstone A, Andrews N, Stowe J, Miller E. Is guillain barre syndrome/fisher syndrome associated with swine 'flu vaccination in children? Results: from a UK-wide epidemiological study. SOURCE Archives of Disease in Childhood (2011) 96 SUPPL. 1 (A5-A6). Date of Publication: April 2011 CONFERENCE NAME Annual Conference of the Royal College of Paediatrics and Child Health, RCPCH 2011 CONFERENCE LOCATION Warwick, United Kingdom CONFERENCE DATE 2011-04-05 to 2011-04-07. 2011.

176. Vesikari T, Esposito S, Kimura A, et al. Immunogenicity of an investigational multicomponent meningococcal serogroup B vaccine in healthy infants at 2, 4 and 6 months of age. Canadian Journal of Infectious Diseases and Medical Microbiology. 2010 Winter;21 (4):183.

177. Wade A, Crawford G, Pumford N, McConnachie A. Sensitivity of pro's in evaluating adverse events in people receiving influenza vaccination. Value in Health. 2011 November;14 (7):A282.

178. Walker AM, Puenpatom T, Li J, et al. Search for new safety signals in the patterns of care following MMR vaccine. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S347-S8.

179. Wang FT, Mast TC, Glass RJ, Loughlin J, Seeger JD. Effectiveness of the pentavalent rotavirus vaccine in preventing gastroenteritis in the United States: A claims-based analysis. Pharmacoepidemiology and Drug Safety. 2009 August;(2009) 18 (S1):S26.

180. Wang M, Khromava A, Mahmood A, Dickson N. Pregnant women receiving tetanus-diphtheria-acellular pertussis (Tdap) vaccine: 6 Years of adacel vaccine pregnancy registry data. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S60-S1.

181. Wijnans E, Dieleman J, Voordouw A, Sturkenboom M. Estimating the effectiveness of pandemic influenza vaccination in a dutch population. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S363.

182. Winnick A, Mitsiev I, Diflo T, Fahmy A, Morgan G, Teperman L. The effects of H1N1 vaccination in liver transplantation. Liver Transplantation. 2011 June;17 SUPPL. 1:S94-S5.

183. Winston D, Mullane K, Boeckh M, et al. Safety and immunogenicity of heat-treated zoster vaccine (ZV(HT)) in adults with allogeneic or autologous hematopoietic stem-cell transplants (HCT). Biology of Blood and Marrow Transplantation. 2011 February;17 (2 SUPPL. 1):S273.

184. Wood D, Group WHOIC. WHO informal consultation on quality, safety and efficacy specifications for live attenuated rotavirus vaccines Mexico City, Mexico, 8-9 February 2005. Vaccine. 2005 Dec 1;23 (48-49):5478-87. PMID 16129525.

185. Wood N, Cannings K, Quinn H, et al. Rotavirus vaccines and intussusception: An increased risk. Journal of Paediatrics and Child Health. 2011 May;47 SUPPL. 2:16.

186. Yuki N, Ihara T, Ito S, Odaka M. Do influenza vaccines induce anti-ganglioside antibodies? Journal of the Peripheral Nervous System. 2010 September;15 (3):291.

187. Zaiem A, El Adii S, Kastalli S, et al. Adverse effect following immunization associated with diphtheria-tetanus-pertussis and oral poliomyelitis vaccine. Drug Safety. 2009 2009;32 (10):942.

188. Zangwill KM, Greenberg DP, Wong VK, et al. Safety and immunogenicity of two lots of pneumococcal conjugate vaccine in infants. Pediatric Research. 1996 Apr;39 (4):1116-. PMID WOS:A1996UD23801116.

189. Zhang J, Delzell ES, Xie F, et al. The use, safety and effectiveness of herpes zoster vaccination in individuals with inflammatory and autoimmune diseases. Pharmacoepidemiology and Drug Safety. 2011 August;20 SUPPL. 1:S363-S4.

190. Zhang J, Xie F, Delzell ES, et al. Safety of zoster vaccine in individuals with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and inflammatory bowel disease. Arthritis and Rheumatism. 2011;63 (10):2011-11.

191. Zhang J, Xie FL, Delzell ES, et al. Safety of Zoster Vaccine in Individuals with Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, and Inflammatory Bowel Disease. Arthritis and Rheumatism. 2011 Oct;63 (10):S318-S. PMID WOS:000297621501006.

Rejected for Adverse events (or lack of) not mentioned – 438

1. From the Centers for Disease Control and Prevention. Status report on the Childhood Immunization Initiative: national, state, and urban area vaccination coverage levels among children aged 19-35 months--United States, 1996. JAMA. 1997 Aug 27;278 (8):622-3. PMID 9272882.

2. Erratum: Safety and immunogenicity of a fully liquid vaccine containing five-component pertussis-diphtheria-tetanus-inactivated poliomyelitis- Haemophilus influenzae type b conjugate vaccines administered at two, four, six and 18 months of age (Clinical Journal of Infectious Diseases and Medical Microbiology (2007) 18, 4, (241-248)). Canadian Journal of Infectious Diseases and Medical Microbiology. 2007 September/October;18 (5):318. PMID 2007589433.

3. FDA panel recommends continued use of rotarix and rotateq vaccines viral DNA contamination. Formulary. 2010 May;45 (5):167. PMID 2010397508.

4. Rotavirus vaccination and risk of intussusception: Investigation of a possible safety signal. Australian Prescriber. 2011 April;34 (2):47. PMID 2011237396.

5. Aaby P, Benn CS. Non-specific and sex-differential effects of routine vaccines: what evidence is needed to take these effects into consideration in low-income countries? Human Vaccines. 2011 Jan 1;7 (1):120-4. PMID 21278492.

6. Aaby P, Martins CL, Garly ML, et al. Non-specific effects of standard measles vaccine at 4.5 and 9 months of age on childhood mortality: randomised controlled trial. British Medical Journal. 2010 Nov;341 PMID WOS:000285090100006.

7. Abbott KC, Yuan CM, Lee JL. Nothing to sneeze at: Efficacy and cost-effectiveness of the influenza vaccine in patients receiving long-term dialysis. American Journal of Kidney Diseases. 2011 May;57 (5):651-3. PMID 2011205912 MEDLINE PMID 21496725 (http://www.ncbi.nlm.nih.gov/pubmed/21496725).

8. Abramson JS, Almquist JR, Jenkins RR, et al. Prioritisation of routine vaccines: a mistake for the USA. The Lancet. 2008 20080315/21;371 (9616):881-2. PMID 2008126512 MEDLINE PMID 18342670 (http://www.ncbi.nlm.nih.gov/pubmed/18342670).

9. Adamkiewicz TV, Silk BJ, Howgate J, et al. Effectiveness of the 7-valent pneumococcal conjugate vaccine in children with sickle cell disease in the first decade of life. Pediatrics. 2008 Mar;121 (3):562-9. PMID WOS:000253780100015.

10. Adegbola RA, Leach A, Mulholland K, et al. Antigenuria in Gambian infants following immunization with a Haemophilus influenzae type b polyribosylribitol phosphate-tetanus toxoid protein conjugate (PRP-T) vaccine. Diagnostic Microbiology & Infectious Disease. 1998 Sep;32 (1):15-9. PMID 9791752.

11. Ahlgren C, Oden A, Haghighi S, Andersen O, Bergstrom T, Lycke J. The effect of live

attenuated measles vaccine and measles infection on measles antibody levels in serum and CSF of multiple sclerosis patients. Multiple Sclerosis. 2010 October;16 (10 SUPPL. 1):S28.

12. Ali NK, Bhutta ZA. A review of rotavirus diarrhea in Pakistan: How much do we know? Journal of the College of Physicians and Surgeons Pakistan. 2003 1;13 (5):297-301. PMID 2003256170 MEDLINE PMID 12757686 (http://www.ncbi.nlm.nih.gov/pubmed/12757686).

13. AlonsoDeVelasco E, Verheul AF, Verhoef J, Snippe H. Streptococcus pneumoniae: virulence factors, pathogenesis, and vaccines. Microbiological Reviews. 1995 Dec;59 (4):591-603. PMID 8531887.

14. Amador JJ, Vasquez J, Orozco M, et al. Rotavirus disease burden, Nicaragua 2001-2005: defining the potential impact of a rotavirus vaccination program. International Journal of Infectious Diseases. 2010 July;14 (7):e592-e5. PMID 2010324049 MEDLINE PMID 20022778 (http://www.ncbi.nlm.nih.gov/pubmed/20022778).

15. Ameratunga SN, Lennon DR, Entwistle B, Robinson E, Ameratunga RV. The immunogenicity of Haemophilus influenzae: Meningococcal protein conjugate vaccine in Polynesian and non-Polynesian New Zealand infants. Journal of Paediatrics and Child Health. 1997 1997;33 (2):138-41. PMID 1997158608 MEDLINE PMID 9145357 (http://www.ncbi.nlm.nih.gov/pubmed/9145357).

16. Anar C, Bicmen C, Yapicioglu S, Unsal I, Halilcolar H, Yilmaz U. Evaluation of clinical data and antibody response following influenza vaccination in patients with chronic obstructive pulmonary disease. New Microbiologica. 2010 Apr;33 (2):117-27. PMID WOS:000277651700003.

17. Anderson EL, Kennedy DJ, Geldmacher KM, Donnelly J, Mendelman PM. Immunogenicity of heptavalent pneumococcal conjugate vaccine in infants. Journal of Pediatrics. 1996 May;128 (5 Pt 1):649-53. PMID 8627437.

18. Andrews N, Waight P, Yung CF, Miller E. Age-specific effectiveness of an oil-in-water adjuvanted pandemic (H1N1) 2009 vaccine against confirmed infection in high risk groups in England. Journal of Infectious Diseases. 2011 1;203 (1):32-9. PMID 2011084070 MEDLINE PMID 21148494 (http://www.ncbi.nlm.nih.gov/pubmed/21148494).

19. Andrews N, Waight PA, Borrow R, et al. Using the indirect cohort design to estimate the effectiveness of the seven valent pneumococcal conjugate vaccine in England and Wales. PLoS ONE. 2011;6 (12) PMID 2011662171.

20. Ansaldi F, Sticchi L, Durando P, et al. Decline in pneumonia and acute otitis media after the introduction of childhood pneumococcal vaccination in Liguria, Italy. Journal of International Medical Research. 2008 2008;36 (6):1255-60. PMID 2009188000 MEDLINE PMID 19094434 (http://www.ncbi.nlm.nih.gov/pubmed/19094434).

21. Anttila M, Eskola J, Ahman H, Kayhty H. Differences in the avidity of antibodies evoked by

four different pneumococcal conjugate vaccines in early childhood. Vaccine. 1999 9;17 (15 16):1970-7. PMID 1999131917 MEDLINE PMID 10217596 (http://www.ncbi.nlm.nih.gov/pubmed/10217596).

22. Ardern-Holmes SL, Lennon D, Pinnock R, et al. Trends in hospitalization and mortality from rotavirus disease in New Zealand infants. Pediatric Infectious Disease Journal. 1999 July;18 (7):614-9. PMID 1999261413 MEDLINE PMID 10440437 (http://www.ncbi.nlm.nih.gov/pubmed/10440437).

23. Arkwright PD, Patel L, Moran A, Haeney MR, Ewing CI, David TJ. Atopic eczema is associated with delayed maturation of the antibody response to pneumococcal vaccine. Clinical and Experimental Immunology. 2000 2000;122 (1):16-9. PMID 2000364135 MEDLINE PMID 11012612 (http://www.ncbi.nlm.nih.gov/pubmed/11012612).

24. Auriel E, Gadoth A, Regev K, Karni A. Seasonal and H1N1v influenza vaccines in MS: safety and compliance. Journal of the Neurological Sciences. 2012 Mar 15;314 (1-2):102-3. PMID 22056469.

25. Auvinen A, Hakulinen T, Groves F. Haemophilus influenzae type B vaccination and risk of childhood leukaemia in a vaccine trial in Finland. British Journal of Cancer. 2000 2000;83 (7):956-8. PMID 2000333622 MEDLINE PMID 10970701 (http://www.ncbi.nlm.nih.gov/pubmed/10970701).

26. Babu GR, Bhatnagar T. Influenza vaccination to elderly: Quantifying the potential role of unmeasured confounders through an example. Internet Journal of Epidemiology. 2010;9 (1) PMID 2011071658.

27. Bakir M, Yagci A, Ulger N, et al. Pharyngeal colonization with Haemophilus influenzae type b among healthy Turkish infants and children. Pediatrics International. 2002 Aug;44 (4):381-6. PMID 12139561.

28. Baldo V, Baldovin T, Pellegrini M, et al. Immunogenicity of Three Different Influenza Vaccines against Homologous and Heterologous Strains in Nursing Home Elderly Residents. Clinical & Developmental Immunology. 2010 PMID WOS:000277714800001.

29. Balmer P, Orrow RB, Arkwright PD. The 23-valent pneumococcal polysaccharide vaccine does not provide additional serotype antibody protection in children who have been primed with two doses of heptavalent pneumococcal conjugate vaccine. Vaccine. 2007 Aug;25 (34):6321-5. PMID WOS:000248955000006.

30. Barry DW, Mayner RE, Hochstein HD, et al. Comparative trial of influenza vaccines. II. Adverse reactions in children and adults. Am J Epidemiol. 1976 Jul;104 (1):47-59. PMID 132867.

31. Baxendale HE, Keating SM, Johnson M, Southern J, Miller E, Goldblatt D. The early kinetics of circulating pneumococcal-specific memory B cells following pneumococcal

conjugate and plain polysaccharide vaccines in the elderly. Vaccine. 2010 Jul 5;28 (30):4763-70. PMID 20471437.

32. Bayard V, DeAntonio R, Contreras R, et al. Impact of rotavirus vaccination on childhood gastroenteritis-related mortality and hospital discharges in Panama. International Journal of Infectious Diseases. 2012 February;16 (2):e94-e8. PMID 2012044273 MEDLINE PMID 22154592 (http://www.ncbi.nlm.nih.gov/pubmed/22154592).

33. Bedford HE, Elliman DAC. The adverse effects of vaccines - Fact and fiction. Current Paediatrics. 2002 2002;12 (1):62-6. PMID 2002014928.

34. Bennett EM, Domachowske JB. Progress in adolescent immunization. Clinical Microbiology Newsletter. 2007 1;29 (19):143-8. PMID 2007450065.

35. Beran J, Vesikari T, Wertzova V, et al. Efficacy of inactivated split-virus influenza vaccine against culture-confirmed influenza in healthy adults: a prospective, randomized, placebo-controlled trial. J Infect Dis. 2009 Dec 15;200 (12):1861-9. PMID 19909082.

36. Berger F, Njamkepo E, Minaberry S, et al. Investigation on a pertussis outbreak in a military school: risk factors and approach to vaccine efficacy. Vaccine. 2010 Jul 19;28 (32):5147-52. PMID 20541009.

37. Bhatla N, Suri V, Basu P, Shastri S, Datta SK, Bi D. Erratum: Immunogenicity and safety of human papillomavirus-16/18 AS04-adjuvanted cervical cancer vaccine in healthy Indian women (The Journal of Obstetrics and Gynaecology Research 36:1 (123-132)). Journal of Obstetrics and Gynaecology Research. 2010 April;36 (2):466. PMID 2010197269.

38. Block SL, Busman TA, Paris MM, Bukofzer S. Comparison of five-day cefdinir treatment with ten-day low dose amoxicillin/clavulanate treatment for acute otitis media. Pediatric Infectious Disease Journal. 2004 Sep;23 (9):834-8. PMID 15361722.

39. Bloom DE, Canning D, Shenoy ES. The effect of vaccination on children's physical and cognitive development in the Philippines. Applied Economics. 2012;44 (21):2777-83. PMID WOS:000301540200010.

40. Bluestone CD. Pneumococcal conjugate vaccine - Impact on otitis media and otolaryngology. Archives of Otolaryngology-Head & Neck Surgery. 2001 Apr;127 (4):464-7. PMID WOS:000167936100022.

41. Blum MD, Dagan R, Mendelman PM, et al. A comparison of multiple regimens of pneumococcal polysaccharide-meningococcal outer membrane protein complex conjugate vaccine and pneumococcal polysaccharide vaccine in toddlers. Vaccine. 2000 May 8;18 (22):2359-67. PMID 10738092.

42. Bogaards JA, Coupe VMH, Xiridou M, Meijer CJLM, Wallinga J, Berkhof J. Long-term impact of human papillomavirus vaccination on infection rates, cervical abnormalities, and

cancer incidence. Epidemiology. 2011 July;22 (4):505-15. PMID 2011438768 MEDLINE PMID 21540743 (http://www.ncbi.nlm.nih.gov/pubmed/21540743).

43. Bolgiano B, Mawas F, Burkin K, et al. A retrospective study on the quality of Haemophilus influenzae type b vaccines used in the UK between 1996 and 2004. Human Vaccines. 2007 Sep-Oct;3 (5):176-82. PMID 17786035.

44. Bomprezzi R, Wildemann B. Acute disseminated encephalomyelitis following vaccination against human papilloma virus. Neurology. 2010 Mar 9;74 (10):864; author reply -5. PMID 20211914.

45. Booy R, Hodgson SA, Slack MPE, Anderson EC, Mayonwhite RT, Moxon ER. Invasive Haemophilus-Influenzae Type-B Disease in the Oxford Region (1985-91). Archives of Disease in Childhood. 1993 Aug;69 (2):225-8. PMID WOS:A1993LQ09400014.

46. Braeckman T, Van Herck K, Raes M, Vergison A, Sabbe M, Van Damme P. Rotavirus Vaccines in Belgium Policy and Impact. Pediatric Infectious Disease Journal. 2011 Jan;30 (1):S21-S4. PMID WOS:000285795900005.

47. Breiman RF, Zaman K, Armah G, et al. Analyses of health outcomes from the 5 sites participating in the Africa and Asia clinical efficacy trials of the oral pentavalent rotavirus vaccine. Vaccine. 2012 27;30 (SUPPL. 1):A24-A9. PMID 2012230571 MEDLINE PMID 22520132 (http://www.ncbi.nlm.nih.gov/pubmed/22520132).

48. Bricks LF, Berezin E. Impact of pneumococcal conjugate vaccine on the prevention of invasive pneumococcal diseases. Jornal de Pediatria. 2006 July/August;82 (SUPPL. 1):S67-S74. PMID 2006533782 MEDLINE PMID 16721440 (http://www.ncbi.nlm.nih.gov/pubmed/16721440).

49. Brown B, Blas M, Cabral A, Carcamo C, Gravitt P, Halsey N. Randomized trial of HPV4 vaccine assessing the response to HPV4 vaccine in two schedules among Peruvian female sex workers. Vaccine. 2012 16;30 (13):2309-14. PMID 2012130238 MEDLINE PMID 22306855 (http://www.ncbi.nlm.nih.gov/pubmed/22306855).

50. Buettcher M, Baer G, Bonhoeffer J, Schaad UB, Heininger U. Three-year surveillance of intussusception in children in Switzerland. Pediatrics. 2007 September;120 (3):473-80. PMID 2007433961 MEDLINE PMID 17766518 (http://www.ncbi.nlm.nih.gov/pubmed/17766518).

51. Burwen DR, La Voie L, Braun MM, Houck P, Ball R. Evaluating adverse events after vaccination in the Medicare population. Pharmacoepidemiology & Drug Safety. 2007 Jul;16 (7):753-61. PMID 17385786.

52. Butler JC, Breiman RF, Campbell JF, Lipman HB, Broome CV, Facklam RR. Pneumococcal Polysaccharide Vaccine Efficacy - an Evaluation of Current Recommendations. Jama-Journal of the American Medical Association. 1993 Oct;270 (15):1826-31. PMID WOS:A1993MB46400025.

53. Cai Y, Rodriguez S, Rameswaran R, Draghia-Akli R, Juba Jr RJ, Hebel H. Production of pharmaceutical-grade plasmids at high concentration and high supercoiled percentage. Vaccine. 2010 23;28 (8):2046-52. PMID 2010119217 MEDLINE PMID 19896448 (http://www.ncbi.nlm.nih.gov/pubmed/19896448).

54. Campitelli MA, Rosella LC, Stukel TA, Kwong JC. Influenza vaccination and all-cause mortality in community-dwelling elderly in Ontario, Canada, a cohort study. Vaccine. 2010 Dec 16;29 (2):240-6. PMID 21044667.

55. Carmo GMID, Yen C, Cortes J, et al. Decline in diarrhea mortality and admissions after routine childhood rotavirus immunization in Brazil: A time-series analysis. PLoS Medicine. 2011;8 (4):11. PMID 2011240140.

56. Carty CL, Heagerty P, Nakayama K, et al. Inflammatory response after influenza vaccination in men with and without carotid artery disease. Arterioscler Thromb Vasc Biol. 2006 Dec;26 (12):2738-44. PMID 17023683.

57. Castilla J, Beristain X, Martinez-Artola V, et al. Effectiveness of rotavirus vaccines in preventing cases and hospitalizations due to rotavirus gastroenteritis in Navarre, Spain. Vaccine. 2012 Jan;30 (3):539-43. PMID WOS:000301812300007.

58. Castilla J, Moran J, Martinez-Artola V, et al. Effectiveness of the monovalent influenza A(H1N1)2009 vaccine in Navarre, Spain, 2009-2010: Cohort and case-control study. Vaccine. 2011 11;29 (35):5919-24. PMID 2011409529 MEDLINE PMID 21723358 (http://www.ncbi.nlm.nih.gov/pubmed/21723358).

59. Cavenaugh JS, Awi D, Mendy M, Hill AVS, Whittle H, McConkey SJ. Partially Randomized, Non-Blinded Trial of DNA and MVA Therapeutic Vaccines Based on Hepatitis B Virus Surface Protein for Chronic HBV Infection. PLoS ONE. 2011 Feb;6 (2) PMID WOS:000287369200001.

60. Chan TC, Hung IFN, Luk JKH, et al. Efficacy of dual vaccination of pandemic H1N1 2009 influenza and seasonal influenza on institutionalized elderly: A one-year prospective cohort study. Vaccine. 2011 13;29 (44):7773-8. PMID 2011557539 MEDLINE PMID 21821084 (http://www.ncbi.nlm.nih.gov/pubmed/21821084).

61. Chan TC, Hung IFN, Luk JKH, et al. Prevention of Mortality and Pneumonia Among Nursing Home Older Adults by Dual Pneumococcal and Seasonal Influenza Vaccination During a Pandemic Caused by Novel Pandemic Influenza A (H1N1). Journal of the American Medical Directors Association. 2012.

62. Chang YC, Chou YJ, Liu JY, Yeh TF, Huang N. Additive benefits of pneumococcal and influenza vaccines among elderly persons aged 75 years or older in Taiwan - A representative population-based comparative study. Journal of Infection. 2012;65:231-8.

63. Chen RT, Rastogi SC, Mullen JR, et al. The vaccine adverse event reporting system (VAERS). Vaccine. 1994 1994;12 (6):542-50. PMID 1994117962 MEDLINE PMID 8036829 (http://www.ncbi.nlm.nih.gov/pubmed/8036829).

64. Chen WH, El-Kamary SS. Vaccines for enteric infections. Current Opinion in Gastroenterology. 2012 January;28 (1):18-23. PMID 2012089077 MEDLINE PMID 22080824 (http://www.ncbi.nlm.nih.gov/pubmed/22080824).

65. Chen YE, Beasley S, Grimwood K. Intussusception and rotavirus associated hospitalisation in New Zealand. Archives of Disease in Childhood. 2005 October;90 (10):1077-81. PMID 2005448132 MEDLINE PMID 15964860 (http://www.ncbi.nlm.nih.gov/pubmed/15964860).

66. Cherian MP, Al-Kanani KA, Al Qahtani SS, et al. The rising incidence of type 1 diabetes mellitus and the role of environmental factors - Three decade experience in a primary care health center in Saudi Arabia. Journal of Pediatric Endocrinology and Metabolism. 2010 2010;23 (7):685-95. PMID 2010493713 MEDLINE PMID 20857841 (http://www.ncbi.nlm.nih.gov/pubmed/20857841).

67. Chernin LR, Swender D, Hostoffer RW, Jr. Cracking the shell on egg-hypersensitive patients and egg-containing vaccines. Journal of the American Osteopathic Association. 2011 Oct;111 (10 Suppl 6):S5-6. PMID 22086894.

68. Chi R-C, Reiber GE, Neuzil KM. Influenza and pneumococcal vaccination in older veterans: results from the behavioral risk factor surveillance system. Journal of the American Geriatrics Society. 2006 Feb;54 (2):217-23. PMID 16460371.

69. Choo S, Zhang QB, Seymour L, Akhtar S, Finn A. Primary and booster salivary antibody responses to a 7-valent pneumococcal conjugate vaccine in infants. Journal of Infectious Diseases. 2000 Oct;182 (4):1260-3. PMID WOS:000089712100037.

70. Christenson B, Hedlund J, Lundbergh P, Ortqvist A. Additive preventive effect of influenza and pneumococcal vaccines in elderly persons. European Respiratory Journal. 2004 Mar;23 (3):363-8. PMID 15065822.

71. Christenson B, Pauksen K, Sylvan SPE. Effect of influenza and pneumococcal vaccines in elderly persons in years of low influenza activity. Virology Journal. 2008;5:52. PMID 18442371.

72. Clark. Erratum: Safety, efficacy, and immunogenicity of a live, quadrivalent human-bovine reassortant rotavirus vaccine in healthy infants (Journal of Pediatrics (February 2004) 144 (184-190)). Journal of Pediatrics. 2004 Apr;144 (4):558. PMID 2004161706.

73. Clark HF, Lawley D, Mallette LA, DiNubile MJ, Hodinka RL. Decline in Cases of Rotavirus Gastroenteritis Presenting to The Children's Hospital of Philadelphia after Introduction of a Pentavalent Rotavirus Vaccine. Clinical and Vaccine Immunology. 2009 Mar;16 (3):382-6. PMID WOS:000263854200014.

74. Clark HF, Lawley D, Shrager D, et al. Infant immune response to human rotavirus serotype G1 vaccine candidate reassortant WI79-9: Different dose response patterns to virus surface proteins VP7 and VP4. Pediatric Infectious Disease Journal. 2004 March;23 (3):206-11. PMID 2004121117 MEDLINE PMID 15014293 (http://www.ncbi.nlm.nih.gov/pubmed/15014293).

75. Conterno LO, da Silva Filho CR, Ruggeberg JU, Heath PT. WITHDRAWN: Conjugate vaccines for preventing meningococcal C meningitis and septicaemia. Cochrane Database of Systematic Reviews. 2011 (7):CD001834. PMID 21735387.

76. Correia JB, Patel MM, Nakagomi O, et al. Effectiveness of Monovalent Rotavirus Vaccine (Rotarix) against Severe Diarrhea Caused by Serotypically Unrelated G2P[4] Strains in Brazil. Journal of Infectious Diseases. 2010 Feb;201 (3):363-9. PMID WOS:000273441000008.

77. Cortes JE, Curns AT, Tate JE, et al. Rotavirus vaccine and health care utilization for diarrhea in U.S. children. New England Journal of Medicine. 2011 22;365 (12):1108-17. PMID 2011531196 MEDLINE PMID 21992123 (http://www.ncbi.nlm.nih.gov/pubmed/21992123).

78. Cortese MM, Staat MA, Weinberg GA, et al. Underestimates of intussusception rates among US infants based on inpatient discharge data: implications for monitoring the safety of rotavirus vaccines. Journal of Infectious Diseases. 2009 Nov 1;200 Suppl 1:S264-70. PMID 19817607.

79. Couch RB. Lessons learned from clinical trials in 1976 and 1977 of vaccines for the Newly Emerged swine and Russian Influenza A/H1N1 viruses. Birkhauser Advances in Infectious Diseases. 2011;(359-371). Date of Publication (2011 Influenza Vaccines for the Future, Book Series Title: ISBN 9783034602785):volume. PMID 2011373902.

80. Cowling BJ, Fang VJ, Nishiura H, et al. Increased risk of noninfluenza respiratory virus infections associated with receipt of inactivated influenza vaccine. Clinical Infectious Diseases. 2012 15;54 (12):1778-83. PMID 2012305675.

81. Crocetti E, Arniani S, Bordoni F, Maciocco G, Zappa M, Buiatti E. Effectiveness of influenza vaccination in the elderly in a community in Italy. European Journal of Epidemiology. 2001;17 (2):163-8. PMID WOS:000170953500010.

82. Cunliffe NA, Witte D, Ngwira BM, et al. Efficacy of human rotavirus vaccine against severe gastroenteritis in Malawian children in the first two years of life: A randomized, double-blind, placebo controlled trial. Vaccine. 2012 27;30 (SUPPL. 1):A36-A43. PMID 2012230573 MEDLINE PMID 22520135 (http://www.ncbi.nlm.nih.gov/pubmed/22520135).

83. Czajka H, Schuster V, Zepp F, Esposito S, Douha M, Willems P. Corrigendum to "A combined measles, mumps, rubella and varicella vaccine (Priorix-Tetra <trade>): Immunogenicity and safety profile" Vaccine 27 (2009) 6504-6511. Vaccine. 2010 6;28 (52):8352. PMID 2010666520.

84. Dagan R, Sikuler-Cohen M, Zamir O, Janco J, Givon-Lavi N, Fraser D. Effect of a

conjugate pneumococcal vaccine on the occurrence of respiratory infections and antibiotic use in day-care center attendees. Pediatric Infectious Disease Journal. 2001 2001;20 (10):951-8. PMID 2001359896 MEDLINE PMID 11642629 (http://www.ncbi.nlm.nih.gov/pubmed/11642629).

85. Dalton CB, Cretikos MA, Durrheim DN, Seppelt IM, Rawlinson WD, Dwyer DE. Comparison of adult patients hospitalised with pandemic (H1N1) 2009 influenza and seasonal influenza during the "PROTECT" phase of the pandemic response. Medical Journal of Australia. 2010 15;192 (6):357-8. PMID 2010281127.

86. Das MK, Bhattacharyya N. Paediatric immunisation: Special emphasis on measles and MMR vaccinations. Journal of the Indian Medical Association. 2002 1;100 (5):320-1. PMID 2002365477 MEDLINE PMID 12418635 (http://www.ncbi.nlm.nih.gov/pubmed/12418635).

87. Dashefsky B, Wald E, Guerra N, Byers C. Safety, Tolerability, and Immunogenicity of Concurrent Administration of Haemophilus-Influenzae Type-B Conjugate Vaccine (Meningococcal Protein Conjugate) with Either Measles-Mumps-Rubella Vaccine or Diphtheria-Tetanus-Pertussis and Oral Poliovirus Vaccines in 14-Month-Old to 23-Month-Old Infants. Pediatrics. 1990 Apr;85 (4):682-9. PMID WOS:A1990CZ92900011.

88. Davies K, Woo P. Immunization in rheumatic diseases of childhood: An audit of the clinical practice of british paediatric rheumatology group members and a review of the evidence. Rheumatology. 2002 2002;41 (8):937-41. PMID 2002297972 MEDLINE PMID 12154212 (http://www.ncbi.nlm.nih.gov/pubmed/12154212).

89. Dennehy PH. Effects of vaccine on rotavirus disease in the pediatric population. Current Opinion in Pediatrics. 2012 February;24 (1):76-84. PMID 2012047095 MEDLINE PMID 22189398 (http://www.ncbi.nlm.nih.gov/pubmed/22189398).

90. Dennehy PH, Vesikari T, Matson DO, et al. Efficacy of the pentavalent rotavirus vaccine, RotaTeq[REGISTERED] (RV5), between doses of a 3-dose series and with less than 3 doses (incomplete regimen). Human Vaccines. 2011 May;7 (5):563-8. PMID 21441783.

91. Desselberger U. Prospects for vaccines against rotaviruses. Reviews in Medical Virology. 1998 1998;8 (1):43-52. PMID 1998066826.

92. Desselberger U, Huppertz HI. Immune responses to rotavirus infection and vaccination and associated correlates of protection. Journal of Infectious Diseases. 2011 15;203 (2):188-95. PMID 2011085083 MEDLINE PMID 21288818 (http://www.ncbi.nlm.nih.gov/pubmed/21288818).

93. Dewan P, Gupta P. Burden of Congenital Rubella Syndrome (CRS) in India: A Systematic Review. Indian Pediatrics. 2012 May 8;49 (5):377-99. PMID 22700664.

94. Dey AK, Srivastava IK. Novel adjuvants and delivery systems for enhancing immune responses induced by immunogens. Expert Review of Vaccines. 2011 February;10 (2):227-51.

PMID 2011111488 MEDLINE PMID 21105782 (http://www.ncbi.nlm.nih.gov/pubmed/21105782).

95. D'Heilly S, Bauman WL, Nichol KL. Safety and acceptability of pneumococcal vaccinations administered in nontraditional settings. American Journal of Infection Control. 2002 Aug;30 (5):261-8. PMID 12163859.

96. Di Pasquale A, De Ridder M, Van Der Meeren O. Hepatitis B virus vaccine in chronic kidney diseases: Improved immunogenicity by adjuvants? Limits of a meta-analysis. Vaccine. 2012 17;30 (38):5586. PMID 2012458511.

97. Dodds L, McNeil SA, Fell DB, et al. Impact of influenza exposure on rates of hospital admissions and physician visits because of respiratory illness among pregnant women. Canadian Medical Association Journal. 2007 Feb;176 (4):463-8. PMID WOS:000243991300014.

98. Driver C. Pneumonia part 2: signs, symptoms and vaccinations. British Journal of Nursing. 2012 Feb 23-Mar 7;21 (4):245-9. PMID 22398939.

99. Duclos P, Hofmann CA. Immunisation safety: A priority of the World Health Organization's Department of Vaccines and Biologicals. Drug Safety. 2001 2001;24 (15):1105-12. PMID 2002067895 MEDLINE PMID 11772144 (http://www.ncbi.nlm.nih.gov/pubmed/11772144).

100. Eberly MD, Gorman GH, Eide MB, Olsen CH, Rajnik M. The effect of rotavirus immunization on rotavirus gastroenteritis hospitalization rates in military dependents. Vaccine. 2011 Jan;29 (4):650-9. PMID WOS:000286853500009.

101. Eglee Perez M, Glass R, Alvarez G, et al. Rhesus rotavirus-based quadrivalent vaccine is efficacious despite age, socioeconomic conditions and seasonality in Venezuela. Vaccine. 2000 22;19 (7 8):976-81. PMID 2000425530 MEDLINE PMID 11115724 (http://www.ncbi.nlm.nih.gov/pubmed/11115724).

102. Einollahi B. Immune response to hepatitis B vaccine in patients with chronic kidney disease. Hepatitis Monthly. 2011 October;11 (10):781-2. PMID 2011607112.

103. El Khoury AC, Mast TC, Ciarlet M, Markson LE, Goveia MG. Projecting the effectiveness of RotaTeq(registered trademark) against rotavirus-related hospitalizations and deaths in six Asian countries. Human Vaccines. 2011 May;7 (5):506-10. PMID 2011267189 MEDLINE PMID 21422820 (http://www.ncbi.nlm.nih.gov/pubmed/21422820).

104. Ellenberg SS, Braun MM. Monitoring the safety of vaccines: Assessing the risks. Drug Safety. 2002 2002;25 (3):145-52. PMID 2002168642 MEDLINE PMID 11945111 (http://www.ncbi.nlm.nih.gov/pubmed/11945111).

105. Englund JA, Mbawuike IN, Hammill H, Holleman MC, Baxter BD, Glezen WP. Maternal immunization with influenza or tetanus toxoid vaccine for passive antibody protection in young infants. J Infect Dis. 1993 Sep;168 (3):647-56. PMID 8354906.

106. Farr BM, Johnston BL, Cobb DK, et al. Preventing pneumococcal bacteremia in patients at risk. Results of a matched case-control study. Arch Intern Med. 1995 Nov 27;155 (21):2336-40. PMID 7487259.

107. Fasunla AJ. Challenges of tracheostomy in patients managed for severe tetanus in a developing country. International Journal of Preventive Medicine. 2010;1 (3):176-81. PMID 21566788.

108. Fedson DS. The clinical effectiveness of pneumococcal vaccination: A brief review. Vaccine. 1999 30;17 (SUPPL. 1):S85-S90. PMID 1999273477 MEDLINE PMID 10471188 (http://www.ncbi.nlm.nih.gov/pubmed/10471188).

109. Fedson DS, Liss C. Precise answers to the wrong question: Prospective clinical trials and the meta-analyses of pneumococcal vaccine in elderly and high-risk adults. Vaccine. 2004 25;22 (8):927-46. PMID 2004083344 MEDLINE PMID 15161070 (http://www.ncbi.nlm.nih.gov/pubmed/15161070).

110. Ferreyra L, Bustos D, Biganzoli P, et al. HHV-6 IgG4 isotype response following measles infection. Journal of Medical Virology. 2010 2010;82 (3):396-9. PMID 2010074053 MEDLINE PMID 20087929 (http://www.ncbi.nlm.nih.gov/pubmed/20087929).

111. Ferris DG, Shulman L. Prevention of human papillomavirus in women of childbearing age. Sexuality, Reproduction and Menopause. 2010;8 (2) PMID 2010661372.

112. Findlow H, Southern J, Mabey L, et al. Immunoglobulin G subclass response to a meningococcal quadrivalent polysaccharide-diphtheria toxoid conjugate vaccine. Clinical and Vaccine Immunology. 2006 Apr;13 (4):507-10. PMID WOS:000236962300011.

113. Finn A, Booy R, Moxon R, Sharland M, Heath P. Should the new pneumococcal vaccine be used in high-risk children? Archives of Disease in Childhood. 2002 Jul;87 (1):18-21. PMID 12089114.

114. Fireman B, Black SB, Shinefield HR, Lee J, Lewis E, Ray P. Impact of the pneumococcal conjugate vaccine on otitis media. Pediatric Infectious Disease Journal. 2003 Jan;22 (1):10-6. PMID WOS:000180455900002.

115. Firmansyah A, Dwipoerwantoro PG, Kadim M, et al. Improved growth of toddlers fed a milk containing synbiotics. Asia Pacific Journal of Clinical Nutrition. 2011;20 (1):69-76. PMID 21393113.

116. Fischer TK, Anh DD, Antil L, et al. Health care costs of diarrheal disease and estimates of the cost-effectiveness of rotavirus vaccination in Vietnam. Journal of Infectious Diseases. 2005 15;192 (10):1720-6. PMID 2005506928 MEDLINE PMID 16235169 (http://www.ncbi.nlm.nih.gov/pubmed/16235169).

117. Fischer TK, Gentsch JR. Rotavirus typing methods and algorithms. Reviews in Medical Virology. 2004 March/April;14 (2):71-82. PMID 2004115475 MEDLINE PMID 15027000 (http://www.ncbi.nlm.nih.gov/pubmed/15027000).

118. Fischer TK, Viboud C, Parashar U, et al. Hospitalizations and deaths from diarrhea and rotavirus among children <5 years of age in the United States, 1993-2003. Journal of Infectious Diseases. 2007 15;195 (8):1117-25. PMID 2007168247 MEDLINE PMID 17357047 (http://www.ncbi.nlm.nih.gov/pubmed/17357047).

119. Fleming DM, Verlander NQ, Elliot AJ, et al. An assessment of the effect of statin use on the incidence of acute respiratory infections in England during winters 1998-1999 to 2005-2006. Epidemiology and Infection. 2010 September;138 (9):1281-8. PMID 2010544277 MEDLINE PMID 20109259 (http://www.ncbi.nlm.nih.gov/pubmed/20109259).

120. Flores AR, Szilagyi PG, Auinger P, Fisher SG. Estimated burden of rotavirus-associated diarrhea in ambulatory settings in the United States. Pediatrics. 2010 February;125 (2):e191-e8. PMID 2010090830 MEDLINE PMID 20100749 (http://www.ncbi.nlm.nih.gov/pubmed/20100749).

121. Forstner C, Plefka S, Tobudic S, Winkler HM, Burgmann K, Burgmann H. Effectiveness and immunogenicity of pneumococcal vaccination in splenectomized and functionally asplenic patients. Vaccine. 2012 Aug 10;30 (37):5449-52. PMID 22749594.

122. Foster DA, Talsma A, Furumotodawson A, et al. Influenza Vaccine Effectiveness in Preventing Hospitalization for Pneumonia in the Elderly. American Journal of Epidemiology. 1992 Aug;136 (3):296-307. PMID WOS:A1992JR44600005.

123. Fox PG, Kumchum S. Caring for Myanmar refugees in Thailand. International Nursing Review. 1996 Sep-Oct;43 (5):154-8. PMID 8894842.

124. France EK, Smith-Ray R, McClure D, et al. Impact of maternal influenza vaccination during pregnancy on the incidence of acute respiratory illness visits among infants. Arch Pediatr Adolesc Med. 2006 Dec;160 (12):1277-83. PMID 17146026.

125. Frasch CE, Hiner EE, Gross TP. Haemophilus b disease after vaccination with Haemophilus b polysaccharide or conjugate vaccine. American Journal of Diseases of Children. 1991 Dec;145 (12):1379-82. PMID 1669664.

126. French N, Gilks CF, Mujugira A, Fasching C, O'Brien J, Janoff EN. Pneumococcal vaccination in HIV-1-infected adults in Uganda: Humoral response and two vaccine failures. Aids. 1998 10;12 (13):1683-9. PMID 1998307537 MEDLINE PMID 9764789 (http://www.ncbi.nlm.nih.gov/pubmed/9764789).

127. French N, Nakiyingi J, Carpenter LM, et al. 23-valent pneumococcal polysaccharide vaccine in HIV-1-infected Ugandan adults: double-blind, randomised and placebo controlled trial. Lancet. 2000 Jun 17;355 (9221):2106-11. PMID 10902624.

128. Frenck Jr RW, Yeh S. The development of 13-valent pneumococcal conjugate vaccine and its possible use in adults. Expert Opinion on Biological Therapy. 2012 January;12 (1):63-77. PMID 2011699976 MEDLINE PMID 22074323 (http://www.ncbi.nlm.nih.gov/pubmed/22074323).

129. Fritzell B, Fletcher MA. Pneumococcal polysaccharide-protein (CRM(197)) conjugate vaccines, 7- or 9-valent, in the 2 + 1 schedule. Expert Review of Vaccines. 2011 March;10 (3):263-90. PMID 2011179942 MEDLINE PMID 21434795 (http://www.ncbi.nlm.nih.gov/pubmed/21434795).

130. Gall RM, Witterick IJ, Shargill NS, Hawke M. Control of bleeding in endoscopic sinus surgery: use of a novel gelatin-based hemostatic agent. Journal of Otolaryngology. 2002 Oct;31 (5):271-4. PMID 12512890.

131. Gatibelza ME, Laroye B, Lombard J, Mameli A, Thomas E. Management of a ruptured infected abdominal aortic aneurysm and a spondylodiscitis due to Gemella haemolysans. Annals of Vascular Surgery. 2009 Jul-Aug;23 (4):536.e13-7. PMID 19110401.

132. Gattringer R, Winkler H, Roedler S, Jaksch P, Herkner H, Burgmann H. Immunogenicity of a combined schedule of 7-valent pneumococcal conjugate vaccine followed by a 23-valent polysaccharide vaccine in adult recipients of heart or lung transplants. Transplant Infectious Disease. 2011 Oct;13 (5):540-4. PMID WOS:000295837900018.

133. Giles ML, Visvanathan K, Lewin SR, Sasadeusz J. Chronic Hepatitis B Infection and Pregnancy. Obstetrical & Gynecological Survey. 2012 Jan;67 (1):37-44. PMID WOS:000300220300017.

134. Gilsdorf JR. Haemophilus influenzae type b vaccine. Indian Journal of Pediatrics. 1988 1988;55 (2):218-24. PMID 1988152330 MEDLINE PMID 3042621 (http://www.ncbi.nlm.nih.gov/pubmed/3042621).

135. Glanz JM, McClure DL, Magid DJ, Daley MF, France EK, Hambidge SJ. Parental refusal of varicella vaccination and the associated risk of varicella infection in children. Archives of Pediatrics and Adolescent Medicine. 2010 January;164 (1):66-70. PMID 2010021895 MEDLINE PMID 20048244 (http://www.ncbi.nlm.nih.gov/pubmed/20048244).

136. Gomez E, Zoth SC, Berinstein A. Plant-based vaccines for potential human application: A review. Human Vaccines. 2009 2009;5 (11):738-44. PMID 2010041001 MEDLINE PMID 19829054 (http://www.ncbi.nlm.nih.gov/pubmed/19829054).

137. Govaert TM, Sprenger MJ, Dinant GJ, Aretz K, Masurel N, Knottnerus JA. Immune response to influenza vaccination of elderly people. A randomized double-blind placebo-controlled trial. Vaccine. 1994 Oct;12 (13):1185-9. PMID 7839722.

138. Govaert TME, Thijs C, Masurel N, Sprenger MJW, Dinant GJ, Knottnerus JA. The

Efficacy of Influenza Vaccination in Elderly Individuals - a Randomized Double-Blind Placebo-Controlled Trial. Jama-Journal of the American Medical Association. 1994 Dec;272 (21):1661-5. PMID WOS:A1994PU75900024.

139. Greenberg DP, Vadheim CM, Partridge S, et al. Immunogenicity of Haemophilus-Influenzae Type-B Tetanus Toroid Conjugate Vaccine in Young Infants. Journal of Infectious Diseases. 1994 Jul;170 (1):76-81. PMID WOS:A1994NR96500011.

140. Gross PA, Hermogenes AW, Sacks HS, Lau J, Levandowski RA. The Efficacy of Influenza Vaccine in Elderly Persons - a Metaanalysis and Review of the Literature. Annals of Internal Medicine. 1995 Oct;123 (7):518-27. PMID WOS:A1995RW49500008.

141. Guerra FA. Delays in immunization have potentially serious health consequences. Pediatric Drugs. 2007 2007;9 (3):143-8. PMID 2007268552 MEDLINE PMID 17523694 (http://www.ncbi.nlm.nih.gov/pubmed/17523694).

142. Gulland A. Rotavirus vaccine cuts deaths of Mexican babies from diarrhoea by 40%. British Medical Journal. 2010 Jan;340 PMID WOS:000274089400005.

143. Gurgel RQ, Ilozue C, Correia JB, Centenari C, Oliveira SMT, Cuevas LE. Impact of rotavirus vaccination on diarrhoea mortality and hospital admissions in Brazil. Tropical Medicine and International Health. 2011 September;16 (9):1180-4. PMID 2011431922 MEDLINE PMID 21749584 (http://www.ncbi.nlm.nih.gov/pubmed/21749584).

144. Guthridge S, McIntyre P, Isaacs D, Hanlon M, Patel M. Differing serologic responses to an Haemophilus influenzae type b polysaccharide-Neisseria meningitidis outer membrane protein conjugate (PRP-OMPC) vaccine in Australian Aboriginal and Caucasian infants - implications for disease epidemiology. Vaccine. 2000 May;18 (23):2584-91. PMID WOS:000087151100013.

145. Gutzeit C, Raftery MJ, Peiser M, et al. Identification of an important immunological difference between virulent varicella-zoster virus and its avirulent vaccine: viral disruption of dendritic cell instruction. Journal of Immunology. 2010 Jul 1;185 (1):488-97. PMID 20525895.

146. Hahne S, van den Hoek A, Baayen D, van der Sande M, de Melker H, Boot H. Prevention of perinatal hepatitis B virus transmission in the Netherlands, 2003-2007: Children of Chinese mothers are at increased risk of breakthrough infection. Vaccine. 2012 21;30 (9):1715-20. PMID 2012084011 MEDLINE PMID 22210140 (http://www.ncbi.nlm.nih.gov/pubmed/22210140).

147. Hak E, Hoes AW, Grobbee DE, et al. Conventional influenza vaccination is not associated with complications in working-age patients with asthma or chronic obstructive pulmonary disease. American Journal of Epidemiology. 2003 Apr 15;157 (8):692-700. PMID 12697573.

148. Halsey NA. Safety of combination vaccines: Perception versus reality. Pediatric Infectious Disease Journal. 2001 2001;20 (11 SUPPL.):S40-S4. PMID 2001402763 MEDLINE PMID 11704723 (http://www.ncbi.nlm.nih.gov/pubmed/11704723).

149. Halsey NA, Abramson JS, Chesney PJ, et al. Prevention of rotavirus disease: Guidelines for use of rotavirus vaccine. Pediatrics. 1998 December;102 (6):1483-91. PMID 1998410974 MEDLINE PMID 9832589 (http://www.ncbi.nlm.nih.gov/pubmed/9832589).

150. Hanna JN, Gratten M, Tiley SM, Brookes DL, Bapty G. Pneumococcal vaccination: an important strategy to prevent pneumonia in Aboriginal and Torres Strait Island adults. Australian and New Zealand Journal of Public Health. 1997 Jun;21 (3):281-5. PMID WOS:A1997YK90600010.

151. Hattotuwa KL, Hind CR. Pneumococcal vaccine. Postgraduate Medical Journal. 1997 Apr;73 (858):222-4. PMID 9156124.

152. Healy P, Zochling J, March L. Immunisation of adult patients with rheumatic diseases. Medicine Today. 2008 June;9 (6):69-71. PMID 2008343790.

153. Heath PT, Booy R, Griffiths H, et al. Clinical and immunological risk factors associated with haemophilus influenzae type b conjugate vaccine failure in childhood. Clinical Infectious Diseases. 2000 2000;31 (4):973-80. PMID 2001143513 MEDLINE PMID 11049779 (http://www.ncbi.nlm.nih.gov/pubmed/11049779).

154. Heffelfinger JD, Heckbert SR, Psaty BM, et al. Influenza vaccination and risk of incident myocardial infarction. Hum Vaccin. 2006 Jul-Aug;2 (4):161-6. PMID 17012887.

155. Heinonen S, Silvennoinen H, Lehtinen P, Vainionpaa R, Ziegler T, Heikkinen T. Effectiveness of inactivated influenza vaccine in children aged 9 months to 3 years: an observational cohort study. The Lancet Infectious Diseases. 2011 Jan;11 (1):23-9. PMID 21106443.

156. Hendrickson DJ, Blumberg DA, Joad JP, Jhawar S, McDonald RJ. Five-fold increase in pediatric parapneumonic empyema since introduction of pneumococcal conjugate vaccine. Pediatric Infectious Disease Journal. 2008 November;27 (11):1030-2. PMID 2009248550 MEDLINE PMID 18845981 (http://www.ncbi.nlm.nih.gov/pubmed/18845981).

157. Hensley E, Briars L. Closer look at autism and the measles-mumps-rubella vaccine. Journal of the American Pharmacists Association: JAPhA. 2010 Nov-Dec;50 (6):736-41. PMID 21071320.

158. Heyse JF, Kaplan KM. The reactogenicity and immunogenicity of commercial Haemophilus influenzae type b conjugate vaccines. European Journal of Pediatrics. 2000 Dec;159 (12):932-3. PMID 11131356.

159. Hillman RJ, Giuliano AR, Palefsky JM, et al. Immunogenicity of the quadrivalent human papillomavirus (type 6/11/16/18) vaccine in males 16 to 26 years old. Clinical & Vaccine Immunology: CVI. 2012 Feb;19 (2):261-7. PMID 22155768.

160. Hiner EE, Frasch CE. Spectrum of disease due to Haemophilus influenzae type b occurring

in vaccinated children. Journal of Infectious Diseases. 1988 Aug;158 (2):343-8. PMID 3261314.

161. Hiner EE, Frasch CE. Spectrum of disease due to Haemophilus influenza type b occurring in vaccinated children. Journal of Infectious Diseases. 1988 1988;158 (2):343-8. PMID 1988223249 MEDLINE PMID 3261314 (http://www.ncbi.nlm.nih.gov/pubmed/3261314).

162. Hoare S. HIV infection in children--impact upon ENT doctors. International Journal of Pediatric Otorhinolaryngology. 2003 Dec;67 Suppl 1:S85-90. PMID 14662174.

163. Hoft DF, Babusis E, Worku S, et al. Live and inactivated influenza vaccines induce similar humoral responses, but only live vaccines induce diverse T-cell responses in young children. Journal of Infectious Diseases. 2011 Sep 15;204 (6):845-53. PMID 21846636.

164. Holmes SJ, Lucas AH, Osterholm MT, Froeschle JE, Granoff DM. Immunoglobulin deficiency and idiotype expression in children developing Haemophilus influenzae type b disease after vaccination with conjugate vaccine. The Collaborative Study Group. JAMA. 1991 Oct 9;266 (14):1960-5. PMID 1895474.

165. Hom J, Medwid K. The low rate of bacterial meningitis in children, ages 6 to 18 months, with simple febrile seizures. Academic Emergency Medicine. 2011 Nov;18 (11):1114-20. PMID 22092892.

166. Horst D, Ressing ME, Wiertz E. Exploiting human herpesvirus immune evasion for therapeutic gain: potential and pitfalls. Immunology and Cell Biology. 2011 Mar;89 (3):359-66. PMID WOS:000288539800007.

167. Hoshino Y, Wagner M, Yan XY, Perez-Schael I, Kapikian AZ. Horizontal transmission of rhesus monkey rotavirus-based quadrivalent vaccine during a phase 3 clinical trial in Caracas, Venezuela. Journal of Infectious Diseases. 2003 1;187 (5):791-800. PMID 2003102915 MEDLINE PMID 12599053 (http://www.ncbi.nlm.nih.gov/pubmed/12599053).

168. Howard PF, McCaw JM, Richmond PC, et al. Virus detection and its association with symptoms during influenza-like illness in a sample of healthy adults enrolled in a randomised controlled vaccine trial. Influenza and other Respiratory Viruses. 2012.

169. Huebner RE, Mbelle N, Forrest B, Madore DV, Klugman KP. Immunogenicity after one, two or three doses and impact on the antibody response to coadministered antigens of a nonavalent pneumococcal conjugate vaccine in infants of Soweto, South Africa. Pediatric Infectious Disease Journal. 2002 Nov;21 (11):1004-7. PMID WOS:000179254800004.

170. Hung IFN, Yuen KY. Dual pneumococcal and influenza vaccination in elderly patients with chronic illnesses: Protective benefits overestimated? Clinical Infectious Diseases. 2011 15;52 (4):559. PMID 2011105147.

171. Huo Z, Miles J, Harris T, Riches P. Effect of Pneumovax(registered trademark) II

vaccination in high-risk individuals on specific antibody and opsonic capacity against specific and non-specific antigen. Vaccine. 2002 4;20 (29 30):3532-4. PMID 2002390467.

172. Huss A, Scott P, Stuck AE, Trotter C, Egger M. Efficacy of pneumococcal vaccination in adults: a meta-analysis.[Erratum appears in CMAJ. 2009 May 12;180(10):1038]. CMAJ Canadian Medical Association Journal. 2009 Jan 6;180 (1):48-58. PMID 19124790.

173. Hviid A, Svanstrom H. Antibiotic use and intussusception in early childhood. Journal of Antimicrobial Chemotherapy. 2009 Sep;64 (3):642-8. PMID WOS:000273181400028.

174. Hyser JM, Estes MK. Rotavirus vaccines and pathogenesis: 2008. Current Opinion in Gastroenterology. 2009 January;25 (1):36-43. PMID 2009031642 MEDLINE PMID 19114772 (http://www.ncbi.nlm.nih.gov/pubmed/19114772).

175. Inaba H, Hartford CM, Pei D, et al. Longitudinal analysis of antibody response to immunization in paediatric survivors after allogeneic haematopoietic stem cell transplantation. British Journal of Haematology. 2012 Jan;156 (1):109-17. PMID 22017512.

176. Inoue S, Watanuki Y, Kaneko T, et al. Heterogeneity of the efficacy of the 23-valent pneumococcal polysaccharide vaccine caused by various underlying conditions of chronic pulmonary disease in older patients: prospective cohort study. BMJ Open. 2011 Jan 1;1 (1):e000105. PMID 22021764.

177. Iskander JK, Miller ER, Chen RT. The role of the vaccine adverse event reporting system (VAERS) in monitoring vaccine safety. Pediatric Annals. 2004 September;33 (9):599-606. PMID 2004393883 MEDLINE PMID 15462575 (http://www.ncbi.nlm.nih.gov/pubmed/15462575).

178. Itzler R, Koch G, Matson DO, et al. Robustness of the healthcare utilization results from the Rotavirus Efficacy and Safety Trial (REST) evaluating the human-bovine (WC3) reassortant pentavalent rotavirus vaccine (RV5). Bmc Pediatrics. 2010;10:42. PMID 20540778.

179. Jackowska T, Pluta J. Routine infant immunization with the 7- and 13-valent pneumococcal conjugate vaccines: current perspective on reduced-dosage regimens. Archives of Medical Science. 2012 Jun;8 (3):542-8. PMID WOS:000306150200024.

180. Jackson LA, Peterson D, Dunn J, et al. A randomized placebo-controlled trial of acetaminophen for prevention of post-vaccination fever in infants. PLoS ONE [Electronic Resource]. 2011;6 (6) PMID 2011333756.

181. Jackson LA, Yu O, Nelson JC, et al. Injection site and risk of medically attended local reactions to acellular pertussis vaccine. Pediatrics. 2011 Mar;127 (3):e581-7. PMID 21300679.

182. Jacobs AL. Liability and maternal immunization: In utero injury claims in the VICP. American Journal of Obstetrics and Gynecology. 2012 September;207 (3 SUPPL.):S63-S6. PMID 2012497480.

183. Jacobson RM, Swan A, Adegbenro A, Ludington SL, Wollan PC, Poland GA. Making vaccines more acceptable - Methods to prevent and minimize pain and other common adverse events associated with vaccines. Vaccine. 2001 21;19 (17 19):2418-27. PMID 2001113295 MEDLINE PMID 11257372 (http://www.ncbi.nlm.nih.gov/pubmed/11257372).

184. Jacobson RM, Zabel KS, Poland GA. The challenge of vaccine safety. Seminars in Pediatric Infectious Diseases. 2002 July;13 (3):215-20. PMID 2002294526 MEDLINE PMID 12199618 (http://www.ncbi.nlm.nih.gov/pubmed/12199618).

185. Jaffe S. New rotavirus vaccines on the horizon. Scientist. 2005 Feb;19 (3):37-9. PMID WOS:000227520100026.

186. Jatana SK, Nair MNG. Combination vaccines. Medical Journal Armed Forces India. 2007 April;63 (2):167-71. PMID 2007436684.

187. Jefferson T, Rivetti D, Rivetti A, Rudin M, Di Pietrantonj C, Demicheli V. Efficacy and effectiveness of influenza vaccines in elderly people: a systematic review. Lancet. 2005 Oct;366 (9492):1165-74. PMID WOS:000232311300026.

188. Jiang T, Li X, Liu W, et al. Serum antibody response to the novel influenza A (H1N1) virus in the elderly. Clinical Infectious Diseases. 2010 15;50 (2):285-6. PMID 2010026203 MEDLINE PMID 20034356 (http://www.ncbi.nlm.nih.gov/pubmed/20034356).

189. Johns MC, Eick AA, Blazes DL, et al. Seasonal influenza vaccine and protection against pandemic (H1N1) 2009-associated illness among US military personnel. PLoS One. 2010;5 (5):e10722. PMID 20502705.

190. Johnson B, Gargiullo P, Murphy TV, Parashar UD, Patel MM. Factors associated with bowel resection among infants with intussusception in the United States. Pediatric Emergency Care. 2012 Jun;28 (6):529-32. PMID 22653458.

191. Johnstone J, Eurich DT, Minhas JK, Marrie TJ, Majumdar SR. Impact of the pneumococcal vaccine on long-term morbidity and mortality of adults at high risk for pneumonia. Clinical Infectious Diseases. 2010 Jul 1;51 (1):15-22. PMID 20504233.

192. Jones RG, Bass JW, Weisse ME, Vincent JM. Antigenuria after immunization with Haemophilus influenzae oligosaccharide CRM(197) conjugate (HbOC) vaccine. Pediatric Infectious Disease Journal. 1991 1991;10 (8):557-9. PMID 1992016450 MEDLINE PMID 1891285 (http://www.ncbi.nlm.nih.gov/pubmed/1891285).

193. Jones T. Varivax Merck & Co. Current Opinion in Investigational Drugs. 2002 2002;3 (1):54-7. PMID 2002187573 MEDLINE PMID 12054073 (http://www.ncbi.nlm.nih.gov/pubmed/12054073).

194. Jones TF, McMillian M, Boothe E, Hanna S, Ingram LA. Hospital discharge data for

Guillain-Barre syndrome and influenza A (H1N1) vaccine adverse events. Emerging Infectious Diseases. 2010 Sep;16 (9):1500-1. PMID 20735949.

195. Justice FA, Nguyen LT, Tran SN, et al. Recurrent intussusception in infants. Journal of Paediatrics and Child Health. 2011 November;47 (11):802-5. PMID 2011636695 MEDLINE PMID 21435072 (http://www.ncbi.nlm.nih.gov/pubmed/21435072).

196. Kamboj KK, Kirchner HL, Kimmel R, Greenspan NS, Schreiber JR. Significant variation in serotype-specific immunogenicity of the seven-valent Streptococcus pneumoniae capsular polysaccharide-CRM197 conjugate vaccine occurs despite vigorous T cell help induced by the carrier protein. Journal of Infectious Diseases. 2003 May 15;187 (10):1629-38. PMID 12721943.

197. Kansu E. Late effects of hematopoietic stem cell transplantation. Hematology. 2005 September/October;10 (SUPPL. 1):238-44. PMID 2005582014 MEDLINE PMID 16188682 (http://www.ncbi.nlm.nih.gov/pubmed/16188682).

198. Kapikian AZ, Hoshino Y, Chanock RM, Perez-Schael I. Efficacy of a quadrivalent rhesus rotavirus-based human rotavirus vaccine aimed at preventing severe rotavirus diarrhea in infants and young children. Journal of Infectious Diseases. 1996 1996;174 (SUPPL. 1):S65-S72. PMID 1996270930 MEDLINE PMID 8752293 (http://www.ncbi.nlm.nih.gov/pubmed/8752293).

199. Kapikian AZ, Vesikari T, Ruuska T, et al. An update on the 'Jennerian' and modified 'Jennerian' approach to vaccination of infants and young children against rotavirus diarrhea. Advances in Experimental Medicine and Biology. 1992 1992;327:59-69. PMID 1993042520 MEDLINE PMID 1295353 (http://www.ncbi.nlm.nih.gov/pubmed/1295353).

200. Kapikian AZ, Wyatt RG, Levine MM. Oral administration of human rotavirus to volunteers: Indication of illness and correlates of resistance. Journal of Infectious Diseases. 1983 1983;147 (1):95-106. PMID 1983084078 MEDLINE PMID 6296243 (http://www.ncbi.nlm.nih.gov/pubmed/6296243).

201. Kaplan J. 1997 USPHS/IDSA report on the prevention of opportunistic infections in patients infected with human immunodeficiency virus. Pediatrics. 1998 1998;102 (4 II):1064-85. PMID 1998338714.

202. Karande S, Gogtay NJ, Kshirsagar NA. Improving Drug Safety Monitoring. Indian Pediatrics. 2003 December;40 (12):1167-75. PMID 2004003084 MEDLINE PMID 14722367 (http://www.ncbi.nlm.nih.gov/pubmed/14722367).

203. Kelly HA, Grant KA, Fielding JE, et al. Pandemic influenza H1N1 2009 infection in Victoria, Australia: no evidence for harm or benefit following receipt of seasonal influenza vaccine in 2009. Vaccine. 2011 Aug 26;29 (37):6419-26. PMID 21473950.

204. Kelso JM. Update on vaccination guidelines for allergic children. Expert Review of Vaccines. 2009 November;8 (11):1541-6. PMID 2009589592 MEDLINE PMID 19863246 (http://www.ncbi.nlm.nih.gov/pubmed/19863246).

205. Keyser JS, Derkay CS. Haemophilus influenzae type B epiglottitis after immunization with HbOC conjugate vaccine. American Journal of Otolaryngology. 1994 Nov-Dec;15 (6):436-43. PMID 7872480.

206. Kidd S, Goodson JL, Aramburu J, et al. Poliomyelitis outbreaks in Angola genetically linked to India: risk factors and implications for prevention of outbreaks due to wild poliovirus importations. Vaccine. 2011 May 12;29 (21):3760-6. PMID 21440639.

207. King JC, Jr., Vink PE, Farley JJ, et al. Comparison of the safety and immunogenicity of a pneumococcal conjugate with a licensed polysaccharide vaccine in human immunodeficiency virus and non-human immunodeficiency virus-infected children. Pediatric Infectious Disease Journal. 1996 Mar;15 (3):192-6. PMID 8852905.

208. Kling S. Vaccination and ethical issues. Current Allergy and Clinical Immunology. 2009 November;22 (4):178-80. PMID 2010015136.

209. Kobayashi M, Thompson J, Tollefson SJ, Reed GW, Wright PF. Tetravalent rhesus rotavirus vaccine in young infants. Journal of Infectious Diseases. 1994 1994;170 (5):1260-3. PMID 1994331314 MEDLINE PMID 7963722 (http://www.ncbi.nlm.nih.gov/pubmed/7963722).

210. Koivula I, Sten M, Leinonen M, Makela PH. Clinical efficacy of pneumococcal vaccine in the elderly: A randomized, single-blind population-based trial. American Journal of Medicine. 1997 October;103 (4):281-90. PMID 1997329913 MEDLINE PMID 9382120 (http://www.ncbi.nlm.nih.gov/pubmed/9382120).

211. Kreimer AR, Gonzalez P, Katki HA, et al. Efficacy of a bivalent HPV 16/18 vaccine against anal HPV 16/18 infection among young women: a nested analysis within the Costa Rica Vaccine Trial. Lancet Oncology. 2011 Sep;12 (9):862-70. PMID 21865087.

212. Krueger JG, Ochs HD, Patel P, Gilkerson E, Guttman-Yassky E, Dummer W. Effect of therapeutic integrin (CD11a) blockade with efalizumab on immune responses to model antigens in humans: Results of a randomized, single blind study. Journal of Investigative Dermatology. 2008 November;128 (11):2615-24. PMID 2008485144 MEDLINE PMID 18496564 (http://www.ncbi.nlm.nih.gov/pubmed/18496564).

213. Kuehn BM. CDC panel recommends vaccine for smokers; reviews HPV safety data. JAMA. 2008 Dec 17;300 (23):2713-4. PMID 19088341.

214. Kuehn BM. FDA: Benefits of rotavirus vaccination outweigh potential contamination risk. JAMA - Journal of the American Medical Association. 2010 7;304 (1):30-1. PMID 2010376206 MEDLINE PMID 20606142 (http://www.ncbi.nlm.nih.gov/pubmed/20606142).

215. Kuehn BM. Immunization recommendations expanded for hepatitis B, HPV, pertussis vaccines. JAMA - Journal of the American Medical Association. 2012 28;307 (13):1353-4.

PMID 2012198374 MEDLINE PMID 22474190
(http://www.ncbi.nlm.nih.gov/pubmed/22474190).

216. Kulkarni PS, Sapru A, Bavdekar A, et al. Immunogenicity of two diphtheria-tetanus-whole cell pertussis-hepatitis B vaccines in infants: A comparative trial. Human Vaccines. 2011 September;7 (9):941-4. PMID 2011552858.

217. Kwon S, Kim S, Cho M-h, Seo H. Neurologic complications and outcomes of pandemic (H1N1) 2009 in Korean children. Journal of Korean Medical Science. 2012 Apr;27 (4):402-7. PMID 22468104.

218. Kyaw MH, Bramley JC, Chalmers J, Jones IG, Campbell H. Pneumococcal vaccination: opinion of general practitioners and hospital doctors in Scotland, 1999-2000. Communicable Disease & Public Health. 2001 Mar;4 (1):42-8. PMID 11467019.

219. Ladhani S, Heath PT, Ramsay ME, et al. Long-term immunological follow-up of children with haemophilus influenzae serotype b vaccine failure in the United Kingdom. Clinical Infectious Diseases. 2009 1;49 (3):372-80. PMID 2009376196 MEDLINE PMID 19580418 (http://www.ncbi.nlm.nih.gov/pubmed/19580418).

220. Lambert SB, Faux CE, Hall L, et al. Early evidence for direct and indirect effects of the infant rotavirus vaccine program in Queensland. Medical Journal of Australia. 2009 Aug;191 (3):157-60. PMID WOS:000269171100012.

221. Lamontagne F, Garant M-P, Carvalho J-C, Lanthier L, Smieja M, Pilon D. Pneumococcal vaccination and risk of myocardial infarction. CMAJ Canadian Medical Association Journal. 2008 Oct 7;179 (8):773-7. PMID 18838452.

222. Lanata CF, Black RE, Del Aguila R, et al. Protection of Peruvian children against rotavirus diarrhea of specific serotypes by one, two, or three doses of the RIT 4237 attenuated bovine rotavirus vaccine. Journal of Infectious Diseases. 1989 1989;159 (3):452-9. PMID 1989065893 MEDLINE PMID 2536789 (http://www.ncbi.nlm.nih.gov/pubmed/2536789).

223. Landrum ML, Hullsiek KH, Ganesan A, et al. Hepatitis B vaccination and risk of hepatitis B infection in HIV-infected individuals. Aids. 2010 February;24 (4):545-55. PMID 2010149504 MEDLINE PMID 19487908 (http://www.ncbi.nlm.nih.gov/pubmed/19487908).

224. Lanzieri TM, Linhares AC, Costa I, et al. Impact of rotavirus vaccination on childhood deaths from diarrhea in Brazil. International Journal of Infectious Diseases. 2011 March;15 (3):e206-e10. PMID 2011118561 MEDLINE PMID 21193339 (http://www.ncbi.nlm.nih.gov/pubmed/21193339).

225. Lashkari HP, El Bashir H. Immunisations among school leavers: is there a place for measles-mumps-rubella vaccine? 2010:Bulletin Europeen sur les Maladies Transmissibles = European Communicable Disease Bulletin. 15(7), 2010 Apr 29. PMID 20460082.

226. Laupland KB, Fisman DN. Zoster vaccination: A new opportunity for adult immunization. Canadian Journal of Infectious Diseases and Medical Microbiology. 2009 Winter;20 (4):105-6. PMID 2010033103.

227. Lazarsfeld R, Cavallario S. Two adult vaccination survey papers. Vaccine. 2010 14;28 (22):3757. PMID 2010278607 MEDLINE PMID 20427104 (http://www.ncbi.nlm.nih.gov/pubmed/20427104).

228. Lei T, Siu K-L, Kok K-H, et al. Anti-ganglioside antibodies were not detected in human subjects infected with or vaccinated against 2009 pandemic influenza A (H1N1) virus. Vaccine. 2012 Mar 30;30 (16):2605-10. PMID 22342549.

229. Leonardi S, La Rosa M. Are Hepatitis B Virus and Celiac Disease Linked? Hepatitis Monthly. 2010 Sum;10 (3):173-5. PMID WOS:000280521500004.

230. Levin MJ, Oxman MN, Zhang JH, et al. Varicella-zoster virus-specific immune responses in elderly recipients of a herpes zoster vaccine. J Infect Dis. 2008 Mar 15;197 (6):825-35. PMID 18419349.

231. Lewindon PJ, Harkness L, Lewindon N. Randomised controlled trial of sucrose by mouth for the relief of infant crying after immunisation. Archives of Disease in Childhood. 1998 May;78 (5):453-6. PMID 9659093.

232. Lewis KDC, Dallas MJ, Victor JC, et al. Comparison of two clinical severity scoring systems in two multi-center, developing country rotavirus vaccine trials in Africa and Asia. Vaccine. 2012 27;30 (SUPPL. 1):A159-A66. PMID 2012230588 MEDLINE PMID 22520126 (http://www.ncbi.nlm.nih.gov/pubmed/22520126).

233. Lewis RF, Kisakye A, Gessner BD, et al. Action for child survival: elimination of Haemophilus influenzae type b menigitis in Uganda. Bulletin of the World Health Organization. 2008 Apr;86 (4):292-301. PMID WOS:000255427100012.

234. Liang X, Zhang Y, Xu W, et al. An outbreak of poliomyelitis caused by type 1 vaccine-derived poliovirus in China. Journal of Infectious Diseases. 2006 1;194 (5):545-51. PMID 2006416045 MEDLINE PMID 16897650 (http://www.ncbi.nlm.nih.gov/pubmed/16897650).

235. Licciardi PV, Balloch A, Russell FM, Mulholland EK, Tang MLK. Antibodies to serotype 9V exhibit novel serogroup cross-reactivity following infant pneumococcal immunization. Vaccine. 2010 14;28 (22):3793-800. PMID 2010278613 MEDLINE PMID 20362199 (http://www.ncbi.nlm.nih.gov/pubmed/20362199).

236. Linhares AC, Gabbay YB, Mascarenhas JDP, et al. Immunogenicity, safety and efficacy of tetravalent rhesus-human, reassortant rotavirus vaccine in Belem, Brazil. Bulletin of the World Health Organization. 1996 1996;74 (5):491-500. PMID 1997012640 MEDLINE PMID 9002329 (http://www.ncbi.nlm.nih.gov/pubmed/9002329).

237. Linhares AC, Lanata CF, Hausdorff WP, Gabbay YB, Black RE. Reappraisal of the Peruvian and Brazilian lower titer tetravalent rhesus-human reassortant rotavirus vaccine efficacy trials: analysis by severity of diarrhea. Pediatric Infectious Disease Journal. 1999 Nov;18 (11):1001-6. PMID WOS:000083619500012.

238. Linhares AC, Stupka JA, Ciapponi A, et al. Burden and typing of rotavirus group A in Latin America and the Caribbean: Systematic review and meta-analysis. Reviews in Medical Virology. 2011 March;21 (2):89-109. PMID 2011169270.

239. Liu H. The changing landscape of global vaccine development and market potential. BioPharm International. 2007 October;20 (10):115-24. PMID 2007555743.

240. Liu IF, Huang CC, Chan WL, et al. Effects of annual influenza vaccination on mortality and hospitalization in elderly patients with ischemic heart disease: A nationwide population-based study. Preventive Medicine. 2012 June;54 (6):431-3. PMID 2012319341.

241. Long CB, Ramos I, Rastogi D, et al. Humoral and cell-mediated immune responses to monovalent 2009 influenza A/H1N1 and seasonal trivalent influenza vaccines in high-risk children. Journal of Pediatrics. 2012 Jan;160 (1):74-81. PMID 21840537.

242. Lopert R. Benefit and risks of trivalent 2010 seasonal influenza vaccine in Australian children. Eurosurveillance. 2010 07;15 (40):21. PMID 2010680939.

243. Lopez-Macias C. Virus-like particle (VLP)-based vaccines for pandemic influenza: Performance of a VLP vaccine during the 2009 influenza pandemic. Human Vaccines and Immunotherapeutics. 2012 March;8 (3):402-5. PMID 2012244559.

244. Macartney KK, Porwal M, Dalton D, et al. Decline in rotavirus hospitalisations following introduction of Australia's national rotavirus immunisation programme. Journal of Paediatrics and Child Health. 2011 May;47 (5):266-70. PMID WOS:000290865500006.

245. Madhi SA, Kirsten M, Louw C, et al. Efficacy and immunogenicity of two or three dose rotavirus-vaccine regimen in South African children over two consecutive rotavirus-seasons: A randomized, double-blind, placebo-controlled trial. Vaccine. 2012 Apr;30:A44-A51. PMID WOS:000304850100008.

246. Madhi SA, Kuwanda L, Cutland C, Holm A, Kayhty H, Klugman KP. Quantitative and qualitative antibody response to pneumococcal conjugate vaccine among African human immunodeficiency virus-infected and uninfected children. Pediatric Infectious Disease Journal. 2005 May;24 (5):410-6. PMID WOS:000229226400003.

247. Magnus MC, Vestrheim DF, Nystad W, et al. Decline in Early Childhood Respiratory Tract Infections in the Norwegian Mother and Child Cohort Study After Introduction of Pneumococcal Conjugate Vaccination. Pediatric Infectious Disease Journal. 2012 Sep;31 (9):951-5. PMID WOS:000308197200021.

248. Malakoff D. Aluminum is put on trial as a vaccine booster. Science. 2000 26;288 (5470):1323-4. PMID 2000206728.

249. Mangtani P, Shah A, Roberts JA. Validation of influenza and pneumococcal vaccine status in adults based on self-report. Epidemiology & Infection. 2007 Jan;135 (1):139-43. PMID 16740194.

250. Mansoor O. DTPH vaccine. N Z Med J. 1994 Sep 28;107 (986 Pt 1):382. PMID 7936471.

251. Marchetti F, Assael B, Gabutti G, et al. Monitoring the rate of hospitalization before rotavirus immunization in Italy utilizing ICD9-CM regional databases. Human Vaccines. 2009 2009;5 (3):172-6. PMID 2009301634 MEDLINE PMID 18802404 (http://www.ncbi.nlm.nih.gov/pubmed/18802404).

252. Marlow RD, Finn A. The promise of immunisation against rotavirus. Archives of Disease in Childhood. 2012 August;97 (8):736-40. PMID 2012467186.

253. Maruyama T, Taguchi O, Niederman MS, et al. Efficacy of 23-valent pneumococcal vaccine in preventing pneumonia and improving survival in nursing home residents: double blind, randomised and placebo controlled trial. BMJ. 2010;340:c1004. PMID 20211953.

254. Mascarenhas JDP, Leite JPG, Gabbay YB, Almeida ML, Linhares AC. Tetravalent rhesus-human rotavirus vaccine (RRV-TV) in Belem, Brazil: Efficacy against prevailing P and G genotypes. Journal of Tropical Pediatrics. 2002 Oct;48 (5):300-2. PMID WOS:000178120600009.

255. Mato SP, Perrin K, Scardino D, Begue RE. Evaluation of rotavirus vaccine effectiveness in a pediatric group practice. American Journal of Epidemiology. 2002 Dec;156 (11):1049-55. PMID WOS:000179603300009.

256. Matys K, Mallary S, Bautista O, et al. Mother-infant transfer of anti-human papillomavirus (HPV) antibodies following vaccination with the quadrivalent HPV (type 6/11/16/18) virus-like particle vaccine. Clinical & Vaccine Immunology: CVI. 2012 Jun;19 (6):881-5. PMID 22518014.

257. Mazzone PJ, Mossad SB, Mawhorter SD, Mehta AC, Schilz RJ, Maurer JR. The humoral immune response to influenza vaccination in lung transplant patients. European Respiratory Journal. 2001 Dec;18 (6):971-6. PMID WOS:000173857500012.

258. McKenney D, Pouliot KL, Wang Y, et al. Broadly protective vaccine for Staphylococcus aureus based on an in vivo-expressed antigen. Science. 1999 May 28;284 (5419):1523-7. PMID 10348739.

259. Meier P. Polio trial: An early efficient clinical trial. Statistics in Medicine. 1990 1990;9 (1 2):13-6. PMID 1990300272 MEDLINE PMID 2189187 (http://www.ncbi.nlm.nih.gov/pubmed/2189187).

260. Merlo HC, Vaid SK, Meyer A, Kertesz J, Flake D. Is it safe to vaccinate children against varicella while they're in close contact with a pregnant woman? Journal of Family Practice. 2011 July;60 (7):432-3. PMID 2012088467.

261. Meszner Z, Balogh A, Banyai K, et al. The clinical burden of rotavirus disease: Retrospective analysis of infant and childhood gastroenteritis in seven countries in central and eastern Europe. Pediatric Infectious Disease Journal. 2008 January;27 (1 SUPPL.):S33-S41. PMID 2008008163.

262. Migasena S, Simasathien S, Samakoses R, et al. Simultaneous administration of oral rhesus-human reassortant tetravalent (RRV-TV) rotavirus vaccine and oral poliovirus vaccine (OPV) in Thai infants. Vaccine. 1995 1995;13 (2):168-74. PMID 1995057755 MEDLINE PMID 7625111 (http://www.ncbi.nlm.nih.gov/pubmed/7625111).

263. Mills OF, Rhoads GG. The contribution of the case-control approach to vaccine evaluation: Pneumococcal and Haemophilus influenzae type B PRP vaccines. Journal of Clinical Epidemiology. 1996 Jun;49 (6):631-6. PMID 8656223.

264. Mishra D, John TJ. Hib, measles and varicella vaccine. Indian Pediatrics. 2000 2000;37 (11):1279-81. PMID 2000420113 MEDLINE PMID 11086320 (http://www.ncbi.nlm.nih.gov/pubmed/11086320).

265. Moore SR, Lima AAM, Guerrant RL. Preventing 5 million child deaths from diarrhea in the next 5 years. Nature Reviews Gastroenterology and Hepatology. 2011 July;8 (7):363-4. PMID 2011375298.

266. Moore SW, Kirsten M, Muller EW, et al. Retrospective Surveillance of Intussusception in South Africa, 1998-2003. Journal of Infectious Diseases. 2010 Sep;202:S156-S61. PMID WOS:000280623700021.

267. Morris SK, Awasthi S, Khera A, et al. Rotavirus mortality in India: Estimates based on a nationally representative survey of diarrhoeal deaths ORIGINAL (NON-ENGLISH) TITLE La mortalite du rotavirus en Inde: Estimations fondaes sur une enquete nationale representative des deces par diarrheae. Bulletin of the World Health Organization. 2012 October;90 (10):720-7. PMID 2012587233.

268. Moss SJ, Fenton AC, Toomey JA, Grainger AJ, Smith J, Gennery AR. Responses to a Conjugate Pneumococcal Vaccine in Preterm Infants Immunized at 2, 3, and 4 Months of Age. Clinical and Vaccine Immunology. 2010 Nov;17 (11):1810-6. PMID WOS:000283651200021.

269. Moulton LH, Staat MA, Santosham M, Ward RL. The protective effectiveness of natural rotavirus infection in an American Indian population. Journal of Infectious Diseases. 1998 Dec;178 (6):1562-6. PMID WOS:000077466700002.

270. Moyo S, Hawkridge T, Mahomed H, et al. Determining causes of mortality in children

enrolled in a vaccine field trial in a rural area in the Western Cape Province of South Africa. Journal of Paediatrics & Child Health. 2007 Mar;43 (3):178-83. PMID 17316193.

271. Muhsen K, Chodick G, Goren S, Shalev V, Cohen D. The uptake of rotavirus vaccine and its effectiveness in preventing acute gastroenteritis in the community. Vaccine. 2010 Dec;29 (1):91-4. PMID WOS:000286345000014.

272. Muhsen K, Shulman L, Kasem E, et al. Effectiveness of rotavirus vaccines for prevention of rotavirus gastroenteritis-associated hospitalizations in Israel A case-control study. Human Vaccines. 2010 Jun;6 (6):450-4. PMID WOS:000281998900012.

273. Mulholland K, Hilton S, Adegbola R, et al. Randomised trial of Haemophilus influenzae type-b tetanus protein conjugate for prevention of pneumonia and meningitis in Gambian infants. Lancet. 1997 Apr;349 (9060):1191-7. PMID WOS:A1997WW71700007.

274. Munos MK, Fischer Walker CL, Black RE. The effect of rotavirus vaccine on diarrhoea mortality. International Journal of Epidemiology. 2010 1;39 (SUPPL. 1):i56-i62. PMID 2012544833.

275. Munoz N, Kjaer SK, Sigurdsson K, et al. Impact of Human Papillomavirus (HPV)-6/11/16/18 Vaccine on All HPV-Associated Genital Diseases in Young Women. Journal of the National Cancer Institute. 2010 March;102 (5):325-39. PMID 2010160291 MEDLINE PMID 20139221 (http://www.ncbi.nlm.nih.gov/pubmed/20139221).

276. Musawi MA, Alhindi SJ, Abu-Elyazeed R, Pawinski R. Incidence of intussusception: Five-year hospital-based retrospective review. Bahrain Medical Bulletin. 2010;32 (2) PMID 2010396140.

277. Musher DM, Rueda AM, Nahm MH, Graviss EA, Rodriguez-Barradas MC. Initial and subsequent response to pneumococcal polysaccharide and protein-conjugate vaccines administered sequentially to adults who have recovered from pneumococcal pneumonia. Journal of Infectious Diseases. 2008 1;198 (7):1019-27. PMID 2008439919 MEDLINE PMID 18710324 (http://www.ncbi.nlm.nih.gov/pubmed/18710324).

278. Naidus E, Damon L, Schwartz BS, Breed C, Liu C. Experience with use of Zostavax (R) in patients with hematologic malignancy and hematopoietic cell transplant recipients. American Journal of Hematology. 2012 Jan;87 (1):123-5. PMID WOS:000298257700028.

279. Nates SV, Frias M, Belfiore S, et al. Effect on seroprevalence of anti-poliovirus antibodies and on vaccination coverage of the implementation of a DTwP-IPV-Hib vaccination programme in a South American city. Epidemiology and Infection. 2011 June;139 (6):826-35. PMID 2011270422 MEDLINE PMID 20587121 (http://www.ncbi.nlm.nih.gov/pubmed/20587121).

280. Navar-Boggan AM, Halsey NA, Golden WC, Escobar GJ, Massolo M, Klein NP. Risk of fever and sepsis evaluations after routine immunizations in the neonatal intensive care unit. Journal of Perinatology. 2010 September;30 (9):604-9. PMID 2010478070 MEDLINE PMID

20182438 (http://www.ncbi.nlm.nih.gov/pubmed/20182438).

281. Nelson CM, Sutanto A, Gessner BD, Suradana IG, Steinhoff MC, Arjoso S. Age- and cause-specific childhood mortality in Lombok, Indonesia, as a factor for determining the appropriateness of introducing Haemophilus influenzae type b and pneumococcal vaccines. Journal of Health, Population & Nutrition. 2000 Dec;18 (3):131-8. PMID 11262765.

282. Ng SC, Woodrow S, Patel N, Subhani J, Harbord M. Role of genetic and environmental factors in British twins with inflammatory bowel disease. Inflammatory Bowel Diseases. 2012 April;18 (4):725-36. PMID 2012167381 MEDLINE PMID 21557397 (http://www.ncbi.nlm.nih.gov/pubmed/21557397).

283. Nichol KL. Ten-year durability and success of an organized program to increase influenza and pneumococcal vaccination rates among high-risk adults. American Journal of Medicine. 1998 November;105 (5):385-92. PMID 1998399440 MEDLINE PMID 9831422 (http://www.ncbi.nlm.nih.gov/pubmed/9831422).

284. Nichol KL, MacDonald R, Hauge M. Side effects associated with pneumococcal vaccination. American Journal of Infection Control. 1997 Jun;25 (3):223-8. PMID 9202818.

285. Nightingale SL. Two new child vaccines licenced: Combination DTP and Haemophilus b conjugate vaccine. Journal of the American Medical Association. 1993 1993;269 (19):2491. PMID 1993135917.

286. Nokleby H. Vaccination and anaphylaxis. Current Allergy and Asthma Reports. 2006 February;6 (1):9-13. PMID 2006153479 MEDLINE PMID 16476188 (http://www.ncbi.nlm.nih.gov/pubmed/16476188).

287. Obaro S. Rotavirus vaccine efficacy in African and Asian countries. The Lancet. 2010 December;376 (9756):1897. PMID 2010669126.

288. Offit P, Plotkin SA, Halsey NA. Preventing harm from thimerosal in vaccines [3] (multiple letter). Journal of the American Medical Association. 2000 26;283 (16):2104-5. PMID 2000159072.

289. Offit PA. The rotavirus vaccine. Journal of Clinical Virology. 1998 December;11 (3):155-9. PMID 1999036534 MEDLINE PMID 9949951 (http://www.ncbi.nlm.nih.gov/pubmed/9949951).

290. Offit PA, Clark HF. The rotavirus vaccine. Current Opinion in Pediatrics. 1999 1999;11 (1):9-13. PMID 1999069764 MEDLINE PMID 10084077 (http://www.ncbi.nlm.nih.gov/pubmed/10084077).

291. O'Grady KAF, Lee KJ, Carlin JB, et al. Increased risk of hospitalization for acute lower respiratory tract infection among australian indigenous infants 5-23 months of age following pneumococcal vaccination: A cohort study. Clinical Infectious Diseases. 2010 1;50 (7):970-8.

PMID 2010159432 MEDLINE PMID 20192729
(http://www.ncbi.nlm.nih.gov/pubmed/20192729).

292. Okabayashi T, Hanazaki K. Overwhelming postsplenectomy infection syndrome in adults - A clinically preventable disease. World Journal of Gastroenterology. 2008 Jan;14 (2):176-9. PMID WOS:000252417100003.

293. Ortqvist A, Berggren I, Insulander M, De Jong B, Svenungsson B. Effectiveness of an adjuvanted monovalent vaccine against the 2009 pandemic strain of influenza A(H1N1)v, in Stockholm county, Sweden. Clinical Infectious Diseases. 2011 15;52 (10):1203-11. PMID 2011229426 MEDLINE PMID 21507917 (http://www.ncbi.nlm.nih.gov/pubmed/21507917).

294. Ortqvist A, Granath F, Askling J, Hedlund J. Influenza vaccination and mortality: prospective cohort study of the elderly in a large geographical area. European Respiratory Journal. 2007 Sep;30 (3):414-22. PMID 17537767.

295. Ortqvist A, Hedlund J, Burman LA, et al. Randomised trial of 23-valent pneumococcal capsular polysaccharide vaccine in prevention of pneumonia in middle-aged and elderly people. Swedish Pneumococcal Vaccination Study Group. Lancet. 1998 Feb 7;351 (9100):399-403. PMID 9482293.

296. Osendarp SJM, Fuchs GJ, van Raaij JMA, et al. The effect of zinc supplementation during pregnancy on immune response to hib and BCG vaccines in Bangladesh. Journal of Tropical Pediatrics. 2006 October;52 (5):316-23. PMID 2006499280 MEDLINE PMID 16621858 (http://www.ncbi.nlm.nih.gov/pubmed/16621858).

297. Osterholm MT, Kelley NS, Sommer A, Belongia EA. Efficacy and effectiveness of influenza vaccines: A systematic review and meta-analysis. The Lancet Infectious Diseases. 2012 January;12 (1):36-44. PMID 2011703325 MEDLINE PMID 22032844 (http://www.ncbi.nlm.nih.gov/pubmed/22032844).

298. Otto S, Mahner B, Kadow I, Beck JF, Wiersbitzky SK, Bruns R. General non-specific morbidity is reduced after vaccination within the third month of life--the Greifswald study. Journal of Infection. 2000 Sep;41 (2):172-5. PMID 11023764.

299. Ozkaya E, Cambaz N, Kolsuz LD, Aycan N, Calis S, Samanci N. Vaccination coverage and risk factors for incomplete vaccination in children with recurrent wheeze. Allergologia et Immunopathologia. 2011 July-August;39 (4):222-7. PMID 2011403962 MEDLINE PMID 21208719 (http://www.ncbi.nlm.nih.gov/pubmed/21208719).

300. Pang XL, Joensuu J, Hoshino Y, Kapikian AZ, Vesikari T. Rotaviruses detected by reverse transcription polymerase chain reaction in acute gastroenteritis during a trial of rhesus-human reassortant rotavirus tetravalent vaccine: implications for vaccine efficacy analysis. Journal of Clinical Virology. 1999 Jun;13 (1-2):9-16. PMID WOS:000081178600002.

301. Parashar UD, Bresee JS, Gentsch JR, Glass RI. Rotavirus. Emerging Infectious Diseases.

1998 1998;4 (4):561-70. PMID 1998413712 MEDLINE PMID 9866732 (http://www.ncbi.nlm.nih.gov/pubmed/9866732).

302. Parashar UD, Glass RI. Rotavirus vaccines--early success, remaining questions. New England Journal of Medicine. 2009 Mar 12;360 (11):1063-5. PMID 19279338.

303. Parashar UD, Holman RC, Cummings KC, et al. Trends in intussusception-associated hospitalizations and deaths among US infants. Pediatrics. 2000 2000;106 (6):1413-21. PMID 2000432587 MEDLINE PMID 11099597 (http://www.ncbi.nlm.nih.gov/pubmed/11099597).

304. Parke JC, Schneerson R, Reimer C, et al. Clinical and Immunological Responses to Haemophilus-Influenzae Type-B-Tetanus Toxoid Conjugate Vaccine in Infants Injected at 3, 5, 7, and 18 Months of Age. Journal of Pediatrics. 1991 Feb;118 (2):184-90. PMID WOS:A1991EX30200003.

305. Parsons HK, Metcalf SC, Tomlin K, Read RC, Dockrell DH. Invasive pneumococcal disease and the potential for prevention by vaccination in the United Kingdom. Journal of Infection. 2007 May;54 (5):435-8. PMID 17052760.

306. Patel M, Pedreira C, De Oliveira LH, et al. Association between pentavalent rotavirus vaccine and severe rotavirus diarrhea among children in Nicaragua. JAMA - Journal of the American Medical Association. 2009 3;301 (21):2243-51. PMID 2009275023 MEDLINE PMID 19491186 (http://www.ncbi.nlm.nih.gov/pubmed/19491186).

307. Patel M, Pedreira C, De Oliveira LH, et al. Duration of protection of pentavalent rotavirus vaccination in Nicaragua. Pediatrics. 2012 August;130 (2):e365-e72. PMID 2012454508.

308. Paulke-Korinek M, Rendi-Wagner P, Kundi M, Kronik R, Kollaritsch H. Universal mass vaccination against rotavirus gastroenteritis: Impact on hospitalization rates in Austrian children. Pediatric Infectious Disease Journal. 2010 April;29 (4):319-23. PMID 2010197689 MEDLINE PMID 19935446 (http://www.ncbi.nlm.nih.gov/pubmed/19935446).

309. Pavli A, Maltezou HC. Travelling to Greece for the summer 2011 Special Olympics. Travel Medicine and Infectious Disease. 2011 May;9 (3):135-41. PMID 2011327241 MEDLINE PMID 21570357 (http://www.ncbi.nlm.nih.gov/pubmed/21570357).

310. Paximadi E, Karakasiliotis I, Mamuris Z, Stathopoulos C, Krikelis V, Markoulatos P. Genomic analysis of recombinant Sabin clinical isolates. Virus Genes. 2006 April;32 (2):203-10. PMID 2006170622 MEDLINE PMID 16604453 (http://www.ncbi.nlm.nih.gov/pubmed/16604453).

311. Peltola H. Haemophilus influenzae type b disease and vaccination in Latin America and the Caribbean. Pediatric Infectious Disease Journal. 1997 Aug;16 (8):780-7. PMID WOS:A1997XR53200009.

312. Percheson PB, Trepanier P, Dugre R, Mabrouk T. A Phase I, randomized controlled

clinical trial to study the reactogenicity and immunogenicity of a new split influenza vaccine derived from a non-tumorigenic cell line. Dev Biol Stand. 1999;98:127-32; discussion 33-4. PMID 10494965.

313. Perez N, Iannicelli JC, Girard-Bosch C, et al. Effect of probiotic supplementation on immunoglobulins, isoagglutinins and antibody response in children of low socio-economic status. European Journal of Nutrition. 2010 April;49 (3):173-9. PMID 2010220331 MEDLINE PMID 19838618 (http://www.ncbi.nlm.nih.gov/pubmed/19838618).

314. Perez-Schael I, Blanco M, Vilar M, et al. Clinical studies of a quadrivalent rotavirus vaccine in Venezuelan infants. Journal of Clinical Microbiology. 1990 1990;28 (3):553-8. PMID 1990078477 MEDLINE PMID 2157737 (http://www.ncbi.nlm.nih.gov/pubmed/2157737).

315. Petersen J. HBV treatment and pregnancy. Journal of Hepatology. 2011 December;55 (6):1171-3. PMID 2011634955 MEDLINE PMID 21718670 (http://www.ncbi.nlm.nih.gov/pubmed/21718670).

316. Phrommintikul A, Kuanprasert S, Wongcharoen W. Influenza vaccination reduced cardiovascular events in patients hospitalized with an acute coronary syndrome. Annals of Internal Medicine. 2011 20111115;155 (10):JC5-. PMID 2011626757.

317. Phrommintikul A, Kuanprasert S, Wongcharoen W, Kanjanavanit R, Chaiwarith R, Sukonthasarn A. Influenza vaccination reduces cardiovascular events in patients with acute coronary syndrome. European Heart Journal. 2011 Jul;32 (14):1730-5. PMID 21289042.

318. Pierson DL, Mehta SK, Gilden D, et al. Varicella zoster virus DNA at inoculation sites and in saliva after Zostavax immunization. Journal of Infectious Diseases. 2011 Jun 1;203 (11):1542-5. PMID 21592982.

319. Pilishvili T, Zell ER, Farley MM, et al. Risk factors for invasive pneumococcal disease in children in the era of conjugate vaccine use. Pediatrics. 2010 Jul;126 (1):e9-17. PMID 20547641.

320. Pliaka V, Dedepsidis E, Kyriakopoulou Z, et al. Growth kinetic analysis of bi-recombinant poliovirus vaccine strains. Virus Genes. 2010 Apr;40 (2):200-11. PMID 20091423.

321. Pluta RM, Lynm C, Golub RM. Guillain-Barre syndrome. JAMA - Journal of the American Medical Association. 2011 19;305 (3):319. PMID 2011042009.

322. Pool V, Braun MM, Kelso JM, et al. Prevalence of anti-gelatin IgE antibodies in people with anaphylaxis after measles-mumps rubella vaccine in the United States. Pediatrics. 2002 Dec;110 (6):e71. PMID 12456938.

323. Powell ND, Allen RG, Hufnagle AR, Sheridan JF, Bailey MT. Stressor-Induced Alterations of Adaptive Immunity to Vaccination and Viral Pathogens. Immunology and Allergy Clinics of North America. 2011 February;31 (1):69-79. PMID 2010647643 MEDLINE PMID 21094924 (http://www.ncbi.nlm.nih.gov/pubmed/21094924).

324. Puig-Barbera J, Diez-Domingo J, Hoyos SP, Varea AB, Vidal DG. Effectiveness of the MF59-adjuvanted influenza vaccine in preventing emergency admissions for pneumonia in the elderly over 64 years of age. Vaccine. 2004 Dec;23 (3):283-9. PMID WOS:000225778600004.

325. Rabbone I, Scaramuzza AE, Iafusco D, et al. Pandemic influenza vaccination coverage in children with type 1 diabetes: analysis from seven Italian centers. Human Vaccines. 2011 Dec;7 (12):1291-2. PMID 22108031.

326. Ratajczak HV. Theoretical aspects of autism: Causes-A review. Journal of Immunotoxicology. 2011 January-March;8 (1):68-79. PMID 2011082091 MEDLINE PMID 21299355 (http://www.ncbi.nlm.nih.gov/pubmed/21299355).

327. Rhorer J, Ambrose CS, Dickinson S, et al. Efficacy of live attenuated influenza vaccine in children: A meta-analysis of nine randomized clinical trials. Vaccine. 2009 Feb 11;27 (7):1101-10. PMID 19095024.

328. Robinson CG, Hernanz-Schulman M, Zhu Y, Griffin MR, Gruber W, Edwards KM. Evaluation of anatomic changes in young children with natural rotavirus infection: is intussusception biologically plausible? Journal of Infectious Diseases. 2004 Apr 15;189 (8):1382-7. PMID 15073674.

329. Robke JT, Woods M, Heitz S. Pharmacist impact on pneumococcal vaccination rates through incorporation of immunization assessment into critical pathways in an acute care setting. Hospital Pharmacy. 2002 Oct;37 (10):1050-4. PMID 2002374438.

330. Rodenburg GD, van Gils EJM, Veenhoven RH, et al. Comparability of antibody response to a booster dose of 7-valent pneumococcal conjugate vaccine in infants primed with either 2 or 3 doses. Vaccine. 2010 Feb;28 (5):1391-6. PMID WOS:000275122200035.

331. Rogalewski A, Kraus J, Hasselblatt M, Kraemer C, Schabitz WR. Improvement of advanced postvaccinal demyelinating encephalitis due to plasmapheresis. Neuropsychiatric Disease and Treatment. 2007 2007;3 (6):987-91. PMID 2008025711.

332. Rojas OL, Caicedo L, Guzman C, et al. Evaluation of circulating intestinally committed memory B cells in children vaccinated with attenuated human rotavirus vaccine. Viral Immunology. 2007 Jun;20 (2):300-11. PMID WOS:000247717100008.

333. Rose J, Hawthorn RL, Watts B, Singer ME. Public health impact and cost effectiveness of mass vaccination with live attenuated human rotavirus vaccine (RIX4414) in India: Model based analysis. BMJ. 2009 3;(2009) 339 (7724):787-91. PMID 2009523077.

334. Rowe IA, Parker R, Armstrong MJ, Houlihan D, Mutimer DJ. Hepatitis A virus vaccination in persons with hepatitis C virus infection: Consequences of quality measure implementation. Hepatology. 2012;56 (2):501-6.

335. Ruggeberg JU, Collins C, Clarke P, et al. Immunogenicity and induction of immunological memory of the heptavalent pneumococcal conjugate vaccine in preterm UK infants. Vaccine. 2007 Jan;25 (2):264-71. PMID WOS:000243614900005.

336. Russell FM, Balloch A, Tang MLK, et al. Immunogenicity following one, two, or three doses of the 7-valent pneumococcal conjugate vaccine. Vaccine. 2009 Sep;27 (41):5685-91. PMID WOS:000270070400020.

337. Saaka M, Okoko BJ, Kohberger RC, et al. Immunogenicity and serotype-specific efficacy of a 9-valent pneumococcal conjugate vaccine (PCV-9) determined during an efficacy trial in The Gambia. Vaccine. 2008 Jul;26 (29-30):3719-26. PMID WOS:000257649000023.

338. Santosham M, Rivin B, Wolff M, et al. Prevention of Haemophilus-Influenzae Type-B Infections in Apache and Navajo Children. Journal of Infectious Diseases. 1992 Jun;165:S144-S51. PMID WOS:A1992HW74500048.

339. Schaffer SA, Husain S, Delgado DH, Kavanaugh L, Ross HJ. Impact of Adjuvanted H1N1 Vaccine on Cell-Mediated Rejection in Heart Transplant Recipients. American Journal of Transplantation. 2011 Dec;11 (12):2751-4. PMID WOS:000297411800028.

340. Scheifele D, Bjornsen GL, Arcand T, Jacobsen K. Antigenuria after receipt of Haemophilus b diphtheria toxoid conjugate vaccine. Pediatric Infectious Disease Journal. 1989 Dec;8 (12):887-8. PMID 2626290.

341. Schneider L, Weinberg A, Boguniewicz M, et al. Immune response to varicella vaccine in children with atopic dermatitis compared with nonatopic controls. Journal of Allergy & Clinical Immunology. 2010 Dec;126 (6):1306-7.e2. PMID 20889193.

342. Schneider LC, Insel RA, Howie G, Madore DV, Geha RS. Response to a Haemophilus influenzae type b diphtheria CRM(197) conjugate vaccine in children with a defect of antibody production to Haemophilus influenzae type b polysaccharide. Journal of Allergy and Clinical Immunology. 1990 1990;85 (5):948-53. PMID 1990173492 MEDLINE PMID 2332568 (http://www.ncbi.nlm.nih.gov/pubmed/2332568).

343. Schonbeck Y, Sanders EAM, Hoes AW, Schilder AGM, Verheij TJM, Hak E. Rationale and design of the prevention of respiratory infections and management in children (PRIMAKid) study - A randomized controlled trial on the effectiveness and costs of combined influenza and pneumococcal vaccination in pre-school children with recurrent respiratory tract infections. Vaccine. 2005 Sep;23 (41):4906-14. PMID WOS:000232189500003.

344. Schutz K, Hughes RG, Parker A, et al. Kinetics of IgM and IgA Antibody Response to 23-Valent Pneumococcal Polysaccharide Vaccination in Healthy Subjects. Journal of Clinical Immunology. 2012.

345. Schwartz JL. The first rotavirus vaccine and the politics of acceptable risk. Milbank Quarterly. 2012 Jun;90 (2):278-310. PMID 22709389.

346. Scott JAG, Ojal J, Ashton L, Muhoro A, Burbidge P, Goldblatt D. Pneumococcal conjugate vaccine given shortly after birth stimulates effective antibody concentrations and primes immunological memory for sustained infant protection. Clinical Infectious Diseases. 2011 Oct;53 (7):663-70. PMID 21865175.

347. Scott JR, Millar EV, Lipsitch M, et al. Impact of more than a decade of pneumococcal conjugate vaccine use on carriage and invasive potential in native American communities. Journal of Infectious Diseases. 2012 15;205 (2):280-8. PMID 2012001251 MEDLINE PMID 22128315 (http://www.ncbi.nlm.nih.gov/pubmed/22128315).

348. Shankar S, Dhiman P, Kumar PG. Early undifferentiated arthritis in India: A six month follow up study. Indian Journal of Rheumatology. 2010 September;5 (3):118-23. PMID 2010541421.

349. Sharts-Hopko NC. HIB: a new conjugate and a combination vaccine. MCN Am J Matern Child Nurs. 1994 Jan-Feb;19 (1):56. PMID 8201867.

350. Shaw RD, Fong KJ, Losonsky GA, et al. Epitope-specific immune responses to rotavirus vaccination. Gastroenterology. 1987 1987;93 (5):941-50. PMID 1988000635 MEDLINE PMID 2443417 (http://www.ncbi.nlm.nih.gov/pubmed/2443417).

351. Shehab ZM, Azimi P, Asmar BI, Dunphy MG, Ayoub EM, Dajani AS. Immunogenicity and reactogenicity of Haemophilus influenzae Type b - meningococcus group B outer membrane protein conjugate vaccine in children 2-60 months of age. Scandinavian Journal of Infectious Diseases. 1991 1991;23 (6):763-9. PMID 1992064809 MEDLINE PMID 1815340 (http://www.ncbi.nlm.nih.gov/pubmed/1815340).

352. Shih A, Quinley J, Lee T-K, Messina CR. Assessing pneumococcal revaccination safety among New York State Medicare beneficiaries. Public Health Reports. 2002 Mar-Apr;117 (2):164-73. PMID 12357001.

353. Shin S, Anh DD, Zaman K, et al. Immunogenicity of the pentavalent rotavirus vaccine among infants in two developing countries in Asia, Bangladesh and Vietnam. Vaccine. 2012 Apr;30:A106-A13. PMID WOS:000304850100016.

354. Shinefield HR, Black S. Efficacy of pneumococcal conjugate vaccines in large scale field trials. Pediatric Infectious Disease Journal. 2000 April;19 (4):394-7. PMID 2000142098 MEDLINE PMID 10783042 (http://www.ncbi.nlm.nih.gov/pubmed/10783042).

355. Shinefield HR, Pichichero ME. Rotavirus vaccine (RotaTeq(registered trademark)): Profile report. Drugs and Therapy Perspectives. 2006 2006;22 (10):5-6. PMID 2006453308.

356. Short JA, Van Der Walt JH, Zoanetti DC. Immunization and anesthesia - An international survey. Paediatric Anaesthesia. 2006 May;16 (5):514-22. PMID 2006182206 MEDLINE PMID 16677260 (http://www.ncbi.nlm.nih.gov/pubmed/16677260).

357. Siber GR, Chang I, Baker S, et al. Estimating the protective concentration of anti-pneumococcal capsular polysaccharide antibodies. Vaccine. 2007 May;25 (19):3816-26. PMID WOS:000246419100010.

358. Silfverdal SA, Berg S, Hemlin C, Jokinen I. The cost-burden of paediatric pneumococcal disease in Sweden and the potential cost-effectiveness of prevention using 7-valent pneumococcal vaccine. Vaccine. 2009 Mar;27 (10):1601-8. PMID WOS:000264264600019.

359. Silk H, Zora J, Goldstein J, Tinkelman D, Schiffman G. Response to pneumococcal immunization in children with and without recurrent infections. Journal of Asthma. 1998;35 (1):101-12. PMID WOS:000072401900010.

360. Silvers LE, Ellenberg SS, Wise RP, Varricchio FE, Mootrey GT, Salive ME. The epidemiology of fatalities reported to the Vaccine Adverse Event Reporting System 1990-1997. Pharmacoepidemiology and Drug Safety. 2001 2001;10 (4):279-85. PMID 2001395284 MEDLINE PMID 11760487 (http://www.ncbi.nlm.nih.gov/pubmed/11760487).

361. Simon JK, Ramirez K, Cuberos L, et al. Mucosal IgA responses in healthy adult volunteers following intranasal spray delivery of a live attenuated measles vaccine. Clinical and Vaccine Immunology. 2011 March;18 (3):355-61. PMID 2011144853 MEDLINE PMID 21228137 (http://www.ncbi.nlm.nih.gov/pubmed/21228137).

362. Simpson CR, Ritchie LD, Robertson C, Sheikh A, McMenamin J. Effectiveness of H1N1 vaccine for the prevention of pandemic influenza in Scotland, UK: a retrospective observational cohort study. The Lancet Infectious Diseases. 2012.

363. Sinisalo M, Vilpo J, Itala M, Vakevainen M, Taurio J, Aittoniemi J. Antibody response to 7-valent conjugated pneumococcal vaccine in patients with chronic lymphocytic leukaemia. Vaccine. 2007 Dec;26 (1):82-7. PMID WOS:000252490700010.

364. Siscovick DS, Raghunathan TE, Lin D, et al. Influenza vaccination and the risk of primary cardiac arrest. Am J Epidemiol. 2000 Oct 1;152 (7):674-7. PMID 11032163.

365. Skowronski DM, de Serres G, Crowcroft NS, et al. Association between the 2008-09 seasonal influenza vaccine and pandemic H1N1 illness during spring-summer 2009: Four observational studies from Canada. PLoS Medicine. 2010;7 (4) PMID 2010257356.

366. Smith LM, Brassard P, Kwong JC, Deeks SL, Ellis AK, Levesque LE. Factors associated with initiation and completion of the quadrivalent human papillomavirus vaccine series in an ontario cohort of grade 8 girls. BMC Public Health. 2011 Aug;11 PMID WOS:000295379000001.

367. Smith-Norowitz TA, Wong D, Kusonruksa M, et al. Long term persistence of IgE anti-influenza virus antibodies in pediatric and adult serum post vaccination with influenza virus vaccine. International Journal of Medical Sciences. 2011 2011;8 (3):239-44. PMID 2011237366

MEDLINE PMID 21448311 (http://www.ncbi.nlm.nih.gov/pubmed/21448311).

368. Sood SK, Daum RS. Disease caused by Haemophilus influenzae type b in the immediate period after homologous immunization: Immunologic investigation. Pediatrics. 1990 1990;85 (4 SUPPL.):698-704. PMID 1990099883 MEDLINE PMID 2107522 (http://www.ncbi.nlm.nih.gov/pubmed/2107522).

369. Spackova M, Wiese-Posselt M, Dehnert M, Matysiak-Klose D, Heininger U, Siedler A. Comparative varicella vaccine effectiveness during outbreaks in day-care centres. Vaccine. 2010 8;28 (3):686-91. PMID 2009621836 MEDLINE PMID 19874924 (http://www.ncbi.nlm.nih.gov/pubmed/19874924).

370. Staat MA, Cortese MM, Bresee JS, et al. Rhesus rotavirus vaccine effectiveness and factors associated with receipt of vaccine. Pediatric Infectious Disease Journal. 2006 Nov;25 (11):1013-8. PMID 17072123.

371. Stanley M. Prophylactic HPV vaccines: prospects for eliminating ano-genital cancer. Br J Cancer. 2007 May 7;96 (9):1320-3. PMID 17375045.

372. Stassen PM, Sanders JS, Kallenberg CG, Stegeman CA. Influenza vaccination does not result in an increase in relapses in patients with ANCA-associated vasculitis. Nephrol Dial Transplant. 2008 Feb;23 (2):654-8. PMID 17913738.

373. Steele AD, Neuzil KM, Cunliffe NA, et al. Human rotavirus vaccine Rotarix(trademark) provides protection against diverse circulating rotavirus strains in African infants: a randomized controlled trial. BMC Infectious Diseases. 2012;12 (213) PMID 2012579883.

374. Stenius-Aarniala B, Huttunen JK, Pyhala R, et al. Lack of clinical exacerbations in adults with chronic asthma after immunization with killed influenza virus. Chest. 1986 Jun;89 (6):786-9. PMID 3709244.

375. Stojanovich L. Influenza vaccination of patients with systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA). Clin Dev Immunol. 2006 Jun-Dec;13 (2-4):373-5. PMID 17162380.

376. Svanstrm H, Callrus T, Hviid A. Temporal data mining for adverse events following immunization in nationwide danish healthcare databases. Drug Safety. 2010 2010;33 (11):1015-25. PMID 2010563351 MEDLINE PMID 20925439 (http://www.ncbi.nlm.nih.gov/pubmed/20925439).

377. Swingler GH, Michaels D, Hussey GG. WITHDRAWN: Conjugate vaccines for preventing Haemophilus influenzae type B infections. Cochrane Database of Systematic Reviews. 2009 (4):CD001729. PMID 19821280.

378. Taddio A, Ilersich AL, Ipp M, Kikuta A, Shah V. Physical interventions and injection techniques for reducing injection pain during routine childhood immunizations: Systematic

review of randomized controlled trials and quasi-randomized controlled trials. Clinical Therapeutics. 2009 2009;31 (SUPPL. 2):S48-S76. PMID 2009495233 MEDLINE PMID 19781436 (http://www.ncbi.nlm.nih.gov/pubmed/19781436).

379. Takahashi K, Ohkusa Y, Kim J-Y. The economic disease burden of measles in Japan and a benefit cost analysis of vaccination, a retrospective study. BMC Health Services Research. 2011;11:254. PMID 21978107.

380. Tan TQ, Gerbie MV. Pertussis and patient safety: implementing Tdap vaccine recommendations in hospitals. Joint Commission Journal on Quality & Patient Safety. 2010 Apr;36 (4):173-8. PMID 20402374.

381. Temte JL. Should all children be immunised against hepatitis A? British Medical Journal. 2006 25;332 (7543):715-8. PMID 2006442504 MEDLINE PMID 16565129 (http://www.ncbi.nlm.nih.gov/pubmed/16565129).

382. Tenembaum S, Chitnis T, Ness J, Hahn JS. Acute disseminated encephalomyelitis. Neurology. 2007 April;68 (16 SUPPL. 2):S23-S36. PMID 2007196097 MEDLINE PMID 17438235 (http://www.ncbi.nlm.nih.gov/pubmed/17438235).

383. Tessmer A, Welte T, Schmidt-Ott R, et al. Influenza vaccination is associated with reduced severity of community-acquired pneumonia. European Respiratory Journal. 2011 1;38 (1):147-53. PMID 2011380784 MEDLINE PMID 21148226 (http://www.ncbi.nlm.nih.gov/pubmed/21148226).

384. Tomljenovic L, Shaw CA. No autoimmune safety signal after vaccination with quadrivalent HPV vaccine Gardasil? Journal of Internal Medicine. 2012.

385. Tseng YT, Sun HY, Chang SY, et al. Seroprevalence of hepatitis virus infection in men who have sex with men aged 18-40 years in Taiwan. Journal of the Formosan Medical Association. 2012.

386. Usen S, Adegbola R, Mulholland K, et al. Epidemiology of invasive pneumococcal disease in the Western Region, The Gambia. Pediatric Infectious Disease Journal. 1998 Jan;17 (1):23-8. PMID WOS:000071617000005.

387. Valente C, Hinds J, Pinto F, et al. Decrease in Pneumococcal Co-Colonization following Vaccination with the Seven-Valent Pneumococcal Conjugate Vaccine. PLoS ONE [Electronic Resource]. 2012 Jan;7 (1) PMID WOS:000301357100048.

388. van den Biggelaar AHJ, Pomat W, Bosco A, et al. Pneumococcal conjugate vaccination at birth in a high-risk setting: No evidence for neonatal T-cell tolerance. Vaccine. 2011 26;29 (33):5414-20. PMID 2011390305 MEDLINE PMID 21645573 (http://www.ncbi.nlm.nih.gov/pubmed/21645573).

389. van Gils EJM, Hak E, Veenhoven RH, et al. Effect of Seven-Valent Pneumococcal

Conjugate Vaccine on Staphylococcus aureus Colonisation in a Randomised Controlled Trial. PLoS ONE [Electronic Resource]. 2011 Jun;6 (6) PMID WOS:000291612600007.

390. Van Holle L, Zeinoun Z, Bauchau V, Verstraeten T. Using time-to-onset for detecting safety signals in spontaneous reports of adverse events following immunization: A proof of concept study. Pharmacoepidemiology and Drug Safety. 2012 June;21 (6):603-10. PMID 2012338995.

391. Vandenbruaene M, Colebunders R, Mascartlemone F, et al. Equal Igg Antibody-Response to Pneumococcal Vaccination in All Stages of Human-Immunodeficiency-Virus Disease. Journal of Infectious Diseases. 1995 Aug;172 (2):551-3. PMID WOS:A1995RK46400033.

392. Verstraeten T, DeStefano F, Chen RT, Miller E. Vaccine safety surveillance using large linked databases: Opportunities, hazards and proposed guidelines. Expert Review of Vaccines. 2003 February;2 (1):21-9. PMID 2003192795 MEDLINE PMID 12901594 (http://www.ncbi.nlm.nih.gov/pubmed/12901594).

393. Vesikari T. Clinical trials of live oral rotavirus vaccines: the Finnish experience. Vaccine. 1993;11 (2):255-61. PMID 8382419.

394. Vesikari T. Rotavirus vaccine studies in Europe. Acta Paediatrica, International Journal of Paediatrics, Supplement. 1999 1999;88 (426):9-13. PMID 1999074634 MEDLINE PMID 10088905 (http://www.ncbi.nlm.nih.gov/pubmed/10088905).

395. Vesikari T, Itzler R, Matson DO, et al. Efficacy of a pentavalent rotavirus vaccine in reducing rotavirus-associated health care utilization across three regions (11 countries). International Journal of Infectious Diseases. 2007 Nov;11 Suppl 2:S29-35. PMID 18162243.

396. Vesikari T, Karvonen A, Ferrante SA, Ciarlet M. Efficacy of the pentavalent rotavirus vaccine, RotaTeq[REGISTERED], in Finnish infants up to 3[NON-BREAKING SPACE]years of age: the Finnish Extension Study. European Journal of Pediatrics. 2010 Nov;169 (11):1379-86. PMID 20559656.

397. Vesikari T, Karvonen A, Prymula R, et al. Efficacy of human rotavirus vaccine against rotavirus gastroenteritis during the first 2 years of life in European infants: randomised, double-blind controlled study. Lancet. 2007 24;370 (9601):1757-63. PMID 2007564672 MEDLINE PMID 18037080 (http://www.ncbi.nlm.nih.gov/pubmed/18037080).

398. Vesikari T, Prymula R, Schuster V, et al. Efficacy and Immunogenicity of Live-attenuated Human Rotavirus Vaccine in Breast-fed and Formula-fed European Infants. Pediatric Infectious Disease Journal. 2012 May;31 (5):509-13. PMID WOS:000303730400016.

399. Vesikari T, Ruuska T, Green KY, Flores J, Kapikian AZ. Protective efficacy against serotype 1 rotavirus diarrhea by live oral rhesus-human reassortant rotavirus vaccines with human rotavirus VP7 serotype 1 or 2 specificity. Pediatric Infectious Disease Journal. 1992 1992;11 (7):535-42. PMID 1992228151 MEDLINE PMID 1326741

(http://www.ncbi.nlm.nih.gov/pubmed/1326741).

400. Viboud C, Simonsen L. Does seasonal influenza vaccination increase the risk of illness with the 2009 A/H1N1 pandemic virus? International Journal of Risk and Safety in Medicine. 2011 2011;23 (2):97-102. PMID 2011468274.

401. Vidal K, Bucheli P, Gao Q, et al. Immunomodulatory effects of dietary supplementation with a milk-based wolfberry formulation in healthy elderly: A randomized, double-blind, placebo-controlled trial. Rejuvenation Research. 2012 1;15 (1):89-97. PMID 2012110336 MEDLINE PMID 22352435 (http://www.ncbi.nlm.nih.gov/pubmed/22352435).

402. Vila-Corcoles A, Hospital-Guardiola I, Ochoa-Gondar O, et al. Rationale and design of the CAPAMIS study: effectiveness of pneumococcal vaccination against community-acquired pneumonia, acute myocardial infarction and stroke. BMC Public Health. 2010;10:25. PMID 20085658.

403. Visser A, Hoosen A. Combination vaccines in the South African setting. Vaccine. 2012 7;30 (SUPPL.3):C38-C44. PMID 2012515649.

404. Vlachopoulos C, Xaplanteris P, Sambatakou H, et al. Acute systemic inflammation induced by influenza A (H1N1) vaccination causes a deterioration in endothelial function in HIV-infected patients. HIV Medicine. 2011 November;12 (10):594-601. PMID 2011585144 MEDLINE PMID 21645196 (http://www.ncbi.nlm.nih.gov/pubmed/21645196).

405. Vondracek TG, Pham TP, Huycke MM. A hospital-based pharmacy intervention program for pneumococcal vaccination. Archives of Internal Medicine. 1998 1998;158 (14):1543-7. PMID 1998247282 MEDLINE PMID 9679795 (http://www.ncbi.nlm.nih.gov/pubmed/9679795).

406. Vos BD, Delem A, Hardt K, Bock HL, Meurice F, Innis B. A short report on clinical evaluation of RIX4414: highlights of world-wide development. Vaccine. 2006 1;24 (18):3777-8. PMID 2006202646 MEDLINE PMID 16584814 (http://www.ncbi.nlm.nih.gov/pubmed/16584814).

407. Vu DM, De Boer AW, Danzig L, et al. Priming for immunologic memory in adults by meningococcal group C conjugate vaccination. Clinical and Vaccine Immunology. 2006 June;13 (6):605-10. PMID 2006329179 MEDLINE PMID 16760316 (http://www.ncbi.nlm.nih.gov/pubmed/16760316).

408. Vzquez-Lvarez MDC, Medrano-Lpez C, Camino-Lpez M. H1N1 influenza vaccination and infection in pediatric heart transplants. Journal of Heart and Lung Transplantation. 2010 November;29 (11):1318. PMID 2010595915 MEDLINE PMID 20822923 (http://www.ncbi.nlm.nih.gov/pubmed/20822923).

409. Waites KB, Canupp KC, Edwards K, Palmer P, Gray BM, De Vivo MJ. Immunogenicity of pneumococcal vaccine in persons with spinal cord injury. Archives of Physical Medicine and

Rehabilitation. 1998 Dec;79 (12):1504-9. PMID WOS:000077421800003.

410. Wang FT, Mast TC, Glass RJ, Loughlin J, Seeger JD. Effectiveness of the pentavalent rotavirus vaccine in preventing gastroenteritis in the United States. Pediatrics. 2010 February;125 (2):e208-e13. PMID 2010090832 MEDLINE PMID 20100757 (http://www.ncbi.nlm.nih.gov/pubmed/20100757).

411. Wang TJ, Hu CC, Lin HC. Increased risk of anterior uveitis following herpes zoster: A nationwide population-based study. Archives of Ophthalmology. 2012 April;130 (4):451-5. PMID 2012229090 MEDLINE PMID 22491915 (http://www.ncbi.nlm.nih.gov/pubmed/22491915).

412. Ward J, Brenneman G, Letson GW, Heyward WL. Limited efficacy of Haemophilus influenzae type b conjugate vaccine in Alaska native infants. New England Journal of Medicine. 1990 1990;323 (20):1393-401. PMID 1991010714 MEDLINE PMID 2233906 (http://www.ncbi.nlm.nih.gov/pubmed/2233906).

413. Ward RL, Bernstein DI, Smith VE, et al. Rotaviras immunoglobulin A responses stimulated by each of 3 doses of a quadrivalent human/bovine reassortant rotaviras vaccine. Journal of Infectious Diseases. 2004 15;189 (12):2290-3. PMID 2004254623.

414. Warne G. Letter from Australia [2]. National Medical Journal of India. 2007 November/December;20 (6):313-4. PMID 2008076759.

415. Wehrle PF. Injury associated with the use of vaccines. Clinical Therapeutics. 1985 1985;7 (3):282-4. PMID 1985174497 MEDLINE PMID 3873276 (http://www.ncbi.nlm.nih.gov/pubmed/3873276).

416. Weinberg A, Song LY, Walker R, et al. Anti-Influenza Serum and Mucosal Antibody Responses After Administration of Live Attenuated or Inactivated Influenza Vaccines to HIV-Infected Children. Jaids-Journal of Acquired Immune Deficiency Syndromes. 2010 Oct;55 (2):189-96. PMID WOS:000282504100014.

417. Weinberg GA, Murphy TV, Granoff DM. Haemophilus influenzae type b polysaccharide-diphtheria toxoid conjugate vaccine in vaccinated children who developed Haemophilus disease. Pediatrics. 1990 Oct;86 (4):617-20. PMID 2216629.

418. Weinberg SH, Butchart AT, Davis MM. Size of clinical trials and introductory prices of prophylactic vaccine series. Human Vaccines and Immunotherapeutics. 2012 August;8 (8):1066-70. PMID 2012533263.

419. Weir E. Meningococcal disease: Oh no, not another childhood vaccine. Canadian Medical Association Journal. 2002 2002;166 (8):1064-6. PMID 2002139317 MEDLINE PMID 12002985 (http://www.ncbi.nlm.nih.gov/pubmed/12002985).

420. Wenger JD, Pierce R, Deaver KA, Plikaytis BD, Facklam RR, Broome CV. Efficacy of

Haemophilus-Influenzae Type-B Polysaccharide-Diphtheria Toxoid Conjugate Vaccine in United-States Children Aged 18-59 Months. Lancet. 1991 Aug;338 (8764):395-8. PMID WOS:A1991GB44600001.

421. Whitney CG, Pilishvili T, Farley MM, et al. Effectiveness of seven-valent pneumococcal conjugate vaccine against invasive pneumococcal disease: a matched case-control study. Lancet. 2006 Oct;368 (9546):1495-502. PMID WOS:000241582700027.

422. Widdowson MA, Steele D, Vojdani J, Wecker J, Parashar U. Global rotavirus surveillance: Determining the need and measuring the impact of rotavirus vaccines. Journal of Infectious Diseases. 2009 November;200 (SUPPL. 1):S1-S8. PMID 2010002010 MEDLINE PMID 19817589 (http://www.ncbi.nlm.nih.gov/pubmed/19817589).

423. Winston CA, Wortley PM, Lees KA. Factors associated with vaccination of medicare beneficiaries in five US Communities: Results from the racial and ethnic adult disparities in immunization initiative survey, 2003. Journal of the American Geriatrics Society. 2006 Feb;54 (2):303-10. PMID WOS:000235098300015.

424. Wiwanitkit V. MR finding in vaccine-associated paralytic poliomyelitis. Pediatric Radiology. 2010 Sep;40 (9):1583; author reply 4. PMID 20567967.

425. Wolfe MS. Travel medicine. Current Opinion in Infectious Diseases. 1999 1999;12 (5):433-8. PMID 1999431286.

426. Wong CM, Yang L, Chan KP, et al. Influenza-associated hospitalization in a subtropical city. PLoS Medicine / Public Library of Science. 2006 Apr;3 (4):e121. PMID 16515368.

427. Wood N, McIntyre P, Marshall H, Roberton D. Acellular pertussis vaccine at birth and one month induces antibody responses by two months of age. Pediatric Infectious Disease Journal. 2010 Mar;29 (3):209-15. PMID 20009964.

428. Wortley PM, Farizo KM, Sorillo F, et al. Pneumococcal and Influenza Vaccination Levels among Hiv-Infected Adolescents and Adults Receiving Medical-Care in the United-States. AIDS. 1994 Jul;8 (7):941-4. PMID WOS:A1994NU94700010.

429. Wymann MN, Richard J-L, Vidondo B, Heininger U. Prospective pertussis surveillance in Switzerland, 1991-2006. Vaccine. 2011 Mar 3;29 (11):2058-65. PMID 21251904.

430. Yalcin SS, Kondolot M, Albayrak N, et al. Serological response to influenza vaccine after hematopoetic stem cell transplantation. Annals of Hematology. 2010 Sep;89 (9):913-8. PMID 20119669.

431. Yao X, Hamilton RG, Weng NP, et al. Frailty is associated with impairment of vaccine-induced antibody response and increase in post-vaccination influenza infection in community-dwelling older adults. Vaccine. 2011 12;29 (31):5015-21. PMID 2011358003 MEDLINE PMID 21565245 (http://www.ncbi.nlm.nih.gov/pubmed/21565245).

432. Yawn BP, Wollan P, St Sauver J. Comparing shingles incidence and complication rates from medical record review and administrative database estimates: how close are they? American Journal of Epidemiology. 2011 Nov 1;174 (9):1054-61. PMID 21920944.

433. Ye Y, Wang W, Wang X, Yu H. The clinical epidemiology of pediatric patients with measles from 2000 to 2009 in shanghai, china. Clinical Pediatrics. 2011 Oct;50 (10):916-22. PMID 21561935.

434. Yen C, Figueroa JR, Uribe ES, et al. Monovalent rotavirus vaccine provides protection against An emerging fully heterotypic G9P[4] rotavirus strain in Mexico. Journal of Infectious Diseases. 2011 1;204 (5):783-6. PMID 2011456652 MEDLINE PMID 21810915 (http://www.ncbi.nlm.nih.gov/pubmed/21810915).

435. Zerr DM, Blume HK, Berg AT, et al. Nonfebrile illness seizures: A unique seizure category? Epilepsia. 2005 Jun;46 (6):952-5. PMID WOS:000229802200018.

436. Zhang J, Delzell E, Xie F, et al. The use, safety, and effectiveness of herpes zoster vaccination in individuals with inflammatory and autoimmune diseases: a longitudinal observational study. Arthritis Research & Therapy. 2011;13 (5):R174. PMID 22024532.

437. Zhang Q, Pettitt E, Burkinshaw R, Race G, Shaw L, Finn A. Mucosal immune responses to meningococcal conjugate polysaccharide vaccines in infants. Pediatric Infectious Disease Journal. 2002 2002;21 (3):209-13. PMID 2002097518 MEDLINE PMID 12005084 (http://www.ncbi.nlm.nih.gov/pubmed/12005084).

438. Zwiauer KF, Weinzettel R, Zwiauer VM. Clinical manifestation of intusseption before and after introduction of an oral rotavirus vaccine in austria. Journal of Pediatric Gastroenterology and Nutrition. 2011 June;52 SUPPL. 1:E165-E6.

Rejected for Design (individual case report, no comparison group, commentary, non-systematic review, passive surveillance) – 1,450

1. Polio vaccine and congenital defects. British Medical Journal. 1967 Feb 25;1 (5538):510. PMID 6017538.

2. Pneumococcal polysaccharide vaccine. Recommendation of the Immunization Practices Advisory Committee. Annals of Internal Medicine. 1982 Feb;96 (2):203-5. PMID 6277218.

3. Pneumococcal vaccine. Health and Public Policy Committee, American College of Physicians. Annals of Internal Medicine. 1986 Jan;104 (1):118-20. PMID 3940479.

4. Immunization during pregnancy. ACOG technical bulletin number 160--October 1991. International Journal of Gynaecology & Obstetrics. 1993 Jan;40 (1):69-79. PMID 8094357.

5. Facts about pertussis and DTP vaccine. EPI Newsletter. 1994 Jun;16 (3):5. PMID 12345538.

6. WHO meeting on maternal and neonatal pneumococcal immunization. Weekly Epidemiological Record. 1998 Jun 19;73 (25):187-8. PMID 9648498.

7. From the Centers for Disease Control and Prevention. Withdrawal of rotavirus vaccine recommendation. JAMA. 1999 Dec 8;282 (22):2113-4. PMID 10591321.

8. Measles immunization in HIV-infected children. American Academy of Pediatrics. Committee on Infectious Diseases and Committee on Pediatric AIDS. Pediatrics. 1999 May;103 (5 Pt 1):1057-60. PMID 10224192.

9. Pneumococcal vaccination for elderly subjects: license extension. Still no proof of clinical efficacy. Prescrire International. 2000 Aug;9 (48):106-9. PMID 11067718.

10. 7-valent pneumococcal conjugate vaccine: new preparation. Prevents rare invasive infections in infants. Prescrire International. 2002 Feb;11 (57):7-10. PMID 11985376.

11. Rotavirus vaccine ready for licensing. WHO Drug Information. 2004 2004;18 (2):129-30. PMID 2004362555.

12. CDC's advisory committee recommends new vaccine to prevent rotavirus. Indian Journal of Medical Sciences. 2006 Feb;60 (2):89-90. PMID 16538799.

13. Global Advisory Committee on Vaccine Safety, 1-2 December 2005. Weekly Epidemiological Record. 2006 Jan 13;81 (2):15-9. PMID 16671243.

14. New rotavirus vaccine is likely on its way. Child Health Alert. 2006 Feb;24:1. PMID 16526105.

15. Infant immunisation with a pneumococcal conjugate vaccine: from the age of two months, for all infants. Prescrire International. 2006 Dec;15 (86):227-33. PMID 17167934.

16. RotaTeq: A new oral rotavirus vaccine. Medical Letter on Drugs and Therapeutics. 2006 31;48 (1240):61-3. PMID 2008221795 MEDLINE PMID 16874281 (http://www.ncbi.nlm.nih.gov/pubmed/16874281).

17. New rotavirus vaccines safe and effective in large clinical trials. Gastroenterology. 2006 Mar;130 (3):627-8. PMID WOS:000236210100001.

18. Rotavirus vaccine and intussusception. WHO Drug Information. 2007 2007;21 (1):8. PMID 2008001204.

19. Safety updates on rotavirus vaccine. Expert Review of Vaccines. 2007 Apr;6 (2):130-. PMID WOS:000245821400005.

20. Adjuvanted hepatitis B vaccine: new drug. Patients with renal failure: similar response rate

but fewer boosters needed. Prescrire International. 2008 Dec;17 (98):234-6. PMID 19422145.

21. Risk levels for febrile seizures with combined measles-mumps-rubella-varicella vaccine. Expert Review of Vaccines. 2010 Aug;9 (8):810-. PMID WOS:000281104800004.

22. Herpes zoster vaccine (Zostavax) revisited. Medical Letter on Drugs and Therapeutics. 2010 31;52 (1339):41. PMID 2010390996 MEDLINE PMID 20508580 (http://www.ncbi.nlm.nih.gov/pubmed/20508580).

23. Adverse effects of papillomavirus vaccination: 2009 data. Prescrire International. 2010 Jun;19 (107):124. PMID 20738043.

24. Safety of rotavirus vaccines: postmarketing surveillance in the WHO Region of the Americas. Weekly Epidemiological Record. 2011 Feb 18;86 (8):66-72. PMID 21337810.

25. Aaby P, Benn C, Nielsen J, Lisse IM, Rodrigues A, Ravn H. Testing the hypothesis that diphtheria-tetanus-pertussis vaccine has negative non-specific and sex-differential effects on child survival in high-mortality countries. BMJ Open. 2012;2 (3) PMID 2012335376.

26. Aaby P, Jensen H, Samb B, et al. Differences in female-male mortality after high-titre measles vaccine and association with subsequent vaccination with diphtheria-tetanus-pertussis and inactivated poliovirus: reanalysis of West African studies. Lancet. 2003 Jun 28;361 (9376):2183-8. PMID 12842371.

27. Aaby P, Knudsen K, Whittle H, et al. Long-term survival after Edmonston-Zagreb measles vaccination in Guinea-Bissau: increased female mortality rate. Journal of Pediatrics. 1993 Jun;122 (6):904-8. PMID 8501567.

28. Aaby P, Martins C, Bale C, et al. Sex Differences in the Effect of Vaccines on the Risk of Hospitalization Due to Measles in Guinea-Bissau. Pediatric Infectious Disease Journal. 2010 Apr;29 (4):324-8. PMID WOS:000276565600008.

29. Aagaard L, Hansen EW, Hansen EH. Adverse events following immunization in children: Retrospective analysis of spontaneous reports over a decade. European Journal of Clinical Pharmacology. 2011 March;67 (3):283-8. PMID 2011203245 MEDLINE PMID 21079934 (http://www.ncbi.nlm.nih.gov/pubmed/21079934).

30. Aagaard L, Weber CB, Hansen EH. Adverse drug reactions in the paediatric population in denmark: A retrospective analysis of reports made to the danish medicines agency from 1998 to 2007. Drug Safety. 2010 2010;33 (4):327-39. PMID 2010179689 MEDLINE PMID 20297864 (http://www.ncbi.nlm.nih.gov/pubmed/20297864).

31. Abarca K, Ibanez I, de la Fuente P, et al. Immunogenicity and tolerability of a paediatric presentation of a virosomal hepatitis A vaccine in Chilean children aged 1-16 years. Vaccine. 2011 08;29 (48):8855-62. PMID 2011659714 MEDLINE PMID 21983354 (http://www.ncbi.nlm.nih.gov/pubmed/21983354).

32. Abramson JS, Baker CJ, Fisher MC, et al. Possible association of intussusception with rotavirus vaccination. Pediatrics. 1999 1999;104 (3 I):575. PMID 1999316531 MEDLINE PMID 10469790 (http://www.ncbi.nlm.nih.gov/pubmed/10469790).

33. Abzug MJ, Pelton SI, Song L-Y, et al. Immunogenicity, safety, and predictors of response after a pneumococcal conjugate and pneumococcal polysaccharide vaccine series in human immunodeficiency virus-infected children receiving highly active antiretroviral therapy. Pediatric Infectious Disease Journal. 2006 Oct;25 (10):920-9. PMID 17006288.

34. Acharya D, Desai A, Nanavaty N, et al. Evaluation of immunogenicity and tolerance of single dose haemophilus influenzae type B (PRP-T) vaccine. Indian Pediatrics. 1995 Oct;32 (10):1077-82. PMID 8984044.

35. Adam D, Fehnle K. Safety and effectiveness against respiratory tract infections for pneumococcal conjugate vaccine co-administered with routine vaccine combinations. Vaccine. 2008 Nov 5;26 (47):5944-51. PMID 18801402.

36. Adunsky A, Bernheim J. Pneumococcal vaccine in systemic lupus erythematosus. Arthritis & Rheumatism. 1980 Nov;23 (11):1330. PMID 7447971.

37. Agergaard J, Nante E, Poulstrup G, et al. Diphtheria-tetanus-pertussis vaccine administered simultaneously with measles vaccine is associated with increased morbidity and poor growth in girls. A randomised trial from Guinea-Bissau. Vaccine. 2011 Jan 10;29 (3):487-500. PMID 21093496.

38. Aguilar-Betancourt A, Gonzalez-Delgado CA, Cinza-Estevez Z, et al. Safety and immunogenicity of a combined hepatitis B virus-Haemophilus influenzae type B vaccine comprising a synthetic antigen in healthy adults. Human Vaccines. 2008 Jan-Feb;4 (1):54-9. PMID 18441530.

39. Aguilar-Betancourt A, Gonzalez-Delgado CA, Cinza-Estevez Z, et al. Safety and immunogenicity of a combined hepatitis B virus Haemophilus influenzae type B vaccine comprising a synthetic antigen in healthy adults. Human Vaccines. 2008 Jan-Feb;4 (1):54-9. PMID WOS:000257001000008.

40. Ahman H, Kayhty H, Tamminen P, Vuorela A, Malinoski F, Eskola J. Pentavalent pneumococcal oligosaccharide conjugate vaccine PncCRM is well- tolerated and able to induce an antibody response in infants. Pediatric Infectious Disease Journal. 1996 1996;15 (2):134-9. PMID 1996059433 MEDLINE PMID 8822286 (http://www.ncbi.nlm.nih.gov/pubmed/8822286).

41. Ahmed F, Steinhoff MC, Rodriguez-Barradas MC, Hamilton RG, Musher DM, Nelson KE. Effect of human immunodeficiency virus type 1 infection on the antibody response to a glycoprotein conjugate pneumococcal vaccine: Results from a randomized trial. Journal of Infectious Diseases. 1996 1996;173 (1):83-90. PMID 1996005021 MEDLINE PMID 8537687

(http://www.ncbi.nlm.nih.gov/pubmed/8537687).

42. Ahonkhai VI, Lukacs LJ, Jonas LC, Calandra GB. Clinical experience with PedvaxHIB, a conjugate vaccine of Haemophilus influenzae type b polysaccharide--Neisseria meningitidis outer membrane protein. Vaccine. 1991 Jun;9 Suppl:S38-41; discussion S2-3. PMID 1891956.

43. Ahonkhai VI, Lukacs LJ, Jonas LC, et al. Haemophilus influenzae type b conjugate vaccine (meningococcal protein conjugate) (PedvaxHIB(registered trademark)): Clinical evaluation. Pediatrics. 1990 1990;85 (4 SUPPL.):676-81. PMID 1990099879 MEDLINE PMID 2107518 (http://www.ncbi.nlm.nih.gov/pubmed/2107518).

44. Aikawa NE, Campos LMA, Silva CA, et al. Glucocorticoid: major factor for reduced immunogenicity of 2009 influenza A (H1N1) vaccine in patients with juvenile autoimmune rheumatic disease. Journal of Rheumatology. 2012 Jan;39 (1):167-73. PMID 22089462.

45. Aikawa NE, Campos LMA, Silva CA, et al. Glucocorticoid: Major factor for reduced immunogenicity of 2009 influenza A (H1N1) vaccine in juvenile autoimmune rheumatic diseases patients. Arthritis and Rheumatism. 2011;63 (10):2011-11.

46. Alavian SM, Tabatabaei SV. Effects of Oral Levamisole as an Adjuvant to Hepatitis B Vaccine in Adults With End-Stage Renal Disease: A Meta-Analysis of Controlled Clinical Trials. Clinical Therapeutics. 2010 Jan;32 (1):1-10. PMID WOS:000275078600001.

47. al-Eissa YA. Reactogenicity and safety of meningococcal A and C vaccine in Saudi children. Annals of Tropical Paediatrics. 1994;14 (4):275-9. PMID 7880088.

48. Allwinn R, Gauer S, Hofeld H, et al. Efficacy and side effects of H1N1 vaccination in renal transplant and dialysis patients. Transplant International. 2011 October;24 SUPPL. 3:34.

49. Al-Mazrou Y, Khalil M, Findlow H, et al. Immunogenicity and Safety of a Meningococcal Quadrivalent Conjugate Vaccine in Saudi Arabian Adolescents Previously Vaccinated with One Dose of Bivalent and Quadrivalent Meningococcal Polysaccharide Vaccines: a Phase III, Controlled, Randomized, and Modified Blind-Observer Study. Clinical & Vaccine Immunology: CVI. 2012 Jul;19 (7):999-1004. PMID 22552602.

50. Almeida VDC, Mussi-Pinhata MM, De Souza CBS, et al. Immunogenicity of 23-valent pneumococcal polysaccharide vaccine in HIV-infected pregnant women and kinetics of passively acquired antibodies in young infants. Vaccine. 2009 Jun 12;27 (29):3856-61. PMID 19443091.

51. Al-Mendalawi MD. Post varicella zoster virus myelitis in immunocompetent patients. Neurosciences. 2011 October;16 (4):388. PMID 2011575327 MEDLINE PMID 21983391 (http://www.ncbi.nlm.nih.gov/pubmed/21983391).

52. Al-Sukaiti N, Reid B, Lavi S, et al. Safety and efficacy of measles, mumps, and rubella vaccine in patients with DiGeorge syndrome. Journal of Allergy & Clinical Immunology. 2010 Oct;126 (4):868-9. PMID 20810153.

53. Amanna IJ. Balancing the efficacy and safety of vaccines in the elderly. Open Longevity Science. 2012 2012;6:64-72. PMID 2012422054.

54. Ambrosch F, Wiedermann G, Crooy P, George AM. Immunogenicity and side-effects of a new tetravalent meningococcal polysaccharide vaccine. Bulletin of the World Health Organization. 1983;61 (2):317-23. PMID 6407768.

55. Amendola A, Tanzi E, Zappa A, et al. Safety and immunogenicity of 23-valent pneumococcal polysaccharide vaccine in HIV-1 infected former drug users. Vaccine. 2002 Nov 1;20 (31-32):3720-4. PMID 12399200.

56. Amir J, Melamed R, Bader J, et al. Immunogenicity and safety of a liquid combination of DTP-PRP-T [corrected] vs lyophilized PRP-T reconstituted with DTP.[Erratum appears in Vaccine 1997 Nov;15(16):1813]. Vaccine. 1997 Feb;15 (2):149-54. PMID 9066031.

57. Anderson EJ. Rotavirus vaccines: viral shedding and risk of transmission. The Lancet Infectious Diseases. 2008 October;8 (10):642-9. PMID 2008443646 MEDLINE PMID 18922486 (http://www.ncbi.nlm.nih.gov/pubmed/18922486).

58. Anderson EL, Decker MD, Englund JA, et al. Interchangeability of conjugated Haemophilus influenzae type b vaccines in infants. JAMA. 1995 Mar 15;273 (11):849-53. PMID 7869554.

59. Anderson P, Pichichero M, Edwards K, Porch CR, Insel R. Priming and induction of Haemophilus influenzae type b capsular antibodies in early infancy by Dpo20, an oligosaccharide-protein conjugate vaccine. Journal of Pediatrics. 1987 Nov;111 (5):644-50. PMID 3499499.

60. Anderson P, Pichichero ME. Haemophilus influenzae type b vaccine. Pediatrics. 1989 Jan;83 (1):145-6. PMID 2909967.

61. Andrade D, Seguro L, Ribeiro A, et al. Is H1N1 influenza vaccine safe and effective in patients with SSc? Rheumatology. 2012 February;51 SUPPL. 2:ii23.

62. Andre FE, D'Hondt E, Delem A, Safary A. Clinical assessment of the safety and efficacy of an inactivated hepatitis A vaccine: Rationale and summary of findings. Vaccine. 1992 1992;10 (SUPPL. 1):S160-S8. PMID 1992360501 MEDLINE PMID 1335652 (http://www.ncbi.nlm.nih.gov/pubmed/1335652).

63. Andrews NJ, Walker WT, Finn A, et al. Predictors of immune response and reactogenicity to AS03B-adjuvanted split virion and non-adjuvanted whole virion H1N1 (2009) pandemic influenza vaccines. Vaccine. 2011 Oct 19;29 (45):7913-9. PMID 21875635.

64. Andrisani G, Frasca D, Armuzzi A, et al. Response to the 2009 vaccine for influenza A/H1N1 in patients with inflammatory bowel disease on anti TNF(alpha) therapy. Journal of Crohn's and Colitis. 2011 February;5 (1):S78-S9.

65. Andrisani G, Frasca D, Romero M, et al. Immune response to influenza A/H1N1 vaccine in inflammatory bowel disease patients treated with anti TNF-(alpha) agents: Effects of combined therapy with immunosuppressants. Journal of Crohn's and Colitis. 2012.

66. Anh DD, Carlos CC, Thiem DV, et al. Immunogenicity, reactogenicity and safety of the human rotavirus vaccine RIX4414 (Rotarix (TM)) oral suspension (liquid formulation) when co-administered with expanded program on immunization (EPI) vaccines in Vietnam and the Philippines in 2006-2007. Vaccine. 2011 Mar;29 (11):2029-36. PMID WOS:000288731000008.

67. Annunziata P, Carnicelli N, Galluzzi P, et al. Erratum: Miller-Fisher syndrome following vaccination against influenza virus A/H1N1 in an AIDS patient. Infection. 2012 April;40 (2):233. PMID 2012378205.

68. Ansari F, Baker RD, Patel R, Baker SS. Varicella immunity in inflammatory bowel disease. Journal of Pediatric Gastroenterology & Nutrition. 2011 Oct;53 (4):386-8. PMID 21505365.

69. Aplasca-De Los Reyes MR, Dimaano E, Macalalad N, et al. The investigational meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate vaccine (ACWY-TT) and the seasonal influenza virus vaccine are immunogenic and well-tolerated when co-administered in adults. Human Vaccines and Immunotherapeutics. 2012 July;8 (7):881-7. PMID 2012427210.

70. Arguedas A, Soley C, Abdelnour A, et al. Assessment of the safety, tolerability and kinetics of the immune response to A/H1N1v vaccine formulations with and without adjuvant in healthy pediatric subjects from 3 through 17 years of age. Human Vaccines. 2011 Jan 1;7 (1):58-66. PMID 21285531.

71. Arguedas A, Soley C, Lindert K. Responses to 2009 H1N1 vaccine in children 3 to 17 years of age. N Engl J Med. 2010 Jan 28;362 (4):370-2. PMID 20042746.

72. Aristegui J, Dal-Re R, Diez-Delgado J, et al. Comparison of the reactogenicity and immunogenicity of a combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated polio (DTPa-HBV-IPV) vaccine, mixed with the Haemophilus influenzae type b (Hib) conjugate vaccine and administered as a single injection, with the DTPa-IPV/Hib and hepatitis B vaccines administered in two simultaneous injections to infants at 2, 4 and 6 months of age. Vaccine. 2003 Sep 8;21 (25-26):3593-600. PMID 12922087.

73. Aristegui J, Dal-Re R, Garrote E, Gonzalez A, Arrate JP, Perez A. Assessment of the immunogenicity and reactogenicity of a quadrivalent diphtheria, tetanus, acellular pertussis and hepatitis B (DTPa-HBV) vaccine administered in a single injection with Haemophilus influenzae type b conjugate vaccine, to infants at 2, 4 and 6 months of age. Vaccine. 1998 Dec;16 (20):1976-81. PMID 9796053.

74. Arnold WC, Steele RW, Rastogi SP, Flanigan WJ. Response to pneumococcal vaccine in renal allograft recipients. American Journal of Nephrology. 1985;5 (1):30-4. PMID 3881958.

75. Arnou R, Eavis P, Pardo J-RDJ, Ambrozaitis A, Kazek M-P, Weber F. Immunogenicity, large scale safety and lot consistency of an intradermal influenza vaccine in adults aged 18-60 years: Randomized, controlled, phase III trial. Human Vaccines. 2010 Apr;6 (4):346-54. PMID 20372053.

76. Arnou R, Fiquet A, Thomas S, Sadorge C. Immunogenicity and safety of ZOSTAVAX([REGISTERED]) approaching expiry potency in individuals aged >=50 years. Human Vaccines. 2011 Oct;7 (10):1060-5. PMID 21941091.

77. Arya LS, Ghai OP, Saraya AK. Thrombocytopenic purpura following DPT vaccination. Pediatr Hematol Oncol. 1993 Oct-Dec;10 (4):381-3. PMID 8292527.

78. Asahina N, Matsunami Y, Sueda K, Shiraishi H, Saitoh S. Vaccine-associated paralytic poliomyelitis in a non-immunocompromised infant. Pediatrics International. 2010 Oct;52 (5):838-41. PMID 20880307.

79. Asante KP, Abdulla S, Agnandji S, et al. Safety and efficacy of the RTS,S/AS01E candidate malaria vaccine given with expanded-programme-on-immunisation vaccines: 19 month follow-up of a randomised, open-label, phase 2 trial.[Erratum appears in Lancet Infect Dis. 2011 Oct;11(10):727]. The Lancet Infectious Diseases. 2011 Oct;11 (10):741-9. PMID 21782519.

80. Ashok G, Rajendran P, Jayam S, et al. Assessment of immune response and safety of two recombinant hepatitis B vaccines in healthy infants in India. African Journal of Biotechnology. 2011 Oct;10 (59) PMID WOS:000299737800027.

81. Ashok G, Rajendran P, Jayam S, et al. Assessment of immune response and safety of two recombinant hepatitis B vaccines in healthy infants in India. African Journal of Biotechnology. 2011 3;10 (59):12707-10. PMID 2011562015.

82. Asindi AA, Bell EJ, Browning MJ, Stephenson JB. Vaccine-induced polioencephalomyelitis in Scotland. Scottish Medical Journal. 1988 1988;33 (4):306-7. PMID 1988227422 MEDLINE PMID 2847313 (http://www.ncbi.nlm.nih.gov/pubmed/2847313).

83. Aspinall S, Traynor D, Bedford P, Hartmann K. Lot-to-lot consistency study of the fully liquid pentavalent DTwP-HepB-Hib vaccine Quinvaxem(registered trademark) demonstrating clinical equivalence, suitability of the vaccine as a booster and concomitant administration with measles vaccine. Human Vaccines and Immunotherapeutics. 2012 August;8 (8):1109-18. PMID 2012533269.

84. Atanasovski M, Dele-Michael A, Dasgeb B, Ganger L, Mehregan D. A case report of Gianotti-Crosti post vaccination with MMR and dTaP. International Journal of Dermatology. 2011 May;50 (5):609-10. PMID 2011221443 MEDLINE PMID 21506982 (http://www.ncbi.nlm.nih.gov/pubmed/21506982).

85. Auriel E, Regev K, Dori A, Karni A. Safety of influenza and H1N1 vaccinations in patients with myasthenia gravis, and patient compliance. Muscle & Nerve. 2011 Jun;43 (6):893-4. PMID

21607970.

86. Austrian R. Prevention of pneumococcal infection by immunization with capsular polysaccharides of Streptococcus pneumoniae: current status of polyvalent vaccines. Journal of Infectious Diseases. 1977 Aug;136 Suppl:S38-42. PMID 19543.

87. Autret-Leca E, Grimaldi-Bensouda L, Daubin C, Poggi P, Collignon AE, Jonville-Bera AP. Heptavalent pneumococcal conjugate vaccine (PCV7): French survey of serious adverse reactions. Therapie. 2011 January-February;66 (1):81-6. PMID 2011203530.

88. Avdicova M, Prikazsky V, Hudeckova H, Schuerman L, Willems P. Immunogenicity and reactogenicity of a novel hexavalent DTPa-HBV-IPV/Hib vaccine compared to separate concomitant injections of DTPa-IPV/Hib and HBV vaccines, when administered according to a 3, 5 and 11 month vaccination schedule. European Journal of Pediatrics. 2002 Nov;161 (11):581-7. PMID 12424582.

89. Avery RK. Influenza vaccines in the setting of solid-organ transplantation: Are they safe? Current Opinion in Infectious Diseases. 2012;15.

90. Awaidy SA, Bawikar S, Prakash KP, Alrawahi B, Mohammed AJ. Surveillance of adverse events following immunization: 10 years' experience in Oman ORIGINAL (NON-ENGLISH) TITLE Surveillance des manifestations postvaccinales indesirables: Dix ans d'experience a Oman. Eastern Mediterranean Health Journal. 2010 May;16 (5):474-80. PMID 2010348624 MEDLINE PMID 20799545 (http://www.ncbi.nlm.nih.gov/pubmed/20799545).

91. Bader MS. Immunization for the elderly. American Journal of the Medical Sciences. 2007 Dec;334 (6):481-6. PMID 18091370.

92. Badsha H, Daher M, Edwards CJ. Live polio vaccine exposure while receiving anti-TNF therapy for reactive arthritis. International Journal of Rheumatic Diseases. 2010 May;13 (2):184-6. PMID 2010348985 MEDLINE PMID 20536606 (http://www.ncbi.nlm.nih.gov/pubmed/20536606).

93. Bagatin D, Augustin G, Bagatin T. Post-vaccination dermatolipomyonecrosis. Wiener Klinische Wochenschrift. 2009 September;121 (17 18):551. PMID 2009604746 MEDLINE PMID 19890743 (http://www.ncbi.nlm.nih.gov/pubmed/19890743).

94. Bakare N, Menschik D, Tiernan R, Hua W, Martin D. Severe combined immunodeficiency (SCID) and rotavirus vaccination: reports to the Vaccine Adverse Events Reporting System (VAERS). Vaccine. 2010 Sep 14;28 (40):6609-12. PMID 20674876.

95. Baker CJ, Kasper DL. Group B streptococcal vaccines. Reviews of Infectious Diseases. 1985 Jul-Aug;7 (4):458-67. PMID 3898306.

96. Baker CJ, Rench MA, Edwards MS, Carpenter RJ, Hays BM, Kasper DL. Immunization of pregnant women with a polysaccharide vaccine of group B streptococcus. New England Journal

of Medicine. 1988 Nov 3;319 (18):1180-5. PMID 3050524.

97. Ball R, Ball LK, Wise RP, Braun MM, Beeler JA, Salive ME. Stevens-Johnson syndrome and toxic epidermal necrolysis after vaccination: Reports to the Vaccine Adverse Event Reporting System. Pediatric Infectious Disease Journal. 2001 2001;20 (2):219-23. PMID 2001066762 MEDLINE PMID 11224848 (http://www.ncbi.nlm.nih.gov/pubmed/11224848).

98. Banda R, Yambayamba V, Lalusha BD, Sinkala E, Kapulu MC, Kelly P. Safety of live, attenuated oral vaccines in HIV-infected Zambian adults: Oral vaccines in HIV. Vaccine. 2012 Aug 17;30 (38):5656-60. PMID 22789509.

99. Banzhoff A, Haertel S, Praus M. Passive surveillance of adverse events of an MF59-adjuvanted H1N1v vaccine during the pandemic mass vaccinations. Human Vaccines. 2011 May;7 (5):539-48. PMID 21422814.

100. Banzhoff A, Stoddard JJ. Effective influenza vaccines for children: A critical unmet medical need and a public health priority. Human Vaccines and Immunotherapeutics. 2012 March;8 (3):389-93. PMID 2012244556.

101. Barnes G. Intussusception and rotavirus vaccine. Journal of Pediatric Gastroenterology and Nutrition. 1999 1999;29 (4):375. PMID 2000199297 MEDLINE PMID 10512393 (http://www.ncbi.nlm.nih.gov/pubmed/10512393).

102. Barnes G, Srivastava A, Carlin J, Francis I. Delta-F508 cystic fibrosis mutation is not linked to intussusception: implications for rotavirus vaccine. Journal of Paediatrics & Child Health. 2003 Sep-Oct;39 (7):516-7. PMID 12969205.

103. Barnett ED, Pelton SI, Cabral HJ, et al. Immune response to pneumococcal conjugate and polysaccharide vaccines in otitis-prone and otitis-free children. Clinical Infectious Diseases. 1999 1999;29 (1):191-2. PMID 1999252965 MEDLINE PMID 10433584 (http://www.ncbi.nlm.nih.gov/pubmed/10433584).

104. Bartlett BL, Tyring SK. Safety and efficacy of vaccines. Dermatologic Therapy. 2009 March-April;22 (2):97-103. PMID 2009149338 MEDLINE PMID 19335721 (http://www.ncbi.nlm.nih.gov/pubmed/19335721).

105. Barton M, Wasfy S, Dipchand AI, et al. Seven-valent pneumococcal conjugate vaccine in pediatric solid organ transplant recipients: a prospective study of safety and immunogenicity. Pediatric Infectious Disease Journal. 2009 Aug;28 (8):688-92. PMID 19633514.

106. Basilico FC, Bernat JL. Vaccine-associated poliomyelitis in a contact. Journal of the American Medical Association. 1978 1978;239 (21):2275. PMID 1978344721 MEDLINE PMID 650811 (http://www.ncbi.nlm.nih.gov/pubmed/650811).

107. Bassily S, Kotkat A, Gray G, et al. Comparative study of the immunogenicity and safety of two dosing schedules of hepatitis B vaccine in neonates. American Journal of Tropical Medicine

& Hygiene. 1995 Oct;53 (4):419-22. PMID 7485697.

108. Bassis AV, Fairley JA, Ameln RT, Swick BL. Cutaneous Rosai-Dorfman disease following pneumococcal vaccination. Journal of the American Academy of Dermatology. 2011 October;65 (4):890-2. PMID 2011516782 MEDLINE PMID 21920257 (http://www.ncbi.nlm.nih.gov/pubmed/21920257).

109. Bavdekar SB, Maiya PP, Subba Rao SD, Datta SK, Bock HL. Immunogenicity and safety of combined diphtheria tetanus whole cell pertussis hepatitis B/ Haemophilus influenzae type b vaccine in Indian infants. Indian Pediatrics. 2007 Jul;44 (7):505-10. PMID 17684303.

110. Baxter D. Impaired functioning of immune defences to infection in premature and term infants and their implications for vaccination. Human Vaccines. 2010 June;6 (6):494-505. PMID 2010504455 MEDLINE PMID 20519937 (http://www.ncbi.nlm.nih.gov/pubmed/20519937).

111. Baxter R, Baine Y, Ensor K, Bianco V, Friedland LR, Miller JM. Immunogenicity and safety of an investigational quadrivalent meningococcal ACWY tetanus toxoid conjugate vaccine in healthy adolescents and young adults 10 to 25 years of age. Pediatric Infectious Disease Journal. 2011 Mar;30 (3):e41-8. PMID 21200360.

112. Baxter R, Jeanfreau R, Block SL, et al. A Phase III evaluation of immunogenicity and safety of two trivalent inactivated seasonal influenza vaccines in US children. Pediatric Infectious Disease Journal. 2010 Oct;29 (10):924-30. PMID 20431425.

113. Baxter R, Patriarca PA, Ensor K, Izikson R, Goldenthal KL, Cox MM. Evaluation of the safety, reactogenicity and immunogenicity of FluBlok[REGISTERED] trivalent recombinant baculovirus-expressed hemagglutinin influenza vaccine administered intramuscularly to healthy adults 50-64 years of age. Vaccine. 2011 Mar 9;29 (12):2272-8. PMID 21277410.

114. Begg NT, Miller E, Fairley CK, et al. Antibody responses and symptoms after DTP and either tetanus or diphtheria Haemophilus influenzae type B conjugate vaccines given for primary immunisation by separate or mixed injection. Vaccine. 1995 Nov;13 (16):1547-50. PMID 8578840.

115. Begg NT, Miller E, Fairley CK, et al. Antibody-Responses and Symptoms after Dtp and Either Tetanus or Diphtheria Haemophilus-Influenzae Type-B Conjugate Vaccines Given for Primary Immunization by Separate or Mixed Injection. Vaccine. 1995 Nov;13 (16):1547-50. PMID WOS:A1995TF20500011.

116. Begue P, Stagnara J, Vie-Le-Sage F, Bernard JC, Xerri B, Abitbol V. Immunogenicity and reactogenicity of a booster dose of diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccines given concurrently with Haemophilus type b conjugate vaccine or as pentavalent vaccine. Pediatric Infectious Disease Journal. 1997 Aug;16 (8):787-94. PMID 9271042.

117. Belec L, Authier F-J, Gherardi RK. Safety and immunogenicity of hepatitis B vaccine

regimens in adults with HIV-1. JAMA. 2011 Jul 13;306 (2):156; author reply -7. PMID 21750288.

118. Bell F, Heath P, MacLennan J, et al. Adverse effects and sero-responses to an acellular pertussis/diphtheria/tetanus vaccine when combined with Haemophilus influenzae type b vaccine in an accelerated schedule. European Journal of Pediatrics. 1999 Apr;158 (4):329-36. PMID 10206134.

119. Bell F, Heath P, Shackley F, et al. Effect of combination with an acellular pertussis, diphtheria, tetanus vaccine on antibody response to Hib vaccine (PRP-T). Vaccine. 1998 Apr;16 (6):637-42. PMID 9569476.

120. Bell F, Martin A, Blondeau C, Thornton C, Chaplais J, Finn A. Combined diphtheria, tetanus, pertussis, and Haemophilus influenzae type b vaccines for primary immunisation. Archives of Disease in Childhood. 1996 Oct;75 (4):298-303. PMID 8984914.

121. Belliveau MJ, Kratky V, Evans GA, Almeida DRP, El-Defrawy S. Acute orbital inflammatory syndrome following H1N1 immunization. Canadian Journal of Ophthalmology. 2011 December;46 (6):552-3. PMID 2011710782 MEDLINE PMID 22153648 (http://www.ncbi.nlm.nih.gov/pubmed/22153648).

122. Belongia EA, Irving SA, Shui IM, et al. Real-time surveillance to assess risk of intussusception and other adverse events after pentavalent, bovine-derived rotavirus vaccine. Pediatric Infectious Disease Journal. 2010 Jan;29 (1):1-5. PMID 19907356.

123. Belshe RB, Frey SE, Graham I, et al. Safety and immunogenicity of influenza A H5 subunit vaccines: effect of vaccine schedule and antigenic variant. Journal of Infectious Diseases. 2011 Mar 1;203 (5):666-73. PMID 21282194.

124. Benn CS. Combining vitamin A and vaccines: convenience or conflict? Danish Medical Journal. 2012 Jan;59 (1):B4378. PMID 22239846.

125. Benn CS, Aaby P. Diphtheria-tetanus-pertussis vaccination administered after measles vaccine: Increased female mortality? SOURCE Pediatric Infectious Disease Journal (2012). Date of Publication: 7 Jun 2012. 2012.

126. Benn CS, Lund S, Fisker A, Jorgensen MJ, Aaby P. Should infant girls receive micronutrient supplements? International Journal of Epidemiology. 2009 2009;38 (2):586-90. PMID 2009174576 MEDLINE PMID 19147706 (http://www.ncbi.nlm.nih.gov/pubmed/19147706).

127. Bennett JV, Fernandez de Castro J, Poblete RM, et al. A new, rapid, and promising approach to aerosol immunization: inflatable bags and valved masks. Vaccine. 2009 Jul 23;27 (34):4571-5. PMID 19539584.

128. Bentsi-Enchill AD, Zongo I, Khamassi S, et al. Monitoring of adverse events during the

2003 mass vaccination campaign with a trivalent meningococcal A/C/W135 polysaccharide vaccine in Burkina Faso. Vaccine. 2007 Sep 3;25 Suppl 1:A72-8. PMID 17544552.

129. Beran J, Beutels M, Levie K, et al. A single dose, combined vaccine against typhoid fever and hepatitis A: consistency, immunogenicity and reactogenicity. Journal of Travel Medicine. 2000 Sep-Oct;7 (5):246-52. PMID 11231208.

130. Beran J, Hobzova L, Wertzova V, et al. Safety and immunogenicity of an investigational adjuvanted hepatitis B vaccine (HB-AS02(V)) in healthy adults. Human Vaccines. 2010 July;6 (7):578-84. PMID 2010520518 MEDLINE PMID 20523113 (http://www.ncbi.nlm.nih.gov/pubmed/20523113).

131. Beran J, Kervyn D, Wertzova V, et al. Comparison of long-term (10 years) immunogenicity of two- and three-dose regimens of a combined hepatitis A and B vaccine in adolescents. Vaccine. 2010 Aug 23;28 (37):5993-7. PMID 20637766.

132. Bergfors E, Trollfors B, Inerot A. Unexpectedly high incidence of persistent itching nodules and delayed hypersensitivity to aluminium in children after the use of adsorbed vaccines from a single manufacturer. Vaccine. 2003 8;22 (1):64-9. PMID 2003446835 MEDLINE PMID 14604572 (http://www.ncbi.nlm.nih.gov/pubmed/14604572).

133. Berkowitz CD, Ward JI, Meier K, et al. Safety and immunogenicity of Haemophilus influenzae type b polysaccharide and polysaccharide diphtheria toxoid conjugate vaccines in children 15 to 24 months of age. Journal of Pediatrics. 1987 Apr;110 (4):509-14. PMID 3550021.

134. Bermal N, Huang L-M, Dubey AP, et al. Safety and immunogenicity of a tetravalent meningococcal serogroups A, C, W-135 and Y conjugate vaccine in adolescents and adults. Human Vaccines. 2011 Feb;7 (2):239-47. PMID 21343698.

135. Bermal N, Szenborn L, Edison A, et al. Safety and immunogenicity of a booster dose of the 10-valent pneumococcal nontypeable Haemophilus influenzae protein D conjugate vaccine coadministered with DTPw-HBV/Hib and poliovirus vaccines. Pediatric Infectious Disease Journal. 2011 Jan;30 (1):69-72. PMID 20980933.

136. Berner R, Boisnard F, Thomas S, Mwawasi G, Reynolds D. Safety and immunogenicity of fully liquid DTaP(5)-IPV-Hib pediatric combination vaccine (Pediacel((registered trademark))) compared to DTaP(3)-HBV-IPV/Hib (Infanrix((registered trademark)) Hexa) when coadministered with heptavalent pneumococcal conjugate vaccine (PCV7) as a booster at 11-18 months of age: A phase III, modified double-blind, randomized, controlled, multicenter study. Vaccine. 2012.

137. Berner R, Boisnard F, Thomas S, Mwawasi G, Reynolds D. Safety and immunogenicity of fully liquid DTaP(5)-IPV-Hib pediatric combination vaccine (Pediacel([REGISTERED])) compared to DTaP(3)-HBV-IPV/Hib (Infanrix([REGISTERED]) Hexa) when coadministered with heptavalent pneumococcal conjugate vaccine (PCV7) as a booster at 11-18 months of age:

A phase III, modified double-blind, randomized, controlled, multicenter study. Vaccine. 2012 Jul 27;30 (35):5270-7. PMID 22691430.

138. Bernier RH, Frank Jr JA, Dondero Jr TJ, Turner P. Diphtheria-tetanus toxoids-pertussis vaccination and sudden infant deaths in Tennessee. Journal of Pediatrics. 1982 1982;101 (3):419-21. PMID 1982209354 MEDLINE PMID 7108666 (http://www.ncbi.nlm.nih.gov/pubmed/7108666).

139. Bernsen RM, van der Wouden JC. Is childhood immunisation associated with atopic disease from age 7 to 32 years? Thorax. 2007 Oct;62 (10):925; author reply 6. PMID 17909195.

140. Bernsen RMD, Van Der Wouden JC. Re: No epidemiological evidence for infant vaccinations to cause allergic disease. Vaccine. 2005 10;23 (12):1427. PMID 2005053523 MEDLINE PMID 15670875 (http://www.ncbi.nlm.nih.gov/pubmed/15670875).

141. Bernstein D. Efficacy of the pentavalent rotavirus vaccine in subjects after 1 or 2 doses in the rotavirus efficacy and safety trial. Pediatrics. 2008 Jan;121 (1):223; author reply -4. PMID 18166579.

142. Bernstein DI, Glass RI, Rodgers G, Davidson BL, Sack DA. Evaluation of rhesus rotavirus monovalent and tetravalent reassortant vaccines in US children. US Rotavirus Vaccine Efficacy Group. JAMA. 1995 Apr 19;273 (15):1191-6. PMID 7707626.

143. Bernstein DI, Ward RL. Rotarix: development of a live attenuated monovalent human rotavirus vaccine. Pediatric Annals. 2006 Jan;35 (1):38-43. PMID 16466074.

144. Bernstein HH, Noriega F. Immunogenicity and safety of a combined diphtheria, tetanus, 5-component acellular pertussis, inactivated poliomyelitis, Haemophilus type b conjugate vaccine when administered concurrently with a pneumococcal conjugate vaccine: A randomized, open-label, phase 3 study. Vaccine. 2011 2011;29 (11):2212-21. PMID 2011104692 MEDLINE PMID 20609398 (http://www.ncbi.nlm.nih.gov/pubmed/20609398).

145. Bewley KM, Schwab JG, Ballanco GA, Daum RS. Interchangeability of Haemophilus influenzae type b vaccines in the primary series: evaluation of a two-dose mixed regimen. Pediatrics. 1996 Nov;98 (5):898-904. PMID 8909483.

146. Bhandari N, Sharma P, Taneja S, et al. A dose-escalation safety and immunogenicity study of live attenuated oral rotavirus vaccine 116E in infants: a randomized, double-blind, placebo-controlled trial. Journal of Infectious Diseases. 2009 Aug 1;200 (3):421-9. PMID 19545211.

147. Biai S, Rodrigues A, Nielsen J, Sodemann M, Aaby P. Vaccination status and sequence of vaccinations as risk factors for hospitalisation among outpatients in a high mortality country. Vaccine. 2011 May;29 (20):3662-9. PMID WOS:000290977700007.

148. Billal DS, Hotomi M, Yamanaka N. Rotavirus vaccine for developing countries. The Lancet. 2008 20080809/15;372 (9637):444. PMID 2008373042.

149. Bines J. Intussusception and rotavirus vaccines. Vaccine. 2006 May 1;24 (18):3772-6. PMID 16099078.

150. Bines JE. Rotavirus vaccines and intussusception risk. Current Opinion in Gastroenterology. 2005 Jan;21 (1):20-5. PMID 15687880.

151. Bingham CO, 3rd, Looney RJ, Deodhar A, et al. Immunization responses in rheumatoid arthritis patients treated with rituximab: results from a controlled clinical trial. Arthritis & Rheumatism. 2010 Jan;62 (1):64-74. PMID 20039397.

152. Bird SM. Febrile convulsions after seasonal influenza immunisation in UK. Lancet. 2011 Jul 30;378 (9789):399-400; author reply PMID 21803201.

153. Bissantz N, Jenke AC, Trampisch M, et al. Hospital-based, prospective, multicentre surveillance to determine the incidence of intussusception in children aged below 15 years in Germany. Bmc Gastroenterology. 2011;11:26. PMID 21435207.

154. Bjune G, Closs O, Froholm LO, Gronnesby JK, Hoiby EA, Nokleby H. Design of clinical trials with an outer membrane vesicle vaccine against systemic serogroup B meningococcal disease in Norway. NIPH Annals. 1991 Dec;14 (2):81-91; discussion -3. PMID 1812439.

155. Black S. The clinical impact of pneumococcal conjugate vaccines. American Journal of Managed Care. 1999 Nov;5 (SUPPL. 17):S1010-S7. PMID 2000000365.

156. Black S, Friedland LR, Ensor K, Weston WM, Howe B, Klein NP. Diphtheria-tetanus-acellular pertussis and inactivated poliovirus vaccines given separately or combined for booster dosing at 4-6 years of age. Pediatric Infectious Disease Journal. 2008 Apr;27 (4):341-6. PMID 18316985.

157. Black S, Shinefield H. Safety and efficacy of the seven-valent pneumococcal conjugate vaccine: evidence from Northern California. European Journal of Pediatrics. 2002 Dec;161 Suppl 2:S127-31. PMID 12494258.

158. Black S, Shinefield H, Fireman B, et al. Efficacy, safety and immunogenicity of heptavalent pneumococcal conjugate vaccine in children. Northern California Kaiser Permanente Vaccine Study Center Group. Pediatric Infectious Disease Journal. 2000 Mar;19 (3):187-95. PMID 10749457.

159. Black S, Shinefield H, Ray P, et al. Postmarketing evaluation of the safety and effectiveness of varicella vaccine. Pediatric Infectious Disease Journal. 1999 December;18 (12):1041-6. PMID 1999436773 MEDLINE PMID 10608621 (http://www.ncbi.nlm.nih.gov/pubmed/10608621).

160. Black SB, Cimino CO, Hansen J, et al. Immunogenicity and safety of measles-mumps-rubella, varicella and Haemophilus influenzae type b vaccines administered concurrently with a

fourth dose of heptavalent pneumococcal conjugate vaccine compared with the vaccines administered without heptavalent pneumococcal conjugate vaccine. Pediatric Infectious Disease Journal. 2006 Apr;25 (4):306-11. PMID 16567981.

161. Black SB, Shinefield HR. b-CAPSA I Haemophilus influenzae, type b, capsular polysaccharide vaccine safety. Pediatrics. 1987 Mar;79 (3):321-5. PMID 3822630.

162. Black SB, Shinefield HR, Fireman B, Hiatt R. Safety, immunogenicity, and efficacy in infancy of oligosaccharide conjugate Haemophilus influenzae type b vaccine in a United States population: possible implications for optimal use. Journal of Infectious Diseases. 1992 Jun;165 Suppl 1:S139-43. PMID 1588149.

163. Black SB, Shinefield HR, Ray P, et al. Safety of combined oligosaccharide conjugate Haemophilus influenzae type b (HbOC) and whole cell diphtheria-tetanus toxoids-pertussis vaccine in infancy. The Kaiser Permanente Pediatric Vaccine Study Group. Pediatric Infectious Disease Journal. 1993 Dec;12 (12):981-5. PMID 8108224.

164. Blatter M, Friedland LR, Weston WM, Li P, Howe B. Immunogenicity and safety of a tetanus toxoid, reduced diphtheria toxoid and three-component acellular pertussis vaccine in adults 19-64 years of age. Vaccine. 2009 Jan 29;27 (5):765-72. PMID 19041352.

165. Blatter MM, Klein NP, Shepard JS, et al. Immunogenicity and Safety of two tetravalent (measles, mumps, rubella, varicella) vaccines coadministered with hepatitis a and pneumococcal conjugate vaccines to children twelve to fourteen months of age. Pediatric Infectious Disease Journal. 2012 August;31 (8):e133-e40. PMID 2012419784.

166. Blitshteyn S. Postural tachycardia syndrome after vaccination with Gardasil. European Journal of Neurology. 2010 July;17 (7):e52. PMID 2010352058 MEDLINE PMID 20402758 (http://www.ncbi.nlm.nih.gov/pubmed/20402758).

167. Block SL, Falloon J, Hirschfield JA, et al. Immunogenicity and safety of a quadrivalent live attenuated influenza vaccine in children. Pediatric Infectious Disease Journal. 2012 Jul;31 (7):745-51. PMID 22466322.

168. Block SL, Ruiz-Palacios GM, Guerrero ML, Beygo J, Sales V, Holmes SJ. Dose-range Study of MF59-adjuvanted Versus Nonadjuvanted Monovalent A/H1N1 Pandemic Influenza Vaccine in Six- to Less Than Thirty-Six-month-old Children. Pediatric Infectious Disease Journal. 2012 Jul;31 (7):e92-8. PMID 22481427.

169. Block SL, Yi T, Sheldon E, Dubovsky F, Falloon J. A randomized, double-blind noninferiority study of quadrivalent live attenuated influenza vaccine in adults. Vaccine. 2011 Nov 21;29 (50):9391-7. PMID 21983154.

170. Boccara F, Benhaiem-Sigaux N, Cohen A. Acute myopericarditis after diphtheria, tetanus, and polio vaccination. Chest. 2001 2001;120 (2):671-2. PMID 2001332118 MEDLINE PMID 11502677 (http://www.ncbi.nlm.nih.gov/pubmed/11502677).

171. Bocchini Jr JA. Efficacy of the pentavalent rotavirus vaccine in subjects after 1 or 2 doses in the rotavirus efficacy and safety trial: In reply [6]. Pediatrics. 2008 January;121 (1):223-4. PMID 2008022043.

172. Boghani DC, Ali QK. Patient with probable side effect of hepatitis vaccination. CME Journal Ophthalmology. 2000 2000;4 (3):86-7. PMID 2001103434.

173. Booy R, Richmond P, Nolan T, et al. Immediate and longer term immunogenicity of a single dose of the combined Haemophilus influenzae type b-Neisseria meningitidis serogroup c-tetanus toxoid conjugate vaccine in primed toddlers 12 to 18 months of age. Pediatric Infectious Disease Journal. 2011 April;30 (4):340-2. PMID 2011214242 MEDLINE PMID 21068692 (http://www.ncbi.nlm.nih.gov/pubmed/21068692).

174. Booy R, Taylor SA, Dobson SRM, et al. Immunogenicity and Safety of Prp-T Conjugate Vaccine Given According to the British Accelerated Immunization Schedule. Archives of Disease in Childhood. 1992 Apr;67 (4):475-8. PMID WOS:A1992HR68500002.

175. Borba EF, Saad CGS, Pasoto SG, et al. Influenza A/H1N1 vaccination of patients with SLE: can antimalarial drugs restore diminished response under immunosuppressive therapy? Rheumatology. 2012 Jun;51 (6):1061-9. PMID 22298793.

176. Borner N, Muhlberger N, Jelinek T. Tolerability of multiple vaccinations in travel medicine. Journal of Travel Medicine. 2003 March/April;10 (2):112-6. PMID 2003138738 MEDLINE PMID 12650655 (http://www.ncbi.nlm.nih.gov/pubmed/12650655).

177. Botet Asensi FI, Veronese A, Del Carmen Otero M, Desamparados Tamarit Perez M, Hontangas Lopez JL, Viviani S. Immunogenicity and safety in infants of a DTwPHib full liquid vaccine. Acta Paediatrica. 2003 May;92 (5):541-5. PMID 12839281.

178. Botham SJ, Isaacs D. Incidence of apnoea and bradycardia in preterm infants following triple antigen immunization. J Paediatr Child Health. 1994 Dec;30 (6):533-5. PMID 7865269.

179. Botham SJ, Isaacs D, Henderson-Smart DJ. Incidence of apnoea and bradycardia in preterm infants following DTP(w) and Hib immunization: A prospective study. Journal of Paediatrics and Child Health. 1997 1997;33 (5):418-21. PMID 1997331261 MEDLINE PMID 9401886 (http://www.ncbi.nlm.nih.gov/pubmed/9401886).

180. Boudville IC, Phua KB, Quak SH, et al. The epidemiology of paediatric intussusception in Singapore: 1997 to 2004. Annals of the Academy of Medicine, Singapore. 2006 Oct;35 (10):674-9. PMID 17102889.

181. Bouree P. Immunity and immunization in elderly. Pathologie Biologie. 2003 Dec;51 (10):581-5. PMID 14622949.

182. Bradley SF. Influenza in the elderly: Prevention is the best strategy in high-risk

populations. Postgraduate Medicine. 1996 1996;99 (2):138-44+46-49. PMID 1996056403 MEDLINE PMID 8632963 (http://www.ncbi.nlm.nih.gov/pubmed/8632963).

183. Brakemeier S, Schweiger B, Lachmann N, et al. Immune response to an adjuvanted influenza A H1N1 vaccine (Pandemrix(registered trademark)) in renal transplant recipients. Nephrology Dialysis Transplantation. 2012 January;27 (1):423-8. PMID 2012075978 MEDLINE PMID 21613386 (http://www.ncbi.nlm.nih.gov/pubmed/21613386).

184. Breiman RF, Brooks WA, Goswami D, et al. A multinational, randomized, placebo-controlled trial to assess the immunogenicity, safety, and tolerability of live attenuated influenza vaccine coadministered with oral poliovirus vaccine in healthy young children. Vaccine. 2009 Sep 4;27 (40):5472-9. PMID 19616493.

185. Bridy-Pappas AE, Margolis MB, Center KJ, Isaacman DJ. Streptococcus pneumoniae: description of the pathogen, disease epidemiology, treatment, and prevention. Pharmacotherapy:The Journal of Human Pharmacology & Drug Therapy. 2005 Sep;25 (9):1193-212. PMID 16164394.

186. Broeders NE, Hombrouck A, Lemy A, et al. Influenza A/H1N1 vaccine in patients treated by kidney transplant or dialysis: a cohort study. Clinical Journal of The American Society of Nephrology: CJASN. 2011 Nov;6 (11):2573-8. PMID 21921153.

187. Brophy JC, Ward BJ, Samson L, Read S, Bitnun A. Immunogenicity of AS03-adjuvanted H1N1 pandemic influenza vaccine in HIV-infected children. Canadian Journal of Infectious Diseases and Medical Microbiology. 2011 Spring;22 SUPPL. SB:36B.

188. Bryan P, Seabroke S. No increased risk of febrile convulsions after seasonal influenza immunisation in UK. Lancet. 2011 Mar 12;377 (9769):904. PMID 21397766.

189. Bryant KA, Block SL, Baker SA, Gruber WC, Scott DA, Group PCVIS. Safety and immunogenicity of a 13-valent pneumococcal conjugate vaccine. Pediatrics. 2010 May;125 (5):866-75. PMID 20435707.

190. Bryant KA, Marshall GS, Marchant CD, et al. Immunogenicity and safety of H influenzae type b-N meningitidis C/Y conjugate vaccine in infants. Pediatrics. 2011 June;127 (6):e1375-e85. PMID 2011303443 MEDLINE PMID 21624883 (http://www.ncbi.nlm.nih.gov/pubmed/21624883).

191. Buettcher M, Heininger U, Braun M, et al. Hypotonic-hyporesponsive episode (HHE) as an adverse event following immunization in early childhood: Case definition and guidelines for data collection, analysis, and presentation. Vaccine. 2007 1;25 (31):5875-81. PMID 2007335610.

192. Bulkow LR, McMahon BJ, Wainwright RB, Parkinson AJ, Wainwright KY, House J. Safety and immunogenicity of a combined hepatitis B virus-Haemophilus influenzae type B vaccine formulation in healthy adults. Arctic Medical Research. 1993 Jul;52 (3):118-26. PMID 8397580.

193. Bults M, Kemmeren JM, van der Maas NAT. Adverse events following booster doses of diphtheria-tetanus-inactivated poliovirus and acellular pertussis vaccines for 4-year-old children in The Netherlands. Vaccine. 2007 Jul 20;25 (29):5272-7. PMID 17573165.

194. Bunupuradah T, Ananworanich J, Pancharoen C, et al. Randomized study of intradermal compared to intramuscular hepatitis B vaccination in HIV-infected children without severe immunosuppression. Vaccine. 2011 Apr;29 (16):2962-7. PMID WOS:000290062700021.

195. Busse WW, Peters SP, Fenton MJ, et al. Vaccination of patients with mild and severe asthma with a 2009 pandemic H1N1 influenza virus vaccine. Journal of Allergy & Clinical Immunology. 2011 Jan;127 (1):130-7, 7.e1-3. PMID 21145578.

196. Cadorna-Carlos J, Vidor E, Bonnet MC. Randomized controlled study of fractional doses of inactivated poliovirus vaccine administered intradermally with a needle in the Philippines. International Journal of Infectious Diseases. 2012 February;16 (2):e110-e6. PMID 2012044276.

197. Cadoz M, Armand J, Arminjon F, et al. A new 23 valent pneumococcal vaccine: immunogenicity and reactogenicity in adults. Journal of Biological Standardization. 1985 Jul;13 (3):261-5. PMID 4030796.

198. Caillet C, Durrieu G, Jacquet A, et al. Safety surveillance of influenza A(H1N1)v monovalent vaccines during the 2009-2010 mass vaccination campaign in France. European Journal of Clinical Pharmacology. 2011 Jun;67 (6):649-51. PMID 21153631.

199. Cakir FB, Timur C, Yoruk A, Cakir E, Ayhan AC. Seroconversion status after single dose and double doses of varicella vaccination in children with leukemia. Pediatric Hematology & Oncology. 2012 Mar;29 (2):191-4. PMID 21787125.

200. Calbo F, Dal-Re R, Diez-Delgado J, et al. Comparative trial to assess the reactogenicity of the diphtheria-tetanusacellular pertussis (DTPa) vaccine plus Haemophilus influenza type b (Hib) conjugate vaccine and that of the diphtheria-tetanus-whole cell pertussis (DTPw) vaccine plus Hib conjugate vaccine, administered in single injection as a booster dose to 14-20 months-old children. Medicina Clinica. 2002 19;118 (1):1-4. PMID 2002064432 MEDLINE PMID 11803003 (http://www.ncbi.nlm.nih.gov/pubmed/11803003).

201. Cale CM, Klein NJ. The link between rotavirus vaccination and intussusception: implications for vaccine strategies. Gut. 2002 Jan;50 (1):11-2. PMID 11772959.

202. Calmy A, Bel M, Nguyen A, et al. Strong serological responses and HIV RNA increase following AS03-adjuvanted pandemic immunization in HIV-infected patients. HIV Medicine. 2012 April;13 (4):207-18. PMID 2012139702 MEDLINE PMID 22093373 (http://www.ncbi.nlm.nih.gov/pubmed/22093373).

203. Campagne G, Garba A, Fabre P, et al. Safety and immunogenicity of three doses of a Neisseria meningitidis A + C diphtheria conjugate vaccine in infants from Niger. Pediatric

Infectious Disease Journal. 2000 Feb;19 (2):144-50. PMID 10694002.

204. Campbell AL, Bryant KA. Routine childhood immunizations. Primary Care; Clinics in Office Practice. 2001 Dec;28 (4):713-38, vi. PMID 11739027.

205. Campbell H, Byass P, Ahonkhai VI, Vella PP, Greenwood BM. Serologic responses to an Haemophilus influenzae type b polysaccharide-Neisseria meningitidis outer membrane protein conjugate vaccine in very young Gambian infants. Pediatrics. 1990 Jul;86 (1):102-7. PMID 2113671.

206. Campbell JD, Chambers CV, Brady RC, et al. Immunologic non-inferiority of a newly licensed inactivated trivalent influenza vaccine versus an established vaccine: a randomized study in US adults. Human Vaccines. 2011 Jan 1;7 (1):81-8. PMID 21285532.

207. Campbell WN, Hendrix E, Cryz S, Jr., Cross AS. Immunogenicity of a 24-valent Klebsiella capsular polysaccharide vaccine and an eight-valent Pseudomonas O-polysaccharide conjugate vaccine administered to victims of acute trauma. Clinical Infectious Diseases. 1996 Jul;23 (1):179-81. PMID 8816151.

208. Caniza MA, Hunger SP, Schrauder A, et al. The controversy of varicella vaccination in children with acute lymphoblastic leukemia. Pediatric Blood and Cancer. 2012 January;58 (1):12-6. PMID 2011629669 MEDLINE PMID 20848637 (http://www.ncbi.nlm.nih.gov/pubmed/20848637).

209. Caniza MA, Hunger SP, Schrauder A, et al. The controversy of varicella vaccination in children with acute lymphoblastic leukemia. Pediatric Blood & Cancer. 2012 Jan;58 (1):12-6. PMID 20848637.

210. Capeding MR, Cadorna-Carlos J, Book-Montellano M, Ortiz E. Immunogenicity and safety of a DTaP-IPV//PRP approximately T combination vaccine given with hepatitis B vaccine: a randomized open-label trial. Bulletin of the World Health Organization. 2008 Jun;86 (6):443-51. PMID 18568273.

211. Capeding MZR, Puumalainen T, Gepanayao CP, Kayhty H, Lucero MG, Nohynek H. Safety and immunogenicity of three doses of an eleven-valent diphtheria toxoid and tetanus protein--conjugated pneumococcal vaccine in Filipino infants. BMC Infectious Diseases. 2003 Aug 10;3:17. PMID 12908876.

212. Cappelletti M, Taddeo A, Colombo E, et al. Immunogenicity and Safety of Seasonal Influenza Vaccination in Patients with Classic Kaposi's Sarcoma. Journal of Investigative Dermatology. 2012;24.

213. Carlsson RM, Claesson BA, Selstam U, et al. Safety and immunogenicity of a combined diphtheria-tetanus-acellular pertussis-inactivated polio vaccine-Haemophilus influenzae type b vaccine administered at 2-4-6-13 or 3-5-12 months of age. Pediatric Infectious Disease Journal. 1998 Nov;17 (11):1026-33. PMID 9849987.

214. Carmona A, Miranda M, Barrio F, et al. Reactogenicity and immunogenicity of combined haemophilus influenzae type B-meningococcal serogroup C conjugate vaccine booster dose coadministered with measles, mumps, and rubella vaccinehib-menc-TT booster with routine MMR vaccine. Pediatric Infectious Disease Journal. 2010 March;29 (3):269-71. PMID 2010145503 MEDLINE PMID 19952860 (http://www.ncbi.nlm.nih.gov/pubmed/19952860).

215. Carmona A, Omenaca F, Tejedor JC, et al. Immunogenicity and safety of AS03-adjuvanted 2009 influenza A H1N1 vaccine in children 6-35 months. Vaccine. 2010 Aug 16;28 (36):5837-44. PMID 20600478.

216. Carniel EF, Antonio MARGM, Zanolli ML, Vilela MMS. Clinical trials field strategies with novel vaccines produced in Brazil ORIGINAL (NON-ENGLISH) TITLE Estrategias de campo em ensaios clinicos com novas vacinas produzidas no Brasil. Revista Paulista de Pediatria. 2012 June;30 (2):202-9. PMID 2012438939.

217. Carr S, Allison KJ, Van De Velde L-A, et al. Safety and immunogenicity of live attenuated and inactivated influenza vaccines in children with cancer. Journal of Infectious Diseases. 2011 Nov 15;204 (10):1475-82. PMID 21949042.

218. Carraro G, Naso A, Montomoli E, et al. Thymosin-alpha 1 (Zadaxin) enhances the immunogenicity of an adjuvated pandemic H1N1v influenza vaccine (Focetria) in hemodialyzed patients: a pilot study. Vaccine. 2012 Feb 1;30 (6):1170-80. PMID 22178096.

219. Cartwright K, Morris R, Rumke H, et al. Immunogenicity and reactogenicity in UK infants of a novel meningococcal vesicle vaccine containing multiple class 1 (PorA) outer membrane proteins. Vaccine. 1999 4;17 (20 21):2612-9. PMID 1999235600 MEDLINE PMID 10418910 (http://www.ncbi.nlm.nih.gov/pubmed/10418910).

220. Carvajal A, Ortega PG, Sainz M, et al. Adverse events associated with pandemic influenza vaccines: comparison of the results of a follow-up study with those coming from spontaneous reporting. Vaccine. 2011 Jan 10;29 (3):519-22. PMID 21112311.

221. Castro JF, Bennett JV, Rincon HG, Munoz MT, Sanchez LA, Santos JI. Evaluation of immunogenicity and side effects of triple viral vaccine (MMR) in adults, given by two routes: subcutaneous and respiratory (aerosol). Vaccine. 2005 Jan 11;23 (8):1079-84. PMID 15620482.

222. Center KJ, Hansen JR, Lewis E, Fireman BH, Hilton B. Lack of association of Kawasaki disease after immunization in a cohort of infants followed for multiple autoimmune diagnoses in a large, phase-4 observational database safety study of 7-valent pneumococcal conjugate vaccine: lack of association between Kawasaki disease and seven-valent pneumococcal conjugate vaccine. Pediatric Infectious Disease Journal. 2009 May;28 (5):438-40. PMID 19319016.

223. Center KJ, Strauss A. Safety experience with heptavalent pneumococcal CRM197-conjugate vaccine (Prevenar) since vaccine introduction. Vaccine. 2009 May 26;27 (25-

26):3281-4. PMID 19200818.

224. Centers for Disease C, Prevention. Suspension of rotavirus vaccine after reports of intussusception--United States, 1999.[Erratum appears in MMWR Morb Mortal Wkly Rep. 2004 Sep 24;53(37):879]. MMWR - Morbidity & Mortality Weekly Report. 2004 Sep 3;53 (34):786-9. PMID 15343145.

225. Centers for Disease C, Prevention. Postmarketing monitoring of intussusception after RotaTeq vaccination--United States, February 1, 2006-February 15, 2007. MMWR - Morbidity & Mortality Weekly Report. 2007 Mar 16;56 (10):218-22. PMID 17363890.

226. Centers for Disease C, Prevention. Addition of history of intussusception as a contraindication for rotavirus vaccination. MMWR - Morbidity & Mortality Weekly Report. 2011 Oct 21;60 (41):1427. PMID 22012117.

227. Centers for Disease C, Prevention. Licensure of 13-valent pneumococcal conjugate vaccine for adults aged 50 years and older. MMWR - Morbidity & Mortality Weekly Report. 2012 Jun;61 (21):394-5. PMID 22647745.

228. Centers for Disease C, Prevention, Advisory Committee on Immunization P. Update: recommendations from the Advisory Committee on Immunization Practices (ACIP) regarding administration of combination MMRV vaccine. MMWR Morb Mortal Wkly Rep. 2008 Mar 14;57 (10):258-60. PMID 18340332.

229. Chaibou MS, Bako H, Salisou L, et al. Monitoring adverse events following immunization with a new conjugate vaccine against group A meningococcus in Niger, September 2010. Vaccine. 2012 Jul 27;30 (35):5229-34. PMID 22709955.

230. Chandramohan D, Hodgson A, Coleman P, et al. An evaluation of the immunogenicity and safety of a new trivalent meningococcal polysaccharide vaccine. Vaccine. 2007 Sep 3;25 Suppl 1:A83-91. PMID 17521782.

231. Chandran A, Santosham M. RotaTeq: a three-dose oral pentavalent reassortant rotavirus vaccine. Expert Review of Vaccines. 2008 Dec;7 (10):1475-80. PMID 19053204.

232. Chandwani S, Beeler J, Li H, et al. Safety and immunogenicity of early measles vaccination in children born to HIV-infected mothers in the United States: results of Pediatric AIDS Clinical Trials Group (PACTG) protocol 225. Journal of Infectious Diseases. 2011 Jul;204 Suppl 1:S179-89. PMID 21666159.

233. Chang HG, Smith PF, Ackelsberg J, Morse DL, Glass RI. Intussusception, rotavirus diarrhea, and rotavirus vaccine use among children in New York state. Pediatrics. 2001 Jul;108 (1):54-60. PMID 11433054.

234. Chang S, Ball R, Braun MM. Elective termination of pregnancy after vaccination reported to the Vaccine Adverse Event Reporting System (VAERS): 1990-2006. Vaccine. 2008 2;26

(19):2428-32. PMID 2008210701 MEDLINE PMID 18406499 (http://www.ncbi.nlm.nih.gov/pubmed/18406499).

235. Chang Y-T, Guo C-Y, Tsai M-S, et al. Poor immune response to a standard single dose non-adjuvanted vaccination against 2009 pandemic H1N1 influenza virus A in the adult and elder hemodialysis patients. Vaccine. 2012 Jul 13;30 (33):5009-18. PMID 22658967.

236. Charkoudian LD, Kaiser GM, Steinmetz RL, Srivastava SK. Acute retinal necrosis after herpes zoster vaccination. Archives of Ophthalmology. 2011 Nov;129 (11):1495-7. PMID 22084222.

237. Charman T. The highs and lows of counting autism. American Journal of Psychiatry. 2011 September;168 (9):873-5. PMID 2011496939 MEDLINE PMID 21890797 (http://www.ncbi.nlm.nih.gov/pubmed/21890797).

238. Chatterjee A, O'Keefe C, Varman M, et al. Comparative immunogenicity and safety of different multivalent component pertussis vaccine formulations and a 5-component acellular pertussis vaccine in infants and toddlers: A randomized, controlled, open-label, multicenter study. Vaccine. 2012 14;30 (23):3360-8. PMID 2012222630.

239. Chatterjee S, Rego SJ, D'Souza F, et al. The immunogenicity and safety of a reduced PRP-content DTPw-HBV/Hib vaccine when administered according to the accelerated EPI schedule. BMC Infectious Diseases. 2010;10:298. PMID 20950457.

240. Chavant F, Favreliere S, Lafay-Chebassier C, Plazanet C, Perault-Pochat MC. Memory disorders associated with consumption of drugs: Updating through a case/noncase study in the French PharmacoVigilance Database. British Journal of Clinical Pharmacology. 2011 December;72 (6):898-904. PMID 2011622723 MEDLINE PMID 21557759 (http://www.ncbi.nlm.nih.gov/pubmed/21557759).

241. Chazono M, Hirota T, Yoshida I, Konobe T, Takaku K, Fukai K. Safety follow-up in a cohort of Biken acellular DPT vaccine recipients in Japan. Developments in Biological Standardization. 1991;73:323-7. PMID 1778326.

242. Chen J, Heyse JF, Heaton P, Kuter BJ. Age dependence of the risk of intussusception following [corrected] rhesus-human reassortant rotavirus tetravalent vaccine: is it beyond doubt?.[Erratum appears in Am J Epidemiol. 2010 Jul 1;172(1):125]. American Journal of Epidemiology. 2010 May 1;171 (9):1046-54. PMID 20400464.

243. Chen J, Heyse JF, Heaton P, Kuter BJ. Re: "Age Dependence of the Risk of Intussusception Following Tetravalent Rhesus-Human Reassortant Rotavirus Tetravalent Vaccine: Is It Beyond Doubt?" Reply. American Journal of Epidemiology. 2010 Oct;172 (7) PMID WOS:000282166900019.

244. Chen RT. Evaluation of vaccine safety after the events of 11 September 2001: Role of cohort and case-control studies. Vaccine. 2004 7;22 (15 16):2047-53. PMID 2004198046

MEDLINE PMID 15121321 (http://www.ncbi.nlm.nih.gov/pubmed/15121321).

245. Chen RT, Glasser JW, Rhodes PH, et al. Vaccine Safety Datalink project: a new tool for improving vaccine safety monitoring in the United States. The Vaccine Safety Datalink Team. Pediatrics. 1997 Jun;99 (6):765-73. PMID 9164767.

246. Chen RT, Pool V, Takahashi H, Weniger BG, Patel B. Combination vaccines: Postlicensure safety evaluation. Clinical Infectious Diseases. 2001 15;33 (SUPPL. 4):S327-S33. PMID 2001441953 MEDLINE PMID 11709768 (http://www.ncbi.nlm.nih.gov/pubmed/11709768).

247. Chen WH, Winokur PL, Edwards KM, et al. Phase 2 assessment of the safety and immunogenicity of two inactivated pandemic monovalent H1N1 vaccines in adults as a component of the U.S. pandemic preparedness plan in 2009. Vaccine. 2012 13;30 (28):4240-8. PMID 2012314753.

248. Cheng HK, Rajadurai VS, Amin Z, et al. Immunogenicity and reactogenicity of two regimens of diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated polio and Haemophilus influenzae type b vaccines administered to infants primed at birth with hepatitis B vaccine. Southeast Asian Journal of Tropical Medicine & Public Health. 2004 Sep;35 (3):685-92. PMID 15689088.

249. Cheong HJ, Song JY, Heo JY, et al. Immunogenicity and safety of influenza A (H1N1) 2009 monovalent inactivated split vaccine in Korea. Vaccine. 2011 Jan 10;29 (3):523-7. PMID 21055502.

250. Cheong HJ, Song JY, Heo JY, et al. Immunogenicity and safety of the influenza A/H1N1 2009 inactivated split-virus vaccine in young and older adults: MF59-adjuvanted vaccine versus nonadjuvanted vaccine. Clinical & Vaccine Immunology: CVI. 2011 Aug;18 (8):1358-64. PMID 21715575.

251. Cherian T, Thomas N, Raghupathy P, Durot I, Dutta A. Safety and immunogenicity of Haemophilus influenzae type B vaccine given in combination with DTwP at 6, 10 and 14 weeks of age. Indian Pediatrics. 2002 May;39 (5):427-36. PMID 12037271.

252. Chevallier B, Vesikari T, Brzostek J, et al. Safety and reactogenicity of the 10-valent pneumococcal non-typeable Haemophilus influenzae protein D conjugate vaccine (PHiD-CV) when coadministered with routine childhood vaccines. Pediatric Infectious Disease Journal. 2009 Apr;28 (4 Suppl):S109-18. PMID 19325447.

253. Chi R-C, Rock MT, Neuzil KM. Immunogenicity and safety of intradermal influenza vaccination in healthy older adults. Clinical Infectious Diseases. 2010 May 15;50 (10):1331-8. PMID 20377407.

254. Chioato A, Noseda E, Felix SD, et al. Influenza and meningococcal vaccinations are effective in healthy subjects treated with the interleukin-1 beta-blocking antibody canakinumab:

results of an open-label, parallel group, randomized, single-center study. Clinical & Vaccine Immunology: CVI. 2010 Dec;17 (12):1952-7. PMID 20962212.

255. Chippaux JP, Garba A, Ethevenaux C, et al. Immunogenicity, safety, and memory of different schedules of Neisseria meningitidis A/C-diphtheria toxoid conjugate vaccine in infants in Niger. Vaccine. 2004 3;22 (25 26):3303-11. PMID 2004349307 MEDLINE PMID 15308353 (http://www.ncbi.nlm.nih.gov/pubmed/15308353).

256. Chiu HH, Huang LM, Lee PI, Safary A, Lee CY. Diphtheria, tetanus and whole cell pertussis vaccine combined with hepatitis B vaccines: A comparison of two doses (10 (mu)g and 5 (mu)g). Pediatric Infectious Disease Journal. 1998 March;17 (3):206-11. PMID 1998106916 MEDLINE PMID 9535247 (http://www.ncbi.nlm.nih.gov/pubmed/9535247).

257. Choe YJ, Cho H, Bae G-R, Lee J-K. Guillain-Barre syndrome following receipt of influenza A (H1N1) 2009 monovalent vaccine in Korea with an emphasis on Brighton Collaboration case definition. Vaccine. 2011 Mar 3;29 (11):2066-70. PMID 21255684.

258. Choe YJ, Cho H, Kim SN, Bae G-R, Lee J-K. Serious adverse events following receipt of trivalent inactivated influenza vaccine in Korea, 2003-2010. Vaccine. 2011 Oct 13;29 (44):7727-32. PMID 21827815.

259. Choe YJ, Cho H, Song KM, et al. Active surveillance of adverse events following immunization against pandemic influenza A (H1N1) in Korea. Japanese Journal of Infectious Diseases. 2011;64 (4):297-303. PMID 21788704.

260. Choi J-H, Choo EJ, Huh A, et al. Immunogenicity and safety of diphtheria-tetanus vaccine in adults. Journal of Korean Medical Science. 2010 Dec;25 (12):1727-32. PMID 21165286.

261. Choi U, Lee SY, Kwak GY, et al. Immunogenicity and safety of primary and secondary DTaP booster vaccination. Journal of the Korean Medical Association. 2011 September;54 (9):979-87. PMID 2011560263.

262. Choo S, Zuckerman J, Goilav C, Hatzmann E, Everard J, Finn A. Immunogenicity and reactogenicity of a group C meningococcal conjugate vaccine compared with a group A+C meningococcal polysaccharide vaccine in adolescents in a randomised observer-blind controlled trial. Vaccine. 2000 Jun 1;18 (24):2686-92. PMID 10781855.

263. Chou JF, Kernan NA, Prockop S, et al. Safety and immunogenicity of the live attenuated varicella vaccine following T replete or T cell-depleted related and unrelated allogeneic hematopoietic cell transplantation (alloHCT). Biology of Blood & Marrow Transplantation. 2011 Nov;17 (11):1708-13. PMID 21664979.

264. Chouraqui JP, Van Egroo LD, Fichot MC. Acidified milk formula supplemented with bifidobacterium lactis: Impact on infant diarrhea in residential care settings. Journal of Pediatric Gastroenterology and Nutrition. 2004 Mar;38 (3):288-92. PMID WOS:000220589600010.

265. Christenson B, Lundbergh P, Hedlund J, Ortqvist A. Effects of a large-scale intervention with influenza and 23-valent pneumococcal vaccines in adults aged 65 years or older: a prospective study. Lancet. 2001 Mar 31;357 (9261):1008-11. PMID 11293594.

266. Christie CDC, Duncan ND. Rotavirus vaccine trial in Jamaica. West Indian Medical Journal. 2012;61 (4) PMID 2012529420.

267. Christou EM, Wargon O. Stevens-Johnson syndrome after varicella vaccination. Medical Journal of Australia. 2012 5;196 (4):240-1. PMID 2012132562 MEDLINE PMID 22409681 (http://www.ncbi.nlm.nih.gov/pubmed/22409681).

268. Chu DWS, Kwong ASK, Tsui WWS, et al. Cross-clade immunogenicity and safety of an AS03A-adjuvanted prepandemic H5N1 influenza vaccine in Hong Kong. Hong Kong Medical Journal. 2011 Feb;17 (1):39-46. PMID 21282825.

269. Ciarlet M, He S, Lai S, et al. Concomitant use of the 3-dose oral pentavalent rotavirus vaccine with a 3-dose primary vaccination course of a diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated polio-Haemophilus influenzae type b vaccine: immunogenicity and reactogenicity. Pediatric Infectious Disease Journal. 2009 Mar;28 (3):177-81. PMID 19209092.

270. Ciarlet M, Sani-Grosso R, Yuan G, et al. Concomitant use of the oral pentavalent human-bovine reassortant rotavirus vaccine and oral poliovirus vaccine. Pediatric Infectious Disease Journal. 2008 Oct;27 (10):874-80. PMID 18756184.

271. Ciarlet M, Schodel F. Development of a rotavirus vaccine: clinical safety, immunogenicity, and efficacy of the pentavalent rotavirus vaccine, RotaTeq. Vaccine. 2009 Dec 30;27 Suppl 6:G72-81. PMID 20006144.

272. Citron ML, Moss BM. Pneumococcal-vaccine-induced thrombocytopenia. JAMA. 1982 Sep 10;248 (10):1178. PMID 7109129.

273. Claesson BA, Trollfors B, Lagergard T, et al. Clinical and immunologic responses to the capsular polysaccharide of Haemophilus influenzae type b alone or conjugated to tetanus toxoid in 18- to 23-month-old children. Journal of Pediatrics. 1988 May;112 (5):695-702. PMID 3361379.

274. Clarke M, Marshall H. Rotavirus vaccination for prevention of serious acute gastroenteritis and the importance of postlicensure safety monitoring. Journal of Infectious Diseases. 2012 1;206 (1):3-5. PMID 2012308449 MEDLINE PMID 22539816 (http://www.ncbi.nlm.nih.gov/pubmed/22539816).

275. Clarke SC. Control of pneumococcal disease in the United Kingdom - The start of a new era. Journal of Medical Microbiology. 2006 August;55 (8):975-80. PMID 2006387505 MEDLINE PMID 16849715 (http://www.ncbi.nlm.nih.gov/pubmed/16849715).

276. Clarkson A, Conroy S, Burroughs K, Choonara I. Surveillance for adverse drug reactions in

children: A paediatric regional monitoring centre. Paediatric and Perinatal Drug Therapy. 2004 2004;6 (1):20-3. PMID 2004358628.

277. Classen JB, Classen DC. Association between type 1 diabetes and hib vaccine. Causal relation is likely. BMJ. 1999 Oct 23;319 (7217):1133. PMID 10531116.

278. Clements KM, Chancellor J, Nichol K, Delong K, Thompson D. Cost-effectiveness of a recommendation of universal mass vaccination for seasonal influenza in the United States. Value in Health. 2011 September-October;14 (6):800-11. PMID 2011512561 MEDLINE PMID 21914499 (http://www.ncbi.nlm.nih.gov/pubmed/21914499).

279. Clements-Mann ML, Wright PF, Hoshino Y, et al. Safety and immunogenicity of live attenuated human-bovine (UK) reassortant rotavirus vaccines with VP7-specificity for serotypes 1, 2, 3 or 4 in adults, children and infants. Vaccine. 1999 4;17 (20 21):2715-25. PMID 1999235613 MEDLINE PMID 10418923 (http://www.ncbi.nlm.nih.gov/pubmed/10418923).

280. Clerici M, Rizzardini G, Cossu MV, Jespersen L, Calder P, Eskesen D. Probiotic strains BB-12(registered trademark) and L. casei 431(registered trademark) increase the immune response to an influenza vaccine: A randomized, double-blind, placebo-controlled study. European Journal of Pharmacology. 2011 September;668 SUPPL. 1:e3-e4.

281. Clifford V, Crawford NW, Royle J, et al. Recurrent apnoea post immunisation: Informing re-immunisation policy. Vaccine. 2011 05;29 (34):5681-7. PMID 2011399970 MEDLINE PMID 21693156 (http://www.ncbi.nlm.nih.gov/pubmed/21693156).

282. Cohen J. Medicine. Rethinking a vaccine's risk.[Erratum appears in Science 2001 Sep 14;293(5537):1997]. Science. 2001 Aug 31;293 (5535):1576-7. PMID 11533457.

283. Collignon P, Doshi P, Jefferson T. Ramifications of adverse events in children in Australia. BMJ. 2010;(2010) 340 (7759):1262. PMID 2010343617.

284. Collins CL, Salt P, McCarthy N, et al. Immunogenicity and safety of a low-dose diphtheria, tetanus and acellular pertussis combination vaccine with either inactivated or oral polio vaccine as a pre-school booster in UK children. Vaccine. 2004 Oct 22;22 (31-32):4262-9. PMID 15474717.

285. Committee on Obstetric P. ACOG Committee Opinion No. 521: Update on immunization and pregnancy: tetanus, diphtheria, and pertussis vaccination. Obstetrics & Gynecology. 2012 Mar;119 (3):690-1. PMID 22353979.

286. Cook IF, Pond D, Hartel G. Comparative reactogenicity and immunogenicity of 23 valent pneumococcal vaccine administered by intramuscular or subcutaneous injection in elderly adults. Vaccine. 2007 Jun 15;25 (25):4767-74. PMID 17512098.

287. Cook J. Australian experience with non-adjuvant H1N1 vaccine (Panvax and Panvax Junior). Australian Prescriber. 2010 August;33 (4):121-3. PMID 2010533658.

288. Cook KM, Evans G. The national vaccine injury compensation program. Pediatrics. 2011 May;127 (SUPPL. 1):S74-S7. PMID 2011239120 MEDLINE PMID 21502255 (http://www.ncbi.nlm.nih.gov/pubmed/21502255).

289. Cooper C, Klein M, Walmsley S, et al. High-level immunogenicity is achieved vaccine with adjuvanted pandemic H1N1(2009) and improved with booster dosing in a randomized trial of HIV-infected adults. HIV Clinical Trials. 2012 1;13 (1):23-32. PMID 2012150842 MEDLINE PMID 22306585 (http://www.ncbi.nlm.nih.gov/pubmed/22306585).

290. Cooper C, Mackie D. Hepatitis B surface antigen-1018 ISS adjuvant-containing vaccine: a review of HEPLISAV (TM) safety and efficacy. Expert Review of Vaccines. 2011 Apr;10 (4):417-27. PMID WOS:000290834400009.

291. Cooper C, Thorne A, Canadian Institutes of Health Research-Canadian HIVTNIVRG. Influenza vaccine oculorespiratory syndrome incidence is reduced in HIV. Vaccine. 2011 Oct 19;29 (45):7876-7. PMID 21872629.

292. Cooper C, Thorne A, Klein M, et al. Immunogenicity is not improved by increased antigen dose or booster dosing of seasonal influenza vaccine in a randomized trial of HIV infected adults. PLoS ONE [Electronic Resource]. 2011;6 (3):e17758. PMID 21512577.

293. Cooper PA, Madhi SA, Huebner RE, et al. Apnea and its possible relationship to immunization in ex-premature infants. Vaccine. 2008 25;26 (27 28):3410-3. PMID 2008273451 MEDLINE PMID 18490084 (http://www.ncbi.nlm.nih.gov/pubmed/18490084).

294. Cordero E, Perez-Ordonez A, Aydillo TA, et al. Therapy with m-TOR inhibitors decreases the response to the pandemic influenza A H1N1 vaccine in solid organ transplant recipients. American Journal of Transplantation. 2011 Oct;11 (10):2205-13. PMID 21831151.

295. Cordonnier C, Labopin M, Chesnel V, et al. Immune response to the 23-valent polysaccharide pneumococcal vaccine after the 7-valent conjugate vaccine in allogeneic stem cell transplant recipients: Results from the EBMT IDWP01 trial. Vaccine. 2010 24;28 (15):2730-4. PMID 2010153577 MEDLINE PMID 20117269 (http://www.ncbi.nlm.nih.gov/pubmed/20117269).

296. Correia O, Nunes JP, Vaz-da-Silva MJ, Pires S, Brandao F, Mesquita-Guimaraes J. Acute exanthematous pustular dermatitis after pneumococcal vaccine [3]. Dermatology. 1993 1993;187 (3):217. PMID 1993267320 MEDLINE PMID 8219429 (http://www.ncbi.nlm.nih.gov/pubmed/8219429).

297. Coursaget P, Bringer L, Sarr G, et al. Comparative immunogenicity in children of mammalian cell-derived recombinant hepatitis B vaccine and plasma-derived hepatitis B vaccine. Vaccine. 1992;10 (6):379-82. PMID 1534640.

298. Couzin-Frankel J. New network to track drugs and vaccines in pregnancy. Science. 2010

26;327 (5969):1066-7. PMID 2010145181.

299. Crawford N. Immunizations in children with cancer. Paediatrics and Child Health. 2012 March;22 (3):121-2. PMID 2012139859.

300. Crespo M, Collado S, Mir M, et al. Efficacy of influenza A H1N1/2009 vaccine in hemodialysis and kidney transplant patients. Clinical Journal of The American Society of Nephrology: CJASN. 2011 Sep;6 (9):2208-14. PMID 21852661.

301. Cristiani C, Tuccori M, Pepe P, et al. Safety of MF-59 adjuvanted vaccine for pandemic influenza: results of the vaccination campaign in an Italian health district. Vaccine. 2011 Apr 18;29 (18):3443-8. PMID 21396903.

302. Cronin J, Scorr A, Russell S, McCoy S, Walsh S, O'Sullivan R. A review of a paediatric emergency department vaccination programme for patients at risk of allergy/anaphylaxis. Acta Paediatrica. 2012 Sep;101 (9):941-5. PMID 22612789.

303. Crum-Cianflone NF, Eberly LE, Duplessis C, et al. Immunogenicity of a monovalent 2009 influenza a (H1N1) vaccine in an immunocompromised population: A prospective study comparing HIV-infected adults with HIV-uninfected adults. Clinical Infectious Diseases. 2011 1;52 (1):138-46. PMID 2011093231 MEDLINE PMID 21148532 (http://www.ncbi.nlm.nih.gov/pubmed/21148532).

304. Crum-Cianflone NF, Hullsiek KH, Roediger M, et al. A randomized clinical trial comparing revaccination with pneumococcal conjugate vaccine to polysaccharide vaccine among HIV-infected adults. Journal of Infectious Diseases. 2010 1;202 (7):1114-25. PMID 2010562671 MEDLINE PMID 20795819 (http://www.ncbi.nlm.nih.gov/pubmed/20795819).

305. Cserti-Gazdewich CM, Pendergrast JM, Reis M. Postvaccination hyperhemolysis coinciding with remission of Epstein Barr virus (EBV)-associated immune thrombocytopenic purpura (ITP). American Journal of Hematology. 2009 September;84 (9):612-3. PMID 2009465276 MEDLINE PMID 19610018 (http://www.ncbi.nlm.nih.gov/pubmed/19610018).

306. Cuba IPVSCG. Randomized, placebo-controlled trial of inactivated poliovirus vaccine in Cuba. New England Journal of Medicine. 2007 Apr 12;356 (15):1536-44. PMID 17429085.

307. Cullen G, Baden RP, Cheifetz AS. Vaccination in inflammatory bowel disease. American Journal of Gastroenterology. 2011 Jan;106 (1):168. PMID 21212760.

308. Cunningham CK, Rudy BJ, Xu J, et al. Randomized trial to determine safety and immunogenicity of two strategies for hepatitis B vaccination in healthy urban adolescents in the United States. Pediatric Infectious Disease Journal. 2010 Jun;29 (6):530-4. PMID 20173677.

309. Cutts FT, Franceschi S, Goldie S, et al. Human papillomavirus and HPV vaccines: A review. Bulletin of the World Health Organization. 2007 September;85 (9):719-26. PMID 2007453401 MEDLINE PMID 18026629 (http://www.ncbi.nlm.nih.gov/pubmed/18026629).

310. Czajka H, Volker S, Fred Z, Susanna E, Martine D, Paul W. Erratum to "A combined measles, mumps, rubella and varicella vaccine (Priorix-Tetra(trademark)): Immunogenicity and safety profile" by Czajka et al. [Vaccine 27 (47) (2009) 6504-6511] (DOI:10.1016/j.vaccine.2009.07.076). Vaccine. 2012.

311. D'Acremont V, Tremblay S, Genton B. Impact of vaccines given during pregnancy on the offspring of women consulting a travel clinic: a longitudinal study. Journal of Travel Medicine. 2008 Mar-Apr;15 (2):77-81. PMID 18346239.

312. Dagan R. Immunisation with a pneumococcal 7-valent conjugate vaccine. International Journal of Clinical Practice. 2002 May;56 (4):287-91. PMID 12074212.

313. Dagan R, Amir J, Livni G, et al. Concomitant administration of a virosome-adjuvanted hepatitis a vaccine with routine childhood vaccines at age twelve to fifteen months: a randomized controlled trial.[Erratum appears in Pediatr Infect Dis J. 2007 Nov;26(11):1071 Note: Froesner, Gert [corrected to Foresner, Gert]; Schaetzl, Hermann M [corrected to Schatzl, Hermann M]]. Pediatric Infectious Disease Journal. 2007 Sep;26 (9):787-93. PMID 17721372.

314. Dagan R, Igbaria K, Piglansky L, et al. Safety and immunogenicity of a combined pentavalent diphtheria, tetanus, acellular pertussis, inactivated poliovirus and Haemophilus influenzae type b-tetanus conjugate vaccine in infants, compared with a whole cell pertussis pentavalent vaccine. Pediatric Infectious Disease Journal. 1997 Dec;16 (12):1113-21. PMID 9427455.

315. Dagan R, Kayhty H, Wuorimaa T, et al. Tolerability and immunogenicity of an eleven valent mixed carrier Streptococcus pneumoniae capsular polysaccharide-diphtheria toxoid or tetanus protein conjugate vaccine in Finnish and Israeli infants. Pediatric Infectious Disease Journal. 2004 Feb;23 (2):91-8. PMID 14872172.

316. D'Alessandro D, Ciriminna S, Rossini A, Bossa MC, Fara GM. Requests of medical examinations after pneumococcal & influenza vaccination in the elderly. Indian Journal of Medical Research. 2004 May;119 Suppl:108-14. PMID 15232174.

317. Dallar Y, Bostanci I, Bozdayi G, et al. Rotavirus-associated intussusception followed by spontaneous resolution. Turkish Journal of Gastroenterology. 2009 September;20 (3):209-13. PMID 2009551548 MEDLINE PMID 19821204 (http://www.ncbi.nlm.nih.gov/pubmed/19821204).

318. Damm O, Rose MA, Greiner W, et al. Cost-effectiveness of vaccinating children aged 2-17 years with intranasal live attenuated influenza vaccine (LAIV) in germany. Value in Health. 2011 November;14 (7):A280.

319. Daum RS, Hogerman D, Rennels MB, et al. Infant immunization with pneumococcal CRM197 vaccines: effect of saccharide size on immunogenicity and interactions with simultaneously administered vaccines. Journal of Infectious Diseases. 1997 Aug;176 (2):445-55.

PMID 9237711.

320. David S, Vermeer-de Bondt PE, van der Maas NAT. Reactogenicity of infant whole cell pertussis combination vaccine compared with acellular pertussis vaccines with or without simultaneous pneumococcal vaccine in the Netherlands. Vaccine. 2008 Oct 29;26 (46):5883-7. PMID 18775463.

321. Davidson G, Elliott EJ, Kirkwood C, Pearce R. Preventing rotavirus gastroenteritis: do you have the facts? Journal of Paediatrics & Child Health. 2007 Jul-Aug;43 (7-8):564-7. PMID 17635688.

322. Davidson LE, Fiorino AM, Snydman DR, Hibberd PL. Lactobacillus GG as an immune adjuvant for live-attenuated influenza vaccine in healthy adults: a randomized double-blind placebo-controlled trial. European Journal of Clinical Nutrition. 2011 Apr;65 (4):501-7. PMID 21285968.

323. Davis RL, Marcuse E, Black S, et al. MMR2 immunization at 4 to 5 years and 10 to 12 years of age: a comparison of adverse clinical events after immunization in the Vaccine Safety Datalink project. The Vaccine Safety Datalink Team. Pediatrics. 1997 Nov;100 (5):767-71. PMID 9346975.

324. Dayan GH, Thorley M, Yamamura Y, et al. Serologic response to inactivated poliovirus vaccine: A randomized clinical trial comparing 2 vaccination schedules in Puerto Rico. Journal of Infectious Diseases. 2007 1;195 (1):12-20. PMID 2006625373 MEDLINE PMID 17152004 (http://www.ncbi.nlm.nih.gov/pubmed/17152004).

325. Dbaibo G, Van der Wielen M, Reda M, et al. The tetravalent meningococcal serogroups A, C, W-135, and Y tetanus toxoid conjugate vaccine is immunogenic with a clinically acceptable safety profile in subjects previously vaccinated with a tetravalent polysaccharide vaccine. International Journal of Infectious Diseases. 2012 Aug;16 (8):e608-15. PMID 22704725.

326. D'Cruz OF, Shapiro ED, Spiegelman KN, et al. Acute inflammatory demyelinating polyradiculoneuropathy (Guillain-Barre syndrome) after immunization with Haemophilus influenzae type b conjugate vaccine. Journal of Pediatrics. 1989 Nov;115 (5 Pt 1):743-6. PMID 2809907.

327. De Aristegui Fernandez J, Cos Arregui B, Zurimendi Carril A, et al. Evaluation of the safety and immunogenicity of pneumococcal seven-valent conjugate vaccine (Prevenar(registered trademark)) administered in previously unvaccinated Spanish children aged 24 to 36 months. Vaccine. 2005 14;23 (16):1917-22. PMID 2005095973 MEDLINE PMID 15793941 (http://www.ncbi.nlm.nih.gov/pubmed/15793941).

328. de Aristegui Fernandez J, Cos Arregui B, Zurimendi Carril A, et al. Evaluation of the safety and immunogenicity of pneumococcal seven-valent conjugate vaccine (Prevenar) administered in previously unvaccinated Spanish children aged 24 to 36 months. Vaccine. 2005 Mar 14;23 (16):1917-22. PMID 15793941.

329. de Carvalho JF, Shoenfeld Y. Status epilepticus and lymphocytic pneumonitis following hepatitis B vaccination. European Journal of Internal Medicine. 2008 Jul;19 (5):383-5. PMID 18549949.

330. De Roux A, Schmoele-Thoma B, Siber GR, et al. Comparison of pneumococcal conjugate polysaccharide and free polysaccharide vaccines in elderly adults: Conjugate vaccine elicits improved antibacterial immune responses and immunological memory. Clinical Infectious Diseases. 2008 1;46 (7):1015-23. PMID 2008201282 MEDLINE PMID 18444818 (http://www.ncbi.nlm.nih.gov/pubmed/18444818).

331. de Roux A, Schmole-Thoma B, Siber GR, et al. Comparison of pneumococcal conjugate polysaccharide and free polysaccharide vaccines in elderly adults: conjugate vaccine elicits improved antibacterial immune responses and immunological memory.[Erratum appears in Clin Infect Dis. 2008 May 1;46(9):1488 Note: Schmoele-Thoma, B [corrected to Schmole-Thoma, B]]. Clinical Infectious Diseases. 2008 Apr 1;46 (7):1015-23. PMID 18444818.

332. De Schryver A, Verstrepen K, Vandersmissen L, et al. Comparative immunogenicity of two vaccination schedules of a combined hepatitis A and B vaccine in healthy volunteers. Journal of Viral Hepatitis. 2011 Apr;18 (4):e5-10. PMID 20735800.

333. de Serres G, Gariepy MC, Coleman B, et al. Short and long-term safety of the 2009 AS03-adjuvanted pandemic vaccine. PLoS ONE [Electronic Resource]. 2012;7 (7) PMID 2012395916.

334. De Sousa A, Rabarijaona LP, Tenkorang O, et al. Pharmacovigilance of malaria intermittent preventive treatment in infants coupled with routine immunizations in 6 African countries. Journal of Infectious Diseases. 2012 1;205 (SUPPL. 1):S82-S90. PMID 2012094779 MEDLINE PMID 22315391 (http://www.ncbi.nlm.nih.gov/pubmed/22315391).

335. De Wals P, Black S, Borrow R, Pearce D. Modeling the impact of a new vaccine on pneumococcal and nontypable Haemophilus influenzae diseases: A new simulation model. Clinical Therapeutics. 2009 October;31 (10):2152-69. PMID 2009630031 MEDLINE PMID 19922887 (http://www.ncbi.nlm.nih.gov/pubmed/19922887).

336. de Whalley P, Walker W, Snape MD, et al. A 1-year follow-on study from a randomised, head-to-head, multicentre, open-label study of two pandemic influenza vaccines in children. Health Technology Assessment (Winchester, England). 2011 Dec;15 (45):v-vi, xi-xiii, 1-128. PMID 22257497.

337. deBruyn JCC, Hilsden R, Fonseca K, et al. Immunogenicity and safety of influenza vaccination in children with inflammatory bowel disease. Inflammatory Bowel Diseases. 2012 Jan;18 (1):25-33. PMID 21472826.

338. Decker MD, Edwards KM, Bradley R, Palmer P. Comparative trial in infants of four conjugate Haemophilus influenzae type b vaccines. Journal of Pediatrics. 1992 Feb;120 (2 Pt 1):184-9. PMID 1735812.

339. Deeks SL, Lim GH, Simpson MA, et al. Estimating background rates of Guillain-Barre Syndrome in Ontario in order to respond to safety concerns during pandemic H1N1/09 immunization campaign. BMC Public Health. 2011;11:329. PMID 21586163.

340. Deforest A, Long SS, Lischner HW, et al. Simultaneous administration of measles-mumps-rubella vaccine with booster doses of diphtheria-tetanus-pertussis and poliovirus vaccines. Pediatrics. 1988 Feb;81 (2):237-46. PMID 3340474.

341. Della Cioppa G, Nicolay U, Lindert K, et al. Superior immunogenicity of seasonal influenza vaccines containing full dose of MF59 ([REGISTERED]) adjuvant: results from a dose-finding clinical trial in older adults. Human vaccines & Immunotherapeutics. 2012 Feb;8 (2):216-27. PMID 22426371.

342. Della Cioppa G, Vesikari T, Sokal E, Lindert K, Nicolay U. Trivalent and quadrivalent MF59((registered trademark))-adjuvanted influenza vaccine in young children: A dose- and schedule-finding study. Vaccine. 2011 03;29 (47):8696-704. PMID 2011659678 MEDLINE PMID 21906647 (http://www.ncbi.nlm.nih.gov/pubmed/21906647).

343. Dell'Era L, Corona F, Daleno C, Scala A, Principi N, Esposito S. Immunogenicity, safety and tolerability of MF59-adjuvanted seasonal influenza vaccine in children with juvenile idiopathic arthritis. Vaccine. 2012 Jan 20;30 (5):936-40. PMID 22138210.

344. Delong G. A positive association found between autism prevalence and childhood vaccination uptake across the U.S. population. Journal of Toxicology and Environmental Health - Part A: Current Issues. 2011 January;74 (14):903-16. PMID 2011330687 MEDLINE PMID 21623535 (http://www.ncbi.nlm.nih.gov/pubmed/21623535).

345. Deng M-P, Hu Z-H, Wang H-L, Deng F. Developments of subunit and VLP vaccines against influenza a virus. Virologica Sinica. 2012 Jun;27 (3):145-53. PMID 22684468.

346. Denholm JT, Neal A, Yan B, et al. Acute encephalomyelitis syndromes associated with H1N1 09 influenza vaccination. Neurology. 2010 Dec 14;75 (24):2246-8. PMID 21172848.

347. Dennehy PH, North American Human Rotavirus Vaccine Study G. A short report on the highlights of world-wide development of RIX4414: a North American experience comparative evaluation of safety and immunogenicity of two dosages of an oral live attenuated human rotavirus vaccine (RIX4414) in infants in the United States and Canada. Vaccine. 2006 May 1;24 (18):3780-1. PMID 16111790.

348. Desai R, Cortese MM, Meltzer MI, et al. Potential intussusception risk versus benefits of rotavirus vaccination in the United States. Pediatric Infectious Disease Journal. 2012;27.

349. DeStefano F, Vaccine Safety Datalink Research G. The Vaccine Safety Datalink project. Pharmacoepidemiology & Drug Safety. 2001 Aug-Sep;10 (5):403-6. PMID 11802585.

350. DeStefano F, Weintraub ES, Chen RT. Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. Neurology. 2005 Apr 12;64 (7):1317; author reply PMID 15832457.

351. DeWilde S, Carey IM, Richards N, Hilton SR, Cook DG. Do children who become autistic consult more often after MMR vaccination? Br J Gen Pract. 2001 Mar;51 (464):226-7. PMID 11255906.

352. DeWolfe Miller F. Intussusception and an oral rotavirus vaccine. New England Journal of Medicine. 2001 Jun 14;344 (24):1866; author reply -7. PMID 11407352.

353. Dhingra MS, Rao R, Bhat S, et al. Evaluation of the immunogenicity and safety of an indigenously developed DTwP-Hib tetravalent combination vaccine (Shan 4) with EasyFourTM in Indian infants administered per EPI schedule: a phase III trial. Human Vaccines. 2010 Jul;6 (7):572-7. PMID 20421723.

354. Di Lernia V, Ricci C. Skin manifestations with Rotavirus infections. International Journal of Dermatology. 2006 June;45 (6):759-61. PMID 2006337742 MEDLINE PMID 16796645 (http://www.ncbi.nlm.nih.gov/pubmed/16796645).

355. Diaz-Mitoma F, Halperin SA, Tapiero B, et al. Safety and immunogenicity of three different formulations of a liquid hexavalent diphtheria-tetanus-acellular pertussis-inactivated poliovirus-Haemophilus influenzae b conjugate-hepatitis B vaccine at 2, 4, 6 and 12-14 months of age. Vaccine. 2011 Feb 1;29 (6):1324-31. PMID 21134456.

356. Diaz-Ortega JL, Bennett JV, Castaneda D, Vieyra JR, Valdespino-Gomez JL, Fernandez de Castro J. Successful seroresponses to measles and rubella following aerosolized Triviraten vaccine, but poor response to aerosolized mumps (Rubini) component: Comparisons with injected MMR. Vaccine. 2010 8;28 (3):692-8. PMID 2009626889 MEDLINE PMID 19861187 (http://www.ncbi.nlm.nih.gov/pubmed/19861187).

357. Diaz-Ortega J-L, Bennett JV, Castaneda D, Martinez D, Fernandez de Castro J. Aerosolized MMR vaccine: Evaluating potential transmission of components to vaccine administrators and contacts of vaccinees. Biologicals. 2012 Jul;40 (4):278-81. PMID 22494953.

358. Dicko A, Odusanya OO, Diallo AI, et al. Primary vaccination with the 10-valent pneumococcal non-typeable Haemophilus influenzae protein D conjugate vaccine (PHiD-CV) in infants in Mali and Nigeria: a randomized controlled trial. BMC Public Health. 2011;11:882. PMID 22112189.

359. Diez-Domingo J, Cantarino MVP, Torrenti JMB, et al. A randomized, multicenter, open-label clinical trial to assess the immunogenicity of a meningococcal C vaccine booster dose administered to children aged 14 to 18 months. Pediatric Infectious Disease Journal. 2010 Feb;29 (2):148-52. PMID 19927040.

360. Diez-Domingo J, Delgado JD, Ballester A, et al. Immunogenicity and reactogenicity of a

combined adsorbed tetanus toxoid, low dose diphtheria toxoid, five component acellular pertussis and inactivated polio vaccine in six-year-old children. Pediatric Infectious Disease Journal. 2005 Mar;24 (3):219-24. PMID 15750457.

361. Diez-Domingo J, Flores SA, Martin JC, Klopfer SO, Schodel FP, Bhuyan PK. A Randomized, Multicenter, Open-Label Clinical Trial to Assess the Anamnestic Immune Response 4 to 8 Years after a Primary Hepatitis B Vaccination Series. Pediatric Infectious Disease Journal. 2010 Oct;29 (10):972-4. PMID WOS:000282069700017.

362. Dinleyici EC, Yargic ZA. Pneumococcal conjugated vaccine: PHiD-CV. Expert Review of Antiinfective Therapy. 2009 Nov;7 (9):1063-74. PMID 19883326.

363. Dip RM, Cabrera MAS. Influenza vaccination in non-institutionalized elderly: a population-based study in a medium-sized city in Southern Brazil. Cadernos de Saude Publica. 2010 May;26 (5):1035-44. PMID 20563403.

364. Domachowske JB, Blatter M, Chandrasekaran V, Liu A, Jain VK, Fries L. A Randomized, Controlled Trial in Children to Assess the Immunogenicity and Safety of a Thimerosal-free Trivalent Seasonal Influenza Vaccine. Pediatric Infectious Disease Journal. 2012 Jun;31 (6):605-15. PMID 22333695.

365. Donalisio MR, Rodrigues SMCP, Mendes ET, Krutman M. Adverse events after pneumococcal vaccination. Jornal Brasileiro De Pneumologia: Publicacao Oficial Da Sociedade Brasileira De Pneumologia E Tisilogia. 2007 Feb;33 (1):51-6. PMID 17568868.

366. Donato CM, Ch'Ng LS, Boniface KF, et al. Identification of strains of rotateq rotavirus vaccine in infants with gastroenteritis following routine vaccination. Journal of Infectious Diseases. 2012 1;206 (3):377-83. PMID 2012417551.

367. Donnini I, Scappini B, Guidi S, Longo G, Bosi A. Acquired severe aplastic anemia after H1N1 influenza virus vaccination successfully treated with allogeneic bone marrow transplantation. Annals of Hematology. 2012 March;91 (3):475-6. PMID 2012108872 MEDLINE PMID 21681390 (http://www.ncbi.nlm.nih.gov/pubmed/21681390).

368. Dransfield MT, Harnden S, Burton RL, et al. Long-term comparative immunogenicity of protein conjugate and free polysaccharide pneumococcal vaccines in chronic obstructive pulmonary disease. Clinical Infectious Diseases. 2012 1;55 (5):e35-e44. PMID 2012475151.

369. Dransfield MT, Nahm MH, Han MK, et al. Superior immune response to protein-conjugate versus free pneumococcal polysaccharide vaccine in chronic obstructive pulmonary disease. American Journal of Respiratory and Critical Care Medicine. 2009 15;180 (6):499-505. PMID 2009474484 MEDLINE PMID 19556517 (http://www.ncbi.nlm.nih.gov/pubmed/19556517).

370. Drucker J. Poliomyelitis in France: epidemiology and vaccination status. Pediatric Infectious Disease Journal. 1991 Dec;10 (12):967-9. PMID 1766723.

371. Duggan ST. Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) [Prevenar 13([REGISTERED])]: profile report. Paediatric Drugs. 2012 Feb 1;14 (1):67-9. PMID 22149553.

372. Duggan ST, Plosker GL. Intanza(registered trademark) 15(mu)g intradermal seasonal influenza vaccine: In older adults (aged (greater-than or equal to)60 Years). Drugs and Aging. 2010 2010;27 (7):597-605. PMID 2010365583.

373. Durando P, Alicino C, De Florentiis D, Martini M, Icardi G. Improving the protection against Streptococcus pneumoniae with the new generation 13-valent pneumococcal conjugate vaccine. Journal of Preventive Medicine and Hygiene. 2012 June;53 (2):68-77. PMID 2012467780.

374. Dutta AK, Verghese VP, Pemde HK, Mathew LG, Ortiz E. Immunogenicity and safety of a pentavalent diphtheria, tetanus, acellular pertussis, inactivated poliovirus, Haemophilus influenzae type B conjugate combination vaccine (Pentaxim) with hepatitis B vaccine. Indian Pediatrics. 2009 Nov;46 (11):975-82. PMID 19955579.

375. Edelman R. Perspective on the development and deployment of rotavirus vaccines. Pediatric Infectious Disease Journal. 1987 1987;6 (8):704-10. PMID 1987218510 MEDLINE PMID 2823210 (http://www.ncbi.nlm.nih.gov/pubmed/2823210).

376. Ehrlich HJ, Muller M, Kollaritsch H, et al. Pre-vaccination immunity and immune responses to a cell culture-derived whole-virus H1N1 vaccine are similar to a seasonal influenza vaccine. Vaccine. 2012 Jun 22;30 (30):4543-51. PMID 22475864.

377. Einstein MH, Baron M, Levin MJ, et al. Comparative immunogenicity and safety of human papillomavirus (HPV)-16/18 vaccine and HPV-6/11/16/18 vaccine: follow-up from months 12-24 in a Phase III randomized study of healthy women aged 18-45 years. Human Vaccines. 2011 Dec;7 (12):1343-58. PMID 22048173.

378. El Bashir H, Heath PT, Papa T, et al. Antibody responses to meningococcal (groups A, C, Y and W135) polysaccharide diphtheria toxoid conjugate vaccine in children who previously received meningococcal C conjugate vaccine. Vaccine. 2006 Mar 24;24 (14):2544-9. PMID 16417952.

379. El Sahly H. MF59(trademark) as a vaccine adjuvant: A review of safety and immunogenicity. Expert Review of Vaccines. 2010 October;9 (10):1135-41. PMID 2010571720.

380. El Sahly HM, Davis C, Kotloff K, et al. Higher antigen content improves the immune response to 2009 H1N1 influenza vaccine in HIV-infected adults: A randomized clinical trial. Journal of Infectious Diseases. 2012 1;205 (5):703-12. PMID 2012093406 MEDLINE PMID 22275399 (http://www.ncbi.nlm.nih.gov/pubmed/22275399).

381. El-Darouti MA, Hegazy RA, Abdel Hay RM, Abdel Halim DM. Live attenuated varicella vaccine: A new effective adjuvant weapon in the battlefield against severe resistant psoriasis, a

pilot randomized controlled trial. Journal of the American Academy of Dermatology. 2012 March;66 (3):511-3. PMID 2012113496 MEDLINE PMID 22342019 (http://www.ncbi.nlm.nih.gov/pubmed/22342019).

382. Elkayam O, Ablin J, Caspi D. Safety and efficacy of vaccination against streptococcus pneumonia in patients with rheumatic diseases. Autoimmunity Reviews. 2007 Apr;6 (5):312-4. PMID 17412304.

383. Elkayam O, Amir S, Mendelson E, et al. Efficacy and safety of vaccination against pandemic 2009 influenza A (H1N1) virus among patients with rheumatic diseases. Arthritis care & research. 2011 Jul;63 (7):1062-7. PMID 21425247.

384. Elkayam O, Paran D, Caspi D, et al. Immunogenicity and safety of pneumococcal vaccination in patients with rheumatoid arthritis or systemic lupus erythematosus. Clinical Infectious Diseases. 2002 Jan 15;34 (2):147-53. PMID 11740700.

385. Ellenberg SS, Foulkes MA, Midthun K, Goldenthal KL. Evaluating the safety of new vaccines: Summary of a workshop. American Journal of Public Health. 2005 May;95 (5):800-7. PMID 2005198869 MEDLINE PMID 15855455 (http://www.ncbi.nlm.nih.gov/pubmed/15855455).

386. Ellison VJ, Davis PG, Doyle LW. Adverse reactions to immunization with newer vaccines in the very preterm infant. Journal of Paediatrics & Child Health. 2005 Aug;41 (8):441-3. PMID 16101980.

387. Engels EA, Chen J, Viscidi RP, et al. Poliovirus vaccination during pregnancy, maternal seroconversion to simian virus 40, and risk of childhood cancer. American Journal of Epidemiology. 2004 15;160 (4):306-16. PMID 2004340755 MEDLINE PMID 15286015 (http://www.ncbi.nlm.nih.gov/pubmed/15286015).

388. Englund JA, Glezen WP. Passive immunization for the prevention of otitis media. Vaccine. 2000 Dec 8;19 Suppl 1:S116-21. PMID 11163474.

389. Englund JA, Walter EB, Gbadebo A, Monto AS, Zhu Y, Neuzil KM. Immunization with trivalent inactivated influenza vaccine in partially immunized toddlers. Pediatrics. 2006 September;118 (3):e579-e85. PMID 2007030586 MEDLINE PMID 16950949 (http://www.ncbi.nlm.nih.gov/pubmed/16950949).

390. Eriksson KaH, Jan. Recent advances in mucosal vaccines and adjuvants. Current Opinion in Immunology. 2002 1;14 (5):666-72. PMID 2002383933 MEDLINE PMID 12183170 (http://www.ncbi.nlm.nih.gov/pubmed/12183170).

391. Escolano S, Farrington CP, Hill C, Tubert-Bitter P. Intussusception after rotavirus vaccination--spontaneous reports. New England Journal of Medicine. 2011 Dec 1;365 (22):2139. PMID 22129263.

392. Eskola J, Kilpi T, Palmu A, et al. Efficacy of a pneumococcal conjugate vaccine against acute otitis media. New England Journal of Medicine. 2001 Feb 8;344 (6):403-9. PMID 11172176.

393. Eskola J, Olander RM, Hovi T, Litmanen L, Peltola S, Kayhty H. Randomised trial of the effect of co-administration with acellular pertussis DTP vaccine on immunogenicity of Haemophilus influenzae type b conjugate vaccine. Lancet. 1996 Dec 21-28;348 (9043):1688-92. PMID 8973430.

394. Espinosa-Padilla SE, Murata C, Estrada-Parra S, et al. Immunogenicity of A 23-Valent Pneumococcal Polysaccharide Vaccine Among Mexican Children. Archives of Medical Research. 2012 July;43 (5):402-5. PMID 2012540268.

395. Esposito S, Daleno C, Picciolli I, et al. Immunogenicity and safety of intradermal influenza vaccine in children. Vaccine. 2011 Oct 13;29 (44):7606-10. PMID 21855592.

396. Esposito S, D'Angelo E, Daleno C, et al. Immunogenicity, safety and tolerability of monovalent 2009 pandemic influenza A/H1N1 MF59-adjuvanted vaccine in patients with beta-thalassemia major. Vaccine. 2010 Nov 23;28 (50):7825-8. PMID 20888873.

397. Esposito S, Marchisio P, Ansaldi F, et al. A randomized clinical trial assessing immunogenicity and safety of a double dose of virosomal-adjuvanted influenza vaccine administered to unprimed children aged 6-35 months. Vaccine. 2010 Aug 31;28 (38):6137-44. PMID 20670909.

398. Esposito S, Meregalli E, Daleno C, et al. An open-label, randomized clinical trial assessing immunogenicity, safety and tolerability of pandemic influenza A/H1N1 MF59-adjuvanted vaccine administered sequentially or simultaneously with seasonal virosomal-adjuvanted influenza vaccine to paediatric kidney transplant recipients. Nephrology Dialysis Transplantation. 2011 Jun;26 (6):2018-24. PMID 20974645.

399. Esposito S, Pugni L, Bosis S, et al. Immunogenicity, safety and tolerability of heptavalent pneumococcal conjugate vaccine administered at 3, 5 and 11 months post-natally to pre- and full-term infants. Vaccine. 2005 Feb 25;23 (14):1703-8. PMID 15705475.

400. Esposito S, Pugni L, Daleno C, et al. Influenza A/H1N1 MF59-adjuvanted vaccine in preterm and term children aged 6 to 23 months. Pediatrics. 2011 May;127 (5):e1161-8. PMID 21464195.

401. Esposito S, Selicorni A, Daleno C, et al. Immunogenicity, safety and tolerability of monovalent 2009 pandemic influenza A/H1N1 MF59-adjuvanted vaccine in children and adolescents with Williams or Cornelia De Lange syndrome. Human Vaccines. 2011 Jun;7 (6):613-7. PMID 21508673.

402. Esposito S, Tagliaferri L, Daleno C, et al. Pandemic influenza A/H1N1 vaccine administered sequentially or simultaneously with seasonal influenza vaccine to HIV-infected

children and adolescents. Vaccine. 2011 Feb 11;29 (8):1677-82. PMID 21199699.

403. Esposito S, Tansey S, Thompson A, et al. Safety and immunogenicity of a 13-valent pneumococcal conjugate vaccine compared to those of a 7-valent pneumococcal conjugate vaccine given as a three-dose series with routine vaccines in healthy infants and toddlers. Clinical & Vaccine Immunology: CVI. 2010 Jun;17 (6):1017-26. PMID 20427630.

404. Esteghamati A, Keshtkar A, Heshmat R, et al. Adverse reactions following immunization with MMR vaccine in children at selected provinces of Iran. Archives of Iranian Medicine. 2011 Mar;14 (2):91-5. PMID 21361714.

405. Estivariz CF, Molnar Z, Venczel L, et al. Paralytic poliomyelitis associated with Sabin monovalent and bivalent oral polio vaccines in Hungary. American Journal of Epidemiology. 2011 Aug 1;174 (3):316-25. PMID 21685412.

406. Fabrizi F, Dixit V, Messa P, Martin P. Intradermal vs intramuscular vaccine against hepatitis B infection in dialysis patients: a meta-analysis of randomized trials. Journal of Viral Hepatitis. 2011 Oct;18 (10):730-7. PMID WOS:000295091500034.

407. Fabrizi F, Dixit V, Messa P, Martin P. Hepatitis B virus vaccine in chronic kidney disease: Improved immunogenicity by adjuvants? A meta-analysis of randomized trials. Vaccine. 2012 Mar;30 (13):2295-300. PMID WOS:000302050500007.

408. Faingezicht I, Avila-Aguerro ML, Cervantes Y, Fourneau M, Clemens SAC. Primary and booster vaccination with DTPw-HB/Hib pentavalent vaccine in Costa Rican children who had received a birth dose of hepatitis B vaccine. Pan American Journal of Public Health. 2002 Oct;12 (4):247-57. PMID 12431356.

409. Fairley CK, Begg N, Borrow R, Fox AJ, Jones DM, Cartwright K. Conjugate meningococcal serogroup A and C vaccine: reactogenicity and immunogenicity in United Kingdom infants. Journal of Infectious Diseases. 1996 Dec;174 (6):1360-3. PMID 8940235.

410. Faldella G, Galletti S, Corvaglia L, Ancora G, Alessandroni R. Safety of DTaP-IPV-HIb-HBV hexavalent vaccine in very premature infants. Vaccine. 2007 Jan 22;25 (6):1036-42. PMID 17088013.

411. Falvo C, Horowitz H. Adverse reactions associated with simultaneous administration of multiple vaccines to travelers. Journal of General Internal Medicine. 1994 1994;9 (5):255-60. PMID 1994158851 MEDLINE PMID 8046527 (http://www.ncbi.nlm.nih.gov/pubmed/8046527).

412. Farr C. Intussusception alert. Nursing. 2007 Apr;37 (4):10. PMID 17413328.

413. Farrell RA. Comment: Human papillomavirus vaccination, induced autoimmunity, and neuromyelitis optica. Neurology. 2012 Jul 17;79 (3):287. PMID 22722623.

414. Feikin DR, Elie CM, Goetz MB, et al. Randomized trial of the quantitative and functional antibody responses to a 7-valent pneumococcal conjugate vaccine and/or 23-valent polysaccharide vaccine among HIV-infected adults. Vaccine. 2001 Nov 12;20 (3-4):545-53. PMID 11672921.

415. Felldin M, Studahl M, Svennerholm B, Friman V. The antibody response to pandemic H1N1 2009 influenza vaccine in adult organ transplant patients. Transplant International. 2012 Feb;25 (2):166-71. PMID 22117586.

416. Ferguson M, Risi G, Davis M, et al. Safety and long-term humoral immune response in adults after vaccination with an H1N1 2009 pandemic influenza vaccine with or without AS03 adjuvant. Journal of Infectious Diseases. 2012 Mar;205 (5):733-44. PMID 22315336.

417. Fernandes P, Jorge S, Lopes JA. Relapse of Nephrotic Syndrome Following the Use of 2009 Pandemic Influenza A(H1N1) Vaccine. American Journal of Kidney Diseases. 2010 July;56 (1):185-6. PMID 2010341744 MEDLINE PMID 20620684 (http://www.ncbi.nlm.nih.gov/pubmed/20620684).

418. Fernandez JD, Arregui BC, Carril AZ, et al. Evaluation of the safety and immunogenicity of pneumococcal seven-valent conjugate vaccine (Prevenar (R)) administered in previously unvaccinated Spanish children aged 24 to 36 months. Vaccine. 2005 Mar;23 (16):1917-22. PMID WOS:000227769800004.

419. Ferraz-Filho JRL, dos Santos Torres U, de Oliveira EP, Souza AS. MRI findings in an infant with vaccine-associated paralytic poliomyelitis. Pediatric Radiology. 2010 Dec;40 Suppl 1:S138-40. PMID 20440488.

420. Ferrera G, Cuccia M, Mereu G, et al. Booster vaccination of pre-school children with reduced-antigen-content diphtheria-tetanus-acellular pertussis-inactivated poliovirus vaccine co-administered with measles-mumps-rubella-varicella vaccine: A randomized, controlled trial in children primed according to a 2+1 schedule in infancy. Human Vaccines and Immunotherapeutics. 2012 March;8 (3):345-52. PMID 2012244551.

421. Findlow H, Borrow R, Andrews N, et al. Immunogenicity of a single dose of meningococcal group C conjugate vaccine given at 3 months of age to healthy infants in the United Kingdom. Pediatric Infectious Disease Journal. 2012 June;31 (6):616-22. PMID 2012304671.

422. Fine HF, Kim E, Flynn TE, Gomes NL, Chang S. Acute posterior multifocal placoid pigment epitheliopathy following varicella vaccination. British Journal of Ophthalmology. 2010 March;94 (3):282-3+363. PMID 2010174467 MEDLINE PMID 18728052 (http://www.ncbi.nlm.nih.gov/pubmed/18728052).

423. Fisher JPH, Bate J, Hambleton S. Preventing varicella in children with malignancies: what is the evidence? Current Opinion in Infectious Diseases. 2011 Jun;24 (3):203-11. PMID 21455062.

424. Fleming JD, Fogo AJ, Creamer DJ. Stevens-Johnson syndrome triggered by seasonal influenza vaccination and flucloxacillin: A pathogenetic hypothesis. European Journal of Dermatology. 2011 May-June;21 (3):434-5. PMID 2011413504 MEDLINE PMID 21680282 (http://www.ncbi.nlm.nih.gov/pubmed/21680282).

425. Fletcher MA, Fabre P, Debois H, Saliou P. Vaccines administered simultaneously: directions for new combination vaccines based on an historical review of the literature. International Journal of Infectious Diseases. 2004 Nov;8 (6):328-38. PMID 15494254.

426. Flynn PM, Cunningham CK, Rudy B, et al. Hepatitis B vaccination in HIV-infected youth: A randomized trial of three regimens. Journal of Acquired Immune Deficiency Syndromes. 2011 1;56 (4):325-32. PMID 2011137338 MEDLINE PMID 21350366 (http://www.ncbi.nlm.nih.gov/pubmed/21350366).

427. Folkenberg M, Callreus T, Svanstrom H, Valentiner-Branth P, Hviid A. Spontaneous reporting of adverse events following immunisation against pandemic influenza in Denmark November 2009-March 2010. Vaccine. 2011 Feb 1;29 (6):1180-4. PMID 21172382.

428. Fombonne E, Chakrabarti S. No evidence for a new variant of measles-mumps-rubella-induced autism. Pediatrics. 2001 Oct;108 (4):E58. PMID 11581466.

429. Forrest BD, Steele AD, Hiemstra L, Rappaport R, Ambrose CS, Gruber WC. A prospective, randomized, open-label trial comparing the safety and efficacy of trivalent live attenuated and inactivated influenza vaccines in adults 60 years of age and older. Vaccine. 2011 May 9;29 (20):3633-9. PMID 21440036.

430. Fortner KB, Kuller JA, Rhee EJ, Edwards KM. Influenza and tetanus, diphtheria, and acellular pertussis vaccinations during pregnancy. Obstetrical and Gynecological Survey. 2012 April;67 (4):251-7. PMID 2012224216.

431. Fox BC, Peterson A. Leukocytoclastic vasculitis after pneumococcal vaccination. American Journal of Infection Control. 1998 Jun;26 (3):365-6. PMID 9638297.

432. Fox RI, Fox CM. Sjogren's syndrome: Infections that may play a role in pathogenesis, mimic the disease, or complicate the patient's course. Indian Journal of Rheumatology. 2011 March;6 (1):13-25. PMID 2011259578.

433. Frampton JE. DTaP(5)-IPV-Hib vaccine (Pediacel[REGISTERED]). Paediatric Drugs. 2011 Dec 1;13 (6):401-15. PMID 21999652.

434. Frank AL, Labotka RJ, Rao S, et al. Haemophilus influenzae type b immunization of children with sickle cell diseases. Pediatrics. 1988 Oct;82 (4):571-5. PMID 3262857.

435. Frasch CE, Preziosi MP, LaForce FM. Development of a group A meningococcal conjugate vaccine, MenAfriVac (TM). Human Vaccines & Immunotherapeutics. 2012 Jun;8

(6):715-24. PMID WOS:000307105200013.

436. Fraunfelder FW, Suhler EB, Fraunfelder FT. Hepatitis B vaccine and uveitis: an emerging hypothesis suggested by review of 32 case reports. Cutaneous and Ocular Toxicology. 2010 Mar;29 (1):26-9. PMID WOS:000274856100005.

437. Frayha HH, Dent P, Shannon HS, Johnson SE, Gordon L. Safety and immunogenicity of subcutaneous H. influenzae vaccines in 15-17 month-old children. Clinical & Investigative Medicine - Medecine Clinique et Experimentale. 1991 Oct;14 (5):379-87. PMID 1742915.

438. Frayha HH, Shaheen H, Ganelin RS, et al. Clinical and Serologic Responses of Saudi Children to Haemophilus-Influenzae Type-B Capsular Polysaccharide Diphtheria Toxoid Conjugate Vaccine. Annals of Saudi Medicine. 1993 May;13 (3):215-21. PMID WOS:A1993LU63500002.

439. Freedman SB, Reed J, Burwen DR, Wise RP, Weiss A, Ball R. Transient bulging fontanelle after vaccination: case report and review of the vaccine adverse event reporting system. Journal of Pediatrics. 2005 Nov;147 (5):640-4. PMID 16291356.

440. French N, Gordon SB, Mwalukomo T, et al. A trial of a 7-valent pneumococcal conjugate vaccine in HIV-infected adults. New England Journal of Medicine. 2010 Mar 4;362 (9):812-22. PMID 20200385.

441. Frenck Jr RW, Gurtman A, Rubino J, et al. Randomized, controlled trial of a 13-valent pneumococcal conjugate vaccine administered concomitantly with an influenza vaccine in healthy adults. Clinical and Vaccine Immunology. 2012 August;19 (8):1296-303. PMID 2012459613.

442. Frenck R, Jr., Thompson A, Yeh SH, et al. Immunogenicity and safety of 13-valent pneumococcal conjugate vaccine in children previously immunized with 7-valent pneumococcal conjugate vaccine. Pediatric Infectious Disease Journal. 2011 Dec;30 (12):1086-91. PMID 21983216.

443. Frenck RW, Jr., Belshe R, Brady RC, et al. Comparison of the immunogenicity and safety of a split-virion, inactivated, trivalent influenza vaccine (Fluzone[REGISTERED]) administered by intradermal and intramuscular route in healthy adults. Vaccine. 2011 Aug 5;29 (34):5666-74. PMID 21699951.

444. Fridman D, Monti A, Bonnet M-C, Armoni J, Stamboulian D. Safety of a second dose of varicella vaccine administered at 4 to 6 years of age in healthy children in Argentina. Human Vaccines. 2011 Oct;7 (10):1066-71. PMID 21989288.

445. Fu C, Xu J, Tan H, Wang M. Serious adverse reactions should be further monitored after influenza A (H1N1) vaccination among children: postmarketing experience with 570,000 vaccinations between October 2009 and August 2010 in Guangzhou, China. Pediatric Infectious Disease Journal. 2011 Jul;30 (7):631-2. PMID 21673552.

446. Fuchshuber A, Kuhnemund O, Keuth B, Lutticken R, Michalk D, Querfeld U. Pneumococcal vaccine in children and young adults with chronic renal disease. Nephrology Dialysis Transplantation. 1996 Mar;11 (3):468-73. PMID 8671817.

447. Fujii T, Naganuma M, Kunisaki R, Yoshimura N, Takeuchi Y, Watanabe M. Prevalence of influenza infection and safety of human infection with influenza a (H1N1) vaccine in patients with IBD patients treated with immunomodulators and biologics. Gastroenterology. 2011 May;140 (5 SUPPL. 1):S771.

448. Fukase H, Furuie H, Yasuda Y, et al. Assessment of the immunogenicity and safety of varying doses of an MF59([REGISTERED])-adjuvanted cell culture-derived A/H1N1 pandemic influenza vaccine in Japanese paediatric, adult and elderly subjects. Vaccine. 2012 Jul 13;30 (33):5030-7. PMID 22472791.

449. Fukuda K, Thompson WW, Cox N. Vaccinating Japanese schoolchildren against influenza. New England Journal of Medicine. 2001 Jun 21;344 (25):1946-7; author reply 7-8. PMID 11419435.

450. Funkhouser AW, Wassilak SG, Orenstein WA, Hinman AR, Mortimer EA, Jr. Estimated effects of a delay in the recommended vaccination schedule for diphtheria and tetanus toxoids and pertussis vaccine. JAMA. 1987 Mar 13;257 (10):1341-6. PMID 3493356.

451. Furck AK, Richter JW, Kattner E. Very low birth weight infants have only few adverse events after timely immunization. Journal of Perinatology. 2010 February;30 (2):118-21. PMID 2010102377 MEDLINE PMID 19710678 (http://www.ncbi.nlm.nih.gov/pubmed/19710678).

452. Gabay C, Bel M, Combescure C, et al. Impact of synthetic and biologic disease-modifying antirheumatic drugs on antibody responses to the AS03-adjuvanted pandemic influenza vaccine: a prospective, open-label, parallel-cohort, single-center study. Arthritis & Rheumatism. 2011 Jun;63 (6):1486-96. PMID 21384334.

453. Gabutti G, Zepp F, Schuerman L, et al. Evaluation of the immunogenicity and reactogenicity of a DTPa-HBV-IPV combination vaccine co-administered with a hib conjugate vaccine either as a single injection of a hexavalent combination or as two separate injections at 3, 5 and 11 months of age. Scandinavian Journal of Infectious Diseases. 2004 2004;36 (8):585-92. PMID 2004403850 MEDLINE PMID 15370670 (http://www.ncbi.nlm.nih.gov/pubmed/15370670).

454. Gadzinowski J, Albrecht P, Hasiec B, et al. Phase 3 trial evaluating the immunogenicity, safety, and tolerability of manufacturing scale 13-valent pneumococcal conjugate vaccine. Vaccine. 2011 Apr 5;29 (16):2947-55. PMID 21335032.

455. Gadzinowski J, Tansey S, Mellelieu T, Baker S, Giardina PC, Scott DA. A phase 3 trial evaluating the safety, tolerability and immunogenicity of manufacturing scale 13-valent pneumococcal conjugate vaccine. Vaccine. 2008 PMID WOS:000268750600111.

456. Gaebler JW, Kleiman MB, French MLV. Neurologic complications in oral polio vaccine recipients. Journal of Pediatrics. 1986 1986;108 (6):878-81. PMID 1986175866 MEDLINE PMID 3012055 (http://www.ncbi.nlm.nih.gov/pubmed/3012055).

457. Gaglani MJ, Piedra PA, Riggs M, Herschler G, Fewlass C, Glezen WP. Safety of the intranasal, trivalent, live attenuated influenza vaccine (LAIV) in children with intermittent wheezing in an open-label field trial. Pediatr Infect Dis J. 2008 May;27 (5):444-52. PMID 18401289.

458. Gagneur A, Nowak E, Lemaitre T, et al. Impact of rotavirus vaccination on hospitalizations for rotavirus diarrhea: The IVANHOE study. Vaccine. 2011 12;29 (21):3753-9. PMID 2011226126 MEDLINE PMID 21443962 (http://www.ncbi.nlm.nih.gov/pubmed/21443962).

459. Gajdos V, Soubeyrand B, Vidor E, et al. Immunogenicity and safety of combined adsorbed low-dose diphtheria, tetanus and inactivated poliovirus vaccine (REVAXIS (R)) versus combined diphtheria, tetanus and inactivated poliovirus vaccine (DT Polio (R)) given as a booster dose at 6 years of age. Human Vaccines. 2011 May;7 (5):549-56. PMID WOS:000291095300016.

460. Gajdos V, Soubeyrand B, Vidor E, et al. Immunogenicity and safety of combined adsorbed low-dose diphtheria, tetanus and inactivated poliovirus vaccine (REVAXIS ([REGISTERED])) versus combined diphtheria, tetanus and inactivated poliovirus vaccine (DT Polio ([REGISTERED])) given as a booster dose at 6 years of age. Human Vaccines. 2011 May;7 (5):549-56. PMID 21441781.

461. Galindo Santana BM, Concepcion D, Galindo MA, Perez A, Saiz J. Vaccine-related adverse events in Cuban children, 1999-2008. MEDICC Review. 2012 January;14 (1):38-43. PMID 2012066223.

462. Galiza EP, Heath PT. Pneumococcal conjugate vaccines. A review. Minerva Medica. 2007 Apr;98 (2):131-43. PMID 17519855.

463. Gall SA. Prevention of Pertussis, Tetanus, and Diphtheria Among Pregnant, Postpartum Women, and Infants. Clinical Obstetrics and Gynecology. 2012 Jun;55 (2):498-588. PMID WOS:000303042500017.

464. Garcia-Sicilia J, Gillard P, Carmona A, et al. Immunogenicity and safety of AS03-adjuvanted H1N1 pandemic vaccines in children and adolescents. Vaccine. 2011 Jun 10;29 (26):4353-61. PMID 21504774.

465. Gargiullo PM, Murphy TV, Davis RL. Is there a safe age for vaccinating infants with tetravalent rhesus-human reassortant rotavirus vaccine? Journal of Infectious Diseases. 2006 Dec 15;194 (12):1793-4; author reply 4-5. PMID 17109356.

466. Gasparini R, Amicizia D, Lai PL, Panatto D. Aflunov(registered trademark): A

prepandemic influenza vaccine. Expert Review of Vaccines. 2012 February;11 (2):145-57. PMID 2012089452 MEDLINE PMID 22309663 (http://www.ncbi.nlm.nih.gov/pubmed/22309663).

467. Gasparini R, Conversano M, Bona G, et al. Randomized trial on the safety, tolerability, and immunogenicity of MenACWY-CRM, an investigational quadrivalent meningococcal glycoconjugate vaccine, administered concomitantly with a combined tetanus, reduced diphtheria, and acellular pertussis vaccine in adolescents and young adults. Clinical & Vaccine Immunology: CVI. 2010 Apr;17 (4):537-44. PMID 20164251.

468. Gasparini R, Lai P. Utility of virosomal adjuvated influenza vaccines: A review of the literature. Journal of Preventive Medicine and Hygiene. 2010 March;51 (1):1-6. PMID 2010374744 MEDLINE PMID 20853669 (http://www.ncbi.nlm.nih.gov/pubmed/20853669).

469. Gasparini R, Schioppa F, Lattanzi M, et al. Impact of prior or concomitant seasonal influenza vaccination on MF59-adjuvanted H1N1v vaccine (Focetria) in adult and elderly subjects. International Journal of Clinical Practice. 2010 Mar;64 (4):432-8. PMID 20039974.

470. Gatchalian S, Reyes M, Bernal N, et al. A new DTPw-HBV/Hib vaccine is immunogenic and safe when administered according to the EPI (Expanded Programme for Immunization) schedule and following hepatitis B vaccination at birth. Human Vaccines. 2005 Sep-Oct;1 (5):198-203. PMID 17012860.

471. Gatchalian S, Yao Y, Zhou B, et al. Comparison of the immunogenicity and safety of measles vaccine administered alone or with live, attenuated Japanese encephalitis SA 14-14-2 vaccine in Philippine infants. Vaccine. 2008 24;26 (18):2234-41. PMID 2008192614 MEDLINE PMID 18394765 (http://www.ncbi.nlm.nih.gov/pubmed/18394765).

472. Gatchalian SR, Ramakrishnan G, Bock HL, Lefevre I, Jacquet JM. Immunogenicity, reactogenicity and safety of three-dose primary and booster vaccination with combined diphtheria-tetanus-whole-cell pertussis-hepatitis B-reduced antigen content Haemophilus influenzae type b vaccine in Filipino children. Human Vaccines. 2010 Aug;6 (8):664-72. PMID 20657177.

473. Gatchatian S, Patestroque E, De Vleeschauwer I, et al. The development of a new heptavalent diphtheria-tetanus-whole cell pertussis-hepatitis B-Hoemophilus influenzae type b-Neisseria meningitidis serogroups A and C vaccine: a randomized dose-ranging trial of the conjugate vaccine components. International Journal of Infectious Diseases. 2008 May;12 (3):278-88. PMID WOS:000255834000010.

474. Gaughran F, Walwyn R, Lambkin-Williams R, et al. Flu: effect of vaccine in elderly care home residents: a randomized trial. J Am Geriatr Soc. 2007 Dec;55 (12):1912-20. PMID 18081669.

475. Gay N, Ramsay M, Waight P. Rotavirus vaccination and intussusception [12]. Lancet. 1999 11;354 (9182):956. PMID 1999315893 MEDLINE PMID 10489989

(http://www.ncbi.nlm.nih.gov/pubmed/10489989).

476. Geier DA, Geier MR. An evaluation of the effects of thimerosal on neurodevelopmental disorders reported following DTP and Hib vaccines in comparison to DTPH vaccine in the United States. Journal of Toxicology & Environmental Health Part A. 2006 Aug;69 (15):1481-95. PMID 16766480.

477. Geier DA, King PG, Sykes LK, Geier MR. RotaTeq vaccine adverse events and policy considerations. Medical Science Monitor. 2008 Mar;14 (3):PH9-16. PMID 18301365.

478. Geier DA, King PG, Sykes LK, Geier MR. The temporal relationship between RotaTeq immunization and intussusception adverse events in the Vaccine Adverse Event Reporting System (VAERS). Medical Science Monitor. 2012 Feb;18 (2):PH12-7. PMID 22293889.

479. Gensicke H, Datta AN, Dill P, Schindler C, Fischer D. Increased incidence of Guillain-Barre Syndrome after surgery. European Journal of Neurology. 2012.

480. Gentile A, Umido V, Czerniuk P, et al. Immunogenicity and reactogenicity of a combined fully liquid DTPw-HepB-Hib pentavalent vaccine in healthy infants: no clinically relevant impact of a birth dose of hepatitis B vaccine. International Journal of Infectious Diseases. 2011 Jan;15 (1):e24-9. PMID 21093342.

481. Gershon AA, Levin MJ, Weinberg A, et al. A phase I-II study of live attenuated varicella-zoster virus vaccine to boost immunity in human immunodeficiency virus-infected children with previous varicella. Pediatr Infect Dis J. 2009 Jul;28 (7):653-5. PMID 19561431.

482. Gervaix A, Caflisch M, Suter S, Haenggeli CA. Guillain-Barre-Syndrome Following Immunization with Haemophilus-Influenzae Type-B Conjugate Vaccine. European Journal of Pediatrics. 1993 Jul;152 (7):613-4. PMID WOS:A1993LJ08700017.

483. Gidudu J, Sack DA, Pina M, et al. Diarrhea: Case definition and guidelines for collection, analysis, and presentation of immunization safety data. Vaccine. 2011 29;29 (5):1053-71. PMID 2011043493 MEDLINE PMID 21130754 (http://www.ncbi.nlm.nih.gov/pubmed/21130754).

484. Gilbert CL, Klopfer SO, Martin JC, Schodel FP, Bhuyan PK. Safety and immunogenicity of a modified process hepatitis B vaccine in healthy adults >= 50 years. Human Vaccines. 2011 Dec;7 (12):1336-42. PMID WOS:000299784500021.

485. Gil-Bistes D, Kluger N, Bessis D, Guillot B, Raison-Peyron N. Pityriasis lichenoides chronic after measles-mumps-rubella vaccination. Journal of Dermatology. 2012 May;39 (5):492-3. PMID 2012218636.

486. Gilca R, Deceuninck G, De Serres G, et al. Effectiveness of pandemic H1N1 vaccine against influenza-related hospitalization in children. Pediatrics. 2011 November;128 (5):e1084-e91. PMID 2011606732 MEDLINE PMID 21987710 (http://www.ncbi.nlm.nih.gov/pubmed/21987710).

487. Gilderman LI, Lawless JF, Nolen TM, et al. A double-blind, randomized, controlled, multicenter safety and immunogenicity study of a refrigerator-stable formulation of Zostavax. Clin Vaccine Immunol. 2008 Feb;15 (2):314-9. PMID 18077611.

488. Gillberg C., Heijbel H. MMR and autism. Autism. 1998;2:423-24.

489. Gimenez-Sanchez F, Kieninger DM, Kueper K, et al. Immunogenicity of a combination vaccine containing diphtheria toxoid, tetanus toxoid, three-component acellular pertussis, hepatitis B, inactivated polio virus, and Haemophilus influenzae type b when given concomitantly with 13-valent pneumococcal conjugate vaccine. Vaccine. 2011 Aug;29 (35):6042-8. PMID WOS:000294145900028.

490. Girgis CM, Russo RR, Benson K. Subacute thyroiditis following the H1N1 vaccine. Journal of Endocrinological Investigation. 2010 July-August;33 (7):506. PMID 2010541712 MEDLINE PMID 20671410 (http://www.ncbi.nlm.nih.gov/pubmed/20671410).

491. Gisbert JP, Menchen L, Garcia-Sanchez V, Marin I, Villagrasa JR, Chaparro M. Comparison of the effectiveness of two protocols for vaccination (standard and double dosage) against hepatitis B virus in patients with inflammatory bowel disease. Alimentary Pharmacology and Therapeutics. 2012 June;35 (12):1379-85. PMID 2012283976.

492. Givon-Lavi N, Greenberg D, Dagan R. Immunogenicity of alternative regimens of the conjugated 7-valent pneumococcal vaccine: A randomized controlled trial. Pediatric Infectious Disease Journal. 2010 August;29 (8):756-62. PMID 2010417404 MEDLINE PMID 20661103 (http://www.ncbi.nlm.nih.gov/pubmed/20661103).

493. Glass RI. New hope for defeating rotavirus. Scientific American. 2006 Apr;294 (4):46-51, 4-5. PMID 16596879.

494. Glass RI, Bresee J, Jiang B, Parashar U, Yee E, Gentsch J. Rotavirus and rotavirus vaccines. Advances in Experimental Medicine & Biology. 2006;582:45-54. PMID 16802618.

495. Glass RI, Bresee JS, Parashar UD, Jiang B, Gentsch J. The future of rotavirus vaccines: a major setback leads to new opportunities. Lancet. 2004 May 8;363 (9420):1547-50. PMID 15135605.

496. Glass RI, Parashar UD. Rotavirus vaccines - Reply. New England Journal of Medicine. 2006 Apr;354 (16):1750-1. PMID WOS:000236893900021.

497. Glass RI, Parashar UD, Bresee JS, et al. Rotavirus vaccines: current prospects and future challenges. Lancet. 2006 Jul 22;368 (9532):323-32. PMID 16860702.

498. Glezen WP, Simonsen L. Commentary: benefits of influenza vaccine in US elderly--new studies raise questions. Int J Epidemiol. 2006 Apr;35 (2):352-3. PMID 16368723.

499. Gloriani NG, Srinivasa K, Bock HL, Hoet B. Immunogenicity of Hbv Vaccine during Stated Shelf-Life. Southeast Asian Journal of Tropical Medicine and Public Health. 2010 Jul;41 (4):876-82. PMID WOS:000280521900013.

500. Gold R, Artenstein MS. Meningococcal infections. 2. Field trial of group C meningococcal polysaccharide vaccine in 1969-70. Bulletin of the World Health Organization. 1971;45 (3):279-82. PMID 5316907.

501. Gold R, Barreto L, Ferro S, et al. Safety and immunogenicity of a fully liquid vaccine containing five-component pertussis-diphtheria-tetanus-inactivated poliomyelitis-Haemophilus influenzae type b conjugate vaccines administered at two, four, six and 18 months of age. The Canadian Journal of Infectious Diseases & Medical Microbiology. 2007 Jul;18 (4):241-8. PMID 18923741.

502. Gold R, Scheifele D, Barreto L, et al. Safety and immunogenicity of Haemophilus influenzae vaccine (tetanus toxoid conjugate) administered concurrently or combined with diphtheria and tetanus toxoids, pertussis vaccine and inactivated poliomyelitis vaccine to healthy infants at two, four and six months of age. Pediatric Infectious Disease Journal. 1994 May;13 (5):348-55. PMID 8072815.

503. Goldblatt D, Southern J, Andrews N, et al. The immunogenicity of 7-valent pneumococcal conjugate vaccine versus 23-valent polysaccharide vaccine in adults aged 50-80 years. Clinical Infectious Diseases. 2009 November;49 (9):1318-25. PMID 2010000660 MEDLINE PMID 19814624 (http://www.ncbi.nlm.nih.gov/pubmed/19814624).

504. Goldblatt D, Southern J, Ashton L, et al. Immunogenicity and boosting after a reduced number of doses of a pneumococcal conjugate vaccine in infants and toddlers. Pediatric Infectious Disease Journal. 2006 April;25 (4):312-9. PMID 2006163612 MEDLINE PMID 16567982 (http://www.ncbi.nlm.nih.gov/pubmed/16567982).

505. Goldstein GL. Pneumococcal vaccine in asthmatics. New England Journal of Medicine. 1982 Jun 24;306 (25):1554. PMID 7078621.

506. Gomber S, Sharma R, Ramachandran VG. Immunogenicity of low dose intradermal hepatitis B vaccine and its comparison with standard dose intramuscular vaccination. Indian Pediatrics. 2004 Sep;41 (9):922-6. PMID 15475635.

507. Goodman MJ, Nordin JD, Belongia EA, Mullooly JP, Baggs J. Henoch-Schonlein Purpura and Polysaccharide Meningococcal Vaccine. Pediatrics. 2010 Aug;126 (2):E325-E9. PMID WOS:000280565700034.

508. Goodman MJ, Nordin JD, Belongia EA, Mullooly JP, Baggs J. Henoch-Scholein purpura and polysaccharide meningococcal vaccine. Pediatrics. 2010 Aug;126 (2):e325-9. PMID 20624811.

509. Gordon DL, Sajkov D, Woodman RJ, et al. Randomized clinical trial of immunogenicity

and safety of a recombinant H1N1/2009 pandemic influenza vaccine containing Advax(trademark) polysaccharide adjuvant. Vaccine. 2012.

510. Gordon SB, Malamba R, Mthunthama N, et al. Inhaled delivery of 23-valent pneumococcal polysaccharide vaccine does not result in enhanced pulmonary mucosal immunoglobulin responses. Vaccine. 2008 3;26 (42):5400-6. PMID 2008429083 MEDLINE PMID 18708114 (http://www.ncbi.nlm.nih.gov/pubmed/18708114).

511. Gottfredsson M, Reynisson IK, Ingvarsson RF, et al. Comparative long-term adverse effects elicited by invasive group B and C meningococcal infections. Clinical Infectious Diseases. 2011 Nov;53 (9):e117-24. PMID 21946191.

512. Goulleret N, Mauvisseau E, Essevaz-Roulet M, Quinlivan M, Breuer J. Safety profile of live varicella virus vaccine (Oka/Merck): five-year results of the European Varicella Zoster Virus Identification Program (EU VZVIP). Vaccine. 2010 Aug 16;28 (36):5878-82. PMID 20600487.

513. Grabenstein JD, Manoff SB. Pneumococcal polysaccharide 23-valent vaccine: long-term persistence of circulating antibody and immunogenicity and safety after revaccination in adults. Vaccine. 2012 Jun 22;30 (30):4435-44. PMID 22542818.

514. Granoff DM, Osterholm MT. Safety and efficacy of Haemophilus influenzae type b polysaccharide vaccine. Pediatrics. 1987 Oct;80 (4):590-2. PMID 3498928.

515. Greenberg DP, Vadheim CM, Marcy SM, et al. Safety and immunogenicity of a recombinant hepatitis B vaccine administered to infants at 2, 4 and 6 months of age. The Kaiser-UCLA Vaccine Study Group. Vaccine. 1996 Jun;14 (8):811-6. PMID 8817829.

516. Greenberg DP, Vadheim CM, Wong VK, et al. Comparative safety and immunogenicity of two recombinant hepatitis B vaccines given to infants at two, four and six months of age. Pediatric Infectious Disease Journal. 1996 July;15 (7):590-6. PMID 1996218974 MEDLINE PMID 8823852 (http://www.ncbi.nlm.nih.gov/pubmed/8823852).

517. Greenberg DP, Ward JI, Burkart K, Christenson PD, Guravitz L, Marcy SM. Factors influencing immunogenicity and safety of two Haemophilus influenzae type b polysaccharide vaccines in children 18 and 24 months of age. Pediatric Infectious Disease Journal. 1987 Jul;6 (7):660-5. PMID 3497380.

518. Greenberg DP, Wong VK, Partridge S, et al. Immunogenicity of a Haemophilus influenzae type b-tetanus toxoid conjugate vaccine when mixed with a diphtheria-tetanus-acellular pertussis-hepatitis B combination vaccine. Pediatric Infectious Disease Journal. 2000 Dec;19 (12):1135-40. PMID 11144372.

519. Greenberg DP, Wong VK, Partridge S, Howe BJ, Ward JI. Safety and immunogenicity of a combination diphtheria-tetanus toxoids-acellular pertussis-hepatitis B vaccine administered at two, four and six months of age compared with monovalent hepatitis B vaccine administered at

birth, one month and six months of age. Pediatric Infectious Disease Journal. 2002 Aug;21 (8):769-77. PMID 12192167.

520. Greenhawt MJ, Chernin AS, Howe L, Li JT, Sanders G. The safety of the H1N1 influenza A vaccine in egg allergic individuals. Annals of Allergy, Asthma, & Immunology. 2010 Nov;105 (5):387-93. PMID 21055666.

521. Griffiss JM, Brandt BL, Altieri PL, Pier GB, Berman SL. Safety and immunogenicity of group Y and group W135 meningococcal capsular polysaccharide vaccines in adults. Infection & Immunity. 1981 Dec;34 (3):725-32. PMID 6800954.

522. Griffiss JM, Brandt BL, Altieri PL, Pier GB, Berman SL. Safety and immunogenicity of a group 29E meningococcal capsular polysaccharide vaccine in adults. Infection & Immunity. 1983 Jan;39 (1):247-52. PMID 6401693.

523. Grilli G, Fuiano L, Biasio LR, et al. Simultaneous influenza and pneumococcal vaccination in elderly individuals. European Journal of Epidemiology. 1997 Apr;13 (3):287-91. PMID 9258527.

524. Grimprel E, Laudat F, Patterson S, et al. Immunogenicity and safety of a 13-valent pneumococcal conjugate vaccine (PCV13) when given as a toddler dose to children immunized with PCV7 as infants. Vaccine. 2011 Dec 6;29 (52):9675-83. PMID 22008822.

525. Grimprel E, Wysocki J, Boisnard F, Thomas S, Mwawasi G, Reynolds D. Immunogenicity and safety of fully liquid DTaP5-IPV-Hib compared with DTaP3-IPV/Hib when both coadministered with a heptavalent pneumococcal conjugate vaccine (PCV7) at 2, 3, 4, and 12 to 18 months of age: a phase III, single-blind, randomised, controlled, multicentre study. Vaccine. 2011 Oct 6;29 (43):7370-8. PMID 21807056.

526. Grimwood K. Unraveling rotaviruses, oral vaccines and intussusception. Journal of Paediatrics & Child Health. 2005 Sep-Oct;41 (9-10):471-2. PMID 16150060.

527. Gross TP, Hayes SW. Haemophilus conjugate vaccine and Guillain-Barre syndrome. Journal of Pediatrics. 1991 Jan;118 (1):161. PMID 1986087.

528. Groth N, Montomoli E, Gentile C, Manini I, Bugarini R, Podda A. Safety, tolerability and immunogenicity of a mammalian cell-culture-derived influenza vaccine: a sequential Phase I and Phase II clinical trial. Vaccine. 2009 Jan 29;27 (5):786-91. PMID 19027046.

529. Guerra FA, Blatter MM, Greenberg DP, Pichichero M, Noriega FR, Pentacel Study G. Safety and immunogenicity of a pentavalent vaccine compared with separate administration of licensed equivalent vaccines in US infants and toddlers and persistence of antibodies before a preschool booster dose: a randomized, clinical trial. Pediatrics. 2009 Jan;123 (1):301-12. PMID 19117896.

530. Guerra FA, Gress J, Werzberger A, et al. Safety, tolerability and immunogenicity of

VAQTA given concomitantly versus nonconcomitantly with other pediatric vaccines in healthy 12-month-old children. Pediatric Infectious Disease Journal. 2006 Oct;25 (10):912-9. PMID 17006287.

531. Gumede N, Muthambi V, Schoub BD. Immunodeficiency-associated vaccine-derived poliovirus type 3 in infant, South Africa, 2011. Emerging Infectious Diseases. 2012 Jun;18 (6):992-4. PMID 22607733.

532. Gupta A, Agarwal SK. Immunization in Renal Transplant Recipients: Where Do We Stand? Hong Kong Journal of Nephrology. 2010 April;12 (1):6-11. PMID 2010239625.

533. Gustafsson L, Hallander HO, Olin P, Reizenstein E, Storsaeter J. A controlled trial of a two-component acellular, a five-component acellular, and a whole-cell pertussis vaccine. N Engl J Med. 1996 Feb 8;334 (6):349-55. PMID 8538705.

534. Gyhrs A, Lyngholm E, Larsen SO, Aggerbeck H, Heron I. Immunogenicity and safety of a tetravalent diphtheria-tetanus-acellular pertussis-inactivated poliovirus vaccine. Scandinavian Journal of Infectious Diseases. 1999;31 (6):579-85. PMID 10680989.

535. Haber P, Iskander J, Walton K, Campbell SR, Kohl KS. Internet-based reporting to the vaccine adverse event reporting system: A more timely and complete way for providers to support vaccine safety. Pediatrics. 2011 May;127 (SUPPL. 1):S39-S44. PMID 2011239116 MEDLINE PMID 21502243 (http://www.ncbi.nlm.nih.gov/pubmed/21502243).

536. Haber P, Patel M, Iskander J, Gargiullo P, Baggs J, Parashar U. Importance of On-time RotaTeq Vaccination and Long-term Active Surveillance In Reply. Pediatrics. 2008 Nov;122 (5):1154-. PMID WOS:000260542500032.

537. Haber P, Patel M, Izurieta HS, et al. Postlicensure monitoring of intussusception after RotaTeq vaccination in the United States, February 1, 2006, to September 25, 2007. Pediatrics. 2008 Jun;121 (6):1206-12. PMID 18519491.

538. Hajiabdolbaghi M, Jam S, SeyedAlinaghi S, Jafari S, Badie BM, Sabzvari D. Adverse reactions of trivalent influenza vaccine in HIV-infected individuals. Acta Medica Iranica. 2010 Mar-Apr;48 (2):95-100. PMID 21133001.

539. Hak E, van Loon S, Buskens E, et al. Design of the Dutch prevention of influenza, surveillance and management (PRISMA) study. Vaccine. 2003 Apr 2;21 (15):1719-24. PMID 12639495.

540. Hakim H, Allison KJ, Van De Velde L-A, Li Y, Flynn PM, McCullers JA. Immunogenicity and safety of inactivated monovalent 2009 H1N1 influenza A vaccine in immunocompromised children and young adults. Vaccine. 2012 Jan 20;30 (5):879-85. PMID 22155630.

541. Halasa NB, Gerber MA, Chen Q, Wright PF, Edwards KM. Safety and immunogenicity of trivalent inactivated influenza vaccine in infants. J Infect Dis. 2008 May 15;197 (10):1448-54.

PMID 18444800.

542. Hales K, Barriere SL. Polyvalent pneumococcal vaccines: a review. American Journal of Hospital Pharmacy. 1979 Jun;36 (6):773-7. PMID 380332.

543. Hall AJ. Ecological studies and debate on rotavirus vaccine and intussusception. Lancet. 2001 Oct 13;358 (9289):1197-8. PMID 11675051.

544. Halperin BA, Halperin SA, McGrath P, Smith B, Houston T. Use of lidocaine-prilocaine patch to decrease intramuscular injection pain does not adversely affect the antibody response to diphtheria-tetanus-acellular pertussis-inactivated poliovirus-Haemophilus influenzae type b conjugate and hepatitis B vaccines in infants from birth to six months of age. Pediatric Infectious Disease Journal. 2002 May;21 (5):399-405. PMID 12150176.

545. Halperin SA, Barreto L, Eastwood BJ, Medd L, Guasparini R, Mills E. Safety and immunogenicity of an acellular pertussis diphtheria tetanus vaccine given as a single injection with Haemophilus influenzae b conjugate vaccine. Vaccine. 1997 Feb;15 (3):295-300. PMID 9139489.

546. Halperin SA, Davies HD, Barreto L, et al. Safety and immunogenicity of two inactivated poliovirus vaccines in combination with an acellular pertussis vaccine and diphtheria and tetanus toxoids in seventeen- to nineteen-month-old infants. Journal of Pediatrics. 1997 Apr;130 (4):525-31. PMID 9108847.

547. Halperin SA, Diaz-Mitoma F, Dull P, Anemona A, Ceddia F. Safety and immunogenicity of an investigational quadrivalent meningococcal conjugate vaccine after one or two doses given to infants and toddlers. European Journal of Clinical Microbiology & Infectious Diseases. 2010 Mar;29 (3):259-67. PMID 20033465.

548. Halperin SA, Gupta A, Jeanfreau R, et al. Comparison of the safety and immunogenicity of an investigational and a licensed quadrivalent meningococcal conjugate vaccine in children 2-10 years of age. Vaccine. 2010 Nov 23;28 (50):7865-72. PMID 20943209.

549. Halperin SA, King J, Law B, Mills E, Willems P. Safety and immunogenicity of Haemophilus influenzae-tetanus toxoid conjugate vaccine given separately or in combination with a three-component acellular pertussis vaccine combined with diphtheria and tetanus toxoids and inactivated poliovirus vaccine for the first four doses. Clinical Infectious Diseases. 1999 May;28 (5):995-1001. PMID 10452624.

550. Halperin SA, Langley JM, Hesley TM, et al. Safety and immunogenicity of two formulations of a hexavalent diphtheria-tetanus-acellular pertussis-inactivated poliovirus-Haemophilus influenzae conjugate-hepatitis B vaccine in 15 to 18-month-old children. Human Vaccines. 2005 Nov-Dec;1 (6):245-50. PMID 17012871.

551. Halperin SA, McDonald J, Samson L, et al. Simultaneous administration of meningococcal C conjugate vaccine and diphtheria-tetanus-acellular pertussis-inactivated poliovirus-

Haemophilus influenzae type b conjugate vaccine in children: a randomized double-blind study. Clinical & Investigative Medicine - Medecine Clinique et Experimentale. 2002 Dec;25 (6):243-51. PMID 12516995.

552. Halperin SA, McNeil S, Langley J, et al. Tolerability and antibody response in adolescents and adults revaccinated with tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine adsorbed (Tdap) 4-5 years after a previous dose. Vaccine. 2011 Oct 26;29 (46):8459-65. PMID 21803091.

553. Halperin SA, Scheifele D, Barreto L, et al. Comparison of a fifth dose of a five-component acellular or a whole cell pertussis vaccine in children four to six years of age. Pediatric Infectious Disease Journal. 1999 Sep;18 (9):772-9. PMID 10493336.

554. Halperin SA, Scheifele D, Mills E, et al. Nature, evolution, and appraisal of adverse events and antibody response associated with the fifth consecutive dose of a five-component acellular pertussis-based combination vaccine. Vaccine. 2003 Jun 2;21 (19-20):2298-306. PMID 12744860.

555. Halperin SA, Smith B, Mabrouk T, et al. Safety and immunogenicity of a trivalent, inactivated, mammalian cell culture-derived influenza vaccine in healthy adults, seniors, and children. Vaccine. 2002 Jan 15;20 (7-8):1240-7. PMID 11803087.

556. Halperin SA, Smith B, Russell M, et al. Adult formulation of a five component acellular pertussis vaccine combined with diphtheria and tetanus toxoids and inactivated poliovirus vaccine is safe and immunogenic in adolescents and adults. Pediatric Infectious Disease Journal. 2000 Apr;19 (4):276-83. PMID 10783014.

557. Halperin SA, Tapiero B, Diaz-Mitoma F, et al. Safety and immunogenicity of a hexavalent diphtheria-tetanus-acellular pertussis-inactivated poliovirus-Haemophilus influenzae b conjugate-hepatitis B vaccine at 2, 3, 4, and 12-14 months of age. Vaccine. 2009 Apr 28;27 (19):2540-7. PMID 19124057.

558. Halperin SA, Tapiero B, Law B, et al. Interchangeability of two diphtheria and tetanus toxoids, acellular pertussis, inactivated poliovirus, Haemophilus influenzae type b conjugate vaccines as a fourth dose in 15-20-month-old toddlers. Vaccine. 2006 May 1;24 (18):4017-23. PMID 16516357.

559. Halperin SA, Ward B, Cooper C, et al. Comparison of safety and immunogenicity of two doses of investigational hepatitis B virus surface antigen co-administered with an immunostimulatory phosphorothioate oligodeoxyribonucleotide and three doses of a licensed hepatitis B vaccine in healthy adults 18-55 years of age. Vaccine. 2012 Mar;30 (15):2556-63. PMID WOS:000302822600008.

560. Halperin SA, Ward B, Cooper C, et al. Comparison of safety and immunogenicity of two doses of investigational hepatitis B virus surface antigen co-administered with an immunostimulatory phosphorothioate oligodeoxyribonucleotide and three doses of a licensed

hepatitis B vaccine in healthy adults 18-55 years of age. Vaccine. 2012 Mar 28;30 (15):2556-63. PMID 22326642.

561. Halsey NA. A causal association between Haemophilus influenzae type b (Hib) vaccine and diabetes. Autoimmunity. 2003 May;36 (3):123. PMID 12911277.

562. Halsey NA, Blatter M, Bader G, et al. Inactivated poliovirus vaccine alone or sequential inactivated and oral poliovirus vaccine in two-, four- and six-month-old infants with combination Haemophilus influenzae type b hepatitis B vaccine. Pediatric Infectious Disease Journal. 1997 Jul;16 (7):675-9. PMID WOS:A1997XK75600009.

563. Halsey NA, Spika JS, Lum GM, Schiffman GS, Lauer BA. Adverse reactions to pneumococcal polysaccharide vaccine in children. Pediatric Infectious Disease. 1982 Jan-Feb;1 (1):34-6. PMID 7177893.

564. Halvorsen S. The meningococcal serogroup B vaccine protection trial in Norway 1988-1991: trial surveillance by an independent group. NIPH Annals. 1991 Dec;14 (2):135-6; discussion 6-7. PMID 1812427.

565. Hammitt LL, Bulkow LR, Singleton RJ, et al. Repeat revaccination with 23-valent pneumococcal polysaccharide vaccine among adults aged 55-74 years living in Alaska: No evidence of hyporesponsiveness. Vaccine. 2011 2011;29 (12):2287-95. PMID 2011104705 MEDLINE PMID 21255685 (http://www.ncbi.nlm.nih.gov/pubmed/21255685).

566. Han F, Lin L, Warby SC, et al. Narcolepsy onset is seasonal and increased following the 2009 H1N1 pandemic in China. Annals of Neurology. 2011 Sep;70 (3):410-7. PMID 21866560.

567. Hao L, Toyokawa S, Kobayashi Y. Poisson-model analysis of the risk of vaccine-associated paralytic poliomyelitis in Japan between 1971 and 2000. Japanese Journal of Infectious Diseases. 2008 Mar;61 (2):100-3. PMID 18362395.

568. Harmark L, van Hunsel F, Hak E, van Grootheest K. Monitoring the safety of influenza A (H1N1) vaccine using web-based intensive monitoring. Vaccine. 2011 Feb 24;29 (10):1941-7. PMID 21236235.

569. Harris G, Nolan T, Hartman L. Clinical signs associated with triple antigen (DTP) vaccination in infants. Journal of Paediatrics and Child Health. 1995 1995;31 (3):228-32. PMID 1995173209 MEDLINE PMID 7669385 (http://www.ncbi.nlm.nih.gov/pubmed/7669385).

570. Hasan S, Yousef M, Shridharani S. Severe febrile systemic reaction to pneumococcal vaccine. Journal of the National Medical Association. 2005 Feb;97 (2):284-5. PMID 15712794.

571. Hatz C, Cramer JP, Vertruyen A, et al. A randomised, single-blind, dose-range study to assess the immunogenicity and safety of a cell-culture-derived A/H1N1 influenza vaccine in adult and elderly populations. Vaccine. 2012 Jul 6;30 (32):4820-7. PMID 22626675.

572. Hatz C, von Sonnenburg F, Casula D, Lattanzi M, Leroux-Roels G. A randomized clinical trial to identify the optimal antigen and MF59([REGISTERED]) adjuvant dose of a monovalent A/H1N1 pandemic influenza vaccine in healthy adult and elderly subjects. Vaccine. 2012 May 14;30 (23):3470-7. PMID 22446638.

573. Haupt RM, Sings HL. The efficacy and safety of the quadrivalent human papillomavirus 6/11/16/18 vaccine Gardasil. Journal of Adolescent Health. 2011 November;49 (5):467-75. PMID 2011593965.

574. Hawcutt DB, Mainie P, Riordan A, Smyth RL, Pirmohamed M. Reported paediatric adverse drug reactions in the UK 2000-2009. British Journal of Clinical Pharmacology. 2012 March;73 (3):437-46. PMID 2012087844 MEDLINE PMID 21988288 (http://www.ncbi.nlm.nih.gov/pubmed/21988288).

575. Heath PT, McVernon J. The UK hib vaccine experience. Archives of Disease in Childhood. 2002 2002;86 (6):396-9. PMID 2002199926 MEDLINE PMID 12023165 (http://www.ncbi.nlm.nih.gov/pubmed/12023165).

576. Heaton PM, Goveia MG, Miller JM, Offit P, Clark HF. Development of a pentavalent rotavirus vaccine against prevalent serotypes of rotavirus gastroenteritis. Journal of Infectious Diseases. 2005 Sep 1;192 Suppl 1:S17-21. PMID 16088800.

577. Heijbel H, Jefferson T. Vaccine safety - Improving monitoring. Vaccine. 2001 21;19 (17 19):2457-60. PMID 2001113300 MEDLINE PMID 11257377 (http://www.ncbi.nlm.nih.gov/pubmed/11257377).

578. Heininger U, Group D-H-I-S, Sanger R, Jacquet JM, Schuerman L. Booster immunization with a hexavalent diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliovirus vaccine and Haemophilus influenzae type b conjugate combination vaccine in the second year of life: safety, immunogenicity and persistence of antibody responses. Vaccine. 2007 Jan 22;25 (6):1055-63. PMID 17049692.

579. Helle EPJ, Koskenvuo K, Heikkila J. Myocardial complications of immunisations. Annals of Clinical Research. 1978 1978;10 (5):280-7. PMID 1979078262 MEDLINE PMID 736507 (http://www.ncbi.nlm.nih.gov/pubmed/736507).

580. Hengge UR, Scharf RE, Kroon FP, Pfeffer K. Severe serum sickness following pneumococcal vaccination in an AIDS patient. International Journal of Std & Aids. 2006 Mar;17 (3):210-1. PMID 16510015.

581. Herberts C, Melgert B, Van Der Laan JW, Faas M. New adjuvanted vaccines in pregnancy: What is known about their safety? Expert Review of Vaccines. 2010 December;9 (12):1411-22. PMID 2010654059 MEDLINE PMID 21105777 (http://www.ncbi.nlm.nih.gov/pubmed/21105777).

582. Herceg A. Haemophilus influenzae type b vaccination [13]. Medical Journal of Australia.

1993 1993;159 (1):70. PMID 1993247750 MEDLINE PMID 8316135 (http://www.ncbi.nlm.nih.gov/pubmed/8316135).

583. Hernandez-Bernal F, Aguilar-Betancourt A, Aljovin V, et al. Comparison of four recombinant hepatitis B vaccines applied on an accelerated schedule in healthy adults. Human Vaccines. 2011 Oct;7 (10):1026-36. PMID WOS:000296564800015.

584. Hernandez-Bernal F, Aguilar-Betancourt A, Aljovin V, et al. Comparison of four recombinant hepatitis B vaccines applied on an accelerated schedule in healthy adults. Human Vaccines. 2011;7 (10) PMID 2011578241.

585. Hesley TM, Reisinger KS, Sullivan BJ, et al. Concomitant administration of a bivalent Haemophilus influenzae type b-hepatitis B vaccine, measles-mumps-rubella vaccine and varicella vaccine: safety, tolerability and immunogenicity. Pediatric Infectious Disease Journal. 2004 Mar;23 (3):240-5. PMID 15014300.

586. Hessel L, Guenaneche F, Biasio LR, Di Marzo R. Reply to "Panico MG, Caporale V, Attena F. Adverse events following hexavalent vaccine (Hexavac): knowledge and information sources". Vaccine. 2007 Mar 30;25 (14):2539-40. PMID 17465039.

587. Higashigawa M, Maegawa K, Honma H, et al. Vaccine-associated paralytic poliomyelitis in an infant with perianal abscesses. Journal of Infection & Chemotherapy. 2010 Oct;16 (5):356-9. PMID 20449625.

588. Hilleman MR, Carlson AJ, Jr., McLean AA, Vella PP, Weibel RE, Woodhour AF. Streptococcus pneumoniae polysaccharide vaccine: age and dose responses, safety, persistence of antibody, revaccination, and simultaneous administration of pneumococcal and influenza vaccines. Reviews of Infectious Diseases. 1981 Mar-Apr;3 Suppl:S31-42. PMID 7025159.

589. Hirtz DG, Nelson KB, Ellenberg JH. Seizures following childhood immunizations. Journal of Pediatrics. 1983 1983;102 (1):14-8. PMID 1983061690 MEDLINE PMID 6848712 (http://www.ncbi.nlm.nih.gov/pubmed/6848712).

590. Hirve S, Bavdekar A, Juvekar S, et al. A comparative study to evaluate the safety and immunogenicity of two lots of Haemophilus influenzae type-B conjugate vaccine manufactured at different scales. Vaccine. 2011 Jul 26;29 (33):5363-7. PMID 21651947.

591. Hirve S, Bavdekar A, Pandit A, et al. Immunogenicity and safety of a new meningococcal A conjugate vaccine in Indian children aged 2-10 years: A Phase II/III double-blind randomized controlled trial. Vaccine. 2012.

592. Ho C-F, Lin T-Y. Pneumococcal vaccines. Chang Gung Medical Journal. 2005 Nov;28 (11):765-72. PMID 16422182.

593. Hodgson A, Forgor AA, Chandramohan D, et al. A phase II, randomized study on an investigational DTPw-HBV/Hib-MenAC conjugate vaccine administered to infants in Northern

Ghana. PLoS ONE [Electronic Resource]. 2008;3 (5):e2159. PMID 18478093.

594. Hofmann C, Baur M-O, Schroten H. Anti-NMDA receptor encephalitis after TdaP-IPV booster vaccination: cause or coincidence? Journal of Neurology. 2011 Mar;258 (3):500-1. PMID 20878418.

595. Hojsak I, Avitzur Y, Mor E, et al. Antibody response to influenza vaccine in pediatric liver transplant recipients. Pediatric Infectious Disease Journal. 2011 June;30 (6):491-4. PMID 2011306239 MEDLINE PMID 21248658 (http://www.ncbi.nlm.nih.gov/pubmed/21248658).

596. Holdiness MR. Rare systemic dermatologic reaction after pneumococcal vaccine administration. Southern Medical Journal. 2003 Jan;96 (1):64-5. PMID 12602719.

597. Holmes SJ, Fritzell B, Guito KP, et al. Immunogenicity of Haemophilus influenzae type b polysaccharide-tetanus toxoid conjugate vaccine in infants. American Journal of Diseases of Children. 1993 Aug;147 (8):832-6. PMID 8352217.

598. Holmlund E, Nohynek H, Quiambao B, Ollgren J, Kayhty H. Mother-infant vaccination with pneumococcal polysaccharide vaccine: Persistence of maternal antibodies and responses of infants to vaccination. Vaccine. 2011 20;29 (28):4565-75. PMID 2011316318 MEDLINE PMID 21550374 (http://www.ncbi.nlm.nih.gov/pubmed/21550374).

599. Honkanen PO, Keistinen T, Kivela SL. Reactions following administration of influenza vaccine alone or with pneumococcal vaccine to the elderly. Archives of Internal Medicine. 1996 Jan 22;156 (2):205-8. PMID 8546555.

600. Honkanen PO, Makela PH. Pneumococcal vaccination in the elderly: an underused option? BioDrugs. 1999 Jul;12 (1):19-25. PMID 18031159.

601. Hoppenbrouwers K, Kanra G, Roelants M, et al. Priming effect, immunogenicity and safety of an Haemophilus influenzae type b-tetanus toxoid conjugate (PRP-T) and diphtheria-tetanus-acellular pertussis (DTaP) combination vaccine administered to infants in Belgium and Turkey. Vaccine. 1999 Feb 26;17 (7-8):875-86. PMID 10067694.

602. Hoppenbrouwers K, Lagos R, Swennen B, et al. Safety and immunogenicity of an Haemophilus influenzae type b-tetanus toxoid conjugate (PRP-T) and diphtheria-tetanus-pertussis (DTP) combination vaccine administered in a dual-chamber syringe to infants in Belgium and Chile. Vaccine. 1998 May-Jun;16 (9-10):921-7. PMID 9682338.

603. Hoppenbrouwers K, Roelants M, Ethevenaux C, Vandermeulen C, Knops J, Desmyter J. The effect of reconstitution of an Haemophilus influenzae type b-tentanus toxoid conjugate (PRP-T) vaccine on the immune responses to a diphtheria-tetanus-whole cell pertussis (DTwP) vaccine: a five-year follow-up. Vaccine. 1999 Jun 4;17 (20-21):2588-98. PMID 10418907.

604. Hosoda M, Inoue H, Miyazawa Y, Kusumi E, Shibuya K. Vaccine-associated paralytic poliomyelitis in Japan. Lancet. 2012 Feb 11;379 (9815):520. PMID 22325660.

605. Hottinger AF, George A-CC, Bel M, et al. A prospective study of the factors shaping antibody responses to the AS03-adjuvanted influenza A/H1N1 vaccine in cancer outpatients. Oncologist. 2012;17 (3):436-45. PMID 22357731.

606. Houston TP. Small-vessel vasculitis following simultaneous influenza and pneumococcal vaccination. New York State Journal of Medicine. 1983 Oct-Nov;83 (11-12):1182-3. PMID 6580565.

607. Hua L, Hongtao H, Shunqin W, et al. Simultaneous vaccination of Chinese applicants for a United States immigrant visa. Travel Medicine & Infectious Disease. 2008 May;6 (3):130-6. PMID 18486068.

608. Hua W, Izurieta HS, Slade B, et al. Kawasaki disease after vaccination: reports to the vaccine adverse event reporting system 1990-2007. Pediatric Infectious Disease Journal. 2009 Nov;28 (11):943-7. PMID 19755926.

609. Huang DT-N, Chiu N-C, Chi H, Huang F-Y. Protracted fever with cellulitis-like reaction in pneumococcal polysaccharide-vaccinated children. Pediatric Infectious Disease Journal. 2008 Oct;27 (10):937-9. PMID 18776824.

610. Huang HH, Huang CC, Hsueh PY, Lee TJ. Bilateral sudden deafness following H1N1 vaccination. Otolaryngology - Head and Neck Surgery. 2010 December;143 (6):849-50. PMID 2010653645 MEDLINE PMID 21109091 (http://www.ncbi.nlm.nih.gov/pubmed/21109091).

611. Huang L-M, Lin T-Y, Juergens C. Immunogenicity and safety of a 13-valent pneumococcal conjugate vaccine given with routine pediatric vaccines in Taiwan. Vaccine. 2012 Mar 9;30 (12):2054-9. PMID 22198517.

612. Huang W-T, Chen W-C, Teng H-J, et al. Adverse events following pandemic A (H1N1) 2009 monovalent vaccines in pregnant women--Taiwan, November 2009-August 2010. PLoS ONE [Electronic Resource]. 2011;6 (8):e23049. PMID 21850250.

613. Huber BM, Goetschel P. Extensive limb swelling after vaccination. Journal of Pediatrics. 2011 June;158 (6):1033. PMID 2011270657 MEDLINE PMID 21315373 (http://www.ncbi.nlm.nih.gov/pubmed/21315373).

614. Hulbert-Powell E, Perez-Gaxiola G. Review: Flu vaccines provide a moderate risk reduction in healthy children. Archives of Disease in Childhood: Education and Practice Edition. 2012;11.

615. Huppertz H-I, Soriano-Gabarro M, Grimprel E, et al. Intussusception among young children in Europe. Pediatric Infectious Disease Journal. 2006 Jan;25 (1 Suppl):S22-9. PMID 16397426.

616. Hviid A. Measles-mumps-rubella-varicella combination vaccine increases risk of febrile

seizure. Journal of Pediatrics. 2011 Jan;158 (1):170. PMID 21146049.

617. Hwang S-M, Choe K-W, Cho S-H, et al. The adverse events of influenza A (H1N1) vaccination and its risk factors in healthcare personnel in 18 military healthcare units in Korea. Japanese Journal of Infectious Diseases. 2011;64 (3):183-9. PMID 21617300.

618. Hwang S-M, Kim H-L, Min K-W, et al. Comparison of the Adverse Events Associated with MF59-Adjuvanted and Non-Adjuvanted H1N1 Vaccines in Healthy Young Male Korean Soldiers. Japanese Journal of Infectious Diseases. 2012 May;65 (3):193-7. PMID 22627298.

619. Igari H, Segawa S, Watanabe A, et al. Immunogenicity of a monovalent pandemic influenza A H1N1 vaccine in health-care workers of a university hospital in Japan. Microbiology & Immunology. 2010 Oct;54 (10):618-24. PMID 21118299.

620. Igari H, Watanabe A, Chiba H, et al. Effectiveness and safety of pandemic influenza A (H1N1) 2009 vaccine in healthcare workers at a university hospital in Japan. Japanese Journal of Infectious Diseases. 2011;64 (3):177-82. PMID 21617299.

621. Ikematsu H, Nagai H, Kawashima M, et al. Characterization and long-term persistence of immune response following two doses of an AS03A-adjuvanted H1N1 influenza vaccine in healthy Japanese adults. Human vaccines & Immunotherapeutics. 2012 Feb;8 (2):260-6. PMID 22426369.

622. Ikematsu H, Nagai H, Kawashima M, et al. Immunogenicity and safety of a novel AS03(A)-adjuvanted H1N1 2009 pandemic influenza vaccine in adults in Japan. Human Vaccines. 2010 Nov;6 (11):888-93. PMID 20980795.

623. Inamadar AC, Palit A. Blue cellulitis: A rare entity in the era of Hib conjugate vaccine [3]. Pediatric Dermatology. 2004 January/February;21 (1):90-1. PMID 2004091860 MEDLINE PMID 14871339 (http://www.ncbi.nlm.nih.gov/pubmed/14871339).

624. Ipp MM, Gold R, Goldbach M, et al. Adverse reactions to diphtheria, tetanus, pertussis-polio vaccination at 18 months of age: effect of injection site and needle length. Pediatrics. 1989 May;83 (5):679-82. PMID 2717284.

625. Ishigami M, Kamei H, Nakamura T, et al. Different effect of HBV vaccine after liver transplantation between chronic HBV carriers and non-HBV patients who received HBcAb-positive grafts. Journal of Gastroenterology. 2011 Mar;46 (3):367-77. PMID WOS:000289003700011.

626. Issa NC, Marty FM, Gagne LS, et al. Seroprotective titers against 2009 H1N1 influenza A virus after vaccination in allogeneic hematopoietic stem cell transplantation recipients. Biology of Blood & Marrow Transplantation. 2011 Mar;17 (3):434-8. PMID 20950701.

627. Izurieta HS, Sutter RW, Baughman AL, Strebel PM, Stevenson JM, Wharton M. Vaccine-associated paralytic poliomyelitis in the United States: no evidence of elevated risk after

simultaneous intramuscular injections of vaccine. Pediatric Infectious Disease Journal. 1995 Oct;14 (10):840-6. PMID 8584308.

628. Jackson LA, Baxter R, Reisinger K, et al. Phase III comparison of an investigational quadrivalent meningococcal conjugate vaccine with the licensed meningococcal ACWY conjugate vaccine in adolescents. Clin Infect Dis. 2009 Jul 1;49 (1):e1-10. PMID 19476428.

629. Jackson LA, Benson P, Sneller VP, et al. Safety of revaccination with pneumococcal polysaccharide vaccine. JAMA. 1999 Jan 20;281 (3):243-8. PMID 9918479.

630. Jackson LA, Jacobson RM, Reisinger KS, Anemona A, Danzig LE, Dull PM. A randomized trial to determine the tolerability and immunogenicity of a quadrivalent meningococcal glycoconjugate vaccine in healthy adolescents. Pediatr Infect Dis J. 2009 Feb;28 (2):86-91. PMID 19116603.

631. Jackson LA, Nelson JC, Whitney CG, et al. Assessment of the safety of a third dose of pneumococcal polysaccharide vaccine in the Vaccine Safety Datalink population. Vaccine. 2006 Jan 12;24 (2):151-6. PMID 16122845.

632. Jackson LA, Neuzil KM, Nahm MH, et al. Immunogenicity of varying dosages of 7-valent pneumococcal polysaccharide-protein conjugate vaccine in seniors previously vaccinated with 23-valent pneumococcal polysaccharide vaccine. Vaccine. 2007 16;25 (20):4029-37. PMID 2007192289 MEDLINE PMID 17391816 (http://www.ncbi.nlm.nih.gov/pubmed/17391816).

633. Jackson LA, Neuzil KM, Whitney CG, et al. Safety of varying dosages of 7-valent pneumococcal protein conjugate vaccine in seniors previously vaccinated with 23-valent pneumococcal polysaccharide vaccine. Vaccine. 2005 May 25;23 (28):3697-703. PMID 15882530.

634. Jackson LA, Patel SM, Swamy GK, et al. Immunogenicity of an inactivated monovalent 2009 H1N1 influenza vaccine in pregnant women. Journal of Infectious Diseases. 2011 15;204 (6):854-63. PMID 2011480316 MEDLINE PMID 21849282 (http://www.ncbi.nlm.nih.gov/pubmed/21849282).

635. Jacobsen SJ, Ackerson BK, Sy LS, et al. Observational safety study of febrile convulsion following first dose MMRV vaccination in a managed care setting. Vaccine. 2009 23;27 (34):4656-61. PMID 2009321466 MEDLINE PMID 19520201 (http://www.ncbi.nlm.nih.gov/pubmed/19520201).

636. Jacobson RM, Adegbenro A, Pankratz VS, Poland GA. Adverse events and vaccination-the lack of power and predictability of infrequent events in pre-licensure study. Vaccine. 2001 Mar 21;19 (17-19):2428-33. PMID 11257373.

637. Jacquest D, Stout I. Reactions to Haemophilus influenzae type B vaccine. Canadian Journal of Public Health. 1989 1989;80 (4):304-5. PMID 1990148125 MEDLINE PMID 2790640 (http://www.ncbi.nlm.nih.gov/pubmed/2790640).

638. Jacquet JM, Begue P, Grimprel E, et al. Safety and immunogenicity of a combined DTPa-IPV vaccine administered as a booster from 4 years of age: a review. Vaccine. 2006 Mar 20;24 (13):2440-8. PMID 16406224.

639. Janow G, Ilowite NT. Pediatric rheumatic disease: Vaccination in pediatric rheumatic disease - Risks and benefits. Nature Reviews Rheumatology. 2012 April;8 (4):188-90. PMID 2012198498.

640. Jansen AGSC, Sanders EAM, Smulders S, Hoes AW, Hak E. Adverse reactions to simultaneous influenza and pneumococcal conjugate vaccinations in children: randomized double-blind controlled trial. Pediatric Allergy & Immunology. 2008 Sep;19 (6):552-8. PMID 18221474.

641. Jariwala S, Vernon N, Shliozberg J. Henoch-Schonlein Purpura after Hepatitis a Vaccination. Annals of Allergy Asthma & Immunology. 2011 Aug;107 (2):180-1. PMID WOS:000294242500015.

642. Javelle E, Soulier B, Brosset C, Lorcy S, Simon F. Delayed focal lipoatrophy after AS03-adjuvanted influenza A (H1N1) 2009 vaccine. Vaccine. 2011 Feb 1;29 (6):1123-5. PMID 21172376.

643. Jefferson T, Demicheli V. No evidence that vaccines cause insulin dependent diabetes mellitus. J Epidemiol Community Health. 1998 Oct;52 (10):674-5. PMID 10023469.

644. Jenkins DR, Rees JC, Hale JP, Pedler SJ. Childhood neoplasia and Haemophilus influenzae type b vaccine failure [11]. Lancet. 1996 1996;348 (9020):131. PMID 1996212549 MEDLINE PMID 8676697 (http://www.ncbi.nlm.nih.gov/pubmed/8676697).

645. Jin LJ, Wang GY, Zhao XL, et al. Characterization and immune effect of the hepatitis B-BCG combined vaccine for using a needle innoculation. Vaccine. 2010 Aug;28 (37):6041-51. PMID WOS:000281627100018.

646. Johann-Liang R, Josephs S, Dreskin SC. Analysis of anaphylaxis cases after vaccination: 10-year review from the national vaccine injury compensation program. Annals of Allergy, Asthma and Immunology. 2011 May;106 (5):440-3. PMID 2011243366 MEDLINE PMID 21530879 (http://www.ncbi.nlm.nih.gov/pubmed/21530879).

647. Johns TL, Hutter GE. New combination vaccines: DTaP-IPV (Kinrix) and DTaP-IPV/Hib (Pentacel). Annals of Pharmacotherapy. 2010 Mar;44 (3):515-23. PMID 20197476.

648. Jones CE, Naidoo S, De Beer C, Esser M, Kampmann B, Hesseling AC. Maternal HIV Infection and Antibody Responses Against Vaccine-Preventable Diseases in Uninfected Infants. Jama-Journal of the American Medical Association. 2011 Feb;305 (6):576-84. PMID WOS:000287080500022.

649. Jones IG, Tyrrell H, Hill A, Horobin JM, Taylor B. Randomised controlled trial of combined diphtheria, tetanus, whole-cell pertussis vaccine administered in the same syringe and separately with Haemophilus influenzae type b vaccine at two, three and four months of age. Vaccine. 1998 Jan;16 (1):109-13. PMID 9607017.

650. Jonville-Bera AP, Autret E, Galy-Eyraud C, Hessel L. Thrombocytopenic purpura after measles, mumps and rubella vaccination: a retrospective survey by the French regional pharmacovigilance centres and pasteur-merieux serums et vaccins. Pediatr Infect Dis J. 1996 Jan;15 (1):44-8. PMID 8684875.

651. Josefsberg JO, Buckland B. Vaccine process technology. Biotechnology and Bioengineering. 2012 June;109 (6):1443-60. PMID 2012225878.

652. Junqueira ALN, Tavares VR, Martins RMB, et al. Safety and immunogenicity of hepatitis B vaccine administered into ventrogluteal vs. anterolateral thigh sites in infants: A randomised controlled trial. International Journal of Nursing Studies. 2010 Sep;47 (9):1074-9. PMID WOS:000281383500003.

653. Juntunen-Backman K, Peltola H, Backman A, Salo OP. Safe immunization of allergic children against measles, mumps, and rubella. American Journal of Diseases of Children. 1987 Oct;141 (10):1103-5. PMID 3630996.

654. Kallweit U, Hidalgo H, Engel A, Baumann CR, Bassetti CL, Dahmen N. Post H1N1 vaccination narcolepsy-cataplexy with decreased CSF beta-amyloid. Sleep Medicine. 2012 March;13 (3):323. PMID 2012106250.

655. Kamboj KK, King CL, Greenspan NS, Kirchner HL, Schreiber JR. Immunization with Haemophilus influenzae type b-CRM(197) conjugate vaccine elicits a mixed Th1 and Th2 CD(4+) T cell cytokine response that correlates with the isotype of antipolysaccharide antibody. Journal of Infectious Diseases. 2001 Oct 1;184 (7):931-5. PMID 11528593.

656. Kang J-H, Oh C-E, Lee J, et al. Safety and immunogenicity of a new trivalent inactivated split-virus influenza vaccine in healthy Korean children: a randomized, double-blinded, active-controlled, phase III study. Journal of Korean Medical Science. 2011 Nov;26 (11):1421-7. PMID 22065897.

657. Kanra G, Kara A, Demiralp O, et al. Safety and immunogenicity of a new fully liquid DTPw-HepB-Hib combination vaccine in infants. Human Vaccines. 2006 Jul-Aug;2 (4):155-60. PMID 17012890.

658. Kanra G, Viviani S, Yurdakok K, et al. Effect of aluminum adjuvants on safety and immunogenicity of Haemophilus influenzae type b-CRM197 conjugate vaccine. Pediatrics International. 2003 Jun;45 (3):314-8. PMID 12828588.

659. Kanra G, Viviani S, Yurdakok K, et al. Safety, tolerability and immunogenicity of a Haemophilus influenzae type b vaccine containing aluminum phosphate adjuvant administered at

2, 3 and 4 months of age. Turkish Journal of Pediatrics. 1999 Oct-Dec;41 (4):421-7. PMID 10770109.

660. Kanra G, Yurdakok K, Ceyhan M, Ozmert E, Turkay F, Pehlivan T. Immunogenicity and safety of Haemophilus influenzae type b capsular polysaccharide tetanus conjugate vaccine (PRP-T) presented in a dual-chamber syringe with DTP. Acta Paediatrica Japonica. 1997 Dec;39 (6):676-80. PMID 9447756.

661. Kapikian AZ. Ecological studies, rotavirus vaccination, and intussusception.[Erratum appears in Lancet 2002 Aug 10;360(9331):494]. Lancet. 2002 Mar 23;359 (9311):1065-6; author reply 6. PMID 11937208.

662. Kapikian AZ, Simonsen L, Vesikari T, et al. A hexavalent human rotavirus-bovine rotavirus (UK) reassortant vaccine designed for use in developing countries and delivered in a schedule with the potential to eliminate the risk of intussusception. Journal of Infectious Diseases. 2005 Sep 1;192 Suppl 1:S22-9. PMID 16088801.

663. Kapusinszky B, Molnar Z, Szomor KN, Berencsi G. Molecular characterization of poliovirus isolates from children who contracted vaccine-associated paralytic poliomyelitis (VAPP) following administration of monovalent type 3 oral poliovirus vaccine in the 1960s in Hungary. FEMS Immunology & Medical Microbiology. 2010 Mar;58 (2):211-7. PMID 19863665.

664. Karam AG, Cherry JD. Hypotonic and hyporesponsive episodes after diptheria-tetanus-acellular pertussis vaccination. Pediatric Infectious Disease Journal. 2007 October;26 (10):966-7. PMID 2007477250 MEDLINE PMID 17901810 (http://www.ncbi.nlm.nih.gov/pubmed/17901810).

665. Karayiannis P, Main J, Thomas HC. Hepatitis vaccines. British Medical Bulletin. 2004 2004;70:29-49. PMID 2005021038 MEDLINE PMID 15339856 (http://www.ncbi.nlm.nih.gov/pubmed/15339856).

666. Kattan JD, Konstantinou GN, Cox AL, et al. Anaphylaxis to diphtheria, tetanus, and pertussis vaccines among children with cow's milk allergy. Journal of Allergy and Clinical Immunology. 2011 July;128 (1):215-8. PMID 2011361511 MEDLINE PMID 21624648 (http://www.ncbi.nlm.nih.gov/pubmed/21624648).

667. Katzenstein TL. Pneumococcal vaccination of HIV-infected individuals: safety and efficacy. AIDS Patient Care & Stds. 1997 Aug;11 (4):269-75. PMID 11361841.

668. Kau L, Sadowski CA, Hughes C. Vaccinations in older adults: Focus on pneumococcal, influenza and herpes zoster infections. Canadian Pharmacists Journal. 2011 May;144 (3):132-41. PMID 2011310209.

669. Kaur S, Handa S. Erythema multiforme following vaccination in an infant. Indian Journal of Dermatology, Venereology and Leprology. 2008 1;74 (3):251-3. PMID 2008317547

MEDLINE PMID 18583795 (http://www.ncbi.nlm.nih.gov/pubmed/18583795).

670. Kayhty H, Ahman H, Eriksson K, Sorberg M, Nilsson L. Immunogenicity and tolerability of a heptavalent pneumococcal conjugate vaccine administered at 3, 5 and 12 months of age. Pediatric Infectious Disease Journal. 2005 Feb;24 (2):108-14. PMID 15702037.

671. Kayhty H, Peltola H, Eskola J, et al. Immunogenicity of Haemophilus influenzae oligosaccharide-protein and polysaccharide-protein conjugate vaccination of children at 4, 6, and 14 months of age. Pediatrics. 1989 Dec;84 (6):995-9. PMID 2587155.

672. Keating GM. Rotavirus vaccine (RotaTeq). Paediatric Drugs. 2006;8 (3):197-202; discussion 3-4. PMID 16774301.

673. Keating GM. Rotavirus vaccine RIX4414 (Rotarix). Paediatric Drugs. 2006;8 (6):389-95; discussion 96-7. PMID 17154645.

674. Keipp Talbot H, Rock MT, Johnson C, et al. Immunopotentiation of Trivalent Influenza Vaccine When Given with VAX102, a Recombinant Influenza M2e Vaccine Fused to the TLR5 Ligand Flagellin. PLoS ONE [Electronic Resource]. 2010;5 (12) PMID 2011011111.

675. Kelen K, Ferenczi D, Jankovics I, et al. H1N1 vaccination in pediatric renal transplant patients. Transplantation Proceedings. 2011 May;43 (4):1244-6. PMID 21620100.

676. Kelley NS, Osterholm MT, Belongia EA. Safety and effectiveness of a 2009 H1N1 vaccine in Beijing. New England Journal of Medicine. 2011 Mar 24;364 (12):1181; author reply -2. PMID 21428786.

677. Kelly H. Evidence for a causal association between oral polio vaccine and transverse myelitis: A case history and review of the Literature. Journal of Paediatrics & Child Health. 2006 Apr;42 (4):155-9. PMID 16630313.

678. Kelly H, Mercer G, Cowling BJ. The association of seasonal influenza vaccination with pandemic influenza H1N1 2009 infection. Vaccine. 2012 9;30 (12):2037-8. PMID 2012111125 MEDLINE PMID 22119923 (http://www.ncbi.nlm.nih.gov/pubmed/22119923).

679. Kelly H, Valenciano M. Estimating the effect of influenza vaccines. The Lancet Infectious Diseases. 2012 January;12 (1):5-6. PMID 2011703315 MEDLINE PMID 22032845 (http://www.ncbi.nlm.nih.gov/pubmed/22032845).

680. Kelly HA, Skowronski DM, De Serres G, Effler PV. Adverse events associated with 2010 CSL and other inactivated influenza vaccines. Medical Journal of Australia. 2011 Sep 19;195 (6):318-20. PMID 21929484.

681. Kelly WN. Potential risks and prevention, part 4: Reports of significant adverse drug events. American Journal of Health-System Pharmacy. 2001 1;58 (15):1406-12. PMID 2001269949 MEDLINE PMID 11494785 (http://www.ncbi.nlm.nih.gov/pubmed/11494785).

682. Kelso JM, Greenhawt MJ, Li JT, et al. Adverse reactions to vaccines practice parameter 2012 update. Journal of Allergy and Clinical Immunology. 2012 July;130 (1):25-43. PMID 2012369097.

683. Kelton JG. Vaccination-Associated relapse of immune thrombocytopenia. JAMA. 1981 Jan 23-30;245 (4):369-70. PMID 6969806.

684. Kemmeren JM, Timmer SS, van der Maas NAT, de Melker HE. Comparison of the tolerability of an acellular pertussis-containing vaccine given as the fifth booster dose in differently primed children. Vaccine. 2011 Jun 10;29 (26):4373-7. PMID 21514347.

685. Kemmeren JM, van der Maas NAT, de Melker HE. Parental reports of adverse events following simultaneously given dT-IPV and MMR vaccines in healthy 9-year-old children. European Journal of Pediatrics. 2011 Mar;170 (3):339-45. PMID 20857144.

686. Kemmeren JM, Vermeer-de Bondt PE, van der Maas NAT. Discolored leg syndrome after vaccination--descriptive epidemiology. European Journal of Pediatrics. 2009 Jan;168 (1):43-50. PMID 18546020.

687. Kemp ML, Hart MB. MMR vaccine and autism: is there a link? JAAPA. 2010 2010 Jun;23 (6):48. PMID 20653261.

688. Kenter GG, Welters MJ, Valentijn AR, et al. Vaccination against HPV-16 oncoproteins for vulvar intraepithelial neoplasia. N Engl J Med. 2009 Nov 5;361 (19):1838-47. PMID 19890126.

689. Kerzner B, Murray AV, Cheng E, et al. Safety and immunogenicity profile of the concomitant administration of ZOSTAVAX and inactivated influenza vaccine in adults aged 50 and older. J Am Geriatr Soc. 2007 Oct;55 (10):1499-507. PMID 17908055.

690. Khalifa YM, Monahan PM, Acharya NR. Ampiginous choroiditis following quadrivalent human papilloma virus vaccine. British Journal of Ophthalmology. 2010 January;94 (1):137-9. PMID 2010049782 MEDLINE PMID 20385534 (http://www.ncbi.nlm.nih.gov/pubmed/20385534).

691. Khan FS, Virant FS, Furukawa CT, et al. Influenza vaccine administration in egg allergic children. Journal of Allergy and Clinical Immunology. 2012 February;129 (2 SUPPL. 1):AB70.

692. Khare S, Kumari S, Nagpal IS, Sharma D, Verghese T. Oral polio vaccination in infants: beneficial effect of additional dose at birth. Indian Journal of Pediatrics. 1993 Mar-Apr;60 (2):275-81. PMID 8244504.

693. Khetsuriani N, Imnadze P, Baidoshvili L, et al. Impact of unfounded vaccine safety concerns on the nationwide measles-rubella immunization campaign, Georgia, 2008. Vaccine. 2010 Sep 7;28 (39):6455-62. PMID 20674880.

694. Kiefaber RW. Thrombocytopenic purpura after measles vaccination. N Engl J Med. 1981 Jul 23;305 (4):225. PMID 7195464.

695. Kienast AK, Mentze D, Hoeger PH. Nicolau's syndrome induced by intramuscular vaccinations in children: Report of seven patients and review of the literature. Clinical and Experimental Dermatology. 2008 September;33 (5):555-8. PMID 2008392734 MEDLINE PMID 18627396 (http://www.ncbi.nlm.nih.gov/pubmed/18627396).

696. Kieninger DM, Kueper K, Steul K, et al. Safety, tolerability, and immunologic noninferiority of a 13-valent pneumococcal conjugate vaccine compared to a 7-valent pneumococcal conjugate vaccine given with routine pediatric vaccinations in Germany. Vaccine. 2010 7;28 (25):4192-203. PMID 2010290087 MEDLINE PMID 20417262 (http://www.ncbi.nlm.nih.gov/pubmed/20417262).

697. Kilpi T, Ahman H, Jokinen J, et al. Protective Efficacy of a Second Pneumococcal Conjugate Vaccine against Pneumococcal Acute Otitis Media in Infants and Children: Randomized, Controlled Trial of a 7-Valent Pneumococcal Polysaccharide-Meningococcal Outer Membrane Protein Complex Conjugate Vaccine in 1666 Children. Clinical Infectious Diseases. 2003 1;37 (9):1155-64. PMID 2003453178 MEDLINE PMID 14557958 (http://www.ncbi.nlm.nih.gov/pubmed/14557958).

698. Kilpi TM, Silfverdal SA, Nilsson L, et al. Immunogenicity and reactogenicity of two diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated polio virus-Haemophilus influenzae type b vaccines administered at 3, 5 and 11-12 months of age. Human Vaccines. 2009 2009;5 (1):18-25. PMID 2009301611 MEDLINE PMID 18690013 (http://www.ncbi.nlm.nih.gov/pubmed/18690013).

699. Kim C-H, Kim JS, Cha S-H, et al. Response to primary and booster vaccination with 10-valent pneumococcal nontypeable Haemophilus influenzae protein D conjugate vaccine in Korean infants. Pediatric Infectious Disease Journal. 2011 Dec;30 (12):e235-43. PMID 21817957.

700. Kim DS, Shin SH, Lee HJ, et al. Immunogenicity and safety of 13-valent pneumococcal conjugate vaccine given to Korean children receiving routine pediatric vaccines. Pediatric Infectious Disease Journal. 2012;24.

701. Kim J-H, Cho H-Y, Hennessey KA, Lee HJ, Bae GR, Kim HC. Adverse events following immunization (AEFI) with the novel influenza a (H1N1) 2009 vaccine: findings from the national registry of all vaccine recipients and AEFI and the passive surveillance system in South Korea. Japanese Journal of Infectious Diseases. 2012 Mar;65 (2):99-104. PMID 22446114.

702. Kim KH, Kim YK, Kim NH, et al. Immunogenicity and safety of LBVH0101, a new Haemophilus influenzae type b tetanus toxoid conjugate vaccine, compared with Hiberix(trademark) in Korean infants and children: A randomized trial. Vaccine. 2012 27;30 (10):1886-94. PMID 2012115553 MEDLINE PMID 22245607 (http://www.ncbi.nlm.nih.gov/pubmed/22245607).

703. Kim KH, Lee H, Chung EH, et al. Immunogenicity and safety of two different Haemophilus influenzae type b conjugate vaccines in Korean infants. Journal of Korean Medical Science. 2008 Dec;23 (6):929-36. PMID 19119431.

704. Kim SJ, Kim SH, Jee YM, Kim JS. Vaccine-associated paralytic poliomyelitis: a case report of flaccid monoparesis after oral polio vaccine. Journal of Korean Medical Science. 2007 Apr;22 (2):362-4. PMID 17449951.

705. Kim Y-J, Kim K-T, Kim J-H, et al. Vaccination with a human papillomavirus (HPV)-16/18 AS04-adjuvanted cervical cancer vaccine in Korean girls aged 10-14 years.[Erratum appears in J Korean Med Sci. 2010 Dec;25(12):1831 Note: Ng, Timothy [added]; Bi, Dan [added]; OK, Jin-Ju [added]; Descamps, Dominique [added]; Bock, Hans L [added]]. Journal of Korean Medical Science. 2010 Aug;25 (8):1197-204. PMID 20676333.

706. Kimura A, Toneatto D, Kleinschmidt A, Wang H, Dull P. Immunogenicity and safety of a multicomponent meningococcal serogroup B vaccine and a quadrivalent meningococcal CRM197 conjugate vaccine against serogroups A, C, W-135, and Y in adults who are at increased risk for occupational exposure to meningococcal isolates. Clinical & Vaccine Immunology: CVI. 2011 Mar;18 (3):483-6. PMID 21177912.

707. King SD, Ramlal A, Wynter H, et al. Safety and immunogenicity of a new Haemophilus influenzae type b vaccine in infants under one year of age. Lancet. 1981 Oct 3;2 (8249):705-9. PMID 6116855.

708. Kitchin N, Southern J, Morris R, et al. A randomised controlled study of the reactogenicity of an acellular pertussis-containing pentavalent infant vaccine compared to a quadrivalent whole cell pertussis-containing vaccine and oral poliomyelitis vaccine, when given concurrently with meningococcal group C conjugate vaccine to healthy UK infants at 2, 3 and 4 months of age. Vaccine. 2006 1;24 (18):3964-70. PMID 2006223038 MEDLINE PMID 16517034 (http://www.ncbi.nlm.nih.gov/pubmed/16517034).

709. Kitchin NRE, Southern J, Morris R, et al. Evaluation of a diphtheria-tetanus-acellular pertussis-inactivated poliovirus-Haemophilus influenzae type b vaccine given concurrently with meningococcal group C conjugate vaccine at 2, 3 and 4 months of age. Archives of Disease in Childhood. 2007 January;92 (1):11-6. PMID 2007044809 MEDLINE PMID 16670121 (http://www.ncbi.nlm.nih.gov/pubmed/16670121).

710. Klein NP, Fireman B, Yih WK, et al. Measles-mumps-rubella-varicella combination vaccine and the risk of febrile seizures. Pediatrics. 2010 Jul;126 (1):e1-8. PMID 20587679.

711. Klein NP, Gans HA, Sung P, et al. Preterm Infants' T Cell Responses to Inactivated Poliovirus Vaccine. Journal of Infectious Diseases. 2010 Jan;201 (2):214-22. PMID WOS:000273051200008.

712. Klein NP, Lewis E, Baxter R, et al. Measles-containing vaccines and febrile seizures in

children age 4 to 6 years. Pediatrics. 2012 May;129 (5):809-14. PMID 22473362.

713. Klein NP, Reisinger KS, Johnston W, et al. Safety and immunogenicity of a novel quadrivalent meningococcal CRM-conjugate vaccine given concomitantly with routine vaccinations in infants. Pediatric Infectious Disease Journal. 2012 Jan;31 (1):64-71. PMID 22094635.

714. Klein NP, Shepard J, Bedell L, Odrljin T, Dull P. Immunogenicity and safety of a quadrivalent meningococcal conjugate vaccine administered concomitantly with measles, mumps, rubella, varicella vaccine in healthy toddlers. Vaccine. 2012 Jun 6;30 (26):3929-36. PMID 22504039.

715. Klein NP, Weston WM, Kuriyakose S, et al. An open-label, randomized, multi-center study of the immunogenicity and safety of DTaP-IPV (KinrixTM) co-administered with MMR vaccine with or without varicella vaccine in healthy pre-school age children. Vaccine. 2012 Jan 11;30 (3):668-74. PMID 22064267.

716. Klepper MJ, Edwards B. Individual case safety reports--how to determine the onset date of an adverse reaction: a survey. Drug Safety. 2011 Apr 1;34 (4):299-305. PMID 21417502.

717. Klooster TMV, Kemmeren JM, Van Der Maas NAT, De Melker HE. Reported adverse events in girls aged 13-16 years after vaccination with the human papillomavirus (HPV)-16/18 vaccine in the Netherlands. Vaccine. 2011 20;29 (28):4601-7. PMID 2011316322 MEDLINE PMID 21549785 (http://www.ncbi.nlm.nih.gov/pubmed/21549785).

718. Klugman KP, Madhi SA, Huebner RE, et al. A trial of a 9-valent pneumococcal conjugate vaccine in children with and those without HIV infection. New England Journal of Medicine. 2003 Oct 2;349 (14):1341-8. PMID 14523142.

719. Knuf M, Faber J, Barth I, Habermehl P. A combination vaccine against measles, mumps, rubella and varicella. Drugs of Today. 2008 April;44 (4):279-92. PMID 2008310823 MEDLINE PMID 18536786 (http://www.ncbi.nlm.nih.gov/pubmed/18536786).

720. Knuf M, Habermehl P, Cimino C, Petersen G, Schmitt HJ. Immunogenicity, reactogenicity and safety of a 7-valent pneumococcal conjugate vaccine (PCV7) concurrently administered with a DTPa-HBV-IPV/Hib combination vaccine in healthy infants. Vaccine. 2006 May 29;24 (22):4727-36. PMID 16616973.

721. Knuf M, Kieninger-Baum D, Habermehl P, et al. A dose-range study assessing immunogenicity and safety of one dose of a new candidate meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine administered in the second year of life and in young children. Vaccine. 2010 Jan 8;28 (3):744-53. PMID 19887137.

722. Knuf M, Pankow-Culot H, Grunert D, et al. Induction of immunologic memory following primary vaccination with the 10-valent pneumococcal nontypeable haemophilus influenzae protein D conjugate vaccine in infants. Pediatric Infectious Disease Journal. 2012 January;31

(1):e31-e6. PMID 2012016970 MEDLINE PMID 21909049 (http://www.ncbi.nlm.nih.gov/pubmed/21909049).

723. Knuf M, Pantazi-Chatzikonstantinou A, Pfletschinger U, et al. An investigational tetravalent meningococcal serogroups A, C, W-135 and Y-tetanus toxoid conjugate vaccine co-administered with Infanrix(trademark) hexa is immunogenic, with an acceptable safety profile in 12-23-month-old children. Vaccine. 2011 06;29 (25):4264-73. PMID 2011280673 MEDLINE PMID 21420417 (http://www.ncbi.nlm.nih.gov/pubmed/21420417).

724. Knuf M, Pantazi-Chatzikonstantinou A, Pfletschinger U, et al. An investigational tetravalent meningococcal serogroups A, C, W-135 and Y-tetanus toxoid conjugate vaccine co-administered with InfanrixTM hexa is immunogenic, with an acceptable safety profile in 12-23-month-old children. Vaccine. 2011 Jun 6;29 (25):4264-73. PMID 21420417.

725. Knuf M, Schmitt H-J, Wolter J, et al. Neonatal vaccination with an acellular pertussis vaccine accelerates the acquisition of pertussis antibodies in infants. Journal of Pediatrics. 2008 May;152 (5):655-60, 60.e1. PMID 18410769.

726. Knuf M, Vetter V, Celzo F, Ramakrishnan G, Van Der Meeren O, Jacquet JM. Repeated administration of a reduced-antigen-content diphtheria-tetanus-acellular pertussis and poliomyelitis vaccine (dTpa-IPV; BoostrixTM IPV). Human Vaccines. 2010 Jul;6 (7):554-61. PMID 20448468.

727. Knuf M, Vetter V, Celzo F, Ramakrishnan G, Van Der Meeren O, Jacquet JM. Repeated administration of a reduced-antigen-content diphtheria-tetanus-acellular pertussis and poliomyelitis vaccine (dTpa-IPV; Boostrix(trademark) IPV). Human Vaccines. 2010 July;6 (7):554-61. PMID 2010520515.

728. Knuf M, Zepp F, Helm K, et al. Antibody persistence for 3 years following two doses of tetravalent measles-mumps-rubella-varicella vaccine in healthy children. European Journal of Pediatrics. 2012 Mar;171 (3):463-70. PMID WOS:000300668400009.

729. Knuf M, Zepp F, Meyer CU, et al. Safety, immunogenicity and immediate pain of intramuscular versus subcutaneous administration of a measles-mumps-rubella-varicella vaccine to children aged 11-21 months. European Journal of Pediatrics. 2010 Aug;169 (8):925-33. PMID 20148263.

730. Knutsson N, Trollfors B, Taranger J, et al. Immunogenicity and reactogenicity of diphtheria, tetanus and pertussis toxoids combined with inactivated polio vaccine, when administered concomitantly with or as a diluent for a Hib conjugate vaccine. Vaccine. 2001 Aug 14;19 (31):4396-403. PMID 11483264.

731. Kobayashi M, Ohfuji S, Fukushima W, et al. Immunogenicity and reactogenicity of a monovalent inactivated 2009 influenza A vaccine in adolescents: with special reference to pre-existing antibody. Journal of Pediatrics. 2012 Apr;160 (4):632-7.e1. PMID 22094234.

732. Koh KJ, Warren L, Moore L, James C, Thompson GN. Wells' syndrome following thiomersal-containing vaccinations. Australasian Journal of Dermatology. 2003 August;44 (3):199-202. PMID 2003323613 MEDLINE PMID 12869046 (http://www.ncbi.nlm.nih.gov/pubmed/12869046).

733. Kolivras A, Andre J. Gianotti-Crosti syndrome following hepatitis A vaccination. Pediatric Dermatology. 2008 November-December;25 (6):650. PMID 2008572364 MEDLINE PMID 19067881 (http://www.ncbi.nlm.nih.gov/pubmed/19067881).

734. Kondo S, Abe K. The effects of influenza virus infection on FEV1 in asthmatic children. The time-course study. Chest. 1991 Nov;100 (5):1235-8. PMID 1935277.

735. Konno R, Tamura S, Dobbelaere K, Yoshikawa H. Efficacy of human papillomavirus 16/18 AS04-adjuvanted vaccine in Japanese women aged 20 to 25 years: interim analysis of a phase 2 double-blind, randomized, controlled trial. International Journal of Gynecological Cancer. 2010 Apr;20 (3):404-10. PMID 20375805.

736. Konno R, Tamura S, Dobbelaere K, Yoshikawa H. Efficacy of human papillomavirus type 16/18 AS04-adjuvanted vaccine in Japanese women aged 20 to 25 years: final analysis of a phase 2 double-blind, randomized controlled trial. International Journal of Gynecological Cancer. 2010 Jul;20 (5):847-55. PMID 20606533.

737. Kosalaraksa P, Thisyakorn U, Benjaponpitak S, Chokephaibulkit K, Santos-Lima E. Immunogenicity and safety study of a new DTaP-IPV-Hep B-PRP-T combined vaccine compared to a licensed DTaP-IPV-Hep B//PRP-T comparator, both concomitantly administered with a 7-valent pneumococcal conjugate vaccine at 2, 4, and 6 months of age in Thai infants. International Journal of Infectious Diseases. 2011 Apr;15 (4):e249-56. PMID 21334243.

738. Koskiniemi M, Vaheri A. Effect of measles, mumps, rubella vaccination on pattern of encephalitis in children. Lancet. 1989 Jan 7;1 (8628):31-4. PMID 2563011.

739. Kostianovsky A, Charles P, Alves JF, et al. Immunogenicity and safety of seasonal and 2009 pandemic A/H1N1 influenza vaccines for patients with autoimmune diseases: a prospective, monocentre trial on 199 patients. Clinical and Experimental Rheumatology. 2012 Jan-Feb;30 (1):S83-S9. PMID WOS:000304499000018.

740. Kovel A, Wald ER, Guerra N, Serdy C, Meschievitz CK. Safety and immunogenicity of acellular diphtheria-tetanus-pertussis and Haemophilus conjugate vaccines given in combination or at separate injection sites. Journal of Pediatrics. 1992 Jan;120 (1):84-7. PMID 1731030.

741. Kubavat AH, Mittal R, Patel PM, Jarsaniya DH, Pawar PR, Group HNVS. A clinical trial to assess the immunogenicity and safety of Inactivated Influenza Vaccine (Whole Virion) IP (Pandemic Influenza (H1N1) 2009 Monovalent Vaccine; VaxiFlu-STM) in healthy Indian adult population. Journal of Postgraduate Medicine. 2011 Apr-Jun;57 (2):102-8. PMID 21654130.

742. Kuehn BM. IOM review finds vaccine adverse events are rare and usually reversible.

JAMA - Journal of the American Medical Association. 2011 5;306 (13):1427. PMID 2011551799 MEDLINE PMID 21972299 (http://www.ncbi.nlm.nih.gov/pubmed/21972299).

743. Kumar A, Dutta AK, Saili A, Nangia S, Dutta R. Immunogenicity and tolerance of H. influenzae type b, tetanus toxoid conjugate vaccine given concurrently or in combination. Indian Journal of Pediatrics. 1997 Nov-Dec;64 (6):839-47. PMID 10771928.

744. Kumar D, Chen MH, Wong G, et al. A randomized, double-blind, placebo-controlled trial to evaluate the prime-boost strategy for pneumococcal vaccination in adult liver transplant recipients. Clinical Infectious Diseases. 2008 1;47 (7):885-92. PMID 2008450787 MEDLINE PMID 18715160 (http://www.ncbi.nlm.nih.gov/pubmed/18715160).

745. Kumar D, Rotstein C, Miyata G, Arlen D, Humar A. Randomized, double-blind, controlled trial of pneumococcal vaccination in renal transplant recipients. Journal of Infectious Diseases. 2003 15;187 (10):1639-45. PMID 2003201164 MEDLINE PMID 12721944 (http://www.ncbi.nlm.nih.gov/pubmed/12721944).

746. Kung H-C, Huang K-C, Kao T-M, et al. A clinical study to assess the immunogenicity and safety of a monovalent 2009 influenza A (H1N1) vaccine in an area with low-level epidemics of pandemic influenza. Vaccine. 2010 Oct 21;28 (45):7337-43. PMID 20817013.

747. Kurikka S, Kayhty H, Peltola H, Saarinen L, Eskola J, Makela PH. Neonatal immunization: response to Haemophilus influenzae type b-tetanus toxoid conjugate vaccine. Pediatrics. 1995 Jun;95 (6):815-22. PMID 7761204.

748. Kurikka S, Olander RM, Eskola J, Kayhty H. Passively acquired anti-tetanus and anti-Haemophilus antibodies and the response to Haemophilus influenzae type b-tetanus toxoid conjugate vaccine in infancy. Pediatric Infectious Disease Journal. 1996 Jun;15 (6):530-5. PMID 8783351.

749. Kuronen T, Peltola H, Nors T, Haque N, Makela PH. Adverse reactions and endotoxin content of polysaccharide vaccines. Developments in Biological Standardization. 1977;34:117-25. PMID 402298.

750. Kuruma KAM, Borba EF, Lopes MH, de Carvalho JF, Bonfa E. Safety and efficacy of hepatitis B vaccine in systemic lupus erythematosus. Lupus. 2007;16 (5):350-4. PMID WOS:000248089800007.

751. Kussmaul SC, Horn BN, Dvorak CC, Abramovitz L, Cowan MJ, Weintrub PS. Safety of the live, attenuated varicella vaccine in pediatric recipients of hematopoietic SCTs. Bone Marrow Transplantation. 2010 7;45 (11):1602-6. PMID 2010618609 MEDLINE PMID 20190839 (http://www.ncbi.nlm.nih.gov/pubmed/20190839).

752. Kuter BJ, Brown MLH, Hartzel J, et al. Safety and immunogenicity of a combination measles, mumps, rubella and varicella vaccine (ProQuad(registered trademark)). Human Vaccines. 2006 September/October;2 (5):205-14. PMID 2006573463 MEDLINE PMID

17035730 (http://www.ncbi.nlm.nih.gov/pubmed/17035730).

753. Kwak GY, Kwon HJ, Kim JH, et al. The immunogenicity and safety of DTaP interchangeable immunization among Korean children. Vaccine. 2012 Jun 29;30 (31):4644-7. PMID 22579862.

754. Labriola L, Hombrouck A, Marechal C, et al. Immunogenicity of an adjuvanted 2009 pandemic influenza A (H1N1) vaccine in haemodialysed patients. Nephrology Dialysis Transplantation. 2011 April;26 (4):1424-8. PMID 2011198098 MEDLINE PMID 21273236 (http://www.ncbi.nlm.nih.gov/pubmed/21273236).

755. Lackmann GM. Comparative investigation of the safety of hexavalent vaccines for primary scheduled infant immunizations in Germany over a time period of 2 years. Medical Science Monitor. 2004 September;10 (9):PI96-PI8. PMID 2004410721 MEDLINE PMID 15328494 (http://www.ncbi.nlm.nih.gov/pubmed/15328494).

756. Lackner TE, G Hamilton R, J Hill J, Davey C, Guay DRP. Pneumococcal polysaccharide revaccination: immunoglobulin g seroconversion, persistence, and safety in frail, chronically ill older subjects. Journal of the American Geriatrics Society. 2003 Feb;51 (2):240-5. PMID 12558722.

757. Lagler H, Wenisch JM, Tobudic S, et al. Pandemic influenza A H1N1 vaccine in recipients of solid organ transplants: immunogenicity and tolerability outcomes after vero cell derived, non-adjuvanted, whole-virion vaccination. Vaccine. 2011 Sep 16;29 (40):6888-93. PMID 21803100.

758. Lagos R, Munoz A, Levine MM, Watson W, Chang I, Paradiso P. Immunology of combining CRM(197) conjugates for Streptococcus pneumoniae, Neisseria meningitis and Haemophilus influenzae in Chilean infants. Vaccine. 2009 Apr 14;27 (17):2299-305. PMID 19428843.

759. Lagos RE, Munoz AE, Levine MM, et al. Safety and immunogenicity of the 10-valent pneumococcal nontypeable Haemophilus influenzae protein D conjugate vaccine (PHiD-CV) in Chilean children. Human Vaccines. 2011 May;7 (5):511-22. PMID 21441782.

760. Lai YC, Yang KC, Hsieh SM, Yao CA, Lee LT, Huang KC. Persistence of Immunogenicity of a Monovalent Influenza Virus A/H1N1 2009 Vaccine in Healthy Volunteers. Clinical and Vaccine Immunology. 2012 Mar;19 (3):429-35. PMID WOS:000300841200021.

761. Lalwani S, Chatterjee S, Chhatwal J, et al. Immunogenicity, safety, and reactogenicity of the 10-valent pneumococcal non-typeable Hemophilus influenzae protein D conjugate vaccine (PHiD-CV) when co-administered with the DTPw-HBV/Hib vaccine in Indian infants: A single-blind, randomized, controlled study. Human Vaccines and Immunotherapeutics. 2012 May;8 (5):612-22. PMID 2012397558.

762. Lang L. Rotavirus Vaccines Prove Powerful Against Diarrhea. Gastroenterology. 2010

April;138 (4):1221-2. PMID 2010188120.

763. Langley JM, Halperin SA, Rubin E, et al. Safety and immunogenicity of 2 mixed primary infant immunization schedules of pentavalent diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, and Haemophilus influenzae Type B vaccines at 2, 4, and 6 months of age: a randomized controlled trial. Pediatric Infectious Disease Journal. 2012 Feb;31 (2):189-92. PMID 22173143.

764. Langley JM, Predy G, Guasparini R, et al. An adolescent-adult formulation tetanus and diptheria toxoids adsorbed combined with acellular pertussis vaccine has comparable immunogenicity but less reactogenicity in children 4-6 years of age than a pediatric formulation acellular pertussis vaccine and diphtheria and tetanus toxoids adsorbed combined with inactivated poliomyelitis vaccine. Vaccine. 2007 Jan 22;25 (6):1121-5. PMID 17045366.

765. Langley JM, Scheifele DW, Quach C, et al. Safety and immunogenicity of 2010-2011 H1N12009-containing trivalent inactivated influenza vaccine in children 12-59 months of age previously given AS03-adjuvanted H1N12009 pandemic vaccine: a PHAC/CIHR Influenza Research Network (PCIRN) study. Vaccine. 2012 May 14;30 (23):3389-94. PMID 22469860.

766. Langue J, Ethevenaux C, Champsaur A, Fritzell B, Begue P, Saliou P. Safety and immunogenicity of Haemophilus influenzae type b-tetanus toxoid conjugate, presented in a dual-chamber syringe with diphtheria-tetanus-pertussis and inactivated poliomyelitis combination vaccine. European Journal of Pediatrics. 1999 Sep;158 (9):717-22. PMID 10485302.

767. Lapatsanis P, Lapatsanis D. Pertussis vaccine and infantile spasms. Vaccine. 2007 5;25 (3):404-5. PMID 2006593391 MEDLINE PMID 16962689 (http://www.ncbi.nlm.nih.gov/pubmed/16962689).

768. Laroche P, Barrand M, Wood SC, et al. The immunogenicity and safety of a new combined diphtheria, tetanus and poliomyelitis booster vaccine (Td-eIPV). Infection. 1999 Jan-Feb;27 (1):49-56. PMID 10206791.

769. Latipov R, Khudoyorov R, Flem E. Childhood intussusception in Uzbekistan: analysis of retrospective surveillance data. Bmc Pediatrics. 2011;11:22. PMID 21435218.

770. Launay O, Desaint C, Durier C, et al. Safety and immunogenicity of a monovalent 2009 influenza A/H1N1v vaccine adjuvanted with AS03A or unadjuvanted in HIV-infected adults: a randomized, controlled trial. Journal of Infectious Diseases. 2011 Jul 1;204 (1):124-34. PMID 21628666.

771. Launay O, van der Vliet D, Rosenberg AR, et al. Safety and Immunogenicity of 4 Intramuscular Double Doses and 4 Intradermal Low Doses vs Standard Hepatitis B Vaccine Regimen in Adults With HIV-1 A Randomized Controlled Trial. Jama-Journal of the American Medical Association. 2011 Apr;305 (14):1432-40. PMID WOS:000289424100020.

772. Lawrence G, Boyd I, McIntyre P, Isaacs D. Annual report: Surveillance of adverse events

following immunisation in Australia, 2005. Communicable Diseases Intelligence. 2006;30 (3):319-33. PMID 17120485.

773. Lawrence G, Gold MS, Hill R, Deeks S, Glasswell A, McIntyre PB. Annual report: surveillance of adverse events following immunisation in Australia, 2007. Communicable Diseases Intelligence. 2008 Dec;32 (4):371-87. PMID 19374268.

774. Lawrence GL, Aratchige PE, Boyd I, McIntyre PB, Gold MS. Annual report on surveillance of adverse events following immunisation in Australia, 2006. Communicable Diseases Intelligence. 2007 Sep;31 (3):269-82. PMID 17974219.

775. Lazarov A, Attias O, Avinoach I, Halevy S. Infantile acute hemorrhagic edema following vaccine application [2]. Journal of the European Academy of Dermatology and Venereology. 1995 1995;5 (2):203-4. PMID 1995283921.

776. Lazarus R, Clutterbuck E, Yu LM, et al. A randomized study comparing combined pneumococcal conjugate and polysaccharide vaccination schedules in adults. Clinical Infectious Diseases. 2011 15;52 (6):736-42. PMID 2011190872 MEDLINE PMID 21367726 (http://www.ncbi.nlm.nih.gov/pubmed/21367726).

777. LeBaron CW, Bi D, Sullivan BJ, Beck C, Gargiullo P. Evaluation of potentially common adverse events associated with the first and second doses of measles-mumps-rubella vaccine. Pediatrics. 2006 Oct;118 (4):1422-30. PMID 17015532.

778. Lederman MM, Schiffman G, Rodman HM. Pneumococcal immunization in adult diabetics. Diabetes. 1981 Feb;30 (2):119-21. PMID 7202857.

779. Lee A, Goyal R, Shan HY. Severe protracted fever following pneumococcal vaccine. American Journal of the Medical Sciences. 2006 Dec;332 (6):351-3. PMID 17170626.

780. Lee AW, Vesikari T, Gilbert CL, Klopfer SO, Schodel FP, Bhuyan PK. Immunogenicity and safety of a Haemophilus influenzae B (Hib)-hepatitis B vaccine with a modified process hepatitis B component administered with concomitant pneumococcal conjugate vaccine to infants. Vaccine. 2011 Oct 19;29 (45):7942-8. PMID 21875633.

781. Lee BY, Stalter RM, Bacon KM, et al. Cost-effectiveness of adjuvanted versus nonadjuvanted influenza vaccine in adult hemodialysis patients. American Journal of Kidney Diseases. 2011 May;57 (5):724-32. PMID 2011205904 MEDLINE PMID 21396760 (http://www.ncbi.nlm.nih.gov/pubmed/21396760).

782. Lee CY, Lee PI, Huang LM, Chen JM, Chang MH. A simplified schedule to integrate the hepatitis B vaccine into an expanded program of immunization in endemic countries. Journal of Pediatrics. 1997 1997;130 (6):981-6. PMID 1997357698 MEDLINE PMID 9202623 (http://www.ncbi.nlm.nih.gov/pubmed/9202623).

783. Lee CY, Thipphawong J, Huang LM, et al. An evaluation of the safety and

immunogenicity of a five-component acellular pertussis, diphtheria, and tetanus toxoid vaccine (DTaP) when combined with a Haemophilus influenzae type b-tetanus toxoid conjugate vaccine (PRP-T) in Taiwanese infants. Pediatrics. 1999 Jan;103 (1):25-30. PMID 9917435.

784. Lee H, Kim HW, Cho HK, Park EA, Choi KM, Kim K-H. Reappraisal of MMR vaccines currently used in Korea. Pediatrics International. 2011 Jun;53 (3):374-80. PMID 20831649.

785. Lee HJ, Kang JH, Henrichsen J, et al. Immunogenicity and safety of a 23-valent pneumococcal polysaccharide vaccine in healthy children and in children at increased risk of pneumococcal infection. Vaccine. 1995 Nov;13 (16):1533-8. PMID 8578838.

786. Lee SJ, Kim YO, Woo YJ, Kim MK, Nam T-S, Cho YK. Neurologic adverse events following influenza A (H1N1) vaccinations in children. Pediatrics International. 2012 Jun;54 (3):325-30. PMID 22299607.

787. Lee SY, Hwang HS, Kim JH, et al. Immunogenicity and safety of a combined diphtheria, tetanus, acellular pertussis, and inactivated poliovirus vaccine (DTaP-IPV) compared to separate administration of standalone DTaP and IPV vaccines: a randomized, controlled study in infants in the Republic of Korea. Vaccine. 2011 Feb 11;29 (8):1551-7. PMID 21215828.

788. Lee SY, Hwang HS, Kim JH, et al. Immunogenicity and safety of a combined diphtheria, tetanus, acellular pertussis and inactivated poliovirus vaccine (DTaP-IPV) compared to separate administration of standalone DTaP and IPV vaccines: A randomized, controlled study in infants in the Republic of Korea. Vaccine. 2011 11;29 (8):1551-7. PMID 2011150742 MEDLINE PMID 21215828 (http://www.ncbi.nlm.nih.gov/pubmed/21215828).

789. Lee YY, Lee R, Yamamoto LG. Intussusception incidence relative to rotavirus vaccine use in Honolulu. Clinical Pediatrics. 2005 Nov-Dec;44 (9):791-5. PMID 16327966.

790. Leeb A, Carcione D, Richmond PC, Jacoby P, Effler PV. Reactogenicity of two 2010 trivalent inactivated influenza vaccine formulations in adults. Vaccine. 2011 Oct 19;29 (45):7920-4. PMID 21864621.

791. Lehmann D, Kakazo M, Yarsley S, et al. Safety and immunogenicity of Haemophilus influenzae type b conjugate vaccine (PedvaxHIB) in Papua New Guinean children. Papua New Guinea Medical Journal. 1998 Sep-Dec;41 (3-4):102-11. PMID 10934551.

792. Lehmann D, Pomat WS, Riley ID, Alpers MP. Studies of maternal immunisation with pneumococcal polysaccharide vaccine in Papua New Guinea. Vaccine. 2003 Jul 28;21 (24):3446-50. PMID 12850357.

793. Lehtinen M, Paavonen J, Wheeler CM, et al. Overall efficacy of HPV-16/18 AS04-adjuvanted vaccine against grade 3 or greater cervical intraepithelial neoplasia: 4-year end-of-study analysis of the randomised, double-blind PATRICIA trial.[Erratum appears in Lancet Oncol. 2012 Jan;13(1):e1]. Lancet Oncology. 2012 Jan;13 (1):89-99. PMID 22075171.

794. Lennon D. Re: Immunogenicity and safety of a strain-specific MenB OMV vaccine delivered to under 5 year olds in New Zealand, Oster P, O'Hallahan J, Aaberge I, Tilman S, Ypma E, Martin D. Vaccine 2007;25(16):3075-9. Vaccine. 2007 Sep 28;25 (39-40):6835; author reply -6. PMID 17875437.

795. Leonardi M, Bromberg K, Baxter R, et al. Immunogenicity and safety of MMRV and PCV-7 administered concomitantly in healthy children. Pediatrics. 2011 Dec;128 (6):e1387-94. PMID 22123890.

796. Lepow M. Clinical trials of the Haemophilus influenzae type b capsular polysaccharide-diphtheria toxoid conjugate vaccine. Pediatric Infectious Disease Journal. 1987 Aug;6 (8):804-7. PMID 3313246.

797. Lepow ML, Samuelson JS, Gordon LK. Safety and immunogenicity of Haemophilus influenzae type B polysaccharide-diphtheria toxoid conjugate vaccine in adults. Journal of Infectious Diseases. 1984 Sep;150 (3):402-6. PMID 6332863.

798. Lepow ML, Samuelson JS, Gordon LK. Safety and immunogenicity of Haemophilus influenzae type b-polysaccharide diphtheria toxoid conjugate vaccine in infants 9 to 15 months of age. Journal of Pediatrics. 1985 Feb;106 (2):185-9. PMID 3871477.

799. Leroux-Roels G, Haelterman E, Maes C, et al. Randomized trial of the immunogenicity and safety of the Hepatitis B vaccine given in an accelerated schedule coadministered with the human papillomavirus type 16/18 AS04-adjuvanted cervical cancer vaccine. Clinical & Vaccine Immunology: CVI. 2011 Sep;18 (9):1510-8. PMID 21734063.

800. Leroux-Roels I, Vets E, Freese R, et al. Seasonal influenza vaccine delivered by intradermal microinjection: A randomised controlled safety and immunogenicity trial in adults (vol 26, pg 6614, 2008). Vaccine. 2010 Nov;28 (50):8033-. PMID WOS:000285667400027.

801. Leroy Z, Broder K, Menschik D, Shimabukuro T, Martin D. Febrile seizures after 2010-2011 influenza vaccine in young children, United States: a vaccine safety signal from the vaccine adverse event reporting system. Vaccine. 2012 Mar 2;30 (11):2020-3. PMID 22361303.

802. Lertdumrongluk P, Changsirikulchai S, Limkunakul C, et al. Safety and immunogenicity of a 2009 influenza A (H1N1) vaccine in hemodialysis patients. Vaccine. 2012 Feb 1;30 (6):1108-14. PMID 22178515.

803. Leung AK, Chiu AS, Siu TO. Subcutaneous versus intramuscular administration of Haemophilus influenzae type b vaccine. Journal of the Royal Society of Health. 1989 Apr;109 (2):71-3. PMID 2500525.

804. Leung JSM. Adverse events after flu vaccination in patients with immune disorders. Hong Kong Medical Journal. 2010 Apr;16 (2):159. PMID 20354258.

805. Leventhal JS, Berger EM, Brauer JA, Cohen DE. Hypersensitivity Reactions to Vaccine

Constituents: A Case Series and Review of the Literature. Dermatitis. 2012 May-Jun;23 (3):102-9. PMID WOS:000304846700001.

806. Levin MJ, Gershon AA, Weinberg A, et al. Administration of live varicella vaccine to HIV-infected children with current or past significant depression of CD4(+) T cells. J Infect Dis. 2006 Jul 15;194 (2):247-55. PMID 16779732.

807. Levine OS, Lagos R, Losonsky GA, et al. No adverse impact on protection against pertussis from combined administration of Haemophilus influenza type b conjugate and diphtheria-tetanus toxoid-pertussis vaccines in the same syringe. Journal of Infectious Diseases. 1996 Dec;174 (6):1341-4. PMID 8940230.

808. Lexchin J, Arya N, Singh S. Gardasil(registered trademark) - The new HPV vaccine: The right product, the right time? A commentary. Healthcare Policy. 2010 May;5 (4):26-36. PMID 2011083948.

809. Li G, Zhang H, Zhou W, et al. Safety and immunogenicity of a diphtheria, tetanus, acellular pertussis and Haemophilus influenzae Type b combination vaccine compared with separate administration of licensed equivalent vaccines in Chinese infants and toddlers for primary and booster immunization. Vaccine. 2010 Jun 7;28 (25):4215-23. PMID 20399240.

810. Li RC, Li FX, Li YP, et al. Safety and immunogenicity of a 7-valent pneumococcal conjugate vaccine (Prevenar): primary dosing series in healthy Chinese infants. Vaccine. 2008 Apr 24;26 (18):2260-9. PMID 18375021.

811. Li RC, Li FX, Li YP, et al. Antibody persistence at 18-20 months of age and safety and immunogenicity of a booster dose of a combined DTaP-IPV//PRP~T vaccine compared to separate vaccines (DTaP, PRP~T and IPV) following primary vaccination of healthy infants in the People's Republic of China. Vaccine. 2011 Nov 21;29 (50):9337-44. PMID 22001281.

812. Li RC, Li FX, Li YP, et al. Immunogenicity and safety of a pentavalent acellular pertussis combined vaccine including diphtheria, tetanus, inactivated poliovirus and conjugated Haemophilus Influenzae type b polysaccharide for primary vaccination at 2, 3, 4 or 3, 4, 5 months of age in infants in China. Vaccine. 2011 Feb 24;29 (10):1913-20. PMID 21219984.

813. Li RC, Li FX, Li YP, et al. Antibody persistence at 18-20 months of age and safety and immunogenicity of a booster dose of a combined DTaP-IPV//PRP approximately T vaccine compared to separate vaccines (DTaP, PRP approximately T and IPV) following primary vaccination of healthy infants in the People's Republic of China. Vaccine. 2011 Nov 21;29 (50):9337-44. PMID 22001281.

814. Li X, Wang WWB, Liu GF, Chan ISF. Handling missing data in vaccine clinical trials for immunogenicity and safety evaluation. Journal of Biopharmaceutical Statistics. 2011 March;21 (2):294-310. PMID 2011145455 MEDLINE PMID 21391003 (http://www.ncbi.nlm.nih.gov/pubmed/21391003).

815. Liakou CD, Askiti V, Mitsioni A, Stefanidis CJ, Theodoridou MC, Spoulou VI. Safety, immunogenicity and kinetics of immune response to 7-valent pneumococcal conjugate vaccine in children with idiopathic nephrotic syndrome. Vaccine. 2011 Sep 16;29 (40):6834-7. PMID 21803106.

816. Liang X-F, Li L, Liu D-W, et al. Safety of influenza A (H1N1) vaccine in postmarketing surveillance in China.[Erratum appears in N Engl J Med. 2011 Apr 14;364(15):1481]. New England Journal of Medicine. 2011 Feb 17;364 (7):638-47. PMID 21288090.

817. Liang X-F, Wang H-Q, Wang J-Z, et al. Safety and immunogenicity of 2009 pandemic influenza A H1N1 vaccines in China: a multicentre, double-blind, randomised, placebo-controlled trial.[Erratum appears in Lancet. 2010 May 15;375(9727):1694]. Lancet. 2010 Jan 2;375 (9708):56-66. PMID 20018364.

818. Liao G, Li R, Li C, et al. Safety and immunogenicity of inactivated poliovirus vaccine made from Sabin strains: a phase II, randomized, positive-controlled trial. Journal of Infectious Diseases. 2012 Jan 15;205 (2):237-43. PMID 22158682.

819. Liese JG, Rieber N, Malzer T, et al. Reactogenicity of tetanus, diphtheria, 5-component acellular pertussis vaccine administered as a sixth consecutive acellular pertussis vaccine dose to adolescents. Pediatric Infectious Disease Journal. 2010 Dec;29 (12):1067-71. PMID 20616762.

820. Liese JG, Stojanov S, Berut F, et al. Large scale safety study of a liquid hexavalent vaccine (D-T-acP-IPV-PRP--T-HBs) administered at 2, 4, 6 and 12-14 months of age. Vaccine. 2001 Nov 12;20 (3-4):448-54. PMID 11672908.

821. Lim BH, Mahmood TA. Pandemic H1N1 2009 (swine flu) and pregnancy. Obstetrics, Gynaecology and Reproductive Medicine. 2010 April;20 (4):101-6. PMID 2010164273.

822. Lim FS, Phua KB, Lee BW, et al. Safety and reactogenicity of DTPa-HBV-IPV/Hib and DTPa-IPV/I-Hib vaccines in a post-marketing surveillance setting. Southeast Asian Journal of Tropical Medicine & Public Health. 2011 Jan;42 (1):138-47. PMID 21323176.

823. Lim S-H, Lee J-H, Kim B-C, Jung S-U, Park Y-B, Lee C-S. Adverse reaction of influenza A (H1N1) 2009 virus vaccination in pregnant women and its effect on newborns. Vaccine. 2010 Nov 3;28 (47):7455-6. PMID 20832495.

824. Lin CS, Zhu JY, Zheng YB, et al. Effect of GM-CSF in combination with hepatitis B vaccine on revacination of healthy adult. Journal of Infection. 2010 Apr;60 (4):264-70. PMID WOS:000275789100002.

825. Lin CY, Peng CC, Liu HC, Chiu NC. Psychogenic movement disorder after H1N1 influenza vaccination. Journal of Neuropsychiatry and Clinical Neurosciences. 2011 2011;23 (3):E37-E8. PMID 2011595788 MEDLINE PMID 21948923 (http://www.ncbi.nlm.nih.gov/pubmed/21948923).

826. Lin PL, Michaels MG, Green M, et al. Safety and immunogenicity of the American Academy of Pediatrics--recommended sequential pneumococcal conjugate and polysaccharide vaccine schedule in pediatric solid organ transplant recipients. Pediatrics. 2005 Jul;116 (1):160-7. PMID 15995047.

827. Lin TY, Lu CY, Chang LY, et al. Immunogenicity and safety of 10-valent pneumococcal non-typeable Haemophilus influenzae protein D-conjugate vaccine (PHiD-CV) co-administered with routine childhood vaccines in Taiwan. Journal of the Formosan Medical Association. 2012.

828. Lin TY, Wang Y-H, Chang L-Y, et al. A fully liquid diphtheria-tetanus-five component acellular pertussis-inactivated poliomyelitis--Haemophilus influenzae type b conjugate vaccine: immunogenicity and safety of primary vaccination in Taiwanese infants. International Journal of Infectious Diseases. 2007 Mar;11 (2):129-36. PMID 16762579.

829. Lin T-Y, Wang Y-H, Chang L-Y, et al. Safety and immunogenicity of a diphtheria, tetanus, and acellular pertussis-inactivated poliovirus vaccine/Haemophilus influenzae type B combination vaccine administered to Taiwanese infants at 2, 4, and 6 months of age. Chang Gung Medical Journal. 2003 May;26 (5):315-22. PMID 12934847.

830. Lin T-Y, Wang Y-H, Huang Y-C, et al. Booster vaccination at 6-8 years of age with a reduced antigen content dTpa-IPV vaccine is immunogenic and safe after priming with whole-cell pertussis vaccine. Human Vaccines. 2008 Jan-Feb;4 (1):50-3. PMID 18376147.

831. Lin T-Y, Wang Y-H, Huang Y-C, et al. One-year post-primary antibody persistence and booster immune response to a fully liquid five-component acellular pertussis, diphtheria, tetanus, inactivated poliomyelitis, Haemophilus influenzae type b conjugate vaccine. International Journal of Infectious Diseases. 2007 Nov;11 (6):488-95. PMID 17349809.

832. Linchevski I, Klement E, Nir-Paz R. Mycoplasma pneumoniae vaccine protective efficacy and adverse reactions--Systematic review and meta-analysis. Vaccine. 2009 Apr 21;27 (18):2437-46. PMID 19368785.

833. Linhares AC, Velazquez FR. Rotavirus P[4]G2 in a vaccinated population, Brazil. Emerging Infectious Diseases. 2008;14 (5) PMID 2008291627.

834. Lisotti A, Roda G, Brillanti S, Roda E. Reactivation of Crohn's disease after pandemic aH1N1 and seasonal flu vaccinations. Digestive and Liver Disease. 2010 December;42 (12):909-10. PMID 2010648189 MEDLINE PMID 20417161 (http://www.ncbi.nlm.nih.gov/pubmed/20417161).

835. Lloyd-Johnsen C, Justice F, Donath S, Bines JE. Retrospective hospital based surveillance of intussusception in children in a sentinel paediatric hospital: benefits and pitfalls for use in post-marketing surveillance of rotavirus vaccines. Vaccine. 2012 Apr 27;30 Suppl 1:A190-5. PMID 22520131.

836. Lloyd-Puryear MA, Ball LK, Benor D. Should the vaccine injury compensation program be

expanded to cover adults? Public Health Reports. 1998 May-Jun;113 (3):236-42. PMID 9633868.

837. Lode H, Schmoele-Thoma B, Gruber W, et al. Dose-ranging study of a single injection of pneumococcal conjugate vaccine (1 x, 2 x, or 4 x) in healthy subjects aged 70 years or older. Vaccine. 2011 Jul 12;29 (31):4940-6. PMID 21596077.

838. Lodolce AE. Shortened interval between tetanus vaccines. Annals of Pharmacotherapy. 2012 Jun;46 (6):884-8. PMID 22669800.

839. Loebermann M, Anders G, Brestrich G, et al. Safety and immunogenicity of a trivalent single dose seasonal influenza vaccine containing pandemic A(H1N1) antigen in younger and elderly subjects: a phase III open-label single-arm study. Vaccine. 2011 Feb 1;29 (6):1228-34. PMID 21167116.

840. Lolekha S, Hiranchote A, Simasathien S. Safety and immunogenicity of combined or associated administration of PRP-T vaccine with diphtheria, tetanus and pertussis vaccine in Thai children. Journal of Tropical Pediatrics. 2001 Feb;47 (1):24-9. PMID 11245347.

841. Lopert R, Nolan T. Panvax febrile reactions not a predictor. BMJ. 2010;(2010) 341 (7765):163. PMID 2010415137.

842. Lopman BA, Payne DC, Tate JE, Patel MM, Cortese MM, Parashar UD. Post-licensure experience with rotavirus vaccination in high and middle income countries; 2006 to 2011. Current Opinion in Virology. 2012 August;2 (4):434-42. PMID 2012485382.

843. Lottenbach KR, Granoff DM, Barenkamp SJ, et al. Safety and immunogenicity of haemophilus influenzae type B polysaccharide or conjugate vaccines in an elderly adult population. Journal of the American Geriatrics Society. 2004 Nov;52 (11):1883-7. PMID 15507066.

844. Loughlin J, Mast TC, Doherty MC, Wang FT, Wong J, Seeger JD. Postmarketing evaluation of the short-term safety of the pentavalent rotavirus vaccine. Pediatric Infectious Disease Journal. 2012 Mar;31 (3):292-6. PMID 22173146.

845. Lu C-C, Wang Y-C, Lai J-H, Lee TS-H, Lin H-T, Chang D-M. A/H1N1 influenza vaccination in patients with systemic lupus erythematosus: safety and immunity. Vaccine. 2011 Jan 10;29 (3):444-50. PMID 21078406.

846. Lu C-L, Hung C-C, Chuang Y-C, et al. Comparison of serologic responses to vaccination with one dose or two doses of 7-valent pneumococcal conjugate vaccine in HIV-infected adult patients. Vaccine. 2012 May 21;30 (24):3526-33. PMID 22484349.

847. Lum LCS, Borja-Tabora CF, Breiman RF, et al. Influenza vaccine concurrently administered with a combination measles, mumps, and rubella vaccine to young children. Vaccine. 2010 10;28 (6):1566-74. PMID 2010073090 MEDLINE PMID 20003918

(http://www.ncbi.nlm.nih.gov/pubmed/20003918).

848. Macias M, Lanata CF, Zambrano B, et al. Safety and Immunogenicity of an Investigational Fully Liquid Hexavalent DTaP-IPV-Hep B-PRP-T Vaccine at Two, Four and Six Months of Age Compared With Licensed Vaccines in Latin America. Pediatric Infectious Disease Journal. 2012 Aug;31 (8):e126-32. PMID 22531237.

849. MacIntyre CR, Egerton T, McCaughey M, et al. Concomitant administration of zoster and pneumococcal vaccines in adults >=60 years old. Human Vaccines. 2010 Nov;6 (11):894-902. PMID 20980796.

850. Mackay HJ, McGee J, Villa D, et al. Evaluation of pandemic H1N1 (2009) influenza vaccine in adults with solid tumor and hematological malignancies on active systemic treatment. Journal of Clinical Virology. 2011 Mar;50 (3):212-6. PMID 21168361.

851. Mad'ar R, Benesova D, Brandejska D, et al. Vaccination of Patients with Diabetes Mellitus - a Retrospective Study. Central European Journal of Public Health. 2011 Jun;19 (2):98-101. PMID WOS:000291919600009.

852. Mad'ar R, Benesova D, Brandejska D, et al. Vaccination of patients with diabetes mellitus--a retrospective study. Central European Journal of Public Health. 2011 Jun;19 (2):98-101. PMID 21739900.

853. Madhi SA, Cutland C, Jones S, Groome M, Ortiz E. Immunogenicity and safety of an acellular pertussis, diphtheria, tetanus, inactivated poliovirus, Hib-conjugate combined vaccine (Pentaxim) and monovalent hepatitis B vaccine at 6, 10 and 14 weeks of age in infants in South Africa. South African Medical Journal. Suid-Afrikaanse Tydskrif Vir Geneeskunde. 2011 Feb;101 (2):126-31. PMID 21678741.

854. Madhi SA, Cutland C, Jones S, Groome M, Ortiz E. One-year post-primary antibody persistence and booster immune response to a DTaP-IPV//PRP~T vaccine (Pentaxim) given at 18 - 19 months of age in South African children primed at 6, 10 and 14 weeks of age with the same vaccine. South African Medical Journal. Suid-Afrikaanse Tydskrif Vir Geneeskunde. 2011 Dec;101 (12):879-83. PMID 22273029.

855. Madhun AS, Akselsen PE, Sjursen H, et al. An adjuvanted pandemic influenza H1N1 vaccine provides early and long term protection in health care workers. Vaccine. 2010 16;29 (2):266-73. PMID 2010663992 MEDLINE PMID 21034828 (http://www.ncbi.nlm.nih.gov/pubmed/21034828).

856. Madore DV, Johnson CL, Phipps DC, Myers MG, Eby R, Smith DH. Safety and immunogenicity of Haemophilus influenzae type b oligosaccharide-CRM197 conjugate vaccine in infants aged 15 to 23 months. Pediatrics. 1990 Oct;86 (4):527-34. PMID 2216616.

857. Madore DV, Johnson CL, Phipps DC, Myers MG, Eby R, Smith DH. Safety and Immunogenicity of Haemophilus-Influenzae Type-B Oligosaccharide-Crm-197 Conjugate

Vaccine in Infants Aged 15 to 23 Months. Pediatrics. 1990 Oct;86 (4):527-34. PMID WOS:A1990EA80800006.

858. Madore DV, Johnson CL, Phipps DC, Popejoy LA, Eby R, Smith DH. Safety and Immunological Response to Haemophilus-Influenzae Type-B Oligosaccharide-Crm197 Conjugate Vaccine in 1-Month-Old to 6-Month-Old Infants. Pediatrics. 1990 Mar;85 (3):331-7. PMID WOS:A1990CX32100015.

859. Mahadevan U, Cucchiara S, Hyams JS, et al. The London position statement of the World Congress of gastroenterology on biological therapy for IBD with the European Crohn's and Colitis Organisation: Pregnancy and pediatrics. American Journal of Gastroenterology. 2011 February;106 (2):214-23. PMID 2011082151 MEDLINE PMID 21157441 (http://www.ncbi.nlm.nih.gov/pubmed/21157441).

860. Mair S, Fiquet A, Meghlaoui G, Thomas S, Ledesma E. Immunogenicity and safety of PNEUMOVAX II manufactured by a new process in older adults. Human Vaccines. 2009 Sep;5 (9):608-13. PMID 19617717.

861. Mallet E, Brachet E, Fernsten P, et al. Immunogenicity and safety of CRM197 conjugated 9-valent pneumococcal and meningococcal C combination vaccine in healthy infants. Vaccine. 2011 Aug 5;29 (34):5812-9. PMID 21296118.

862. Mallory RM, Yi T, Ambrose CS. Shedding of Ann Arbor strain live attenuated influenza vaccine virus in children 6-59 months of age. Vaccine. 2011 Jun 10;29 (26):4322-7. PMID 21513761.

863. Maltezou HC. Novel (pandemic) influenza A H1N1 in healthcare facilities: implications for prevention and control. Scandinavian Journal of Infectious Diseases. 2010 Jul;42 (6-7):412-20. PMID 20331404.

864. Mangay-Angara A, Fulgencio L, Casabal G, et al. A two-dose schedule for immunization of infants using a more concentrated DPT-vaccine. Developments in Biological Standardization. 1978;41:15-22. PMID 753647.

865. Mantadakis E, Farmaki E, Buchanan GR. Thrombocytopenic purpura after measles-mumps-rubella vaccination: a systematic review of the literature and guidance for management. Journal of Pediatrics. 2010 Apr;156 (4):623-8. PMID 20097358.

866. Manuel O, Humar A, Berutto C, et al. Low-dose intradermal versus intramuscular trivalent inactivated seasonal influenza vaccine in lung transplant recipients. Journal of Heart & Lung Transplantation. 2011 Jun;30 (6):679-84. PMID 21377898.

867. Manuel O, Pascual M, Hoschler K, et al. Humoral response to the influenza A H1N1/09 monovalent AS03-adjuvanted vaccine in immunocompromised patients. Clinical Infectious Diseases. 2011 Jan 15;52 (2):248-56. PMID 21288852.

868. Marchant CD, Miller JM, Marshall GS, et al. Randomized trial to assess immunogenicity and safety of Haemophilus influenzae type b and Neisseria meningitidis serogroups C and Y-tetanus toxoid conjugate vaccine in infants. Pediatric Infectious Disease Journal. 2010 Jan;29 (1):48-52. PMID 20035207.

869. Marcinak JF, Frank AL, Labotka RL, et al. Immunogenicity of Haemophilus-Influenzae Type-B Polysaccharide-Diphtheria Toxoid Conjugate Vaccine in 3-Month-Old to 17-Month-Old Infants with Sickle-Cell Diseases. Journal of Pediatrics. 1991 Jan;118 (1):69-71. PMID WOS:A1991EU22200012.

870. Marin LF, Abrahao A, Carvalho FA, et al. Guillain-Barre syndrome associated with H1N1 vaccination.[Erratum appears in Arq Neuropsiquiatr. 2011 Feb;69(1):147 Note: Abrahao, Ayessandro [corrected to Abrahao, Agessandro]]. Arquivos de Neuro-Psiquiatria. 2010 Dec;68 (6):974-5. PMID 21243265.

871. Marshall GS, Marchant CD, Blatter M, et al. Immune response and one-year antibody persistence after a fourth dose of a novel Haemophilus influenzae type b and Neisseria meningitidis serogroups C and Y-tetanus toxoid conjugate vaccine (HibMenCY) at 12 to 15 months of age. Pediatric Infectious Disease Journal. 2010 May;29 (5):469-71. PMID 20072077.

872. Marshall GS, Marchant CD, Blatter M, Friedland LR, Aris E, Miller JM. Co-administration of a novel Haemophilus influenzae type b and Neisseria meningitidis serogroups C and Y-tetanus toxoid conjugate vaccine does not interfere with the immune response to antigens contained in infant vaccines routinely used in the United States. Human Vaccines. 2011 February;7 (2):258-64. PMID 2011140107 MEDLINE PMID 21307655 (http://www.ncbi.nlm.nih.gov/pubmed/21307655).

873. Marshall H, McIntyre P, Roberton D, Dinan L, Hardt K. Primary and booster immunization with a diphtheria, tetanus, acellular pertussis, hepatitis B (DTPa-HBV) and Haemophilus influenzae type b (Hib) vaccine administered separately or together is safe and immunogenic. International Journal of Infectious Diseases. 2010 Jan;14 (1):e41-9. PMID 19467896.

874. Marshall H, Nolan T, Roberton D, et al. A comparison of booster immunisation with a combination DTPa-IPV vaccine or DTPa plus IPV in separate injections when co-administered with MMR, at age 4-6 years. Vaccine. 2006 Aug 28;24 (35-36):6120-8. PMID 16822597.

875. Martinez-Mir I, Garcia LM, Palop V, et al. A prospective study of adverse drug reactions as a cause of admission to a paediatric hospital. British Journal of Clinical Pharmacology. 1996 1996;42 (3):319-24. PMID 1996262774 MEDLINE PMID 8877022 (http://www.ncbi.nlm.nih.gov/pubmed/8877022).

876. Martinon-Torres F, Gimenez-Sanchez F, Gurtman A, et al. 13-valent pneumococcal conjugate vaccine given with meningococcal C-tetanus toxoid conjugate and other routine pediatric vaccinations: immunogenicity and safety. Pediatric Infectious Disease Journal. 2012 Apr;31 (4):392-9. PMID 22301472.

877. Martins RdM, Camacho LAB, Marcovistz R, et al. Immunogenicity, reactogenicity and consistency of production of a Brazilian combined vaccine against diphtheria, tetanus, pertussis and Haemophilus influenzae type b. Memorias do Instituto Oswaldo Cruz. 2008 Nov;103 (7):711-8. PMID 19057823.

878. Mathian A, Devilliers H, Krivine A, et al. Factors influencing the efficacy of two injections of a pandemic 2009 influenza A (H1N1) nonadjuvanted vaccine in systemic lupus erythematosus. Arthritis & Rheumatism. 2011 Nov;63 (11):3502-11. PMID 21811996.

879. Matjila MJ, Phohu TC, Banzhoff A, et al. Safety and immunogenicity of two Haemophilus influenzae type b conjugate vaccines. South African Medical Journal. Suid-Afrikaanse Tydskrif Vir Geneeskunde. 2004 Jan;94 (1):43-6. PMID 14971232.

880. Matson DO. Letter to the editor. Vaccine. 2001 6;19 (20 22):2763. PMID 2001120350.

881. Mayet A, Ligier C, Gache K, et al. Adverse events following pandemic influenza vaccine Pandemrix[REGISTERED] reported in the French military forces--2009-2010. Vaccine. 2011 Mar 21;29 (14):2576-81. PMID 21296693.

882. Mayet A, Nivoix P, Haus-Cheymol R, et al. Increase in reported adverse events following seasonal influenza vaccination among the French armed forces, 2008-2009: possible role of stimulated reporting and background cases of influenza-like infection. Public Health. 2012 Jan;126 (1):70-6. PMID 22137096.

883. Mazurat N. Vaccines and acute myocardial infarction. Journal (Canadian Dental Association). 2010;76:a174. PMID 21167089.

884. McColgan BP, Borschke FA. Pseudoseptic arthritis after accidental intra-articular deposition of the pneumococcal polyvalent vaccine: a case report. American Journal of Emergency Medicine. 2007 Sep;25 (7):864.e1-3. PMID 17870515.

885. McCormack PL, Joura EA. Spotlight on quadrivalent human papillomavirus(Types 6, 11, 16, 18) recombinant vaccine(Gardasil(registered trademark)) in the prevention of premalignant-genital lesions, genital cancer, and genital warts in women. Biodrugs. 2011 2011;25 (5):339-43. PMID 2011535901 MEDLINE PMID 21942919 (http://www.ncbi.nlm.nih.gov/pubmed/21942919).

886. McCue JD. Adverse reactions to simultaneous influenza and pneumococcal vaccination. Journal of Family Practice. 1981 Aug;13 (2):175-7. PMID 7252446.

887. McEvoy SP. A retrospective survey of the safety of trivalent influenza vaccine among adults working in healthcare settings in south metropolitan Perth, Western Australia, in 2010. Vaccine. 2012 Apr 5;30 (17):2801-4. PMID 21920401.

888. McGann M, O'Rourke DJ, Peake D, et al. Narcolepsy in close temporal relationship to H1N1 vaccination in Irish children. Developmental Medicine and Child Neurology. 2012

January;54 SUPPL.1:29.

889. McIntosh AM, McMahon J, Dibbens LM, et al. Effects of vaccination on onset and outcome of Dravet syndrome: a retrospective study. Lancet Neurology. 2010 Jun;9 (6):592-8. PMID 20447868.

890. McKenzie K. Italians ban Hib vaccine in BSE scare. BMJ. 1997 Feb 8;314 (7078):397. PMID 9040380.

891. McMahon AW, Iskander J, Haber P, et al. Adverse events after inactivated influenza vaccination among children less than 2 years of age: Analysis of reports from the Vaccine Adverse Event Reporting System, 1990-2003. Pediatrics. 2005 Feb;115 (2):453-60. PMID WOS:000226725000045.

892. McNeil MM, Arana J, Stewart B, et al. A cluster of nonspecific adverse events in a military reserve unit following pandemic influenza A (H1N1) 2009 vaccination-possible stimulated reporting? Vaccine. 2012 Mar 23;30 (14):2421-6. PMID 22310205.

893. McNicholas N, Chataway J. Relapse risk in patients with multiple sclerosis after H1N1 vaccination, with or without seasonal influenza vaccination. Journal of Neurology. 2011 Aug;258 (8):1545-7. PMID 21336784.

894. McVernon J, Nolan T, Richmond P, et al. A randomized trial to assess safety and immunogenicity of alternative formulations of a quadrivalent meningococcal (A, C, Y, and W-135) tetanus protein conjugate vaccine in toddlers. Pediatric Infectious Disease Journal. 2012 Jan;31 (1):e15-23. PMID 22094636.

895. Medeiros RH, Figueiredo AEP, Poli-de-Figueiredo CE, d'Avila DO, de los Santos CA. Low response to intradermal hepatitis B vaccination in incident hemodialysis patients. Jornal Brasileiro de Nefrologia. 2011 Mar;33 (1):45-9. PMID 21541462.

896. Medina DMR, Valencia A, de Velasquez A, et al. Safety and immunogenicity of the HPV-16/18 AS04-adjuvanted vaccine: a randomized, controlled trial in adolescent girls. Journal of Adolescent Health. 2010 May;46 (5):414-21. PMID 20413076.

897. Meier S, Bel M, L'Huillier A, et al. Antibody responses to natural influenza A/H1N1/09 disease or following immunization with adjuvanted vaccines, in immunocompetent and immunocompromised children. Vaccine. 2011 Apr 27;29 (19):3548-57. PMID 21419775.

898. Meisel R, Kuypers L, Dirksen U, et al. Pneumococcal conjugate vaccine provides early protective antibody responses in children after related and unrelated allogeneic hematopoietic stem cell transplantation. Blood. 2007 Mar 15;109 (6):2322-6. PMID 17090650.

899. Meloni A, Locci D, Frau G, Masia G, Nurchi AM, Coppola RC. Epidemiology and prevention of rotavirus infection: An underestimated issue? Journal of Maternal-Fetal and Neonatal Medicine. 2011 October;24 (SUPPL. 2):49-52. PMID 2011550735.

900. Melton L. Lifesaving vaccine caught in an ethical minefield. Lancet. 2000 Jul 22;356 (9226):318. PMID 11071196.

901. Memish ZA, Dbaibo G, Montellano M, et al. Immunogenicity of a single dose of tetravalent meningococcal serogroups A, C, W-135, and Y conjugate vaccine administered to 2- to 10-year-olds is noninferior to a licensed-ACWY polysaccharide vaccine with an acceptable safety profile. Pediatric Infectious Disease Journal. 2011 Apr;30 (4):e56-62. PMID 21278617.

902. Mendelman PM, Feeley L, Bird S, et al. Immunogenicity and safety of Haemophilus influenzae type b polysaccharide-Neisseria meningitidis conjugate vaccine in 7.5 micrograms liquid formulation: a comparison of three lots with the 15.0 micrograms lyophilized formulation. Study Group for 7.5 micrograms Liquid PedvaxHIB. Vaccine. 1997 Apr-May;15 (6-7):775-81. PMID 9178481.

903. Menge T, Cree B, Saleh A, et al. Neuromyelitis optica following human papillomavirus vaccination. Neurology. 2012 Jul 17;79 (3):285-7. PMID 22722628.

904. Menzies R, Mahajan D, Gold MS, Roomiani I, McIntyre P, Lawrence G. Annual report: surveillance of adverse events following immunisation in Australia, 2008. Communicable Diseases Intelligence. 2009 Dec;33 (4):365-81. PMID 20301966.

905. Meriste S, Jacquet J-M, Willems P, Lutsar I. Immunologic response to Hib tetanus toxoid conjugated vaccine coadministered with DTPa either mixed or in two separate injections in toddlers not primed with Hib vaccine. Human Vaccines. 2008 Jan-Feb;4 (1):31-5. PMID 18438103.

906. Meriste S, Lutsar I, Tamm E, Willems P. Safety and immunogenicity of a primary course and booster dose of a combined diphtheria, tetanus, acellular pertussis, hepatitis B and inactivated poliovirus vaccine. Scandinavian Journal of Infectious Diseases. 2006;38 (5):350-6. PMID 16709537.

907. Meriste S, Tamm E, Willems P, Lutsar I. Safety and immunogenicity of combined Dtpa-IPV vaccine for primary and booster vaccination. Scandinavian Journal of Infectious Diseases. 1999;31 (6):587-91. PMID 10680990.

908. Mertsola J, Van Der Meeren O, He Q, et al. Decennial administration of a reduced antigen content diphtheria and tetanus toxoids and acellular pertussis vaccine in young adults. Clinical Infectious Diseases. 2010 Sep 15;51 (6):656-62. PMID 20704493.

909. Metanat M, Salehi M, Sharifi-Mood B, Safai MR. Serum antibody responses after intradermal injection of influenza vaccine. International Journal of Virology. 2010 2010;6 (1):41-4. PMID 2012053021.

910. Micheletti F, Moretti U, Tridente G, Zanoni G. Consultancy and surveillance of post-immunisation adverse events in the Veneto region of Italy for 1992-2008. Human Vaccines.

2011 January-February;7 (SUPPL.):234-9. PMID 2012028306.

911. Miernyk KM, Butler JC, Bulkow LR, et al. Immunogenicity and Reactogenicity of Pneumococcal Polysaccharide and Conjugate Vaccines in Alaska Native Adults 55-70 Years of Age. Clinical Infectious Diseases. 2009 Jul;49 (2):241-8. PMID WOS:000267226900013.

912. Miles Braun M, Patriarca PA, Ellenberg SS. Syncope after immunization. Archives of Pediatrics and Adolescent Medicine. 1997 1997;151 (3):255-9. PMID 1997093276 MEDLINE PMID 9080932 (http://www.ncbi.nlm.nih.gov/pubmed/9080932).

913. Miller E. Overview of recent clinical trials of acellular pertussis vaccines. Biologicals. 1999 Jun;27 (2):79-86. PMID 10600188.

914. Miller E, Andrews N, Waight P, et al. Safety and immunogenicity of coadministering a combined meningococcal serogroup C and Haemophilus influenzae type b conjugate vaccine with 7-valent pneumococcal conjugate vaccine and measles, mumps, and rubella vaccine at 12 months of age. Clinical & Vaccine Immunology: CVI. 2011 Mar;18 (3):367-72. PMID 21191076.

915. Miller E, Batten B, Hampton L, Campbell SR, Gao J, Iskander J. Tracking vaccine-safety inquiries to detect signals and monitor public concerns. Pediatrics. 2011 May;127 (SUPPL. 1):S87-S91. PMID 2011239122 MEDLINE PMID 21502241 (http://www.ncbi.nlm.nih.gov/pubmed/21502241).

916. Miller E, Waight P, Laurichesse H, et al. Immunogenicity and reactogenicity of acellular diphtheria/tetanus/pertussis vaccines given as a pre-school booster: effect of simultaneous administration of MMR. Vaccine. 2001 Jul 16;19 (28-29):3904-11. PMID 11427264.

917. Miller FD, Nakagom T, Murphy TV, Gargiull PM, Livengood JR. Intussusception and an oral rotavirus vaccine [1]. New England Journal of Medicine. 2001 14;344 (24):1866-7. PMID 2001213494.

918. Miller MA, Meschievitz CK, Ballanco GA, Daum RS. Safety and immunogenicity of PRP-T combined with DTP: excretion of capsular polysaccharide and antibody response in the immediate post-vaccination period. Pediatrics. 1995 Apr;95 (4):522-7. PMID 7700752.

919. Mills E, Gold R, Thipphawong J, et al. Safety and immunogenicity of a combined five-component pertussis-diphtheria-tetanus-inactivated poliomyelitis-Haemophilus B conjugate vaccine administered to infants at two, four and six months of age. Vaccine. 1998 Apr;16 (6):576-85. PMID 9569468.

920. Milstien JB, Gross TP, Kuritsky JN. Adverse reactions reported following receipt of Haemophilus influenzae type b vaccine: an analysis after 1 year of marketing. Pediatrics. 1987 Aug;80 (2):270-4. PMID 3497381.

921. Minervini G, McCarson BJ, Reisinger KS, et al. Safety and immunogenicity of a modified

process hepatitis B vaccine in healthy neonates. Vaccine. 2012 Feb;30 (8):1476-80. PMID WOS:000301401000009.

922. Miraglia JL, Abdala E, Hoff PM, et al. Immunogenicity and reactogenicity of 2009 influenza A (H1N1) inactivated monovalent non-adjuvanted vaccine in elderly and immunocompromised patients. PLoS ONE [Electronic Resource]. 2011;6 (11):e27214. PMID 22087267.

923. Miriam Pina L, Bassily E, Machmer A, Hou V, Reinhardt A. Safety and immunogenicity of a quadrivalent meningococcal polysaccharide diphtheria-toxoid-conjugate vaccine in infants and toddlers: Three multicenter Phase III studies. Pediatric Infectious Disease Journal. 2012;18.

924. Mizuno Y, Kano S, Urashima M, Genka I, Kanagawa S, Kudo K. Simultaneous vaccination in Japanese travelers. Travel Medicine & Infectious Disease. 2007 Mar;5 (2):85-9. PMID 17298913.

925. Mohammed AJ, AlAwaidy S, Bawikar S, et al. Fractional doses of inactivated poliovirus vaccine in Oman. New England Journal of Medicine. 2010 24;362 (25):2351-9. PMID 2010355698 MEDLINE PMID 20573923 (http://www.ncbi.nlm.nih.gov/pubmed/20573923).

926. Mohty B, Bel M, Vukicevic M, et al. Graft-versus-host disease is the major determinant of humoral responses to the AS03-adjuvanted influenza A/09/H1N1 vaccine in allogeneic hematopoietic stem cell transplant recipients. Haematologica. 2011 June;96 (6):896-904. PMID 2011310637 MEDLINE PMID 21422117 (http://www.ncbi.nlm.nih.gov/pubmed/21422117).

927. Mok CC, Ho LY, Fong LS, To CH. Immunogenicity and safety of a quadrivalent human papillomavirus vaccine in patients with systemic lupus erythematosus: A case-control study. Annals of the Rheumatic Diseases. 2012;15.

928. Mollah AH, Naher N, Rahman S, Chowdhury AM. Antibody titre against 3 doses of hepatitis B vaccine among preterm and term babies. Mymensingh Medical Journal: MMJ. 2012 Jan;21 (1):109-13. PMID 22314464.

929. Moore D, Nelson M, Henderson D. Pneumococcal vaccination and HIV infection. International Journal of Std & Aids. 1998 Jan;9 (1):1-7. PMID 9518008.

930. Moore DL, Le Saux N, Scheifele D, Halperin SA. Lack of evidence of encephalopathy related to pertussis vaccine: Active surveillance by IMPACT, Canada, 1993-2002. Pediatric Infectious Disease Journal. 2004 June;23 (6):568-71. PMID 2004266443 MEDLINE PMID 15194842 (http://www.ncbi.nlm.nih.gov/pubmed/15194842).

931. Moraes JCd, Luna EJdA, Grimaldi RA. Immunogenicity of the Brazilian hepatitis B vaccine in adults. Revista de Saude Publica. 2010 Apr;44 (2):353-9. PMID 20339636.

932. Morales-Olivas FJ, Martinez-Mir I, Ferrer JM, Rubio E, Palop V. Adverse drug reactions in children reported by means of the yellow card in Spain. Journal of Clinical Epidemiology.

2000 October;53 (10):1076-80. PMID 2000355228 MEDLINE PMID 11027942 (http://www.ncbi.nlm.nih.gov/pubmed/11027942).

933. Morelon E, Pouteil Noble C, Daoud S, et al. Immunogenicity and safety of intradermal influenza vaccination in renal transplant patients who were non-responders to conventional influenza vaccination. Vaccine. 2010 Oct 4;28 (42):6885-90. PMID 20709000.

934. Morgan R, King D. Influenza vaccination in the elderly. Postgraduate Medical Journal. 1996 Jun;72 (848):339-42. PMID 8758010.

935. Morley SL, Pollard AJ. Vaccine prevention of meningococcal disease, coming soon? Vaccine. 2001 Dec 12;20 (5-6):666-87. PMID 11738731.

936. Moro PL, Arana J, Cano M, et al. Postlicensure safety surveillance for high-dose trivalent inactivated influenza vaccine in the Vaccine Adverse Event Reporting System, 1 July 2010-31 December 2010. Clinical Infectious Diseases. 2012 Jun;54 (11):1608-14. PMID 22441652.

937. Moro PL, Broder K, Zheteyeva Y, et al. Adverse events following administration to pregnant women of influenza A (H1N1) 2009 monovalent vaccine reported to the Vaccine Adverse Event Reporting System. American Journal of Obstetrics & Gynecology. 2011 Nov;205 (5):473.e1-9. PMID 21861964.

938. Moro PL, Broder K, Zheteyeva Y, et al. Adverse events in pregnant women following administration of trivalent inactivated influenza vaccine and live attenuated influenza vaccine in the Vaccine Adverse Event Reporting System, 1990-2009. American Journal of Obstetrics & Gynecology. 2011 Feb;204 (2):146.e1-7. PMID 20965490.

939. Moro PL, Yue X, Lewis P, Haber P, Broder K. Adverse events after Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine administered to adults 65 years of age and older reported to the Vaccine Adverse Event Reporting System (VAERS), 2005-2010. Vaccine. 2011 21;29 (50):9404-8. PMID 2011622893 MEDLINE PMID 21920404 (http://www.ncbi.nlm.nih.gov/pubmed/21920404).

940. Morris AMS, Elliott EJ, D'Souza RM, Antony J, Kennett M, Longbottom H. Acute flaccid paralysis in Australian children. Journal of Paediatrics & Child Health. 2003 Jan-Feb;39 (1):22-6. PMID 12542807.

941. Moulis G, Pugnet G, Bagheri H, et al. Acquired factor VIII haemophilia following influenza vaccination. European Journal of Clinical Pharmacology. 2010 October;66 (10):1069-70. PMID 2010556771 MEDLINE PMID 20582585 (http://www.ncbi.nlm.nih.gov/pubmed/20582585).

942. Mulholland EK, Ahonkhai VI, Greenwood AM, et al. Safety and immunogenicity of Haemophilus influenzae type B-Neisseria meningitidis group B outer membrane protein complex conjugate vaccine mixed in the syringe with diphtheria-tetanus-pertussis vaccine in young Gambian infants. Pediatric Infectious Disease Journal. 1993 Aug;12 (8):632-7. PMID 8414774.

943. Munch JS, Johnsen BH, Birkeland I, et al. A study of side-effects of Pandemrix[REGISTERED] influenza (H1N1) vaccine on board a Norwegian naval vessel. International Maritime Health. 2010;62 (4):246-50. PMID 21348019.

944. Munoz FM, Englund JA. A step ahead. Infant protection through maternal immunization. Pediatric Clinics of North America. 2000 Apr;47 (2):449-63. PMID 10761514.

945. Munoz FM, Englund JA, Cheesman CC, et al. Maternal immunization with pneumococcal polysaccharide vaccine in the third trimester of gestation. Vaccine. 2001 Dec 12;20 (5-6):826-37. PMID 11738746.

946. Murphy TV, Gargiullo PM, Livengood JR. Intussusception and an oral rotavirus vaccine - Reply. New England Journal of Medicine. 2001 Jun;344 (24):1866-7. PMID WOS:000169231000014.

947. Murphy TV, Gargiullo PM, Wharton M. More on rotavirus vaccination and intussusception. New England Journal of Medicine. 2002 Jan 17;346 (3):211-2. PMID 11796862.

948. Murray DK. Men who have sex with men ... And hepatitis B immunisation. Bmj.(2010) 340 (7751):825. PMID 2010231396.

949. Musher DM, Manof SB, Liss C, et al. Safety and antibody response, including antibody persistence for 5 years, after primary vaccination or revaccination with pneumococcal polysaccharide vaccine in middle-aged and older adults. Journal of Infectious Diseases. 2010 Feb 15;201 (4):516-24. PMID 20092407.

950. Musher DM, Manoff SB, McFetridge RD, et al. Antibody persistence ten years after first and second doses of 23-valent pneumococcal polysaccharide vaccine, and immunogenicity and safety of second and third doses in older adults. Human Vaccines. 2011 Sep;7 (9):919-28. PMID WOS:000295837200014.

951. Nahar K, Jahan M, Nessa A, Tabassum S. Antibody responses after hepatitis B vaccination among maintenance haemodialysis patients. Bangladesh Medical Research Council Bulletin. 2011 2011;37 (3):88-91. PMID 2011681273 MEDLINE PMID 22352227 (http://www.ncbi.nlm.nih.gov/pubmed/22352227).

952. Nailescu C, Xu X, Zhou H, et al. Influenza vaccine after pediatric kidney transplant: a Midwest Pediatric Nephrology Consortium study. Pediatric Nephrology. 2011 Mar;26 (3):459-67. PMID 21181206.

953. Nakada H, Narimatsu H, Tsubokura M, et al. Risk of fatal adverse events after H1N1 influenza vaccination. Clinical Infectious Diseases. 2010 Jun 1;50 (11):1548-9. PMID 20433361.

954. Nakagomi O, Cunliffe NA. Rotavirus vaccines: entering a new stage of deployment.

Current Opinion in Infectious Diseases. 2007 Oct;20 (5):501-7. PMID 17762784.

955. Nakagomi T. Intussusception and an oral rotavirus vaccine. New England Journal of Medicine. 2001 Jun 14;344 (24):1866; author reply -7. PMID 11407353.

956. Nakano T. Japanese vaccinations and practices, with particular attention to polio and pertussis. Travel Medicine & Infectious Disease. 2011 Jul;9 (4):169-75. PMID 21995861.

957. Narayan A, Ganesan S, Shenoy UV, Narayanan E. Provocative poliomyelitis causing postpolio residual paralysis among select communities of two remote villages of North Karnataka in India: a community survey. Indian Journal of Public Health. 2011 Oct-Dec;55 (4):309-12. PMID 22298141.

958. Nascimento Silva JR, Camacho LAB, Siqueira MM, et al. Mutual interference on the immune response to yellow fever vaccine and a combined vaccine against measles, mumps and rubella. Vaccine. 2011 Aug 26;29 (37):6327-34. PMID 21640779.

959. Neuzil KM, Dupont WD, Wright PF, Edwards KM. Efficacy of inactivated and cold-adapted vaccines against influenza A infection, 1985 to 1990: the pediatric experience. Pediatr Infect Dis J. 2001 Aug;20 (8):733-40. PMID 11734733.

960. Nicholson KG, Abrams KR, Batham S, et al. A randomised, partially observer blind, multicentre, head-to-head comparison of a two-dose regimen of Baxter and GlaxoSmithKline H1N1 pandemic vaccines, administered 21 days apart. Health Technology Assessment (Winchester, England). 2010 Dec;14 (55):193-334. PMID 21208550.

961. Nicholson KG, Abrams KR, Batham S, et al. Immunogenicity and safety of a two-dose schedule of whole-virion and AS03A-adjuvanted 2009 influenza A (H1N1) vaccines: a randomised, multicentre, age-stratified, head-to-head trial. The Lancet Infectious Diseases. 2011 Feb;11 (2):91-101. PMID 21168369.

962. Nicol M, Huebner R, Mothupi R, Kayhty H, Mbelle N, Khomo E. Haemophilus influenzae type b conjugate vaccine diluted tenfold in diphtheria-tetanus-whole cell pertussis vaccine: a randomized trial. Pediatric Infectious Disease Journal. 2002 Feb;21 (2):138-41. PMID 11840081.

963. Niederman LG, Marcinak JF. Haemophilus influenzae type b abscess after diphtheria-tetanus toxoids-pertussis immunization. Pediatric Infectious Disease Journal. 1990 1990;9 (8):597-8. PMID 1990266376 MEDLINE PMID 2235180 (http://www.ncbi.nlm.nih.gov/pubmed/2235180).

964. Nilsson L, Faldella G, Jacquet JM, Storsaeter J, Silfverdal SA, Ekholm L. A fourth dose of DTPa-IPV vaccine given to 4-6 year old children in Italy and Sweden following primary vaccination at 3, 5 and 11-12 months of age. Scandinavian Journal of Infectious Diseases. 2005 2005;37 (3):221-9. PMID 2005126138 MEDLINE PMID 15849057 (http://www.ncbi.nlm.nih.gov/pubmed/15849057).

965. Nilsson L, Kjellman NI, Bjorksten B. Allergic disease at the age of 7 years after pertussis vaccination in infancy: results from the follow-up of a randomized controlled trial of 3 vaccines. Arch Pediatr Adolesc Med. 2003 Dec;157 (12):1184-9. PMID 14662571.

966. Nolan T, Hogg G, Darcy MA, Skeljo M, Carlin J. A combined liquid Hib (PRP-OMP), hepatitis B, diphtheria, tetanus and whole-cell pertussis vaccine: uncontrolled preliminary clinical trial of immunogenicity and reactogenicity. Vaccine. 1998 Dec;16 (20):2085-9. PMID 9796068.

967. Nolan T, Hogg G, Darcy MA, Skeljo M, Carlin J, Boslego J. A combined liquid Hib (PRP-OMPC), hepatitis B, diphtheria, tetanus and whole-cell pertussis vaccine: Controlled studies of immunogenicity and reactogenicity. Vaccine. 2001 28;19 (15 16):2127-37. PMID 2001081956 MEDLINE PMID 11228385 (http://www.ncbi.nlm.nih.gov/pubmed/11228385).

968. Nolan T, Hogg G, Darcy MA, Varigos J, McEwen J. Primary course immunogenicity and reactogenicity of a new diphtheria-tetanus whole cell pertussis vaccine (DTPw). Journal of Paediatrics and Child Health. 1997 Oct;33 (5):413-7. PMID WOS:A1997YE21800011.

969. Nolan T, Lambert S, Roberton D, Marshall H, Richmond P, Streeton C. DTPa-HBV-IPV vaccine for primary vaccination of infants. Journal of Paediatrics & Child Health. 2007 Sep;43 (9):587-92. PMID 17688642.

970. Nolan T, Lambert S, Roberton D, et al. A novel combined Haemophilus influenzae type b-Neisseria meningitidis serogroups C and Y-tetanus-toxoid conjugate vaccine is immunogenic and induces immune memory when co-administered with DTPa-HBV-IPV and conjugate pneumococcal vaccines in infants. Vaccine. 2007 Dec 12;25 (51):8487-99. PMID 17996996.

971. Nolan T, McVernon J, Skeljo M, et al. Immunogenicity of a monovalent 2009 influenza A(H1N1) vaccine in infants and children: a randomized trial. JAMA. 2010 Jan 6;303 (1):37-46. PMID 20026597.

972. Nolan T, Richmond P, Marshall H, et al. Immunogenicity and safety of an investigational combined haemophilus influenzae type B-Neisseria meningitidis serogroups C and Y-tetanus toxoid conjugate vaccine. Pediatric Infectious Disease Journal. 2011 Mar;30 (3):190-6. PMID 20948453.

973. Nolan T, Richmond PC, McVernon J, et al. Safety and immunogenicity of an inactivated thimerosal-free influenza vaccine in infants and children. Influenza Other Respi Viruses. 2009 Nov;3 (6):315-25. PMID 19903213.

974. Novadzki IM, Rosario Filho N. Anaphylaxis associated with the vaccine against measles, mumps and rubella. Revista de Saude Publica. 2010 Apr;44 (2):372-6. PMID 20339639.

975. Novadzki IM, Rosario N, Zanoni G, Chiesa E, Puccetti A, Simone R. Hypersensitivity reactions following measles-mumps-rubella vaccine and dextran-specific IgG response. Allergologia et Immunopathologia. 2010 November;38 (6):341-3. PMID 2010629506

MEDLINE PMID 20605313 (http://www.ncbi.nlm.nih.gov/pubmed/20605313).

976. Nurkka A, Joensuu J, Henckaerts I, et al. Immunogenicity and safety of the eleven valent pneumococcal polysaccharide-protein D conjugate vaccine in infants. Pediatric Infectious Disease Journal. 2004 Nov;23 (11):1008-14. PMID 15545855.

977. Obaro SK, Adegbola RA, Chang I, et al. Safety and immunogenicity of a nonavalent pneumococcal vaccine conjugated to CRM197 administered simultaneously but in a separate syringe with diphtheria, tetanus and pertussis vaccines in Gambian infants. Pediatric Infectious Disease Journal. 2000 May;19 (5):463-9. PMID 10819345.

978. Obert J, Burgel PR. Pneumococcal infections: association with asthma and COPD. Medecine et Maladies Infectieuses. 2012 May;42 (5):188-92. PMID 22444165.

979. O'Brien KL, Moulton LH, Reid R, et al. Efficacy and safety of seven-valent conjugate pneumococcal vaccine in American Indian children: group randomised trial. Lancet. 2003 Aug 2;362 (9381):355-61. PMID 12907008.

980. O'Brien KL, Swift AJ, Winkelstein JA, et al. Safety and immunogenicity of heptavalent pneumococcal vaccine conjugated to CRM(197) among infants with sickle cell disease. Pneumococcal Conjugate Vaccine Study Group. Pediatrics. 2000 Nov;106 (5):965-72. PMID 11061761.

981. Occhionero M, Usai G, Di Martino M, Le Moli S, Stroffolini T, Mastrantonio P. Serum antibodies to capsular polysaccharide vaccine of group A and C Neisseria meningitidis in military recruits in Italy. Allergologia et Immunopathologia. 1991 Jan-Feb;19 (1):39-41. PMID 1950941.

982. Offit PA. The future of rotavirus vaccines. Seminars in Pediatric Infectious Diseases. 2002 Jul;13 (3):190-5. PMID 12199615.

983. Offit PA. Rotavirus vaccines: round two. Human Vaccines. 2006 Mar-Apr;2 (2):84-5. PMID 17012884.

984. Offit PA. Thimerosal and vaccines - A cautionary tale. New England Journal of Medicine. 2007 27;357 (13):1278-9. PMID 2007472994 MEDLINE PMID 17898096 (http://www.ncbi.nlm.nih.gov/pubmed/17898096).

985. Offit PA, Clark HF. RotaTeq: a pentavalent bovine--human reassortant rotavirus vaccine. Pediatric Annals. 2006 Jan;35 (1):29-34. PMID 16466073.

986. Ogimi C, Tanaka R, Saitoh A, Oh-Ishi T. Immunogenicity of influenza vaccine in children with pediatric rheumatic diseases receiving immunosuppressive agents. Pediatric Infectious Disease Journal. 2011 Mar;30 (3):208-11. PMID 20861757.

987. Oh C-E, Lee J, Kang J-H, et al. Safety and immunogenicity of an inactivated split-virus

influenza A/H1N1 vaccine in healthy children from 6 months to <18 years of age: a prospective, open-label, multi-center trial. Vaccine. 2010 Aug 16;28 (36):5857-63. PMID 20600483.

988. Okada K, Komiya T, Yamamoto A, et al. Safe and effective booster immunization using DTaP in teenagers. Vaccine. 2010 Nov 10;28 (48):7626-33. PMID 20883738.

989. Okais C, Gay C, Seon F, Buchaille L, Chary E, Soubeyrand B. Disease-specific adverse events following nonlive vaccines: a paradoxical placebo effect or a nocebo phenomenon? Vaccine. 2011 Aug 26;29 (37):6321-6. PMID 21627976.

990. Okike IO, Yung C, Ladhani S, et al. The immunogenicity of a novel A (H1N1) vaccine in HIV-infected children. Vaccine. 2011 Sep 2;29 (38):6636-40. PMID 21742005.

991. Okuda B, Uetani E, Okamoto K. Vaccine-associated paralytic poliomyelitis caused by contact infection. Internal Medicine. 2006;45 (6):373-5. PMID 16617188.

992. Olin P, Rasmussen F, Gottfarb P. Schedules and protection, simultaneous vaccination and safety: Experiences from recent controlled trials. International Journal of Infectious Diseases. 1997 Jan;1 (3):143-7. PMID 1997112644.

993. Olivier C, Belohradsky BH, Stojanov S, Bonnet E, Petersen G, Liese JG. Immunogenicity, reactogenicity, and safety of a seven-valent pneumococcal conjugate vaccine (PCV7) concurrently administered with a fully liquid DTPa-IPV-HBV-Hib combination vaccine in healthy infants. Vaccine. 2008 Jun 13;26 (25):3142-52. PMID 18502545.

994. Omenaca F, Aristegui J, Tejedor JC, et al. Combined Haemophilus Influenzae type B-Neisseria meningitidis serogroup C vaccine is immunogenic and well tolerated in preterm infants when coadministered with other routinely recommended vaccines. Pediatric Infectious Disease Journal. 2011 Nov;30 (11):e216-24. PMID 21747321.

995. Omenaca F, Dal-Re R, D'Apuzzo V, et al. Reactogenicity of DTPa-HBV/Hib vaccine administered as a single injection vs DTPa-HBV and Hib vaccines administered simultaneously at separate sites, to infants at 2, 4 and 6 months of age. Vaccine. 2001 Jul 20;19 (30):4260-6. PMID 11457553.

996. Omenaca F, Garcia-Sicilia J, Boceta R, Garcia-Corbeira P. Hepatitis B response of premature infants after primary and booster immunisation with a diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus/haemophilus influenzae type B vaccine. Infectious Diseases in Obstetrics & Gynecology. 2010;2010:802503. PMID 20396673.

997. Omenaca F, Merino JM, Tejedor J-C, et al. Immunization of preterm infants with 10-valent pneumococcal conjugate vaccine. Pediatrics. 2011 Aug;128 (2):e290-8. PMID 21727108.

998. Omon E, Damase-Michel C, Hurault-Delarue C, et al. Non-adjuvanted 2009 influenza A (H1N1)v vaccine in pregnant women: the results of a French prospective descriptive study.

Vaccine. 2011 Dec 6;29 (52):9649-54. PMID 22036887.

999. Ortalda V, Tomei P, Yabarek T, et al. Immunogenicity and seroconversion after hepatitis B vaccination in haemodialysis patients: Results of two different vaccination schedules. Nephrology Dialysis Transplantation. 2012 May;27 SUPPL. 2:ii513-ii4.

1000. Ortiz Arjona MA, Abd Elaziz KM, Caballero Lanzas JM, Allam MF. Coverage and side effects of influenza A(H1N1) 2009 monovalent vaccine among primary health care workers. Vaccine. 2011 Aug 26;29 (37):6366-8. PMID 21840463.

1001. O'Ryan M. Reply. Gastroenterology. 2006 Oct;131 (4):1354-5. PMID 2006486492.

1002. O'Ryan M. Reply. Journal of Pediatrics. 2007 May;150 (5):e87. PMID 2007188626.

1003. O'Ryan M, Lucero Y, Linhares AC. Rotarix[REGISTERED]: vaccine performance 6 years postlicensure. Expert Review of Vaccines. 2011 Dec;10 (12):1645-59. PMID 22085167.

1004. O'Ryan ML, Matson DO. A quadrivalent rotavirus vaccine. New England Journal of Medicine. 1998 Feb;338 (9):620-1. PMID WOS:000072175700015.

1005. Ostergaard L, Silfverdal S-A, Berglund J, et al. A tetravalent meningococcal serogroups A, C, W-135, and Y tetanus toxoid conjugate vaccine is immunogenic and well-tolerated when co-administered with Twinrix([REGISTERED]) in subjects aged 11-17 years: an open, randomised, controlled trial. Vaccine. 2012 Jan 17;30 (4):774-83. PMID 22107850.

1006. Ota MO, Akinsola A, Townend J, et al. The immunogenicity and impact on nasopharyngeal carriage of fewer doses of conjugate pneumococcal vaccine immunization schedule. Vaccine. 2011 05;29 (16):2999-3007. PMID 2011178040 MEDLINE PMID 21320549 (http://www.ncbi.nlm.nih.gov/pubmed/21320549).

1007. Ottaviani G, Lavezzi AM, Matturri L. Sudden infant death syndrome (SIDS) shortly after hexavalent vaccination: another pathology in suspected SIDS? Virchows Archiv. 2006 Jan;448 (1):100-4. PMID 16231176.

1008. Overton ET, Kang M, Peters MG, et al. Immune response to hepatitis B vaccine in HIV-infected subjects using granulocyte-macrophage colony-stimulating factor (GM-CSF) as a vaccine adjuvant: ACTG study 5220. Vaccine. 2010 Aug;28 (34):5597-604. PMID WOS:000280952300011.

1009. Ozdemir O, Yazgan H, Demirdoven M, Keles E. Rotavirus infection rate after two types of rotavirus vaccination observed in a private research/training hospital in anatolian part of Istanbul, Turkey. Journal of Allergy and Clinical Immunology. 2010 February;125 (2 SUPPL. 1):AB78.

1010. Pace D, Snape M, Westcar S, et al. A new combination haemophilus influenzae type B and Neisseria meningitidis serogroup C-tetanus toxoid conjugate vaccine for primary

immunization of infants. Pediatric Infectious Disease Journal. 2007 Nov;26 (11):1057-9. PMID 17984816.

1011. Pace D, Snape M, Westcar S, et al. A novel combined Hib-MenC-TT glycoconjugate vaccine as a booster dose for toddlers: A phase 3 open randomised controlled trial. Archives of Disease in Childhood. 2008 November;93 (11):963-70. PMID 2008518496 MEDLINE PMID 18463125 (http://www.ncbi.nlm.nih.gov/pubmed/18463125).

1012. Palache AM, Scheepers HS, de Regt V, et al. Safety, reactogenicity and immunogenicity of Madin Darby Canine Kidney cell-derived inactivated influenza subunit vaccine. A meta-analysis of clinical studies. Dev Biol Stand. 1999;98:115-25; discussion 33-4. PMID 10494964.

1013. Palma P, Romiti ML, Bernardi S, et al. Safety and immunogenicity of a monovalent MF59[REGISTERED]-adjuvanted A/H1N1 vaccine in HIV-infected children and young adults. Biologicals. 2012 Mar;40 (2):134-9. PMID 22261282.

1014. Palumbo A, Davies F, Kropff M, et al. Consensus guidelines for the optimal management of adverse events in newly diagnosed, transplant-ineligible patients receiving melphalan and prednisone in combination with thalidomide (MPT) for the treatment of multiple myeloma. Annals of Hematology. 2010 August;89 (8):803-11. PMID 2010519458 MEDLINE PMID 20232066 (http://www.ncbi.nlm.nih.gov/pubmed/20232066).

1015. Paradiso PR. Advances in pneumococcal disease prevention: 13-valent pneumococcal conjugate vaccine for infants and children. Clinical Infectious Diseases. 2011 May;52 (10):1241-7. PMID 21507921.

1016. Park SJ, Shin JI. Henoch-Schonlein purpura after hepatitis a vaccination: The role of interleukin 10? Annals of Allergy, Asthma and Immunology. 2011 December;107 (6):550. PMID 2011673242 MEDLINE PMID 22123392 (http://www.ncbi.nlm.nih.gov/pubmed/22123392).

1017. Park S-W, Lee J-H, Kim ES, et al. Adverse events associated with the 2009 H1N1 influenza vaccination and the vaccination coverage rate in health care workers. American Journal of Infection Control. 2011 Feb;39 (1):69-71. PMID 21122948.

1018. Parke JC, Jr., Schneerson R, Reimer C, et al. Clinical and immunologic responses to Haemophilus influenzae type b-tetanus toxoid conjugate vaccine in infants injected at 3, 5, 7, and 18 months of age. Journal of Pediatrics. 1991 Feb;118 (2):184-90. PMID 1993943.

1019. Parretta E, Ianniello B, Ferrazin F, Rossi F, Capuano A. Italian post-marketing surveillance for adverse event reports after MF59-adjuvanted H1N1v vaccination. Vaccine. 2011 May 9;29 (20):3708-13. PMID 21406267.

1020. Partinen M, Saarenpaa-Heikkila O, Ilveskoski I, et al. Increased incidence and clinical picture of childhood narcolepsy following the 2009 H1N1 pandemic vaccination campaign in Finland. PLoS ONE [Electronic Resource]. 2012;7 (3) PMID 2012183679.

1021. Partridge S, Alvey J, Bernstein H, et al. Safety of a combination diphtheria, tetanus toxoid, acellular pertussis, hepatitis B, and inactivated polio vaccine coadministered with a 7-valent pneumococcal conjugate vaccine and a Haemophilus influenzae type b conjugate vaccine. Vaccine. 2007 Feb 26;25 (10):1806-13. PMID 17240493.

1022. Partridge S, Yeh SH. Clinical evaluation of a DTaP-HepB-IPV combined vaccine. American Journal of Managed Care. 2003 Jan;9 (1 Suppl):S13-22. PMID 12564785.

1023. Parvaneh N, Shahmahmoudi S, Tabatabai H, et al. Vaccine-associated paralytic poliomyelitis in a patient with MHC class II deficiency. Journal of Clinical Virology. 2007 Jun;39 (2):145-8. PMID 17509935.

1024. Patel MK, Patel TK, Tripathi CB. Diphtheria, pertussis (whooping cough), and tetanus vaccine induced recurrent seizures and acute encephalopathy in a pediatric patient: Possibly due to pertussis fraction. Journal of Pharmacology & Pharmacotherapeutics. 2012 Jan;3 (1):71-3. PMID 22368426.

1025. Patel MM. Intussusception Risk of Rotavirus Vaccination REPLY. New England Journal of Medicine. 2011 Dec;365 (22):2138-. PMID WOS:000297499000019.

1026. Patel MM, Clark AD, Glass RI, et al. Broadening the age restriction for initiating rotavirus vaccination in regions with high rotavirus mortality: benefits of mortality reduction versus risk of fatal intussusception. Vaccine. 2009 May 14;27 (22):2916-22. PMID 19428901.

1027. Patel NC, Hertel PM, Estes MK, et al. Vaccine-acquired rotavirus in infants with severe combined immunodeficiency. New England Journal of Medicine. 2010 Jan 28;362 (4):314-9. PMID 20107217.

1028. Patel NC, Palmer WC, Krishna M, Lewis MD, Wallace MB. Lack of an association between autoimmune pancreatitis and Varicella Zoster Virus. Jop: Journal of the Pancreas [Electronic Resource]. 2011 Nov;12 (6):614-5. PMID 22072254.

1029. Patel SR, Ortin M. Varicella-zoster reactivation in a patient receiving routine revaccinations after an allogeneic hemopoietic progenitors transplant. Journal of Pediatric Hematology/Oncology. 2005 February;27 (2):106-8. PMID 2005089603 MEDLINE PMID 15701988 (http://www.ncbi.nlm.nih.gov/pubmed/15701988).

1030. Patja A, Davidkin I, Kurki T, Kallio MJ, Valle M, Peltola H. Serious adverse events after measles-mumps-rubella vaccination during a fourteen-year prospective follow-up. Pediatr Infect Dis J. 2000 Dec;19 (12):1127-34. PMID 11144371.

1031. Payne DC, Edwards KM, Bowen MD, et al. Sibling transmission of vaccine-derived rotavirus (RotaTeq) associated with rotavirus gastroenteritis. Pediatrics. 2010 February;125 (2):e438-e41. PMID 2010090890 MEDLINE PMID 20100758 (http://www.ncbi.nlm.nih.gov/pubmed/20100758).

1032. Pedersen C, Breindahl M, Aggarwal N, et al. Randomized trial: Immunogenicity and safety of coadministered human papillomavirus-16/18 AS04-adjuvanted vaccine and combined hepatitis A and B vaccine in girls. Journal of Adolescent Health. 2012 January;50 (1):38-46. PMID 2011700983 MEDLINE PMID 22188832 (http://www.ncbi.nlm.nih.gov/pubmed/22188832).

1033. Pedersen C, Breindahl M, Aggarwal N, et al. Randomized trial: immunogenicity and safety of coadministered human papillomavirus-16/18 AS04-adjuvanted vaccine and combined hepatitis A and B vaccine in girls. Journal of Adolescent Health. 2012 Jan;50 (1):38-46. PMID 22188832.

1034. Pedersen C, Petaja T, Strauss G, et al. Immunization of early adolescent females with human papillomavirus type 16 and 18 L1 virus-like particle vaccine containing AS04 adjuvant. J Adolesc Health. 2007 Jun;40 (6):564-71. PMID 17531764.

1035. Peltola H, Kayhty H, Kuronen T, Haque N, Sarna S, Makela PH. Meningococcus group A vaccine in children three months to five years of age. Adverse reactions and immunogenicity related to endotoxin content and molecular weight of the polysaccharide. Journal of Pediatrics. 1978 May;92 (5):818-22. PMID 417160.

1036. Peltola H, Makela PH, Elo O, Pettay O, Renkonen OV, Sivonen A. Vaccination against meningococcal group A disease in Finland 1974-75. Scandinavian Journal of Infectious Diseases. 1976;8 (3):169-74. PMID 788143.

1037. Peng LA, Liu J, Gao ZL, Zhao ZX, Lin CS. Inoculation effects of recombinant yeast hepatitis B vaccine used in neonates. Scientific Research and Essays. 2011 Feb;6 (3):658-62. PMID WOS:000287940700020.

1038. Perez Schael I, O'Ryan M, Saez-Llorens X, et al. Clinical development, registration, and introduction of human rotavirus vaccine: The Latin American experience. Trials in Vaccinology. 2012 2012;1:10-20.

1039. Perrett KP, Snape MD, Ford KJ, et al. Immunogenicity and Immune Memory of a Nonadjuvanted Quadrivalent Meningococcal Glycoconjugate Vaccine in Infants. Pediatric Infectious Disease Journal. 2009 Mar;28 (3):186-93. PMID WOS:000264007500005.

1040. Perucchini E, Consonni S, Sandrini MC, Bergamaschini L, Vergani C. Adverse reactions to influenza vaccine alone or with pneumococcal vaccine in the elderly. Journal of the American Geriatrics Society. 2004 Jul;52 (7):1219-20. PMID 15209671.

1041. Petousis-Harris H, Poole T, Turner N, Reynolds G. Febrile events including convulsions following the administration of four brands of 2010 and 2011 inactivated seasonal influenza vaccine in NZ infants and children: The importance of routine active safety surveillance. Vaccine. 2012 Jul 13;30 (33):4945-52. PMID 22664224.

1042. Petridou E, Kouri N, Vadala H, Dalamaga M, Sege R. Frequency and nature of recorded childhood immunization-related errors in Greece. Journal of Toxicology - Clinical Toxicology. 2004 2004;42 (3):273-6. PMID 2004377531 MEDLINE PMID 15362594 (http://www.ncbi.nlm.nih.gov/pubmed/15362594).

1043. Phongsamart W, Sirisanthana V, Wittawatmongkol O, et al. Immunogenicity and safety of monovalent influenza A (H1N1) 2009 in HIV-infected Thai children. Vaccine. 2011 Nov 3;29 (47):8705-11. PMID 21893147.

1044. Phua KB, Emmanuel SC, Goh P, et al. A rotavirus vaccine for infants: The Asian experience. Annals of the Academy of Medicine Singapore. 2006 January;35 (1):38-44. PMID 2006178228 MEDLINE PMID 16470273 (http://www.ncbi.nlm.nih.gov/pubmed/16470273).

1045. Phua KB, Quak SH, Lim FS, et al. Immunogenicity, reactogenicity and safety of a diphtheria-tetanus-acellular pertussis-inactivated polio and Haemophilus influenzae type b vaccine in a placebo-controlled rotavirus vaccine study. Annals of the Academy of Medicine, Singapore. 2008 Jul;37 (7):546-53. PMID 18695765.

1046. Pichichero M, Papa T, Blatter M, et al. Immune memory in children previously vaccinated with an experimental quadrivalent meningococcal polysaccharide diphtheria toxoid conjugate vaccine. Pediatric Infectious Disease Journal. 2006 Nov;25 (11):995-1000. PMID 17072120.

1047. Pichichero ME. Meningococcal conjugate vaccines. Expert Opinion on Biological Therapy. 2005 November;5 (11):1475-89. PMID 2005503770 MEDLINE PMID 16255651 (http://www.ncbi.nlm.nih.gov/pubmed/16255651).

1048. Pichichero ME, Bernstein H, Blatter MM, et al. Immunogenicity and safety of a combination diphtheria, tetanus toxoid, acellular pertussis, hepatitis B, and inactivated poliovirus vaccine coadministered with a 7-valent pneumococcal conjugate vaccine and a Haemophilus influenzae type b conjugate vaccine. Journal of Pediatrics. 2007 Jul;151 (1):43-9, 9.e1-2. PMID 17586189.

1049. Pichichero ME, Blatter MM, Reisinger KS, et al. Impact of a birth dose of hepatitis B vaccine on the reactogenicity and immunogenicity of diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus-Haemophilus influenzae type b combination vaccination. Pediatric Infectious Disease Journal. 2002 Sep;21 (9):854-9. PMID 12352809.

1050. Pichichero ME, Green JL, Francis AB, Marsocci SM, Murphy AML, Buscarino C. Antibody response and reactions to completion of a four-dose series with a two- or three-component acellular pertussis vaccine compared to whole cell pertussis vaccine. Scandinavian Journal of Infectious Diseases. 1996 1996;28 (2):159-63. PMID 1996175519 MEDLINE PMID 8792483 (http://www.ncbi.nlm.nih.gov/pubmed/8792483).

1051. Pichichero ME, Latiolais T, Bernstein DI, et al. Vaccine antigen interactions after a combination diphtheria-tetanus toxoid-acellular pertussis/purified capsular polysaccharide of Haemophilus influenzae type b-tetanus toxoid vaccine in two-, four- and six-month-old infants.

Pediatric Infectious Disease Journal. 1997 Sep;16 (9):863-70. PMID 9306481.

1052. Pier GB. Safety and immunogenicity of high molecular weight polysaccharide vaccine from immunotype 1 Pseudomonas aeruginosa. Journal of Clinical Investigation. 1982 Feb;69 (2):303-8. PMID 6799548.

1053. Pietrzyk JJ, Wysocki J, Pejcz J, et al. Safety and immunogenicity of a DTaP-IPV(Vero) (serum-free) combination vaccine in comparison to DTaP-IPV(Mkc) when administered simultaneously with Haemophilus influenzae type B conjugate vaccine (PRP-T) in children at 2, 3.5, 5 and 16 months of age. Vaccine. 2008 Sep 26;26 (41):5296-303. PMID 18675870.

1054. Pileggi GS, de Souza CBS, Ferriani VPL. Safety and Immunogenicity of Varicella Vaccine in Patients With Juvenile Rheumatic Diseases Receiving Methotrexate and Corticosteroids. Arthritis Care & Research. 2010 Jul;62 (7):1034-9. PMID WOS:000280980000020.

1055. Pirofski LA, Casadevall A. Use of licensed vaccines for active immunization of the immunocompromised host. Clinical Microbiology Reviews. 1998 January;11 (1):1-26. PMID 1998031623 MEDLINE PMID 9457426 (http://www.ncbi.nlm.nih.gov/pubmed/9457426).

1056. Plennevaux E, Blatter M, Cornish MJ, et al. Influenza A (H1N1) 2009 two-dose immunization of US children: an observer-blinded, randomized, placebo-controlled trial. Vaccine. 2011 Feb 11;29 (8):1569-75. PMID 21219979.

1057. Plennevaux E, Sheldon E, Blatter M, Reeves-Hoche M-K, Denis M. Immune response after a single vaccination against 2009 influenza A H1N1 in USA: a preliminary report of two randomised controlled phase 2 trials. Lancet. 2010 Jan 2;375 (9708):41-8. PMID 20018365.

1058. Pliaka V, Kyriakopoulou Z, Markoulatos P. Risks associated with the use of live-attenuated vaccine poliovirus strains and the strategies for control and eradication of paralytic poliomyelitis. Expert Review of Vaccines. 2012 May;11 (5):609-28. PMID 22827246.

1059. Plichta AM. Immunization: protecting older patients from infectious disease. Geriatrics. 1996 Sep;51 (9):47-52; quiz 3. PMID 8814114.

1060. Plosker GL. Pentavalent rotavirus vaccine (RotaTeq): a review of its use in the prevention of rotavirus gastroenteritis in Europe. Drugs. 2010 Jun 18;70 (9):1165-88. PMID 20518582.

1061. Ponka A, Leinonen M. Adverse reactions to polyvalent pneumococcal vaccine. Scandinavian Journal of Infectious Diseases. 1982;14 (1):67-71. PMID 7071529.

1062. Popejoy LA, Rivera AI, Gonzales-Torres I. Side-effects and immunogenicity of Haemophilus influenzae type B polysaccharide vaccine in a multi-ethnic pediatric population. Military Medicine. 1989 1989;154 (1):25-9. PMID 1989039243 MEDLINE PMID 2493601 (http://www.ncbi.nlm.nih.gov/pubmed/2493601).

1063. Potter RC, Gonik B. Prevention of influenza in mothers and infants. Expert Review of Vaccines. 2009 February;8 (2):149-52. PMID 2009075879.

1064. Poullin P, Gabriel B. Thrombocytopenic purpura after recombinant hepatitis B vaccine. Lancet. 1994 Nov 5;344 (8932):1293. PMID 7967998.

1065. Precioso AR, Miraglia JL, Campos LMA, et al. A phase I randomized, double-blind, controlled trial of 2009 influenza A (H1N1) inactivated monovalent vaccines with different adjuvant systems. Vaccine. 2011 Nov 8;29 (48):8974-81. PMID 21945258.

1066. Prosser LA, Lavelle TA, Fiore AE, et al. Cost-effectiveness of 2009 Pandemic influenza A(H1N1) vaccination in the United States. PLoS ONE [Electronic Resource]. 2011;6 (7) PMID 2011417631.

1067. Prymula R, Chlibek R, Splino M, et al. Safety of the 11-valent pneumococcal vaccine conjugated to non-typeable Haemophilus influenzae-derived protein D in the first 2 years of life and immunogenicity of the co-administered hexavalent diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated polio virus, Haemophilus influenzae type b and control hepatitis A vaccines. Vaccine. 2008 Aug 18;26 (35):4563-70. PMID 18602724.

1068. Prymula R, Peeters P, Chrobok V, et al. Pneumococcal capsular polysaccharides conjugated to protein D for prevention of acute otitis media caused by both Streptococcus pneumoniae and non-typable Haemophilus influenzae: A randomised double-blind efficacy study. Lancet. 2006 4;367 (9512):740-8. PMID 2006106626 MEDLINE PMID 16517274 (http://www.ncbi.nlm.nih.gov/pubmed/16517274).

1069. Prymula R, Plisek S. Clinical experience with DTPw-HBV and DTPw-HBV/Hib combination vaccines. Expert Opinion on Biological Therapy. 2008 April;8 (4):503-13. PMID 2008195122 MEDLINE PMID 18352853 (http://www.ncbi.nlm.nih.gov/pubmed/18352853).

1070. Prymula R, Schuerman L. 10-valent pneumococcal nontypeable Haemophilus influenzae PD conjugate vaccine: Synflorix. Expert Review of Vaccines. 2009 Nov;8 (11):1479-500. PMID 19863240.

1071. Prymula R, Siegrist C-A, Chlibek R, et al. Effect of prophylactic paracetamol administration at time of vaccination on febrile reactions and antibody responses in children: two open-label, randomised controlled trials. Lancet. 2009 Oct 17;374 (9698):1339-50. PMID 19837254.

1072. Punjabi NH, Richie EL, Simanjuntak CH, et al. Immunogenicity and safety of four different doses of Haemophilus influenzae type b-tetanus toxoid conjugated vaccine, combined with diphtheria-tetanus-pertussis vaccine (DTP-Hib), in Indonesian infants. Vaccine. 2006 Mar 10;24 (11):1776-85. PMID 16303216.

1073. Quiambao B, Van der Meeren O, Kolhe D, Gatchalian S. A randomized, dose-ranging assessment of the immunogenicity and safety of a booster dose of a combined diphtheria-tetanus-

whole cell pertussis-hepatitis B-inactivated poliovirus-Hemophilus influenzae type b (DTPw-HBV-IPV/Hib) vaccine vs. co-administration of DTPw-HBV/Hib and IPV vaccines in 12 to 24 months old Filipino toddlers. Human Vaccines & Immunotherapeutics. 2012 Mar;8 (3) PMID WOS:000303057200018.

1074. Radzikowski A, Banaszkiewicz A, Lazowska-Przeorek I, et al. Immunogenecity of Hepatitis A Vaccine in Pediatric Patients with Inflammatory Bowel Disease. Inflammatory Bowel Diseases. 2011 May;17 (5):1117-24. PMID WOS:000289367100008.

1075. Rahier JF, Papay P, Salleron J, et al. H1N1 vaccines in a large observational cohort of patients with inflammatory bowel disease treated with immunomodulators and biological therapy. Gut. 2011 Apr;60 (4):456-62. PMID WOS:000288010600010.

1076. Rajantie J, Zeller B, Treutiger I, Rosthoj S, group NIw, five national study g. Vaccination associated thrombocytopenic purpura in children. Vaccine. 2007 Feb 26;25 (10):1838-40. PMID 17126957.

1077. Ramkissoon A, Coovadia HM, Jugnundan P, Willems P, Clemens BR. A new combined DTP-HBV-HIB vaccine - Strategy for incorporation of Hib vaccination into childhood immunisation programmes. South African Medical Journal. 2001 2001;91 (10 I):864-9. PMID 2001404160 MEDLINE PMID 11732460 (http://www.ncbi.nlm.nih.gov/pubmed/11732460).

1078. Rasigade J-P, Sicot N, Laurent F, Lina G, Vandenesch F, Etienne J. A history of Panton-Valentine leukocidin (PVL)-associated infection protects against death in PVL-associated pneumonia. Vaccine. 2011 Jun 6;29 (25):4185-6. PMID 21527300.

1079. Ravanfar P, Satyaprakash A, Creed R, Mendoza N. Existing antiviral vaccines. Dermatologic Therapy. 2009 March-April;22 (2):110-28. PMID 2009153643 MEDLINE PMID 19335723 (http://www.ncbi.nlm.nih.gov/pubmed/19335723).

1080. Rayani A, Bode U, Habas E, et al. Rotavirus infections in paediatric oncology patients: A matched-pairs analysis. Scandinavian Journal of Gastroenterology. 2007 Jan;42 (1):81-7. PMID WOS:000243724800014.

1081. Reinert P, Benkerrou M, de Montalembert M, et al. Immunogenicity and safety of a pneumococcal conjugate 7-valent vaccine in infants with sickle cell disease. Pediatric Infectious Disease Journal. 2007 Dec;26 (12):1105-9. PMID 18043446.

1082. Reinert P, Cinquetti S, Soubeyrand B, et al. Challenge with hepatitis B vaccine in children previously vaccinated with a hepatitis B-containing combination vaccine. Advances in Therapy. 2010 January;27 (1):28-38. PMID 2010215729 MEDLINE PMID 20182924 (http://www.ncbi.nlm.nih.gov/pubmed/20182924).

1083. Reinert P, Fiquet A, Thomas S, Schuyleman A, Watson M, Group HS. Fever as a marker of reactogenicity of an acellular pertussis-containing hexavalent vaccine (HEXAVAC) in a large-scale, open, randomized safety study in healthy French infants. Human Vaccines. 2006

Sep-Oct;2 (5):215-21. PMID 17035735.

1084. Reisinger KS, Baxter R, Block SL, Shah J, Bedell L, Dull PM. Quadrivalent meningococcal vaccination of adults: phase III comparison of an investigational conjugate vaccine, MenACWY-CRM, with the licensed vaccine, Menactra. Clin Vaccine Immunol. 2009 Dec;16 (12):1810-5. PMID 19812260.

1085. Reisinger KS, Block SL. Characteristics of an ideal rotavirus vaccine. Clinical Pediatrics. 2008 Jul;47 (6):555-63. PMID 18467670.

1086. Rennels M, King J, Jr., Ryall R, et al. Dose escalation, safety and immunogenicity study of a tetravalent meninogococcal polysaccharide diphtheria conjugate vaccine in toddlers. Pediatric Infectious Disease Journal. 2002 Oct;21 (10):978-9. PMID 12400528.

1087. Rennels M, King J, Jr., Ryall R, Papa T, Froeschle J. Dosage escalation, safety and immunogenicity study of four dosages of a tetravalent meninogococcal polysaccharide diphtheria toxoid conjugate vaccine in infants. Pediatric Infectious Disease Journal. 2004 May;23 (5):429-35. PMID 15131466.

1088. Rennels MB. Pediatric gastrointestinal infections. Current Opinion in Infectious Diseases. 1991 1991;4 (1):63-6. PMID 1991117279.

1089. Rennels MB, Edwards KM, Keyserling HL, et al. Safety and immunogenicity of four doses of Neisseria meningitidis group C vaccine conjugated to CRM197 in United States infants. Pediatric Infectious Disease Journal. 2001 Feb;20 (2):153-9. PMID 11224833.

1090. Rennels MB, Hohenboken MJ, Reisinger KS, et al. Comparison of acellular pertussis-diphtheria-tetanus toxoids and Haemophilus influenzae type b vaccines administered separately vs. combined in younger vs. older toddlers. Pediatric Infectious Disease Journal. 1998 February;17 (2):164-6. PMID 1998067161 MEDLINE PMID 9493818 (http://www.ncbi.nlm.nih.gov/pubmed/9493818).

1091. Rennels MB, Parashar UD, Holman RC, Le CT, Chang HG, Glass RI. Lack of an apparent association between intussusception and wild or vaccine rotavirus infection. Pediatric Infectious Disease Journal. 1998 1998;17 (10):924-5. PMID 1998374460 MEDLINE PMID 9802640 (http://www.ncbi.nlm.nih.gov/pubmed/9802640).

1092. Rennels MB, Reed GF, Decker MD, et al. Simultaneous administration of Haemophilus influenzae type b vaccine with acellular or whole-cell pertussis vaccine: effects on reactogenicity and immune responses to pertussis vaccines. Pediatrics. 1995 Sep;96 (3 Pt 2):576-9. PMID 7659479.

1093. Resik S, Tejeda A, Lago PM, et al. Randomized Controlled Clinical Trial of Fractional Doses of Inactivated Poliovirus Vaccine Administered Intradermally by Needle-Free Device in Cuba. Journal of Infectious Diseases. 2010 May;201 (9):1344-52. PMID WOS:000276248400011.

1094. Reuman PD, Sawyer MH, Kuter BJ, Matthews H. Safety and immunogenicity of concurrent administration of measles-mumps-rubella-varicella vaccine and PedvaxHIB vaccines in healthy children twelve to eighteen months old. The MMRV Study Group. Pediatric Infectious Disease Journal. 1997 Jul;16 (7):662-7. PMID 9239770.

1095. Reuman PD, Sawyer MH, Kuter BJ, et al. Safety and immunogenicity of concurrent administration of measles-mumps-rubella-varicella vaccine and PedvaxHIB(R) vaccines in healthy children twelve to eighteen months old. Pediatric Infectious Disease Journal. 1997 Jul;16 (7):662-7. PMID WOS:A1997XK75600007.

1096. Reygrobellet C, Viala-Danten M, Meunier J, Weber F, Nguyen VH. Perception and acceptance of intradermal influenza vaccination: Patient reported outcomes from phase 3 clinical trials. Human Vaccines. 2010 April;6 (4):336-45. PMID 2010340982 MEDLINE PMID 20372083 (http://www.ncbi.nlm.nih.gov/pubmed/20372083).

1097. Ribeiro ACM, Guedes LKN, Moraes JCB, et al. Reduced seroprotection after pandemic H1N1 influenza adjuvant-free vaccination in patients with rheumatoid arthritis: implications for clinical practice. Annals of the Rheumatic Diseases. 2011 Dec;70 (12):2144-7. PMID 21859696.

1098. Richardson V, Parashar U, Patel M. Childhood diarrhea deaths after rotavirus vaccination in Mexico. New England Journal of Medicine. 2011 25;365 (8):772-3. PMID 2011477769 MEDLINE PMID 21864191 (http://www.ncbi.nlm.nih.gov/pubmed/21864191).

1099. Richie E, Punjabi NH, Harjanto SJ, et al. Safety and immunogenicity of combined diphtheria-tetanus-pertussis (whole cell and acellular)-Haemophilus influenzae-b conjugate vaccines administered to Indonesian children. Vaccine. 1999 Mar 17;17 (11-12):1384-93. PMID 10195774.

1100. Richmond P, Goldblatt D, Fusco PC, et al. Safety and immunogenicity of a new Neisseria meningitidis serogroup C-tetanus toxoid conjugate vaccine in healthy adults. Vaccine. 1999 Nov 12;18 (7-8):641-6. PMID 10547423.

1101. Ridda I, Seale H, Katelaris AL, et al. Pneumococcal colonisation following influenza infection. Vaccine. 2011 02;29 (38):6444-5. PMID 2011448853 MEDLINE PMID 21549796 (http://www.ncbi.nlm.nih.gov/pubmed/21549796).

1102. Riddell A, Buttery JP, McVernon J, et al. A randomized study comparing the safety and immunogenicity of a conjugate vaccine combination containing meningococcal group C and pneumococcal capsular polysaccharide--CRM197 with a meningococcal group C conjugate vaccine in healthy infants: challenge phase. Vaccine. 2007 May 10;25 (19):3906-12. PMID 17368663.

1103. Riddell A, Buttery JP, McVernon J, et al. A randomized study comparing the safety and immunogenicity of a conjugate vaccine combination containing meningococcal group C and pneumococcal capsular polysaccharide-CRM(197) with a meningococcal group C conjugate

vaccine in healthy infants: Challenge phase. Vaccine. 2007 10;25 (19):3906-12. PMID 2007191727 MEDLINE PMID 17368663 (http://www.ncbi.nlm.nih.gov/pubmed/17368663).

1104. Riedemann S, Reinhardt G, Jara J, et al. Immunogenicity and reactogenicity of combined versus separately administered DTPw-HBV and Hib vaccines given to healthy infants at 2, 4 and 6 months of age, with a booster at 18 months. International Journal of Infectious Diseases. 2002 September;6 (3):215-22. PMID 2002338776.

1105. Ries K, Shemonsky NK. Acute lupus erythematosus (SLE) following polyvalent pneumococcal vaccine. South Dakota Journal of Medicine. 1981 Mar;34 (3):27-8. PMID 6944793.

1106. Rinderknecht S, Bryant K, Nolan T, et al. The safety profile of Haemophilus influenzae type b-Neisseria meningitidis serogroups C and Y tetanus toxoid conjugate vaccine (HibMenCY). Human Vaccines and Immunotherapeutics. 2012 March;8 (3):294-301. PMID 2012244546.

1107. Rinderknecht S, Michaels MG, Blatter M, et al. Immunogenicity and safety of an inactivated hepatitis A vaccine when coadministered with measles-mumps-rubella and varicella vaccines in children less than 2 years of age. Pediatric Infectious Disease Journal. 2011 Oct;30 (10):e179-85. PMID 21617573.

1108. Rivera L, Mazara S, Vargas M, Fragapane E, Casula D, Groth N. Phase III, randomized controlled trial to evaluate lot consistency of a trivalent subunit egg-based influenza vaccine in adults. Vaccine. 2012.

1109. Robbins JB, Schneerson R. Evaluating the Haemophilus influenzae type b conjugate vaccine PRP-D. N Engl J Med. 1990 Nov 15;323 (20):1415-6. PMID 2233910.

1110. Rodrigues LC, Smith PG. Use of the case-control approach in vaccine evaluation: Efficacy and adverse effects. Epidemiologic Reviews. 1999;21 (1):56-72. PMID WOS:000082555000005.

1111. Rodriguez R, Dyer PD. Safety of pneumococcal revaccination. Journal of General Internal Medicine. 1995 Sep;10 (9):511-2. PMID 8523154.

1112. Roman F, Vaman T, Gerlach B, Markendorf A, Gillard P, Devaster J-M. Immunogenicity and safety in adults of one dose of influenza A H1N1v 2009 vaccine formulated with and without AS03A-adjuvant: preliminary report of an observer-blind, randomised trial. Vaccine. 2010 Feb 17;28 (7):1740-5. PMID 20034605.

1113. Roman F, Vaman T, Kafeja F, Hanon E, Van Damme P. AS03(A)-adjuvanted influenza A (H1N1) 2009 vaccine for adults up to 85 years of age. Clinical Infectious Diseases. 2010 15;51 (6):668-77. PMID 2010462473 MEDLINE PMID 20687838 (http://www.ncbi.nlm.nih.gov/pubmed/20687838).

1114. Romano L, Zanetti AR. Safety and immunogenicity of a recombinant hepatitis B vaccine manufactured by a modified process in healthy infants. Expert Review of Vaccines. 2011 Sep;10 (9):1261-4. PMID WOS:000296034400008.

1115. Romano L, Zanetti AR. Safety and immunogenicity of a recombinant hepatitis B vaccine manufactured by a modified process in healthy infants. Expert Review of Vaccines. 2011 September;10 (9):1261-4. PMID 2011525074.

1116. Roscelli JD, Bass JW, Pang L. Guillain-Barre syndrome and influenza vaccination in the US Army, 1980-1988. Am J Epidemiol. 1991 May 1;133 (9):952-5. PMID 2028981.

1117. Rose MA, Gruendler M, Schubert R, Kitz R, Schulze J, Zielen S. Safety and immunogenicity of sequential pneumococcal immunization in preschool asthmatics. Vaccine. 2009 Aug 20;27 (38):5259-64. PMID 19576944.

1118. Rose MA, Schubert R, Strnad N, Zielen S. Priming of immunological memory by pneumococcal conjugate vaccine in children unresponsive to 23-valent polysaccharide pneumococcal vaccine. Clinical and Diagnostic Laboratory Immunology. 2005 October;12 (10):1216-22. PMID 2005469446 MEDLINE PMID 16210486 (http://www.ncbi.nlm.nih.gov/pubmed/16210486).

1119. Rose NR. Conjugate vaccines and autism. Medical Hypotheses. 2011 December;77 (6):937-9. PMID 2011619425 MEDLINE PMID 21907498 (http://www.ncbi.nlm.nih.gov/pubmed/21907498).

1120. Rosenblum H, Shoenfeld Y, Amital H. The Common Immunogenic Etiology of Chronic Fatigue Syndrome: From Infections to Vaccines via Adjuvants to the ASIA Syndrome. Infectious Disease Clinics of North America. 2011 December;25 (4):851-63. PMID 2011610448 MEDLINE PMID 22054760 (http://www.ncbi.nlm.nih.gov/pubmed/22054760).

1121. Rosenfeld RM, Bluestone CD, Casselbrant ML, et al. Treatment. Annals of Otology, Rhinology and Laryngology. 2005 Jan;114 (1 II):114-39. PMID 2005036933.

1122. Rothstein EP, Bernstein HH, Glode MP, et al. Simultaneous administration of a diphtheria and tetanus toxoids and acellular pertussis vaccine with measles-mumps-rubella and oral poliovirus vaccines. American Journal of Diseases of Children. 1993 Aug;147 (8):854-7. PMID 8394646.

1123. Rottem M, Shoenfeld Y. Vaccination and allergy. Current Opinion in Otolaryngology & Head & Neck Surgery. 2004 Jun;12 (3):223-31. PMID 15167034.

1124. Ruiz LP. Re: "Age dependence of the risk of intussusception following tetravalent rhesus-human reassortant rotavirus tetravalent vaccine: is it beyond doubt?". American Journal of Epidemiology. 2010 Oct 1;172 (7):864. PMID 20682522.

1125. Ruiz LP, Jr. Intussusception risk of rotavirus vaccination. New England Journal of

Medicine. 2011 Dec 1;365 (22):2137; author reply 8. PMID 22129261.

1126. Rumke HC, Loch HP, Hoppenbrouwers K, et al. Immunogenicity and safety of a measles-mumps-rubella-varicella vaccine following a 4-week or a 12-month interval between two doses. Vaccine. 2011 May 17;29 (22):3842-9. PMID 21382484.

1127. Rupp ME, Holley HP, Jr., Lutz J, et al. Phase II, randomized, multicenter, double-blind, placebo-controlled trial of a polyclonal anti-Staphylococcus aureus capsular polysaccharide immune globulin in treatment of Staphylococcus aureus bacteremia. Antimicrobial Agents & Chemotherapy. 2007 Dec;51 (12):4249-54. PMID 17893153.

1128. Russell FM, Licciardi PV, Balloch A, et al. Safety and immunogenicity of the 23-valent pneumococcal polysaccharide vaccine at 12 months of age, following one, two, or three doses of the 7-valent pneumococcal conjugate vaccine in infancy. Vaccine. 2010 19;28 (18):3086-94. PMID 2010180096 MEDLINE PMID 20199764 (http://www.ncbi.nlm.nih.gov/pubmed/20199764).

1129. Russell M, Pool V, Kelso JM, Tomazic-Jezic VJ. Vaccination of persons allergic to latex: A review of safety data in the Vaccine Adverse Event Reporting System (VAERS). Vaccine. 2004 16;23 (5):664-7. PMID 2004482529 MEDLINE PMID 15542187 (http://www.ncbi.nlm.nih.gov/pubmed/15542187).

1130. Rutherford EJ, Livengood J, Higginbotham M, et al. Efficacy and safety of pneumococcal revaccination after splenectomy for trauma. Journal of Trauma-Injury Infection & Critical Care. 1995 Sep;39 (3):448-52. PMID 7473907.

1131. Ruuskanen O, Salmi TT, Stenvik M, Lapinleimu K. Inactivated poliovaccine: adverse reactions and antibody responses. Acta Paediatrica Scandinavica. 1980 May;69 (3):397-401. PMID 6246709.

1132. Ruuskanen O, Viljanen MK, Salmi TT, Lehtonen OP, Kouvalainen K, Peltonen T. DTP and DTP-inactivated polio vaccines: comparison of adverse reactions and IGG, IGM and IGA antibody responses to DTP. Acta Paediatrica Scandinavica. 1980 Mar;69 (2):177-82. PMID 6989154.

1133. Ryan MAK, McKeehan JA, Gray GC. Pneumococcal vaccine to counter emerging infectious disease threat in the military. Military Medicine. 2001 Dec;166 (12):1087-90. PMID WOS:000181419700016.

1134. Saad CGS, Borba EF, Aikawa NE, et al. Immunogenicity and safety of the 2009 non-adjuvanted influenza A/H1N1 vaccine in a large cohort of autoimmune rheumatic diseases. Annals of the Rheumatic Diseases. 2011 Jun;70 (6):1068-73. PMID 21540203.

1135. Sabitha P, Prabha Adhikari MR, Chowdary A, et al. Comparison of the immunogenicity and safety of two different brands of Salmonella typhi Vi capsular polysaccharide vaccine. Indian Journal of Medical Sciences. 2004 Apr;58 (4):141-9. PMID 15122049.

1136. Sablan BP, Kim DJ, Barzaga NG, et al. Demonstration of safety and enhanced seroprotection against hepatitis B with investigational HBsAg-1018 ISS vaccine compared to a licensed hepatitis B vaccine. Vaccine. 2012 30;30 (16):2689-96. PMID 2012154623.

1137. Sacarlal J, Aponte JJ, Aide P, et al. Safety of the RTS,S/AS02A malaria vaccine in Mozambican children during a Phase IIb trial. Vaccine. 2008 Jan 10;26 (2):174-84. PMID 18069097.

1138. Saenger R, Maechler G, Potreck M, et al. Booster vaccination with hexavalent DTPa-HBV-IPV/Hib vaccine in the second year of life is as safe as concomitant DTPa-IPV/Hib + HBV administered separately. Vaccine. 2005 Jan 19;23 (9):1135-43. PMID 15629356.

1139. Saez-Llorens X, Guevara JN. Intussusception and rotavirus vaccines: what is the background risk? Pediatric Infectious Disease Journal. 2004 Apr;23 (4):363-5. PMID 15071297.

1140. Sakano T, Kittaka E, Tanaka Y. Vaccine-associated poliomyelitis in an infant with agammaglobulinemia. Acta Paediatrica Scandinavica. 1980 1980;69 (4):549-51. PMID 1980204895 MEDLINE PMID 6255734 (http://www.ncbi.nlm.nih.gov/pubmed/6255734).

1141. Saksawad R, Likitnukul S, Warachit B, Hanvivatvong O, Poovorawan Y, Puripokai P. Immunogenicity and safety of a pediatric dose virosomal hepatitis A vaccine in Thai HIV-infected children. Vaccine. 2011 Jun 24;29 (29-30):4735-8. PMID 21570433.

1142. Salemi S, Picchianti-Diamanti A, Germano V, et al. Influenza vaccine administration in rheumatoid arthritis patients under treatment with TNFalpha blockers: safety and immunogenicity. Clinical Immunology. 2010 Feb;134 (2):113-20. PMID 19846344.

1143. Sandbu S, Feiring B, Oster P, et al. Immunogenicity and safety of a combination of two serogroup B meningococcal outer membrane vesicle vaccines. Clinical & Vaccine Immunology: CVI. 2007 Sep;14 (9):1062-9. PMID 17634513.

1144. Sanders R, Dabbagh A, Featherstone D. Risk Analysis for Measles Reintroduction After Global Certification of Eradication. Journal of Infectious Diseases. 2011 Jul;204:S71-S7. PMID WOS:000293547600011.

1145. Sanger R, Behre U, Krause K-H, et al. Booster vaccination and 1-year follow-up of 4-8-year-old children with a reduced-antigen-content dTpa-IPV vaccine. European Journal of Pediatrics. 2007 Dec;166 (12):1229-36. PMID 17235521.

1146. Sankilampi U, Honkanen PO, Pyhala R, Leinonen M. Associations of prevaccination antibody levels with adverse reactions to pneumococcal and influenza vaccines administered simultaneously in the elderly. Vaccine. 1997 Jul;15 (10):1133-7. PMID 9269058.

1147. Santini-Oliveira M, Camacho LAB, Souza TML, et al. H1N1pdm09 adjuvanted vaccination in HIV-infected adults: A randomized trial of two single versus two double doses.

PLoS ONE [Electronic Resource]. 2012;7 (6) PMID 2012358803.

1148. Santosham M, Englund JA, McInnes P, et al. Safety and antibody persistence following Haemophilus influenzae type b conjugate or pneumococcal polysaccharide vaccines given before pregnancy in women of childbearing age and their infants. Pediatric Infectious Disease Journal. 2001 Oct;20 (10):931-40. PMID 11642626.

1149. Santosham M, Hill J, Wolff M, Reid R, Lukacs L, Ahonkhai V. Safety and immunogenicity of a Haemophilus influenzae type b conjugate vaccine in a high risk American Indian population.[Erratum appears in Pediatr Infect Dis J 1991 May;10(5):369]. Pediatric Infectious Disease Journal. 1991 Feb;10 (2):113-7. PMID 2062601.

1150. Sato HK, Sanajotta AT, Moraes JC, et al. Rubella vaccination of unknowingly pregnant women: the Sao Paulo experience, 2001. Journal of Infectious Diseases. 2011 Sep 1;204 Suppl 2:S737-44. PMID 21954275.

1151. Sauve LJ, Bettinger J, Scheifele D, Halperin S, Vaudry W, Law B. Postvaccination thrombocytopenia in Canada. Pediatric Infectious Disease Journal. 2010 June;29 (6):559-61. PMID 2010315569 MEDLINE PMID 20160658 (http://www.ncbi.nlm.nih.gov/pubmed/20160658).

1152. Savy M, Edmond K, Fine PEM, et al. Landscape analysis of interactions between nutrition and vaccine responses in children. Journal of Nutrition. 2009 November;139 (11):2154S-218S. PMID 2009557228 MEDLINE PMID 19793845 (http://www.ncbi.nlm.nih.gov/pubmed/19793845).

1153. Schatz M, Chambers CD, Jones KL, Louik C, Mitchell AA. Safety of influenza immunizations and treatment during pregnancy: the Vaccines and Medications in Pregnancy Surveillance System. American Journal of Obstetrics & Gynecology. 2011 Jun;204 (6 Suppl 1):S64-8. PMID 21333964.

1154. Scheifele D, Barreto L, Meekison W, Guasparini R, Friesen B. Can Haemophilus influenzae type b-tetanus toxoid conjugate vaccine be combined with diphtheria toxoid-pertussis vaccine-tetanus toxoid? CMAJ Canadian Medical Association Journal. 1993 Oct 15;149 (8):1105-12. PMID 8221449.

1155. Scheifele D, Bjornson G, Barreto L, Meekison W, Guasparini R. Controlled trial of Haemophilus influenzae type B diphtheria toxoid conjugate combined with diphtheria, tetanus and pertussis vaccines, in 18-month-old children, including comparison of arm versus thigh injection. Vaccine. 1992;10 (7):455-60. PMID 1609548.

1156. Scheifele DW, Bjornson GL, Meekison WG, Guasparini R, Mitchell LA. Evaluation of Haemophilus influenzae type b conjugate vaccine (meningococcal protein conjugate) in Canadian infants. Canadian Journal of Infectious Diseases. 1994 Mar;5 (2):75-81. PMID 22451769.

1157. Scheifele DW, Guasparini R, Lavigne P. A comparative study of PENTA vaccine booster doses given at 12, 15, or 18 months of age. Vaccine. 1999 Feb 12;17 (6):543-50. PMID 10075160.

1158. Scheifele DW, Halperin SA, Ochnio JJ, Ferguson AC, Skowronski DM. A modified vaccine reduces the rate of large injection site reactions to the preschool booster dose of diphtheria-tetanus-acellular pertussis vaccine: Results of a randomized, controlled trial. Pediatric Infectious Disease Journal. 2005 December;24 (12):1059-66. PMID 2006003381 MEDLINE PMID 16371866 (http://www.ncbi.nlm.nih.gov/pubmed/16371866).

1159. Scheifele DW, Halperin SA, Ochnio JJ, Mozel M, Duarte-Monteiro D, Wortzman D. Immunologic considerations for the timing of the booster dose of 7-valent pneumococcal conjugate vaccine in young children. Pediatric Infectious Disease Journal. 2007 May;26 (5):387-92. PMID 17468647.

1160. Scheifele DW, Halperin SA, Rubin E, et al. Safety and immunogenicity of a pentavalent combination vaccine (diphtheria, tetanus, acellular pertussis, polio, and haemophilus influenzae type B conjugate) when administered as a fourth dose at 15 to 18 months of age. Human Vaccines. 2005 Sep-Oct;1 (5):180-6. PMID 17012882.

1161. Scheifele DW, Meekison W, Guasparini R, et al. Evaluation of booster doses of Haemophilus influenzae type b-tetanus toxoid conjugate vaccine in 18-month-old children. Vaccine. 1995 Jan;13 (1):104-8. PMID 7762265.

1162. Scheifele DW, Ward BJ, Dionne M, et al. Compatibility of ASO3-adjuvanted H1N1pdm09 and seasonal trivalent influenza vaccines in adults: Results of a randomized, controlled trial. Vaccine. 2012 Jul 6;30 (32):4728-32. PMID 22652402.

1163. Schessl J, Luther B, Kirschner J, Mauff G, Korinthenberg R. Infections and vaccinations preceding childhood Guillain-Barre syndrome: A prospective study. European Journal of Pediatrics. 2006 September;165 (9):605-12. PMID 2006361574 MEDLINE PMID 16691408 (http://www.ncbi.nlm.nih.gov/pubmed/16691408).

1164. Schmeink CE, Bekkers RLM, Josefsson A, et al. Co-administration of human papillomavirus-16/18 AS04-adjuvanted vaccine with hepatitis B vaccine: Randomized study in healthy girls. Vaccine. 2011 Nov;29 (49):9276-83. PMID WOS:000297525500022.

1165. Schmitt HJ, Knuf M, Ortiz E, Sanger R, Uwamwezi MC, Kaufhold A. Primary vaccination of infants with diphtheriatetanus-acellular pertussis-hepatitis B virus-inactivated polio virus and Haemophilus influenzae type b vaccines given as either separate or mixed injections. Journal of Pediatrics. 2000 2000;137 (3):304-12. PMID 2000329506 MEDLINE PMID 10969252 (http://www.ncbi.nlm.nih.gov/pubmed/10969252).

1166. Schmitt HJ, Maechler G, Habermehl P, et al. Immunogenicity, reactogenicity, and immune memory after primary vaccination with a novel Haemophilus influenzae-Neisselia meningitidis serogroup C conjugate vaccine. Clinical and Vaccine Immunology. 2007 Apr;14

(4):426-34. PMID WOS:000245863500014.

1167. Schmitt HJ, Wirsing von Konig CH, Zepp F, et al. Immunogenicity and reactogenicity of HbOC vaccine administered simultaneously with acellular pertussis vaccine (DTaP) into either arms or thighs of infants. Infection. 1997 Sep-Oct;25 (5):298-302. PMID 9334865.

1168. Schmitt HJ, Zepp F, Muschenborn S, et al. Immunogenicity and reactogenicity of a Haemophilus influenzae type b tetanus conjugate vaccine when administered separately or mixed with concomitant diphtheria-tetanus-toxoid and acellular pertussis vaccine for primary and for booster immunizations. European Journal of Pediatrics. 1998 Mar;157 (3):208-14. PMID 9537487.

1169. Schmitt H-J, Maechler G, Habermehl P, et al. Immunogenicity, reactogenicity, and immune memory after primary vaccination with a novel Haemophilus influenzae-Neisseria meningitidis serogroup C conjugate vaccine. Clinical & Vaccine Immunology: CVI. 2007 Apr;14 (4):426-34. PMID 17287313.

1170. Schmitt H-J, Siegrist C-A, Salmaso S, Law B, Booy R. B. Zinka et al., Unexplained cases of sudden infant death shortly after hexavalent vaccination. Vaccine. 2006 Jul 26;24 (31-32):5781-2; author reply 5-6. PMID 16084630.

1171. Schmitt H-J, Steul KS, Borkowski A, Ceddia F, Ypma E, Knuf M. Two versus three doses of a meningococcal C conjugate vaccine concomitantly administered with a hexavalent DTaP-IPV-HBV/Hib vaccine in healthy infants. Vaccine. 2008 Apr 24;26 (18):2242-52. PMID 18407386.

1172. Schonbeck Y, Sanders EAM, Hoes AW, Schilder AGM, Verheij TJM, Hak E. Rationale and design of the prevention of respiratory infections and management in children (PRIMAKid) study: a randomized controlled trial on the effectiveness and costs of combined influenza and pneumococcal vaccination in pre-school children with recurrent respiratory tract infections. Vaccine. 2005 Sep 30;23 (41):4906-14. PMID 16005552.

1173. Schonberger LB, McGowan Jr JE, Gregg MB. Vaccine associated poliomyelitis in the United States, 1961-1972. American Journal of Epidemiology. 1976 1976;104 (2):202-11. PMID 1977167319 MEDLINE PMID 181984 (http://www.ncbi.nlm.nih.gov/pubmed/181984).

1174. Schuerman L, Borys D, Hoet B, Forsgren A, Prymula R. Prevention of otitis media: Now a reality? Vaccine. 2009 25;27 (42):5748-54. PMID 2009471080 MEDLINE PMID 19666154 (http://www.ncbi.nlm.nih.gov/pubmed/19666154).

1175. Schulzke S, Heininger U, Lucking-Famira M, Fahnenstich H. Apnoea and bradycardia in preterm infants following immunisation with pentavalent or hexavalent vaccines. European Journal of Pediatrics. 2005 July;164 (7):432-5. PMID 2005301172 MEDLINE PMID 15843978 (http://www.ncbi.nlm.nih.gov/pubmed/15843978).

1176. Schumacher Z, Bourquin C, Heininger U. Surveillance for adverse events following

immunization (AEFI) in Switzerland-1991-2001. Vaccine. 2010 28;28 (24):4059-64. PMID 2010290078 MEDLINE PMID 20406662 (http://www.ncbi.nlm.nih.gov/pubmed/20406662).

1177. Schuurmans MM, Tini GM, Dalar L, Fretz G, Benden C, Boehler A. Pandemic 2009 H1N1 influenza virus vaccination in lung transplant recipients: coverage, safety and clinical effectiveness in the Zurich cohort (vol 30, pg 685, 2011). Journal of Heart and Lung Transplantation. 2011 Oct;30 (10):1206-. PMID WOS:000295859400019.

1178. Schwartz HJ, Terr AI. The immune response of allergic and normal subjects to pneumococcal polysaccharide. International Archives of Allergy & Applied Immunology. 1971;40 (4-5):520-5. PMID 4397063.

1179. Schwarz TF, Flamaing J, Rumke HC, et al. A randomized, double-blind trial to evaluate immunogenicity and safety of 13-valent pneumococcal conjugate vaccine given concomitantly with trivalent influenza vaccine in adults aged >=65 years. Vaccine. 2011 Jul 18;29 (32):5195-202. PMID 21619909.

1180. Scott DA, Komjathy SF, Hu BT, et al. Phase 1 trial of a 13-valent pneumococcal conjugate vaccine in healthy adults. Vaccine. 2007 14;25 (33):6164-6. PMID 2007355054 MEDLINE PMID 17629361 (http://www.ncbi.nlm.nih.gov/pubmed/17629361).

1181. Scudellari M. Vaccine contamination prompts safety review. Nature Medicine. 2010 May;16 (5):493. PMID 2010272285 MEDLINE PMID 20448549 (http://www.ncbi.nlm.nih.gov/pubmed/20448549).

1182. Selman S, Hayes D, Perin LA, Hayes WS. Pneumococcal conjugate vaccine for young children. Managed Care. 2000 Sep;9 (9):49-52, 4, 6-7 passim. PMID 11116663.

1183. Seltsam A, Shukry-Schulz S, Salama A. Vaccination-associated immune hemolytic anemia in two children. Transfusion. 2000 2000;40 (8):907-9. PMID 2000311459 MEDLINE PMID 10960515 (http://www.ncbi.nlm.nih.gov/pubmed/10960515).

1184. Shafrir Y. Vaccination and Dravet syndrome. Lancet Neurology. 2010 Dec;9 (12):1147-8; author reply 8-9. PMID 21087737.

1185. Shahgholi E, Ehsani MA, Salamati P, Maysamie A, Sotoudeh K, Mokhtariazad T. Immunogenicity of trivalent influenza vaccine in children with acute lymphoblastic leukemia during maintenance therapy. Pediatric Blood and Cancer. 2010 May;54 (5):716-20. PMID 2010217213 MEDLINE PMID 20205258 (http://www.ncbi.nlm.nih.gov/pubmed/20205258).

1186. Shahmahmoodi S, Mamishi S, Aghamohammadi A, et al. Vaccine-associated paralytic poliomyelitis in immunodeficient children, Iran, 1995-2008. Emerging Infectious Diseases. 2010 Jul;16 (7):1133-6. PMID 20587188.

1187. Shann F. The nonspecific effects of vaccines and the expanded program on immunization. Journal of Infectious Diseases. 2011 15;204 (2):182-4. PMID 2011324487 MEDLINE PMID

21673027 (http://www.ncbi.nlm.nih.gov/pubmed/21673027).

1188. Shao PL, Lu CY, Hsieh YC, Bock HL, Huang LM. Immunogenicity and Reactogenicity of Diphtheria-Tetanus-Acellular Pertussis-Hepatitis B-Inactivated Poliovirus and Haemophilus influenzae Type B Vaccines Administered Concomitantly to Infants as a Three-dose Primary Course. Journal of the Formosan Medical Association. 2011 May;110 (5):336-41. PMID WOS:000291081200009.

1189. Shao P-L, Lu C-Y, Chang L-Y, et al. Safety and immunogenicity of heptavalent pneumococcal conjugate vaccine booster in taiwanese toddlers. Journal of the Formosan Medical Association. 2006 Jul;105 (7):542-9. PMID 16877233.

1190. Shao P-L, Lu C-Y, Chang L-Y, et al. Safety and immunogenicity of heptavalent pneumococcal conjugate vaccine in Taiwanese infants. Journal of the Formosan Medical Association. 2004 Aug;103 (8):613-7. PMID 15340660.

1191. Shao P-L, Lu C-Y, Hsieh Y-C, Taiwan Infanrix-049 Study G, Bock HL, Huang L-M. Immunogenicity and reactogenicity of diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus and Haemophilus influenzae type B. Journal of the Formosan Medical Association. 2011 May;110 (5):336-41. PMID 21621155.

1192. Shapiro ED, Capobianco LA, Berg AT, Zitt MQ. The immunogenicity of Hemophilus influenzae type B polysaccharide-Neisseria meningitidis group B outer membrane protein complex vaccine in infants and young children. Journal of Infectious Diseases. 1989 Dec;160 (6):1064-7. PMID 2511254.

1193. Sharma A, Agarwal D, Kapoor S, Garg SR, Malaviya AN. Vaccination as a triggering agent for the development of rheumatoid arthritis. International Journal of Rheumatic Diseases. 2011 Feb;14 (1):e8-9. PMID 21303474.

1194. Sharma H, Yadav S, Lalwani S, et al. A phase III randomized, controlled study to assess the immunogenicity and tolerability of DTPw-HBV-Hib, a liquid pentavalent vaccine in Indian infants. Vaccine. 2011 Mar 16;29 (13):2359-64. PMID 21288803.

1195. Sharma H, Yadav S, Patil V, et al. A phase III randomized, controlled study to assess and compare the immunogenicity and tolerability of single and multi-dose vials of DTwP-Hib, a fully liquid quadravalent vaccine and their comparison with TETRAct-Hib vaccine in Indian infants aged 6-14 weeks. Vaccine. 2011 Nov 8;29 (48):8773-9. PMID 21968445.

1196. Sharma HJ, Multani AS, Dutta AK, et al. Safety and immunogenicity of an indigenously developed Haemophilus influenzae type b conjugate vaccine through various phases of clinical trials. Human Vaccines. 2009 Jul;5 (7):483-7. PMID 19395868.

1197. Sharma HJ, Patil VD, Lalwani SK, et al. Assessment of safety and immunogenicity of two different lots of diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae type b vaccine manufactured using small and large scale manufacturing process. Vaccine. 2012 Jan

11;30 (3):510-6. PMID 22119927.

1198. Sharma HJ, Yadav S, Lalwani SK, et al. Immunogenicity and safety of an indigenously manufactured reconstituted pentavalent (DTwP-HBV+Hib) vaccine in comparison with a foreign competitor following primary and booster immunization in Indian children. Human Vaccines. 2011 Apr;7 (4):451-7. PMID 21403463.

1199. Sharrar RG, LaRussa P, Galea SA, et al. The postmarketing safety profile of varicella vaccine. Vaccine. 2000 Nov 22;19 (7-8):916-23. PMID 11115716.

1200. Shatsky M. Rotavirus vaccine, live, oral, pentavalent (RotaTeq) for prevention of rotavirus gastroenteritis. American Family Physician. 2006 15;74 (6):1014-6. PMID 2006460119.

1201. Sheffield JS, Hickman A, Tang J, et al. Efficacy of an Accelerated Hepatitis B Vaccination Program During Pregnancy. Obstetrics and Gynecology. 2011 May;117 (5):1130-5. PMID WOS:000289771000014.

1202. Sheikh A, Alves B, Dhami S. Pneumococcal vaccine for asthma. Cochrane Database of Systematic Reviews. 2002 (1):CD002165. PMID 11869626.

1203. Sheldon EA, Schwartz H, Jiang Q, Giardina PC, Perez JL. A Phase 1, randomized, open-label, active-controlledtrial to assess the safety of a meningococcal serogroup B bivalent rLP2086 vaccine in healthy adults. Human Vaccines and Immunotherapeutics. 2012 July;8 (7):888-95. PMID 2012427211.

1204. Shibazaki K, Murakami T, Kushida R, Kurokawa K, Terada K, Sunada Y. Acute disseminated encephalomyelitis associated with oral polio vaccine. Internal Medicine. 2006;45 (20):1143-6. PMID 17106158.

1205. Shields WD, Nielsen C, Buch D, et al. Relationship of pertussis immunization to the onset of neurologic disorders: A retrospective epidemiologic study. Journal of Pediatrics. 1988 1988;113 (5):801-5. PMID 1988272572 MEDLINE PMID 3263484 (http://www.ncbi.nlm.nih.gov/pubmed/3263484).

1206. Shin SY, Lee SW, Cho YH, Shin YH. Blood-borne transmission of the measles, mumps, and rubella vaccine virus. Transfusion. 2011 March;51 (3):663-4. PMID 2011140203 MEDLINE PMID 21388395 (http://www.ncbi.nlm.nih.gov/pubmed/21388395).

1207. Shinefield H, Black S, Ray P, Fireman B, Schwalbe J, Lewis E. Efficacy, immunogenicity and safety of heptavalent pneumococcal conjugate vaccine in low birth weight and preterm infants. Pediatric Infectious Disease Journal. 2002 Mar;21 (3):182-6. PMID 12005078.

1208. Shinefield H, Black S, Thear M, et al. Safety and immunogenicity of a measles, mumps, rubella and varicella vaccine given with combined Haemophilus influenzae type b conjugate/hepatitis B vaccines and combined diphtheria-tetanus-acellular pertussis vaccines.

Pediatric Infectious Disease Journal. 2006 Apr;25 (4):287-92. PMID 16567978.

1209. Shinefield HR, Black S, Ray P, et al. Safety and immunogenicity of heptavalent pneumococcal CRM197 conjugate vaccine in infants and toddlers. Pediatric Infectious Disease Journal. 1999 Sep;18 (9):757-63. PMID 10493334.

1210. Shinoki T, Hara R, Kaneko U, et al. Safety and response to influenza vaccine in patients with systemic-onset juvenile idiopathic arthritis receiving tocilizumab. Modern Rheumatology. 2012.

1211. Shneyer E, Strulov A, Rosenfeld Y. Reduced rate of side effects associated with separate administration of MMR and DTaP-Hib-IPV vaccinations. Israel Medical Association Journal: Imaj. 2009 Dec;11 (12):735-8. PMID 20166340.

1212. Shoda A, Hayashi M, Takayama N, et al. Maternal screening and postpartum vaccination for measles infection in Japan: a cohort study. BJOG: An International Journal of Obstetrics & Gynaecology. 2011 Jan;118 (1):88-92. PMID 21197682.

1213. Shu M, Liu Q, Wang J, et al. Measles vaccine adverse events reported in the mass vaccination campaign of Sichuan province, China from 2007 to 2008. Vaccine. 2011 Apr 18;29 (18):3507-10. PMID 19909830.

1214. Shuster J. Ciprofloxacin-induced immunoglobulin a disease; Palonosetron-induced anaphylaxis; Guillain-Barre Syndrome following H1N1 immunization; Acute profound thrombocytopenia following eptifibatide administration; Clozapine-associated cerebral venous thrombosis; Three excellent reviews: Drug-induced black hairy tongue, Increased C. difficile infections with PPI prophylaxis. Hospital Pharmacy. 2010 1;45 (9):680-4. PMID 2010484611.

1215. Siberry GK, Warshaw MG, Williams PL, et al. Safety and immunogenicity of quadrivalent meningococcal conjugate vaccine in 2- to 10-year-old human immunodeficiency virus-infected children. Pediatric Infectious Disease Journal. 2012 Jan;31 (1):47-52. PMID 21987006.

1216. Siddiqui AH, Chitlur MB. Immune thrombocytopenic purpura in a 5-month-old female with rotavirus infection. Pediatric Blood & Cancer. 2010 Apr;54 (4):633. PMID 20054872.

1217. Siebert JN, Posfay-Barbe KM, Habre W, Siegrist CA. Influence of anesthesia on immune responses and its effect on vaccination in children: Review of evidence. Paediatric Anaesthesia. 2007 May;17 (5):410-20. PMID 2007199579 MEDLINE PMID 17474946 (http://www.ncbi.nlm.nih.gov/pubmed/17474946).

1218. Sigurdardottir ST, Davidsdottir K, Arason VA, et al. Safety and immunogenicity of CRM197-conjugated pneumococcal-meningococcal C combination vaccine (9vPnC-MnCC) whether given in two or three primary doses. Vaccine. 2008 Aug 5;26 (33):4178-86. PMID 18606481.

1219. Sigurdardottir ST, Ingolfsdottir G, Davidsdottir K, et al. Immune response to octavalent diphtheria- and tetanus-conjugated pneumococcal vaccines is serotype- and carrier-specific: the choice for a mixed carrier vaccine. Pediatric Infectious Disease Journal. 2002 Jun;21 (6):548-54. PMID 12182380.

1220. Simoes EA, Balraj V, Selvakumar R, John TJ. Antibody response of children to measles vaccine mixed with diphtheria-pertussis-tetanus or diphtheria-pertussis-tetanus-poliomyelitis vaccine. American Journal of Diseases of Children. 1988 Mar;142 (3):309-11. PMID 3257842.

1221. Simon JK, Carter M, Pasetti MF, et al. Safety, tolerability, and immunogenicity of inactivated trivalent seasonal influenza vaccine administered with a needle-free disposable-syringe jet injector. Vaccine. 2011 Nov 28;29 (51):9544-50. PMID 21986218.

1222. Simonsen L, Morens D, Elixhauser A, Gerber M, Van Raden M, Blackwelder W. Effect of rotavirus vaccination programme on trends in admission of infants to hospital for intussusception. Lancet. 2001 Oct 13;358 (9289):1224-9. PMID 11675060.

1223. Simonsen L, Morens DM, Blackwelder WC. Ecological studies, rotavirus vaccination, and intussusception. Lancet. 2002 Mar 23;359 (9311):1066-7; author reply PMID 11937210.

1224. Simonsen L, Taylor RJ, Kapikian AZ. Rotavirus vaccines. New England Journal of Medicine. 2006 Apr 20;354 (16):1747-51; author reply -51. PMID 16625742.

1225. Singleton R, Wenger J, Klejka JA, et al. The 13-valent pneumococcal conjugate vaccine for invasive pneumococcal disease in alaska native children: Results of a clinical trial. Pediatric Infectious Disease Journal. 2012;20.

1226. Siwek J. Hemophilus b conjugate vaccines: good news, bad news. American Family Physician. 1991 Apr;43 (4):1218, 20. PMID 2008809.

1227. Skowronski DM, Hottes TS, Chong M, et al. Randomized controlled trial of dose response to influenza vaccine in children aged 6 to 23 months. Pediatrics. 2011 Aug;128 (2):e276-89. PMID 21768314.

1228. Skowronski DM, Janjua NZ, Hottes TS, Patrick DM, De Serres G. Pneumococcal vaccination and myocardial infarction. CMAJ Canadian Medical Association Journal. 2009 Feb 3;180 (3):319; author reply 20. PMID 19188633.

1229. Skowronski DM, Strauss B, De Serres G, et al. Oculo-respiratory syndrome: a new influenza vaccine-associated adverse event? Clin Infect Dis. 2003 Mar 15;36 (6):705-13. PMID 12627354.

1230. Slack MH, Schapira C, Thwaites RJ, Andrews N, Schapira D. Acellular pertussis and meningococcal C vaccines: Cardio-respiratory events in preterm infants. European Journal of Pediatrics. 2003 1;162 (6):436-7. PMID 2003233006 MEDLINE PMID 12756562 (http://www.ncbi.nlm.nih.gov/pubmed/12756562).

1231. Snape MD, Dawson T, Oster P, et al. Immunogenicity of two investigational serogroup B meningococcal vaccines in the first year of life: A randomized comparative trial. Pediatric Infectious Disease Journal. 2010 November;29 (11):e71-e9. PMID 2010608871 MEDLINE PMID 20844462 (http://www.ncbi.nlm.nih.gov/pubmed/20844462).

1232. Snape MD, Klinger CL, Daniels ED, et al. Immunogenicity and reactogenicity of a 13-valent-pneumococcal conjugate vaccine administered at 2, 4, and 12 months of age: A double-blind randomized active-controlled trial. Pediatric Infectious Disease Journal. 2010 December;29 (12):e80-e90. PMID 2010699823 MEDLINE PMID 21155091 (http://www.ncbi.nlm.nih.gov/pubmed/21155091).

1233. Soares RC, Siqueira MM, Toscano CM, et al. Follow-up study of unknowingly pregnant women vaccinated against rubella in Brazil, 2001-2002. Obstetrical and Gynecological Survey. 2012 January;67 (1):20-2. PMID 2012078383.

1234. Soares-Weiser K, Goldberg E, Tamimi G, Pitan OC, Leibovici L. Rotavirus vaccine for preventing diarrhoea. Cochrane Database of Systematic Reviews. 2004 (1):CD002848. PMID 14973994.

1235. Socan M, Frelih T, Janet E, Petras T, Peternelj B. Reactions after pneumococcal vaccine alone or in combination with influenza vaccine. Vaccine. 2004 Aug 13;22 (23-24):3087-91. PMID 15297059.

1236. Sonder G, Van den Hoek A. Hepatitis B immunization coverage and risk behaviour among Danish travellers: Are immunization strategies based on single journey itineraries rational? Journal of Infection. 2010 April;60 (4):309-10. PMID 2012069875 MEDLINE PMID 20100513 (http://www.ncbi.nlm.nih.gov/pubmed/20100513).

1237. Song JY, Cheong HJ, Woo HJ, et al. Immunogenicity and safety of trivalent inactivated influenza vaccine: a randomized, double-blind, multi-center, phase 3 clinical trial in a vaccine-limited country. Journal of Korean Medical Science. 2011 Feb;26 (2):191-5. PMID 21286008.

1238. Sou T, Meeusen EN, de Veer M, Morton DAV, Kaminskas LM, McIntosh MP. New developments in dry powder pulmonary vaccine delivery. Trends in Biotechnology. 2011 April;29 (4):191-8. PMID 2011151587 MEDLINE PMID 21255854 (http://www.ncbi.nlm.nih.gov/pubmed/21255854).

1239. Souayah N, Michas-Martin PA, Nasar A, et al. Guillain-Barre syndrome after Gardasil vaccination: data from Vaccine Adverse Event Reporting System 2006-2009. Vaccine. 2011 Jan 29;29 (5):886-9. PMID 20869467.

1240. Souayah N, Nasar A, Suri MFK, Qureshi AI. Guillain-barre syndrome after vaccination in United States: Data from the centers for disease control and prevention/food and drug administration vaccine adverse event reporting system (1990-2005). Journal of Clinical Neuromuscular Disease. 2009 September;11 (1):1-6. PMID 2009490545 MEDLINE PMID

19730016 (http://www.ncbi.nlm.nih.gov/pubmed/19730016).

1241. Souayah N, Yacoub HA, Khan HMR, et al. Guillain-Barre Syndrome after H1N1 Vaccination in the United States: A Report Using the CDC/FDA Vaccine Adverse Event Reporting System (2009). Neuroepidemiology. 2012;38 (4):227-32. PMID 22555646.

1242. Southern J, Deane S, Ashton L, et al. Effects of prior polysaccharide vaccination on magnitude, duration, and quality of immune responses to and safety profile of a meningococcal serogroup C tetanus toxoid conjugate vaccination in adults. Clinical & Diagnostic Laboratory Immunology. 2004 Nov;11 (6):1100-4. PMID 15539513.

1243. Souza AR, Braga JAP, de Paiva TM, Loggetto SR, Azevedo RS, Weckx LY. Immunogenicity and tolerability of a virosome influenza vaccine compared to split influenza vaccine in patients with sickle cell anemia. Vaccine. 2010 Jan 22;28 (4):1117-20. PMID 20116631.

1244. Sow SO, Okoko BJ, Diallo A, et al. Immunogenicity and safety of a meningococcal A conjugate vaccine in Africans. New England Journal of Medicine. 2011 Jun 16;364 (24):2293-304. PMID 21675889.

1245. Sox C. Acute otitis media: antibiotics are moderately effective and mildly increase the risk of adverse effects; prevalence of different causative bacteria changed after introduction of the heptavalent pneumococcal conjugate vaccine. Evidence Based Medicine. 2011 Dec;16 (6):181-2. PMID 21561925.

1246. Spinola SM, Sheaffer CI, Gilligan PH. Antigenuria after Haemophilus influenzae type b polysaccharide vaccination. Journal of Pediatrics. 1986 1986;108 (2):247-9. PMID 1986113874 MEDLINE PMID 3484781 (http://www.ncbi.nlm.nih.gov/pubmed/3484781).

1247. Spinola SM, Sheaffer CI, Philbrick KB, Gilligan PH. Antigenuria after Haemophilus influenzae type b polysaccharide immunization: A prospective study. Journal of Pediatrics. 1986 1986;109 (5):835-8. PMID 1987012442 MEDLINE PMID 3490560 (http://www.ncbi.nlm.nih.gov/pubmed/3490560).

1248. Spitaleri G, Delmonte A, Toffalorio F, De Pas TM, Gregorc V. Safety of concomitant administration of seasonal and/or H1N1 flu vaccination in patients receiving erlotinib for advanced non-small cell lung cancer. Journal of Thoracic Oncology: Official Publication of the International Association for the Study of Lung Cancer. 2010 May;5 (5):752-4. PMID 20421772.

1249. Stangenberg S, John G, Healy H, Paterson D. Response of renal transplant recipients to the monovalent pandemic H1N1 vaccine. Nephrology. 2011 September;16 SUPPL. 1:78.

1250. Stanley PJ, Ellis CJ. New vaccines. British Journal of Hospital Medicine. 1989 1989;41 (4):364-7. PMID 1989114717 MEDLINE PMID 2655801 (http://www.ncbi.nlm.nih.gov/pubmed/2655801).

1251. Stavrikj K, Peova S, Petlickovski A, Topuzovska IK, Spiroski M. Safe measles, mumps and rubella vaccine administration in atopic children with high levels of egg white-specific IgE antibody. Macedonian Journal of Medical Sciences. 2011 September;4 (3):271-4. PMID 2011559148.

1252. Stavroulopoulos A, Stamogiannos G, Aresti V. Pandemic 2009 influenza H1N1 virus vaccination: compliance and safety in a single hemodialysis center. Renal Failure. 2010;32 (9):1044-8. PMID 20863207.

1253. Steele AD, De Vos B, Tumbo J, et al. Co-administration study in South African infants of a live-attenuated oral human rotavirus vaccine (RIX4414) and poliovirus vaccines. Vaccine. 2010 September;28 (39):6542-8. PMID 2010488890 MEDLINE PMID 18786585 (http://www.ncbi.nlm.nih.gov/pubmed/18786585).

1254. Steele AD, Madhi SA, Louw CE, et al. Safety, Reactogenicity, and Immunogenicity of Human Rotavirus Vaccine RIX4414 in Human Immunodeficiency Virus-positive Infants in South Africa. Pediatric Infectious Disease Journal. 2011 Feb;30 (2):125-30. PMID 20842070.

1255. Steele RW. Safety and immunogenicity of heptavalent pneumococcal vaccine conjugated to CRM197 in United States infants. Clinical Pediatrics. 1998 Dec;37 (12):760-1. PMID 9864656.

1256. Steentoft J, Konradsen HB, Hilskov J, Gislason G, Andersen JR. Response to pneumococcal vaccine in chronic obstructive lung disease - The effect of ongoing, systemic steroid treatment. Vaccine. 2006 27;24 (9):1408-12. PMID 2006076659 MEDLINE PMID 16297507 (http://www.ncbi.nlm.nih.gov/pubmed/16297507).

1257. Stojanov S, Liese JG, Belohradsky BH, et al. Administration of hepatitis A vaccine at 6 and 12 months of age concomitantly with hexavalent (DTaP-IPV-PRP~T-HBs) combination vaccine. Vaccine. 2007 23;25 (43):7549-58. PMID 2007480826 MEDLINE PMID 17905486 (http://www.ncbi.nlm.nih.gov/pubmed/17905486).

1258. Stojanov S, Liese JG, Bendjenana H, et al. Immunogenicity and safety of a trivalent tetanus, low dose diphtheria, inactivated poliomyelitis booster compared with a standard tetanus, low dose diphtheria booster at six to nine years of age. Munich Vaccine Study Group. Pediatric Infectious Disease Journal. 2000 Jun;19 (6):516-21. PMID 10877165.

1259. Stratton KR, Howe CJ, Johnston RB, Jr. Adverse events associated with childhood vaccines other than pertussis and rubella. Summary of a report from the Institute of Medicine. JAMA. 1994 May 25;271 (20):1602-5. PMID 8182813.

1260. Su EL, Snape MD. A combination recombinant protein and outer membrane vesicle vaccine against serogroup B meningococcal disease. Expert Review of Vaccines. 2011 May;10 (5):575-88. PMID 2011292659 MEDLINE PMID 21604979 (http://www.ncbi.nlm.nih.gov/pubmed/21604979).

1261. Suarez E, Asturias EJ, Hilbert AK, Herzog C, Aeberhard U, Spyr C. A fully liquid DTPw-HepB-Hib combination vaccine for booster vaccination of toddlers in El Salvador. Pan American Journal of Public Health. 2010 Feb;27 (2):117-24. PMID 20339615.

1262. Surquin M, Tielemans C, Nortier J, et al. Anti-HBs antibody persistence following primary vaccination with an investigational AS02(v)-adjuvanted hepatitis B vaccine in patients with renal insufficiency. Human Vaccines. 2011 Sep;7 (9):913-8. PMID WOS:000295837200013.

1263. Surquin M, Tielemans CL, Kulcsar I, et al. Rapid, enhanced, and persistent protection of patients with renal insufficiency by AS02(V)-adjuvanted hepatitis B vaccine. Kidney International. 2010 Feb;77 (3):247-55. PMID WOS:000273573000013.

1264. Sutradhar SC, Wang WW, Schlienger K, et al. Comparison of the levels of immunogenicity and safety of Zostavax in adults 50 to 59 years old and in adults 60 years old or older. Clin Vaccine Immunol. 2009 May;16 (5):646-52. PMID 19261769.

1265. Sutter RW, John TJ, Jain H, et al. Immunogenicity of bivalent types 1 and 3 oral poliovirus vaccine: a randomised, double-blind, controlled trial. Lancet. 2010 Nov 13;376 (9753):1682-8. PMID 20980048.

1266. Szarewski A, Poppe WAJ, Skinner SR, et al. Efficacy of the human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine in women aged 15-25 years with and without serological evidence of previous exposure to HPV-16/18. International Journal of Cancer. 2012 1;131 (1):106-16. PMID 2012234980 MEDLINE PMID 21858807 (http://www.ncbi.nlm.nih.gov/pubmed/21858807).

1267. Szymczakiewicz-Multanowska A, Groth N, Bugarini R, et al. Safety and immunogenicity of a novel influenza subunit vaccine produced in mammalian cell culture. J Infect Dis. 2009 Sep 15;200 (6):841-8. PMID 19673651.

1268. Szynczewska E, Chlebna-Sokol D. Immunogenicity and safety of heptavalent conjugate vaccine against Streptococcus pneumoniae in pre-term Polish infants. Vaccine. 2011 Sep 16;29 (40):7107-13. PMID 21803093.

1269. Tager A. Preliminary report on the treatment of recurrent herpes simplex with poliomyelitis vaccine (Sabin's). Dermatologica. 1974 1974;149 (4):253-5. PMID 1975208668 MEDLINE PMID 4459181 (http://www.ncbi.nlm.nih.gov/pubmed/4459181).

1270. Talbot EA, Brown KH, Kirkland KB, Baughman AL, Halperin SA, Broder KR. The safety of immunizing with tetanus-diphtheria-acellular pertussis vaccine (Tdap) less than 2 years following previous tetanus vaccination: Experience during a mass vaccination campaign of healthcare personnel during a respiratory illness outbreak. Vaccine. 2010 Nov 23;28 (50):8001-7. PMID 20875487.

1271. Tamm E, Veronese A, Contorni M, Meriste S, Nacci P, Viviani S. Double-blind study

comparing the immunogenicity of a licensed DTwPHib-CRM197 conjugate vaccine (Quattvaxem) with three investigational, liquid formulations using lower doses of Hib-CRM197 conjugate. Vaccine. 2005 Feb 25;23 (14):1715-9. PMID 15705477.

1272. Tantawy AAG, Algohary EAM, El-Ghany SMA, Elhadary SF. Haemophilia A patients are not at increased risk of hepatitis A virus infection: An Egyptian experience. Egyptian Journal of Medical Human Genetics. 2012 February;13 (1):93-7. PMID 2012188878.

1273. Tate JE, Simonsen L, Viboud C, et al. Trends in intussusception hospitalizations among US infants, 1993-2004: implications for monitoring the safety of the new rotavirus vaccination program. Pediatrics. 2008 May;121 (5):e1125-32. PMID 18450856.

1274. Tate JE, Steele AD, Bines JE, Zuber PLF, Parashar UD. Research priorities regarding rotavirus vaccine and intussusception: a meeting summary. Vaccine. 2012 Apr 27;30 Suppl 1:A179-84. PMID 22520129.

1275. Tauber T, Lahat E, Dolinsky G, et al. Haemophilus influenza type b vaccine in Israel: Experience in a paediatric ambulatory clinic. Annals of Tropical Paediatrics. 2001 2001;21 (3):231-4. PMID 2001336384 MEDLINE PMID 11579861 (http://www.ncbi.nlm.nih.gov/pubmed/11579861).

1276. Tavares F, Delaigle A, Slavin D, Bauchau V, Fries L, Seifert H. Anaphylaxis following H1N1 pandemic vaccines: safety data in perspective. Vaccine. 2011 Aug 26;29 (37):6402-7. PMID 21527305.

1277. Taweesith W, Puthanakit T, Kowitdamrong E, et al. The immunogenicity and safety of live attenuated varicella-zoster virus vaccine in human immunodeficiency virus-infected children. Pediatric Infectious Disease Journal. 2011 Apr;30 (4):320-4. PMID 20975615.

1278. Taylor B, Lingam R, Simmons A, Stowe J, Miller E, Andrews N. Autism and MMR vaccination in North London; no causal relationship. Mol Psychiatry. 2002;7 Suppl 2:S7-8. PMID 12142932.

1279. Tejedor JC, Moro M, Merino JM, et al. Immunogenicity and reactogenicity of a booster dose of a novel combined Haemophilus influenzae type b-Neisseria meningitidis serogroup C-tetanus toxoid conjugate vaccine given to toddlers of 13-14 months of age with antibody persistence up to 31 months of age. Pediatric Infectious Disease Journal. 2008 Jul;27 (7):579-88. PMID 18536619.

1280. Tejedor JC, Moro M, Ruiz-Contreras J, et al. Immunogenicity and reactogenicity of primary immunization with a novel combined Haemophilus influenzae Type b and Neisseria meningitidis Serogroup C-tetanus toxoid conjugate vaccine coadministered with a Diphtheria-tetanus-acellular Pertussis-hepatitis B-inactivated poliovirus vaccine at 2, 4 and 6 months. Pediatric Infectious Disease Journal. 2007 Jan;26 (1):1-7. PMID 17195697.

1281. Tejedor JC, Moro M, Ruiz-Contreras J, et al. Immunogenicity and reactogenicity of

primary immunization with a hexavalent diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated polio-Haemophilus influenzae type B vaccine coadministered with two doses of a meningococcal C-tetanus toxoid conjugate vaccine. Pediatric Infectious Disease Journal. 2006 Aug;25 (8):713-20. PMID 16874171.

1282. Tejedor J-C, Omenaca F, Garcia-Sicilia J, et al. Antibody persistence after primary vaccination with a hexavalent DTPa-HBV-IPV/HiB vaccine coadministered with a meningococcal C-CRM197 vaccine and response to a DTPa-IPV/HiB booster at 18 months of age. Pediatric Infectious Disease Journal. 2006 Oct;25 (10):943-5. PMID 17006294.

1283. Tennis P, Toback SL, Andrews E, McQuay LJ, Ambrose CS. A postmarketing evaluation of the frequency of use and safety of live attenuated influenza vaccine use in nonrecommended children younger than 5 years. Vaccine. 2011 Jul 12;29 (31):4947-52. PMID 21596087.

1284. Tennis P, Toback SL, Andrews EB, McQuay LJ, Ambrose CS. A US postmarketing evaluation of the frequency and safety of live attenuated influenza vaccine use in nonrecommended children younger than 5 years: 2009-2010 season. Vaccine. 2012 Sep 14;30 (42):6099-102. PMID 22841479.

1285. Tennis P, Toback SL, Andrews EB, McQuay LJ, Ambrose CS. A US postmarketing evaluation of the frequency and safety of live attenuated influenza vaccine use in nonrecommended children younger than 5 years: 2009-2010 season. Vaccine. 2012;30 (42):6099-102.

1286. Tesng HF, Smith N, Sy LS, Jacobsen SJ. Evaluation of the incidence of herpes zoster after concomitant vaccination of a polysaccharide pneumococcal vaccine and a zoster vaccine. American Journal of Epidemiology. 2011 1;173 SUPPL. 11:S23.

1287. Thakur V, Pati NT, Gupta RC, Sarin SK. Efficacy of Shanvac-B recombinant DNA hepatitis B vaccine in health care workers of Northern India. Hepatobiliary & Pancreatic Diseases International. 2010 Aug;9 (4):393-7. PMID WOS:000280723700008.

1288. Thaler A. Miller Fisher syndrome in a 66-year-old female after flu and pneumovax vaccinations. Journal of the American Medical Directors Association. 2008 May;9 (4):283-4. PMID 18457810.

1289. Thanee C, Pancharoen C, Likitnukul S, et al. The immunogenicity and safety of pneumococcal conjugate vaccine in human immunodeficiency virus-infected Thai children. Vaccine. 2011 Aug 11;29 (35):5886-91. PMID 21729732.

1290. Theeten H, Rumke H, Hoppener FJP, et al. Primary vaccination of adults with reduced antigen-content diphtheria-tetanus-acellular pertussis or dTpa-inactivated poliovirus vaccines compared to diphtheria-tetanus-toxoid vaccines. Current Medical Research and Opinion. 2007 November;23 (11):2729-39. PMID 2007567879 MEDLINE PMID 17897485 (http://www.ncbi.nlm.nih.gov/pubmed/17897485).

1291. Thiem VD, Danovaro-Holliday MC, Canh DG, et al. The feasibility of a school-based VI polysaccharide vaccine mass immunization campaign in Hue City, central Vietnam: streamlining a typhoid fever preventive strategy. Southeast Asian Journal of Tropical Medicine & Public Health. 2006 May;37 (3):515-22. PMID 17120972.

1292. Thierry-Carstensen B, Jordan K, Uhlving HH, et al. A randomised, double-blind, non-inferiority clinical trial on the safety and immunogenicity of a tetanus, diphtheria and monocomponent acellular pertussis (TdaP) vaccine in comparison to a tetanus and diphtheria (Td) vaccine when given as booster vaccinations to healthy adults. Vaccine. 2012 Aug 10;30 (37):5464-71. PMID 22776216.

1293. Thisyakorn U, Chotpitayasunondh T, Pancharoen C, Chuenkitmongkol S, Ortiz E. Evaluation of an acellular pertussis, diphtheria, tetanus, inactivated poliovirus, Hib-conjugate combined vaccine (Pentaxim) at 2, 4, and 6 months of age plus hepatitis B vaccine at birth, 2, and 6 months of age in infants in Thailand. Southeast Asian Journal of Tropical Medicine & Public Health. 2010 Mar;41 (2):450-62. PMID 20578530.

1294. Thisyakorn U, Pancharoen C, Chuenkitmongkol S, Ortiz E. Immunogenicity and safety of a DTaP-IPV//PRP-T vaccine (Pentaxim) booster during the second year of life in Thai children primed with an acellular pertussis combined vaccine. Southeast Asian Journal of Tropical Medicine & Public Health. 2009 Mar;40 (2):282-94. PMID 19323013.

1295. Thomas C, Moridani M. Interindividual variations in the efficacy and toxicity of vaccines. Toxicology. 2010 5;278 (2):204-10. PMID 2010619280 MEDLINE PMID 19837123 (http://www.ncbi.nlm.nih.gov/pubmed/19837123).

1296. Thompson DF, Montarella KE. Drug-induced Sweet's syndrome. Annals of Pharmacotherapy. 2007 May;41 (5):802-11. PMID 2007238387 MEDLINE PMID 17426076 (http://www.ncbi.nlm.nih.gov/pubmed/17426076).

1297. Tichmann I, Preidel H, Grunert D, et al. Comparison of the immunogenicity and reactogenicity of two commercially available hexavalent vaccines administered as a primary vaccination course at 2, 4 and 6 months of age. Vaccine. 2005 May 9;23 (25):3272-9. PMID 15837232.

1298. Tichmann-Schumann I, Soemantri P, Behre U, et al. Immunogenicity and reactogenicity of four doses of diphtheria-tetanus-three-component acellular pertussis-hepatitis B-inactivated polio virus-Haemophilus influenzae type b vaccine coadministered with 7-valent pneumococcal conjugate Vaccine. Pediatric Infectious Disease Journal. 2005 Jan;24 (1):70-7. PMID 15665713.

1299. Tielemans CL, Vlasak J, Kosa D, et al. Immunogenicity and safety of an investigational AS02(v)-adjuvanted hepatitis B vaccine in patients with renal insufficiency who failed to respond or to maintain antibody levels after prior vaccination: Results of two open, randomized, comparative trials. Vaccine. 2011 Feb;29 (6):1159-66. PMID WOS:000287339800009.

1300. Tomljenovic L, Shaw CA. Aluminum Vaccine Adjuvants: Are they Safe? Current

Medicinal Chemistry. 2011 Jun;18 (17):2630-7. PMID WOS:000291645700011.

1301. Toneatto D, Ismaili S, Ypma E, Vienken K, Oster P, Dull P. The first use of an investigational multicomponent meningococcal serogroup B vaccine (4CMenB) in humans. Human Vaccines. 2011 Jun;7 (6):646-53. PMID 21904120.

1302. Toneatto D, Oster P, deBoer ACW, et al. Early clinical experience with a candidate meningococcal B recombinant vaccine (rMenB) in healthy adults. Human Vaccines. 2011 Jul;7 (7):781-91. PMID WOS:000294453300018.

1303. Toniolo-Neto J, Weckx LW, Halker E, et al. Safety of simultaneous pneumococcal and influenza vaccination in elderly patients in Brazil. Drugs & Aging. 1999;15 Suppl 1:43-5. PMID 10690795.

1304. Torano G, Toledo ME, Baly A, et al. Phase I clinical evaluation of a synthetic oligosaccharide-protein conjugate vaccine against Haemophilus influenzae type b in human adult volunteers. Clinical & Vaccine Immunology: CVI. 2006 Sep;13 (9):1052-6. PMID 16960118.

1305. Torling J, Hedlund J, Konradsen HB, Ortqvist A. Revaccination with the 23-valent pneumococcal polysaccharide vaccine in middle-aged and elderly persons previously treated for pneumonia. Vaccine. 2003 Dec 8;22 (1):96-103. PMID 14604576.

1306. Traversa G, Spila-Alegiani S, Bianchi C, et al. Sudden unexpected deaths and vaccinations during the first two years of life in Italy: A case series study. PLoS ONE [Electronic Resource]. 2011;6 (1) PMID 2011071441.

1307. Treanor J, Nolan C, O'Brien D, et al. Intranasal administration of a proteosome-influenza vaccine is well-tolerated and induces serum and nasal secretion influenza antibodies in healthy human subjects. Vaccine. 2006 Jan 16;24 (3):254-62. PMID 16129526.

1308. Tregnaghi M, Zambrano B, Santos-Lima E. Antibody persistence after a primary series of a new DTaP-IPV-Hep B-PRP-T combined vaccine or separate DTaP-IPV//PRP-T and hepatitis B vaccines at 2, 4, and 6 months of age and the effect of a subsequent DTaP-IPV//PRP-T booster vaccination at 18 months of age in healthy Argentinean infants. Pediatric Infectious Disease Journal. 2012 Jan;31 (1):e24-30. PMID 22157567.

1309. Tregnaghi MW, Stamboulian D, Vanadia PC, et al. Immunogenicity, Safety, and Tolerability of Two Trivalent Subunit Inactivated Influenza Vaccines: A Phase III, Observer-Blind, Randomized, Controlled Multicenter Study. Viral Immunology. 2012 Jun;25 (3):216-25. PMID 22691101.

1310. Tregnaghi MW, Voelker R, Santos-Lima E, Zambrano B. Immunogenicity and safety of a novel yeast Hansenula polymorpha-derived recombinant Hepatitis B candidate vaccine in healthy adolescents and adults aged 10-45 years. Vaccine. 2010 Apr;28 (20):3595-601. PMID WOS:000277882600014.

1311. Tregnaghi MW, Zambrano B, Santos-Lima E. Immunogenicity and safety of an investigational hexavalent diphtheria-tetanus-acellular pertussis-inactivated poliovirus-hepatitis B-haemophilus influenzae B conjugate combined vaccine in healthy 2-, 4-, and 6-month-old argentinean infants. Pediatric Infectious Disease Journal. 2011 June;30 (6):e88-e96. PMID 2011308075 MEDLINE PMID 21372751 (http://www.ncbi.nlm.nih.gov/pubmed/21372751).

1312. Tro-Baumann B, von Spiczak S, Lotte J, et al. A retrospective study of the relation between vaccination and occurrence of seizures in Dravet syndrome. Epilepsia. 2011 Jan;52 (1):175-8. PMID WOS:000286052800020.

1313. Trofa AF, Klein NP, Paul IM, et al. Immunogenicity and safety of an inactivated hepatitis A vaccine when coadministered with Diphtheria-tetanus-acellular pertussis and haemophilus influenzae type B vaccines in children 15 months of age. Pediatric Infectious Disease Journal. 2011 Sep;30 (9):e164-9. PMID 21494175.

1314. Trofa AF, Levin M, Marchant CD, Hedrick J, Blatter MM. Immunogenicity and safety of an inactivated hepatitis a vaccine administered concomitantly with a pneumococcal conjugate vaccine in healthy children 15 months of age. Pediatric Infectious Disease Journal. 2008 Jul;27 (7):658-60. PMID 18536623.

1315. Trollfors B, Taranger J, Lagergard T, et al. A placebo-controlled trial of a pertussis-toxoid vaccine. N Engl J Med. 1995 Oct 19;333 (16):1045-50. PMID 7675047.

1316. Tsai T, Kyaw MH, Novicki D, Nacci P, Rai S, Clemens R. Exposure to MF59-adjuvanted influenza vaccines during pregnancy--a retrospective analysis. Vaccine. 2010 Feb 17;28 (7):1877-80. PMID 19969117.

1317. Tseng HF, Smith N, Sy LS, Jacobsen SJ. Evaluation of the incidence of herpes zoster after concomitant administration of zoster vaccine and polysaccharide pneumococcal vaccine. Vaccine. 2011 09;29 (20):3628-32. PMID 2011226106 MEDLINE PMID 21435407 (http://www.ncbi.nlm.nih.gov/pubmed/21435407).

1318. Tudor-Williams G, Frankland J, Isaacs D, et al. Haemophilus influenzae type b conjugate vaccine trial in Oxford: implications for the United Kingdom. Archives of Disease in Childhood. 1989 Apr;64 (4):520-4. PMID 2665657.

1319. Tung J, Carlisle E, Smieja M, Kim PT, Lee CH. A randomized clinical trial of immunization with combined hepatitis A and B versus hepatitis B alone for hepatitis B seroprotection in hemodialysis patients. American Journal of Kidney Diseases. 2010 October;56 (4):713-9. PMID 2010514452 MEDLINE PMID 20630640 (http://www.ncbi.nlm.nih.gov/pubmed/20630640).

1320. Tuttle J, Chen RT, Rantala H, Cherry JD, Rhodes PH, Hadler S. The risk of Guillain-Barre syndrome after tetanus-toxoid-containing vaccines in adults and children in the United States. Am J Public Health. 1997 Dec;87 (12):2045-8. PMID 9431302.

1321. Tyring SK, Diaz-Mitoma F, Padget LG, et al. Safety and tolerability of a high-potency zoster vaccine in adults >/= 50 or years of age. Vaccine. 2007 Feb 26;25 (10):1877-83. PMID 17227688.

1322. Urschel S, Rieck BD, Birnbaum J, et al. Impaired cellular immune response to diphtheria and tetanus vaccines in children after thoracic transplantation. Pediatric Transplantation. 2011 May;15 (3):272-80. PMID WOS:000289628100014.

1323. Usonis V, Bakasenas V. Does concomitant injection of a combined diphtheria-tetanus-acellular pertussis - Hepatitis B virus - Inactivated polio virus vaccine influence the reactogenicity and immunogenicity of commercial Haemophilus influenzae type b conjugate vaccines? European Journal of Pediatrics. 1999 1999;158 (5):398-402. PMID 1999151332 MEDLINE PMID 10333123 (http://www.ncbi.nlm.nih.gov/pubmed/10333123).

1324. Uygungil B, Bleesing JJ, Risma KA, McNeal MM, Rothenberg ME. Persistent rotavirus vaccine shedding in a new case of severe combined immunodeficiency: A reason to screen. Journal of Allergy and Clinical Immunology. 2010 January;125 (1 3):270-1. PMID 2010008834 MEDLINE PMID 20109754 (http://www.ncbi.nlm.nih.gov/pubmed/20109754).

1325. Vadheim CM, Greenberg DP, Marcy SM, Froeschle J, Ward JI. Safety evaluation of PRP-D Haemophilus influenzae type b conjugate vaccine in children immunized at 18 months of age and older: follow-up study of 30,000 children. Pediatric Infectious Disease Journal. 1990 Aug;9 (8):555-61. PMID 2235171.

1326. Vadheim CM, Greenberg DP, Partridge S, Jing J, Ward JI. Effectiveness and safety of an Haemophilus influenzae type b conjugate vaccine (PRP-T) in young infants. Kaiser-UCLA Vaccine Study Group. Pediatrics. 1993 Aug;92 (2):272-9. PMID 8337029.

1327. Vajo Z, Tamas F, Jankovics I. A reduced-dose seasonal trivalent influenza vaccine is safe and immunogenic in adult and elderly patients in a randomized controlled trial. Clinical & Vaccine Immunology: CVI. 2012 Mar;19 (3):313-8. PMID 22219315.

1328. Vajo Z, Tamas F, Sinka L, Jankovics I. Safety and immunogenicity of a 2009 pandemic influenza A H1N1 vaccine when administered alone or simultaneously with the seasonal influenza vaccine for the 2009-10 influenza season: a multicentre, randomised controlled trial. Lancet. 2010 Jan 2;375 (9708):49-55. PMID 20018367.

1329. Valenzuela MTB, Altuzarra RH, Trucco OA, et al. Immunogenicity of a 23-valent pneumococcal polysaccharide vaccine in elderly residents of a long-term care facility. Brazilian Journal of Infectious Diseases. 2007 June;11 (3):322-6. PMID 2007514334 MEDLINE PMID 17684633 (http://www.ncbi.nlm.nih.gov/pubmed/17684633).

1330. Van Damme P, Leroux-Roels G, Crasta P, Messier M, Jacquet JM, Van Herck K. Antibody persistence and immune memory in adults, 15 years after a three-dose schedule of a combined hepatitis A and B vaccine. Journal of Medical Virology. 2012 Jan;84 (1):11-7. PMID 22052690.

1331. Van Damme P, Moiseeva A, Marichev I, et al. Five years follow-up following two or three doses of a hepatitis B vaccine in adolescents aged 11-15 years: a randomised controlled study. BMC Infectious Diseases. 2010 Dec;10 PMID WOS:000285919800001.

1332. Van De Geijn EJ, Tukkie R, Van Philips LAM, Punt H. Bilateral optic neuritis with branch retinal artery occlusion associated with vaccination. Documenta Ophthalmologica. 1994 1994;86 (4):403-8. PMID 1994320637 MEDLINE PMID 7835178 (http://www.ncbi.nlm.nih.gov/pubmed/7835178).

1333. Van Der Velden AMT, Van Velzen-Blad H, Claessen AME, et al. The effect of ranitidine on antibody responses to polysaccharide vaccines in patients with B-cell chronic lymphocytic leukaemia. European Journal of Haematology. 2007 July;79 (1):47-52. PMID 2007315665 MEDLINE PMID 17532765 (http://www.ncbi.nlm.nih.gov/pubmed/17532765).

1334. Van Der Vliet D, Pepin S, Lambert M, et al. Similar immunogenicity and safety of the A/H1N1 2009 pandemic influenza strain when used as a monovalent or a trivalent vaccine. Human Vaccines. 2010 October;6 (10):823-8. PMID 2010646055.

1335. Van der Wielen M, Van Damme P. Pentavalent human-bovine (WC3) reassortant rotavirus vaccine in special populations: a review of data from the Rotavirus Efficacy and Safety Trial. European Journal of Clinical Microbiology & Infectious Diseases. 2008 Jul;27 (7):495-501. PMID 18351405.

1336. Van Heerbeek N, Straetemans M, Wiertsema SP, et al. Effect of combined pneumococcal conjugate and polysaccharide vaccination on recurrent otitis media with effusion. Pediatrics. 2006 March;117 (3):603-8. PMID 2007022278.

1337. Vanderkooi OG, Scheifele DW, Girgenti D, et al. Safety and immunogenicity of a 13-valent pneumococcal conjugate vaccine in healthy infants and toddlers given with routine pediatric vaccinations in Canada. Pediatric Infectious Disease Journal. 2012 January;31 (1):72-7. PMID 2012016969 MEDLINE PMID 21960186 (http://www.ncbi.nlm.nih.gov/pubmed/21960186).

1338. Velickovic Z, Jankovic D, Perovic M, et al. Problems in surveillance on safe immunization conducting in everyday practice. Medicinski Arhiv. 2010;64 (4):235-9. PMID 21246924.

1339. Venuta A. Acute arthritis associated with rotavirus gastroenteritis: An unusual extraintestinal manifestation of a common enteric pathogen. Journal of Clinical Rheumatology. 2012 January;18 (1):49. PMID 2012004694 MEDLINE PMID 22157276 (http://www.ncbi.nlm.nih.gov/pubmed/22157276).

1340. Verdijk P, Rots NY, Bakker WAM. Clinical development of a novel inactivated poliomyelitis vaccine based on attenuated Sabin poliovirus strains. Expert Review of Vaccines. 2011 May;10 (5):635-44. PMID 21604984.

1341. Verity CM, Stellitano LS, Winstone AM. The PIND study found no association between vaccination and autism in mitochondrial disease - correction. Developmental Medicine and Child Neurology. 2011 May;53 (5):477-. PMID 2011208743 MEDLINE PMID 21480875 (http://www.ncbi.nlm.nih.gov/pubmed/21480875).

1342. Vermeer-De Bondt PE, Van Der Maas NAT. The effect of age and dose number on the risk of collapse (hypotonic-hyporesponsive episode) after pertussis vaccination. Pediatric Infectious Disease Journal. 2008 April;27 (4):355-7. PMID 2008165788 MEDLINE PMID 18379375 (http://www.ncbi.nlm.nih.gov/pubmed/18379375).

1343. Vernacchio L, Bernstein H, Pelton S, et al. Effect of monophosphoryl lipid A (MPL(registered trademark)) on T-helper cells when administered as an adjuvant with pneumococcal-CRM(197) conjugate vaccine in healthy toddlers. Vaccine. 2002 1;20 (31 32):3658-67. PMID 2002381781 MEDLINE PMID 12399193 (http://www.ncbi.nlm.nih.gov/pubmed/12399193).

1344. Vernacchio L, Neufeld EJ, MacDonald K, et al. Combined schedule of 7-valent pneumococcal conjugate vaccine followed by 23-valent pneumococcal vaccine in children and young adults with sickle cell disease. Journal of Pediatrics. 1998 Aug;133 (2):275-8. PMID 9709721.

1345. Vesikari T. Rotavirus vaccines. Scandinavian Journal of Infectious Diseases. 2008;40 (9):691-5. PMID 19086243.

1346. Vesikari T, Becker T, Gajdos V, et al. Immunogenicity and safety of a two-dose regimen of a combined measles, mumps, rubella and varicella live vaccine (ProQuad((registered trademark))) in infants from 9 months of age. Vaccine. 2012 26;30 (20):3082-9. PMID 2012198189.

1347. Vesikari T, Block SL, Guerra F, et al. Immunogenicity, safety and reactogenicity of a mammalian cell-culture-derived influenza vaccine in healthy children and adolescents three to seventeen years of age. Pediatric Infectious Disease Journal. 2012 May;31 (5):494-500. PMID 22301476.

1348. Vesikari T, Forsten A, Herbinger K-H, et al. Safety and immunogenicity of an MF59([REGISTERED])-adjuvanted A/H5N1 pre-pandemic influenza vaccine in adults and the elderly. Vaccine. 2012 Feb 8;30 (7):1388-96. PMID 22192847.

1349. Vesikari T, Joensuu J. Review of rotavirus vaccine trials in Finland. Journal of Infectious Diseases. 1996 1996;174 (SUPPL. 1):S81-S7. PMID 1996270932 MEDLINE PMID 8752295 (http://www.ncbi.nlm.nih.gov/pubmed/8752295).

1350. Vesikari T, Joensuu J, Baer M, et al. Concurrent administration of rhesus rotavirus tetravalent (RRV-TV) vaccine with pentavalent diphtheria-pertussis-tetanus-Haemophilus influenzae b-inactivated polio and hepatitis B vaccines. Acta Paediatrica, International Journal of

Paediatrics. 1999 1999;88 (5):513-20. PMID 1999218140 MEDLINE PMID 10426173 (http://www.ncbi.nlm.nih.gov/pubmed/10426173).

1351. Vesikari T, Karvonen A, Bianco V, Van der Wielen M, Miller J. Tetravalent meningococcal serogroups A, C, W-135 and Y conjugate vaccine is well tolerated and immunogenic when co-administered with measles-mumps-rubella-varicella vaccine during the second year of life: An open, randomized controlled trial. Vaccine. 2011 Jun 6;29 (25):4274-84. PMID 21443965.

1352. Vesikari T, Karvonen A, Borrow R, et al. Results from a randomized clinical trial of coadministration of RotaTeq, a pentavalent rotavirus vaccine, and NeisVac-C, a meningococcal serogroup C conjugate vaccine. Clinical & Vaccine Immunology: CVI. 2011 May;18 (5):878-84. PMID 21389149.

1353. Vesikari T, Karvonen A, Korhonen T, et al. Immunogenicity of 10-Valent Pneumococcal Nontypeable Haemophilus Influenzae Protein D Conjugate Vaccine When Administered as Catch-up Vaccination to Children 7 Months to 5 Years of Age. Pediatric Infectious Disease Journal. 2011 Aug;30 (8):E130-E41. PMID WOS:000293064200001.

1354. Vesikari T, Karvonen A, Lindblad N, et al. Safety and immunogenicity of a booster dose of the 10-valent pneumococcal nontypeable Haemophilus influenzae protein D conjugate vaccine coadministered with measles-mumps-rubella-varicella vaccine in children aged 12 to 16 months. Pediatric Infectious Disease Journal. 2010 Jun;29 (6):e47-56. PMID 20508478.

1355. Vesikari T, Karvonen A, Prymula R, et al. Immunogenicity and safety of the human rotavirus vaccine Rotarix co-administered with routine infant vaccines following the vaccination schedules in Europe. Vaccine. 2010 Jul 19;28 (32):5272-9. PMID 20538094.

1356. Vesikari T, Knuf M, Wutzler P, et al. Oil-in-water emulsion adjuvant with influenza vaccine in young children. New England Journal of Medicine. 2011 Oct 13;365 (15):1406-16. PMID 21995388.

1357. Vesikari T, Martin JC, Liss CL, Liska V, Schodel FP, Bhuyan PK. Safety and Immunogenicity of a Modified Process Hepatitis B Vaccine in Healthy Infants. Pediatric Infectious Disease Journal. 2011 Jul;30 (7):E109-E13. PMID WOS:000291675100001.

1358. Vidal P, Reyna J, Saldana P, Richardson VL. Events temporarily associated with anti-influenza A (H1N1) vaccination in Mexico. Archives of Medical Research. 2011 Oct;42 (7):627-32. PMID 22036935.

1359. Vigano A, Giacomet V, Pariani E, et al. Long-term immunogenicity after one and two doses of a monovalent MF59-adjuvanted A/H1N1 Influenza virus vaccine coadministered with the seasonal 2009-2010 nonadjuvanted Influenza virus vaccine in HIV-infected children, adolescents, and young adults in a randomized controlled trial. Clinical & Vaccine Immunology: CVI. 2011 Sep;18 (9):1503-9. PMID 21795458.

1360. Vilella A, Dal-Re R, Simo D, et al. Reactogenicity profile of a combined hepatitis A and B vaccine in clinical practice: A naturalistic study in adult travellers. Vaccine. 2005 31;23 (19):2463-7. PMID 2005112501.

1361. von Kries R. Comment on B. Zinka et al., Unexplained cases of sudden infant death shortly after hexavalent vaccination. Vaccine. 2006 Jul 26;24 (31-32):5783-4; author reply 5-6. PMID 16081190.

1362. Von Spiczak S, Helbig I, Drechsel-Baeuerle U, et al. A retrospective population-based study on seizures related to childhood vaccination. Epilepsia. 2011 August;52 (8):1506-12. PMID 2011416874 MEDLINE PMID 21692791 (http://www.ncbi.nlm.nih.gov/pubmed/21692791).

1363. Waddington CS, Andrews N, Hoschler K, et al. Open-label, randomised, parallelgroup, multicentre study to evaluate the safety, tolerability and immunogenicity of an AS03(B)/oil-inwater emulsion-adjuvanted (AS03(B)) split-virion versus non-adjuvanted whole-virion H1N1 influenza vaccine in UK children 6 months to 12 years of age. Health Technology Assessment. 2010 2010;14 (46):1-496. PMID 2010587743 MEDLINE PMID 20923610 (http://www.ncbi.nlm.nih.gov/pubmed/20923610).

1364. Waddington CS, Walker WT, Oeser C, et al. Safety and immunogenicity of AS03B adjuvanted split virion versus non-adjuvanted whole virion H1N1 influenza vaccine in UK children aged 6 months-12 years: open label, randomised, parallel group, multicentre study. BMJ. 2010;340:c2649. PMID 20508026.

1365. Wade AG, Crawford GM, Pumford N, McConnachie A. Patient reported outcome data following influenza A (H1N1p) vaccination in the 2009-2010 season: web-based and telephone evaluation. Therapeutics & Clinical Risk Management. 2011;7:409-20. PMID 22076117.

1366. Waggie Z, Geldenhuys H, Sutter RW, et al. Randomized trial of type 1 and type 3 oral monovalent poliovirus vaccines in newborns in Africa. Journal of Infectious Diseases. 2012 Jan 15;205 (2):228-36. PMID 22158680.

1367. Waites KB, Canupp KC, Chen Y-Y, DeVivo MJ, Nahm MH. Revaccination of adults with spinal cord injury using the 23-valent pneumococcal polysaccharide vaccine. Journal of Spinal Cord Medicine. 2008;31 (1):53-9. PMID 18533412.

1368. Walker FJ, Singleton RJ, Bulkow LR, Strikas RA, Butler JC. Reactions after 3 or more doses of pneumococcal polysaccharide vaccine in adults in Alaska. Clinical Infectious Diseases. 2005 Jun 15;40 (12):1730-5. PMID 15909258.

1369. Walker RI. New vaccines against enteric bacteria for children in less developed countries. Expert Review of Vaccines. 2005 December;4 (6):807-12. PMID 2006012938 MEDLINE PMID 16372876 (http://www.ncbi.nlm.nih.gov/pubmed/16372876).

1370. Walker WT, de Whalley P, Andrews N, et al. H1N1 antibody persistence 1 year after

immunization with an adjuvanted or whole-virion pandemic vaccine and immunogenicity and reactogenicity of subsequent seasonal influenza vaccine: a multicenter follow-on study. Clinical Infectious Diseases. 2012 Mar 1;54 (5):661-9. PMID 22267719.

1371. Walter EB, Moggio MV, Drucker RP, Wilfert CM. Immunogenicity of Haemophilus b conjugate vaccine (meningococcal protein conjugate) in children with prior invasive Haemophilus influenzae type b disease. Pediatric Infectious Disease Journal. 1990 1990;9 (9):632-5. PMID 1990298120 MEDLINE PMID 2235187 (http://www.ncbi.nlm.nih.gov/pubmed/2235187).

1372. Walters JAE, Smith S, Poole P, Granger RH, Wood-Baker R. Injectable vaccines for preventing pneumococcal infection in patients with chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews. 2010 (11) PMID WOS:000284076200001.

1373. Wang IJ, Huang LM, Guo YL, Hsieh WS, Lin TJ, Chen PC. Haemophilus influenzae type b combination vaccines and atopic disorders: A prospective cohort study. Journal of the Formosan Medical Association. 2012.

1374. Ward RL, Bernstein DI. Rotarix: a rotavirus vaccine for the world. Clinical Infectious Diseases. 2009 Jan 15;48 (2):222-8. PMID 19072246.

1375. Watemberg N, Dagan R, Arbelli Y, et al. Safety and immunogenicity of Haemophilus type b-tetanus protein conjugate vaccine, mixed in the same syringe with diphtheria-tetanus-pertussis vaccine in young infants. Pediatric Infectious Disease Journal. 1991 Oct;10 (10):758-63. PMID 1945578.

1376. Waters O, Ahmad T. Opportunistic infections and vaccinations in IBD patients. Journal of Crohn's and Colitis. 2011 June;5 (3):263. PMID 2011269125 MEDLINE PMID 21575894 (http://www.ncbi.nlm.nih.gov/pubmed/21575894).

1377. Watson L, Wilson BJ, Waugh N. Pneumococcal polysaccharide vaccine: a systematic review of clinical effectiveness in adults. Vaccine. 2002 May;20 (17-18):2166-73. PMID WOS:000176092600003.

1378. Wei S-H, Chao Y-N, Huang S-E, Lee T-F, Chang L-Y. Adverse effects of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine in 6- to 7-year-old children. Pediatrics & Neonatology. 2011 Feb;52 (1):38-41. PMID 21385656.

1379. Weinberg A, Allshouse AA, MaWhinney S, et al. Responses to Hepatitis A Virus Vaccine in HIV-Infected Women: Effect of Hormonal Contraceptives and HIV Disease Characteristics. Jaids-Journal of Acquired Immune Deficiency Syndromes. 2012 May;60 (1):E15-E8. PMID WOS:000303112200003.

1380. Werther RL, Crawford NW, Boniface K, Kirkwood CD, Smart JM. Rotavirus vaccine induced diarrhea in a child with severe combined immune deficiency. Journal of Allergy and Clinical Immunology. 2009 September;124 (3):600. PMID 2009459042 MEDLINE PMID

19660805 (http://www.ncbi.nlm.nih.gov/pubmed/19660805).

1381. West DJ, Hesley TM, Jonas LC, et al. Safety and immunogenicity of a bivalent Haemophilus influenzae type b/hepatitis B vaccine in healthy infants. Hib-HB Vaccine Study Group. Pediatric Infectious Disease Journal. 1997 Jun;16 (6):593-9. PMID 9194110.

1382. West DJ, Hesley TM, Jonas LC, et al. Safety and immunogenicity of a bivalent haemophilus influenzae type b/hepatitis B vaccine in healthy infants. Pediatric Infectious Disease Journal. 1997 June;16 (6):593-9. PMID 1997182079 MEDLINE PMID 9194110 (http://www.ncbi.nlm.nih.gov/pubmed/9194110).

1383. Weston WM, Friedland LR, Wu X, Howe B. Immunogenicity and reactogenicity of co-administered tetanus-diphtheria-acellular pertussis (Tdap) and tetravalent meningococcal conjugate (MCV4) vaccines compared to their separate administration. Vaccine. 2011 29;29 (5):1017-22. PMID 2011043488 MEDLINE PMID 21134450 (http://www.ncbi.nlm.nih.gov/pubmed/21134450).

1384. Weston WM, Friedland LR, Wu XF, Howe B. Vaccination of adults 65 years of age and older with tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Boostrix (R)): Results of two randomized trials. Vaccine. 2012 Feb;30 (9):1721-8. PMID WOS:000301558200022.

1385. Weston WM, Klein NP. Kinrix: a new combination DTaP-IPV vaccine for children aged 4-6 years. Expert Review of Vaccines. 2008 Nov;7 (9):1309-20. PMID 18980534.

1386. Whelan J, Hahne S, Berbers G, Van Der Klis F, Wijnands Y, Boot H. Immunogenicity of a hexavalent vaccine co-administered with 7-valent pneumococcal conjugate vaccine: Findings from the national immunization program in the Netherlands. Human Vaccines and Immunotherapeutics. 2012 June;8 (6):743-8. PMID 2012397533.

1387. White CJ, Stinson D, Stachle B, et al. Measles, mumps, rubella, and varicella combination vaccine: Safety and immunogenicity alone and in combination with other vaccines given to children. Clinical Infectious Diseases. 1997 1997;24 (5):925-31. PMID 1997136850 MEDLINE PMID 9142794 (http://www.ncbi.nlm.nih.gov/pubmed/9142794).

1388. White CJ, Stinson D, Staehle B, et al. Measles, mumps, rubella, and varicella combination vaccine: safety and immunogenicity alone and in combination with other vaccines given to children. Measles, Mumps, Rubella, Varicella Vaccine Study Group. Clinical Infectious Diseases. 1997 May;24 (5):925-31. PMID 9142794.

1389. White SJ, Boldt KL, Holditch SJ, Poland GA, Jacobson RM. Measles, mumps, and rubella. Clinical Obstetrics and Gynecology. 2012 June;55 (2):550-9. PMID 2012239410.

1390. Whitney CG. The potential of pneumococcal conjugate vaccines for children. Pediatric Infectious Disease Journal. 2002 Oct;21 (10):961-70. PMID WOS:000178654300016.

1391. Whitney CG. New safety information for an old vaccine. Clinical Infectious Diseases. 2005 Jun 15;40 (12):1736-7. PMID 15909259.

1392. Wilhelm DJ, Paegle RD. Thrombocytopenic purpura and pneumonia following measles vaccination. American Journal of Diseases of Children. 1967 May;113 (5):534-7. PMID 6067240.

1393. Wilkin T, Lee JY, Lensing SY, et al. Safety and Immunogenicity of the Quadrivalent Human Papillomavirus Vaccine in HIV-1-Infected Men. Journal of Infectious Diseases. 2010 Oct;202 (8):1246-53. PMID WOS:000288250900014.

1394. Williams DJ, Hall M, Brogan TV, et al. Influenza Coinfection and Outcomes in Children With Complicated Pneumonia. Archives of Pediatrics & Adolescent Medicine. 2011 Jun;165 (6):506-12. PMID WOS:000291321000005.

1395. Williams SE, Klein NP, Halsey N, et al. Overview of the Clinical Consult Case Review of adverse events following immunization: Clinical Immunization Safety Assessment (CISA) network 2004-2009. Vaccine. 2011 16;29 (40):6920-7. PMID 2011489211 MEDLINE PMID 21801776 (http://www.ncbi.nlm.nih.gov/pubmed/21801776).

1396. Williams SE, Pahud BA, Vellozzi C, et al. Causality assessment of serious neurologic adverse events following 2009 H1N1 vaccination. Vaccine. 2011 Oct 26;29 (46):8302-8. PMID 21893148.

1397. Williamson R. The balance between privacy, safety and community health. Journal of Paediatrics & Child Health. 2003 Sep-Oct;39 (7):507-8. PMID 12969202.

1398. Wilson K, Hawken S. Incidence of adverse events in premature children following 2-mo vaccination. Human Vaccines and Immunotherapeutics. 2012 May;8 (5):592-5. PMID 2012397555.

1399. Wilson K, Hawken S, Potter BK, et al. Patterns of emergency room visits, admissions and death following recommended pediatric vaccinations-A population based study of 969,519 vaccination events. Vaccine. 2011 May;29 (21):3746-52. PMID WOS:000291072500009.

1400. Win KM, Aye M, Htay-Htay H, Safary A, Bock H. Comparison of separate and mixed administration of DTPw-HBV and Hib vaccines: Immunogenicity and reactogenicity profiles. International Journal of Infectious Diseases. 1997 1997;2 (2):79-84. PMID 1998084416.

1401. Wise RP, Salive ME, Braun MM, et al. Postlicensure safety surveillance for varicella vaccine.[Erratum appears in JAMA 2000 Dec 27;284(24):3129]. JAMA. 2000 Sep 13;284 (10):1271-9. PMID 10979114.

1402. Wiwanitkit V. Adverse effect in diabetic patients who get swine flu vaccination: Implication for vaccine safety. Diabetologia Croatica. 2010 2010;39 (2):79. PMID 2010579127.

1403. Wong SH, Lennon DR, Jackson CM, et al. Immunogenicity and tolerability in infants of a New Zealand epidemic strain meningococcal B outer membrane vesicle vaccine. Pediatric Infectious Disease Journal. 2009 May;28 (5):385-90. PMID 2009320834 MEDLINE PMID 19384263 (http://www.ncbi.nlm.nih.gov/pubmed/19384263).

1404. Wong-Chew RM, Garcia-Leon ML, Espinosa-Torres Torrija B, et al. Increasing the time of exposure to aerosol measles vaccine elicits an immune response equivalent to that seen in 9-month-old Mexican children given the same dose subcutaneously. Journal of Infectious Diseases. 2011 Aug 1;204 (3):426-32. PMID 21742842.

1405. Woo EJ, Ball R, Bostrom A, et al. Vaccine risk perception among reporters of autism after vaccination: Vaccine adverse event reporting system 1990-2001. American Journal of Public Health. 2004 June;94 (6):990-5. PMID 2004235158 MEDLINE PMID 15249304 (http://www.ncbi.nlm.nih.gov/pubmed/15249304).

1406. Woo EJ, Miller NB, Ball R. Adverse events after hepatitis A B combination vaccine. Vaccine. 2006 24;24 (14):2685-91. PMID 2006095770 MEDLINE PMID 16310295 (http://www.ncbi.nlm.nih.gov/pubmed/16310295).

1407. Woo EJ, Wise RP, Menschik D, et al. Thrombocytopenia after vaccination: Case reports to the US Vaccine Adverse Event Reporting System, 1990-2008. Vaccine. 2011 1;29 (6):1319-23. PMID 2011043528 MEDLINE PMID 21126606 (http://www.ncbi.nlm.nih.gov/pubmed/21126606).

1408. Wood N, McIntyre P, Wong M. Vaccination for the paediatrician. Journal of Paediatrics & Child Health. 2006 Nov;42 (11):665-73. PMID 17044892.

1409. Wood RA, Berger M, Dreskin SC, et al. An algorithm for treatment of patients with hypersensitivity reactions after vaccines. Pediatrics. 2008 September;122 (3):e771-e7. PMID 2009162190 MEDLINE PMID 18762513 (http://www.ncbi.nlm.nih.gov/pubmed/18762513).

1410. Wu J, Xu F, Lu L, et al. Safety and effectiveness of a 2009 H1N1 vaccine in Beijing. New England Journal of Medicine. 2010 16;363 (25):2416-23. PMID 2010690653 MEDLINE PMID 21158658 (http://www.ncbi.nlm.nih.gov/pubmed/21158658).

1411. Wu J, Zhong X, Li CKF, et al. Optimal vaccination strategies for 2009 pandemic H1N1 and seasonal influenza vaccines in humans. Vaccine. 2011 29;29 (5):1009-16. PMID 2011043487 MEDLINE PMID 21130194 (http://www.ncbi.nlm.nih.gov/pubmed/21130194).

1412. Wuorimaa T, Dagan R, Eskola J, et al. Tolerability and immunogenicity of an eleven-valent pneumococcal conjugate vaccine in healthy toddlers. Pediatric Infectious Disease Journal. 2001 Mar;20 (3):272-7. PMID 11303829.

1413. Wuorimaa T, Kayhty H, Leroy O, Eskola J. Tolerability and immunogenicity of an 11-valent pneumococcal conjugate vaccine in adults. Vaccine. 2001 Feb 28;19 (15-16):1863-9. PMID 11228355.

1414. Wysocki J, Tansey S, Brachet E, et al. Randomised, controlled trial of concomitant pneumococcal and meningococcal conjugate vaccines. Vaccine. 2010 16;28 (49):7779-86. PMID 2010629451 MEDLINE PMID 20883736 (http://www.ncbi.nlm.nih.gov/pubmed/20883736).

1415. Xu S, Zhang L, Nelson JC, et al. Identifying optimal risk windows for self-controlled case series studies of vaccine safety. Statistics in Medicine. 2011 Mar 30;30 (7):742-52. PMID 21394750.

1416. Yacoub H, Khan H, Islam S, Souayah N. Guillain-Barre Syndrome after Influenza Vaccination in the United States. A Report from the CDC/FDA Vaccine Adverse Event Reporting System. (1990-2009). Neurology. 2010 Mar;74 (9):A524-A. PMID WOS:000275274002508.

1417. Yanagisawa N, Maeda K, Ajisawa A, et al. Reduced immune response to influenza A (H1N1) 2009 monovalent vaccine in HIV-infected Japanese subjects. Vaccine. 2011 Aug 5;29 (34):5694-8. PMID 21689709.

1418. Yeager DP, Toy EC, Baker B, 3rd. Influenza vaccination in pregnancy. Am J Perinatol. 1999;16 (6):283-6. PMID 10586981.

1419. Yee SS, Dutta PR, Solin LJ, Vapiwala N, Kao GD. RE: Efficacy and safety of influenza vaccination during chemotherapy treatment. Journal of Supportive Oncology. 2010 November-December;8 (6):272. PMID 2011042975.

1420. Yeh SH, Gurtman A, Hurley DC, et al. Immunogenicity and safety of 13-Valent pneumococcal conjugate vaccine in infants and toddlers. Pediatrics. 2010 September;126 (3):e493-e505. PMID 2010480679 MEDLINE PMID 20732948 (http://www.ncbi.nlm.nih.gov/pubmed/20732948).

1421. Yeh SJ, Huang LM, Chen JM, et al. Safety and immunogenicity of a conjugated Haemophilus influenzae type B polysaccharide-Neisseria meningitidis outer membrane protein vaccine. Journal of the Formosan Medical Association. 1997 Feb;96 (2):110-5. PMID 9071836.

1422. Yen C, Tate JE, Steiner CA, Cortese MM, Patel MM, Parashar UD. Trends in intussusception hospitalizations among US infants before and after implementation of the rotavirus vaccination program, 2000-2009. Journal of Infectious Diseases. 2012 1;206 (1):41-8. PMID 2012308445 MEDLINE PMID 22539812 (http://www.ncbi.nlm.nih.gov/pubmed/22539812).

1423. Yogev R, Arditi M, Chadwick EG, Amer MD, Sroka PA. Haemophilus influenzae type b conjugate vaccine (meningococcal protein conjugate): immunogenicity and safety at various doses. Pediatrics. 1990 Apr;85 (4 Pt 2):690-3. PMID 2107520.

1424. Yong M, Schoonen WM, Li L, et al. Epidemiology of paediatric immune thrombocytopenia in the General Practice Research Database. British Journal of Haematology.

2010 June;149 (6):855-64. PMID 2010294294 MEDLINE PMID 20377590 (http://www.ncbi.nlm.nih.gov/pubmed/20377590).

1425. Young HA, Geier DA, Geier MR. Thimerosal exposure in infants and neurodevelopmental disorders: an assessment of computerized medical records in the Vaccine Safety Datalink. Journal of the Neurological Sciences. 2008 Aug 15;271 (1-2):110-8. PMID 18482737.

1426. Youngster I, Kozer E, Lazarovitch Z, Broide E, Goldman M. Probiotics and the immunological response to infant vaccinations: a prospective, placebo controlled pilot study. Archives of Disease in Childhood. 2011 Apr;96 (4):345-9. PMID 21266337.

1427. Yousef E, Mannan S. Systemic reaction to pneumococcal vaccine: how common in pediatrics? Allergy & Asthma Proceedings. 2008 Jul-Aug;29 (4):397-9. PMID 18702888.

1428. Yuen SK, Wong ML, Chan YK, Chow CK, Tse MW. SIADH After Influenza Vaccination. Hong Kong Journal of Nephrology. 2010 April;12 (1):39-40. PMID 2010239032.

1429. Yuksel N, Beyazova U, Balci IF, et al. Immunogenicity of a Haemophilus influenzae type b-tetanus conjugate vaccine when administered separately or in combined vaccines for primary immunization in two consecutive national schedules in Turkey. International Journal of Infectious Diseases. 2012 May;16 (5):E354-E7. PMID WOS:000302784000007.

1430. Zafrir Y, Agmon-Levin N, Paz Z, Shilton T, Shoenfeld Y. Autoimmunity following Hepatitis B vaccine as part of the spectrum of 'Autoimmune (Auto-inflammatory) Syndrome induced by Adjuvants' (ASIA): Analysis of 93 cases. Lupus. 2012 February;21 (2):146-52. PMID 2012029364.

1431. Zaman K, Roy E, Arifeen SE, et al. Effectiveness of maternal influenza immunization in mothers and infants. New England Journal of Medicine. 2008 9;359 (15):1555-64. PMID 2008479892 MEDLINE PMID 18799552 (http://www.ncbi.nlm.nih.gov/pubmed/18799552).

1432. Zanardi LR, Haber P, Mootrey GT, Niu MT, Wharton M. Intussusception among recipients of rotavirus vaccine: reports to the vaccine adverse event reporting system. Pediatrics. 2001 Jun;107 (6):E97. PMID 11389295.

1433. Zanetti A, Parlato A, Romano L, et al. Challenge with a hepatitis B vaccine in two cohorts of 4-7-year-old children primed with hexavalent vaccines: An open-label, randomised trial in Italy. Vaccine. 2012 24;30 (39):5770-5. PMID 2012477027.

1434. Zangwill KM, Eriksen E, Lee M, et al. A population-based, postlicensure evaluation of the safety of a combination diphtheria, tetanus, acellular pertussis, hepatitis B, and inactivated poliovirus vaccine in a large managed care organization. Pediatrics. 2008 Dec;122 (6):e1179-85. PMID 19047220.

1435. Zangwill KM, Greenberg DP, Chiu C-Y, et al. Safety and immunogenicity of a

heptavalent pneumococcal conjugate vaccine in infants. Vaccine. 2003 May 16;21 (17-18):1894-900. PMID 12706674.

1436. Zangwill KM, Yeh SH, Wong EJ, et al. Paralytic Syndromes in Children: Epidemiology and Relationship to Vaccination. Pediatric Neurology. 2010 March;42 (3):206-12. PMID 2010099397 MEDLINE PMID 20159431 (http://www.ncbi.nlm.nih.gov/pubmed/20159431).

1437. Zastrow A, Schnitzler P, Eckerle I, Herzog W, Friederich HC. Immunogenicity and Safety of H1N1 Vaccination in Anorexia Nervosa-Results from a Pilot Study. International Journal of Eating Disorders. 2012 January;45 (1):146-9. PMID 2011697169 MEDLINE PMID 22170028 (http://www.ncbi.nlm.nih.gov/pubmed/22170028).

1438. Zent O, Arras-Reiter C, Broeker M, Hennig R. Immediate allergic reactions after vaccinations - A post-marketing surveillance review. European Journal of Pediatrics. 2002 2002;161 (1):21-5. PMID 2002013131 MEDLINE PMID 11808876 (http://www.ncbi.nlm.nih.gov/pubmed/11808876).

1439. Zepp F, Behre U, Kindler K, et al. Immunogenicity and safety of a tetravalent measles-mumps-rubella-varicella vaccine co-administered with a booster dose of a combined diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus-Haemophilus influenzae type b conjugate vaccine in healthy children aged 12-23 months. European Journal of Pediatrics. 2007 Aug;166 (8):857-64. PMID 17541639.

1440. Zepp F, Knuf M, Heininger U, et al. Safety, reactogenicity and immunogenicity of a combined hexavalent tetanus, diphtheria, acellular pertussis, hepatitis B, inactivated poliovirus vaccine and Haemophilus influenzae type b conjugate vaccine, for primary immunization of infants. Vaccine. 2004 Jun 2;22 (17-18):2226-33. PMID 15149781.

1441. Zepp F, Schuind A, Meyer C, Sanger R, Kaufhold A, Willems P. Safety and reactogenicity of a novel DTPa-HBV-IPV combined vaccine given along with commercial Hib vaccines in comparison with separate concomitant administration of DTPa, Hib, and OPV vaccines in infants. Pediatrics. 2002 Apr;109 (4):e58. PMID 11927731.

1442. Zhang Z-L, Zhu X-J, Wang X, et al. Interchangeability and tolerability of two inactivated hepatitis A vaccines in Chinese children. Vaccine. 2012 Jun 8;30 (27):4028-33. PMID 22537990.

1443. Zheng H, Chen Y, Wang F, et al. Comparing live attenuated and inactivated hepatitis A vaccines: an immunogenicity study after one single dose. Vaccine. 2011 Nov 8;29 (48):9098-103. PMID 21875638.

1444. Zheteyeva YA, Moro PL, Tepper NK, et al. Adverse event reports after tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccines in pregnant women. American Journal of Obstetrics and Gynecology. 2012 July;207 (1):59.e1-.e7. PMID 2012357312.

1445. Zickafoose JS, Benneyworth BD, Riebschleger MP, Espinosa CM, Davis MM.

Hospitalizations for intussusception before and after the reintroduction of rotavirus vaccine in the United States. Archives of Pediatrics & Adolescent Medicine. 2012 Apr;166 (4):350-5. PMID 22213609.

1446. Zielen S, Buhring I, Strnad N, Reichenbach J, Hofmann D. Immunogenicity and tolerance of a 7-valent pneumococcal conjugate vaccine in nonresponders to the 23-valent pneumococcal vaccine. Infection & Immunity. 2000 Mar;68 (3):1435-40. PMID 10678957.

1447. Zimmerman RK, Middleton DB, Burns IT, Clover RD, Kimmel SR. Routine vaccines across the life span, 2007. Journal of Family Practice. 2007 Feb;56 (2 Suppl Vaccines):S18-37, C1-3. PMID 17270108.

1448. Zinka B, Rauch E, Buettner A, Rueff F, Penning R. Unexplained cases of sudden infant death shortly after hexavalent vaccination. Vaccine. 2006 Jul 26;24 (31-32):5779-80. PMID 15908063.

1449. Zollinger WD, Boslego JE, Frasch CE, Froholm LO. Safety of vaccines containing meningococcal group B polysaccharide. Lancet. 1984 Jul 21;2 (8395):166. PMID 6146064.

1450. Zuccotti GV, Pariani E, Scaramuzza A, et al. Long-lasting immunogenicity and safety of a 2009 pandemic influenza A(H1N1) MF59-adjuvanted vaccine when co-administered with a 2009-2010 seasonal influenza vaccine in young patients with type 1 diabetes mellitus. Diabetic Medicine. 2011 Dec;28 (12):1530-6. PMID 21916971.

Rejected for Already included in the IOM Report – 64

1. Infections and vaccinations as risk factors for childhood type I (insulin-dependent) diabetes mellitus: a multicentre case-control investigation. EURODIAB Substudy 2 Study Group. Diabetologia. 2000 Jan;43 (1):47-53. PMID 10663215.

2. The safety of inactivated influenza vaccine in adults and children with asthma. N Engl J Med. 2001 Nov 22;345 (21):1529-36. PMID 11794219.

3. Abu-Shakra M, Zalmanson S, Neumann L, Flusser D, Sukenik S, Buskila D. Influenza virus vaccination of patients with systemic lupus erythematosus: effects on disease activity. J Rheumatol. 2000 Jul;27 (7):1681-5. PMID 10914851.

4. Ahlgren C, Toren K, Oden A, Andersen O. A population-based case-control study on viral infections and vaccinations and subsequent multiple sclerosis risk. Eur J Epidemiol. 2009;24 (9):541-52. PMID 19633994.

5. Altobelli E, Petrocelli R, Verrotti A, Valenti M. Infections and risk of type I diabetes in childhood: a population-based case-control study. Eur J Epidemiol. 2003;18 (5):425-30. PMID 12889689.

6. Andrews N, Stowe J, Miller E, Taylor B. Post-licensure safety of the meningococcal group C

conjugate vaccine. Hum Vaccin. 2007 Mar-Apr;3 (2):59-63. PMID 17312400.

7. Ashkenazi S, Vertruyen A, Aristegui J, et al. Superior relative efficacy of live attenuated influenza vaccine compared with inactivated influenza vaccine in young children with recurrent respiratory tract infections. Pediatr Infect Dis J. 2006 Oct;25 (10):870-9. PMID 17006279.

8. Barlow WE, Davis RL, Glasser JW, et al. The risk of seizures after receipt of whole-cell pertussis or measles, mumps, and rubella vaccine. N Engl J Med. 2001 Aug 30;345 (9):656-61. PMID 11547719.

9. Belshe RB, Edwards KM, Vesikari T, et al. Live attenuated versus inactivated influenza vaccine in infants and young children. N Engl J Med. 2007 Feb 15;356 (7):685-96. PMID 17301299.

10. Belshe RB, Nichol KL, Black SB, et al. Safety, efficacy, and effectiveness of live, attenuated, cold-adapted influenza vaccine in an indicated population aged 5-49 years. Clin Infect Dis. 2004 Oct 1;39 (7):920-7. PMID 15472840.

11. Bengtsson C, Kapetanovic MC, Kallberg H, et al. Common vaccinations among adults do not increase the risk of developing rheumatoid arthritis: results from the Swedish EIRA study. Ann Rheum Dis. 2010 Oct;69 (10):1831-3. PMID 20603497.

12. Benjamin CM, Chew GC, Silman AJ. Joint and limb symptoms in children after immunisation with measles, mumps, and rubella vaccine. BMJ. 1992 Apr 25;304 (6834):1075-8. PMID 1586818.

13. Bergen R, Black S, Shinefield H, et al. Safety of cold-adapted live attenuated influenza vaccine in a large cohort of children and adolescents. Pediatr Infect Dis J. 2004 Feb;23 (2):138-44. PMID 14872180.

14. Black S, Shinefield H, Ray P, et al. Risk of hospitalization because of aseptic meningitis after measles-mumps-rubella vaccination in one- to two-year-old children: an analysis of the Vaccine Safety Datalink (VSD) Project. Pediatr Infect Dis J. 1997 May;16 (5):500-3. PMID 9154545.

15. Blom L, Nystrom L, Dahlquist G. The Swedish childhood diabetes study. Vaccinations and infections as risk determinants for diabetes in childhood. Diabetologia. 1991 Mar;34 (3):176-81. PMID 1884889.

16. Bueving HJ, Bernsen RM, de Jongste JC, et al. Does influenza vaccination exacerbate asthma in children? Vaccine. 2004 Nov 15;23 (1):91-6. PMID 15519712.

17. Burwen DR, Ball R, Bryan WW, et al. Evaluation of Guillain-Barre Syndrome among recipients of influenza vaccine in 2000 and 2001. Am J Prev Med. 2010 Oct;39 (4):296-304. PMID 20837279.

18. Chen RT, Moses JM, Markowitz LE, Orenstein WA. Adverse events following measles-mumps-rubella and measles vaccinations in college students. Vaccine. 1991 May;9 (5):297-9. PMID 1872012.

19. Confavreux C, Suissa S, Saddier P, Bourdes V, Vukusic S. Vaccinations and the risk of relapse in multiple sclerosis. Vaccines in Multiple Sclerosis Study Group. N Engl J Med. 2001 Feb 1;344 (5):319-26. PMID 11172162.

20. De Serres G, Skowronski DM, Guay M, et al. Recurrence risk of oculorespiratory syndrome after influenza vaccination: randomized controlled trial of previously affected persons. Arch Intern Med. 2004 Nov 8;164 (20):2266-72. PMID 15534165.

21. Del Porto F, Lagana B, Biselli R, et al. Influenza vaccine administration in patients with systemic lupus erythematosus and rheumatoid arthritis. Safety and immunogenicity. Vaccine. 2006 Apr 12;24 (16):3217-23. PMID 16466833.

22. DeStefano F, Mullooly JP, Okoro CA, et al. Childhood vaccinations, vaccination timing, and risk of type 1 diabetes mellitus. Pediatrics. 2001 Dec;108 (6):E112. PMID 11731639.

23. DeStefano F, Verstraeten T, Jackson LA, et al. Vaccinations and risk of central nervous system demyelinating diseases in adults. Arch Neurol. 2003 Apr;60 (4):504-9. PMID 12707063.

24. Farrington P, Pugh S, Colville A, et al. A new method for active surveillance of adverse events from diphtheria/tetanus/pertussis and measles/mumps/rubella vaccines. Lancet. 1995 Mar 4;345 (8949):567-9. PMID 7619183.

25. Fleming DM, Crovari P, Wahn U, et al. Comparison of the efficacy and safety of live attenuated cold-adapted influenza vaccine, trivalent, with trivalent inactivated influenza virus vaccine in children and adolescents with asthma. Pediatr Infect Dis J. 2006 Oct;25 (10):860-9. PMID 17006278.

26. France EK, Glanz JM, Xu S, et al. Safety of the trivalent inactivated influenza vaccine among children: a population-based study. Arch Pediatr Adolesc Med. 2004 Nov;158 (11):1031-6. PMID 15520339.

27. Goodman MJ, Nordin JD, Harper P, Defor T, Zhou X. The safety of trivalent influenza vaccine among healthy children 6 to 24 months of age. Pediatrics. 2006 May;117 (5):e821-6. PMID 16651286.

28. Greene SK, Kulldorff M, Lewis EM, et al. Near real-time surveillance for influenza vaccine safety: proof-of-concept in the Vaccine Safety Datalink Project. Am J Epidemiol. 2010 Jan 15;171 (2):177-88. PMID 19965887.

29. Griffin MR, Ray WA, Mortimer EA, Fenichel GM, Schaffner W. Risk of seizures after measles-mumps-rubella immunization. Pediatrics. 1991 Nov;88 (5):881-5. PMID 1945626.

30. Hambidge SJ, Glanz JM, France EK, et al. Safety of trivalent inactivated influenza vaccine in children 6 to 23 months old. JAMA. 2006 Oct 25;296 (16):1990-7. PMID 17062862.

31. Heijstek MW, Pileggi GC, Zonneveld-Huijssoon E, et al. Safety of measles, mumps and rubella vaccination in juvenile idiopathic arthritis. Ann Rheum Dis. 2007 Oct;66 (10):1384-7. PMID 17284544.

32. Hernan MA, Jick SS, Olek MJ, Jick H. Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. Neurology. 2004 Sep 14;63 (5):838-42. PMID 15365133.

33. Hocine MN, Farrington CP, Touze E, et al. Hepatitis B vaccination and first central nervous system demyelinating events: reanalysis of a case-control study using the self-controlled case series method. Vaccine. 2007 Aug 1;25 (31):5938-43. PMID 17597263.

34. Holvast A, Stegeman CA, Benne CA, et al. Wegener's granulomatosis patients show an adequate antibody response to influenza vaccination. Ann Rheum Dis. 2009 Jun;68 (6):873-8. PMID 18625625.

35. Huang WT, Gargiullo PM, Broder KR, et al. Lack of association between acellular pertussis vaccine and seizures in early childhood. Pediatrics. 2010 Aug;126 (2):263-9. PMID 20643726.

36. Hughes RA, Charlton J, Latinovic R, Gulliford MC. No association between immunization and Guillain-Barre syndrome in the United Kingdom, 1992 to 2000. Arch Intern Med. 2006 Jun 26;166 (12):1301-4. PMID 16801513.

37. Hurwitz ES, Schonberger LB, Nelson DB, Holman RC. Guillain-Barre syndrome and the 1978-1979 influenza vaccine. N Engl J Med. 1981 Jun 25;304 (26):1557-61. PMID 7231501.

38. Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. Childhood vaccination and type 1 diabetes. N Engl J Med. 2004 Apr 1;350 (14):1398-404. PMID 15070789.

39. Juurlink DN, Stukel TA, Kwong J, et al. Guillain-Barre syndrome after influenza vaccination in adults: a population-based study. Arch Intern Med. 2006 Nov 13;166 (20):2217-21. PMID 17101939.

40. Klein NP, Hansen J, Lewis E, et al. Post-marketing safety evaluation of a tetanus toxoid, reduced diphtheria toxoid and 3-component acellular pertussis vaccine administered to a cohort of adolescents in a United States health maintenance organization. Pediatr Infect Dis J. 2010 Jul;29 (7):613-7. PMID 20190673.

41. Kmiecik T, Arnoux S, Kobryn A, Gorski P. Influenza vaccination in adults with asthma: safety of an inactivated trivalent influenza vaccine. J Asthma. 2007 Dec;44 (10):817-22. PMID 18097856.

42. Madsen KM, Hviid A, Vestergaard M, et al. A population-based study of measles, mumps, and rubella vaccination and autism. N Engl J Med. 2002 Nov 7;347 (19):1477-82. PMID

12421889.

43. Makela A, Nuorti JP, Peltola H. Neurologic disorders after measles-mumps-rubella vaccination. Pediatrics. 2002 Nov;110 (5):957-63. PMID 12415036.

44. Miller AE, Morgante LA, Buchwald LY, et al. A multicenter, randomized, double-blind, placebo-controlled trial of influenza immunization in multiple sclerosis. Neurology. 1997 Feb;48 (2):312-4. PMID 9040712.

45. Miller E, Andrews N, Stowe J, Grant A, Waight P, Taylor B. Risks of convulsion and aseptic meningitis following measles-mumps-rubella vaccination in the United Kingdom. Am J Epidemiol. 2007 Mar 15;165 (6):704-9. PMID 17204517.

46. Nicholson KG, Nguyen-Van-Tam JS, Ahmed AH, et al. Randomised placebo-controlled crossover trial on effect of inactivated influenza vaccine on pulmonary function in asthma. Lancet. 1998 Jan 31;351 (9099):326-31. PMID 9652613.

47. Pattison E, Harrison BJ, Griffiths CE, Silman AJ, Bruce IN. Environmental risk factors for the development of psoriatic arthritis: results from a case-control study. Ann Rheum Dis. 2008 May;67 (5):672-6. PMID 17823200.

48. Payne DC, Rose CE, Jr., Kerrison J, Aranas A, Duderstadt S, McNeil MM. Anthrax vaccination and risk of optic neuritis in the United States military, 1998-2003. Arch Neurol. 2006 Jun;63 (6):871-5. PMID 16769869.

49. Pedroza A, Huerta JG, Garcia Mde L, et al. The safety and immunogenicity of influenza vaccine in children with asthma in Mexico. Int J Infect Dis. 2009 Jul;13 (4):469-75. PMID 19084453.

50. Peltola H, Heinonen OP. Frequency of true adverse reactions to measles-mumps-rubella vaccine. A double-blind placebo-controlled trial in twins. Lancet. 1986 Apr 26;1 (8487):939-42. PMID 2871241.

51. Piedra PA, Gaglani MJ, Riggs M, et al. Live attenuated influenza vaccine, trivalent, is safe in healthy children 18 months to 4 years, 5 to 9 years, and 10 to 18 years of age in a community-based, nonrandomized, open-label trial. Pediatrics. 2005 Sep;116 (3):e397-407. PMID 16140685.

52. Ray P, Hayward J, Michelson D, et al. Encephalopathy after whole-cell pertussis or measles vaccination: lack of evidence for a causal association in a retrospective case-control study. Pediatr Infect Dis J. 2006 Sep;25 (9):768-73. PMID 16940831.

53. Scheifele DW, Duval B, Russell ML, et al. Ocular and respiratory symptoms attributable to inactivated split influenza vaccine: evidence from a controlled trial involving adults. Clin Infect Dis. 2003 Apr 1;36 (7):850-7. PMID 12652385.

54. Skowronski DM, De Serres G, Scheifele D, et al. Randomized, double-blind, placebo-controlled trial to assess the rate of recurrence of oculorespiratory syndrome following influenza vaccination among persons previously affected. Clin Infect Dis. 2003 Oct 15;37 (8):1059-66. PMID 14523770.

55. Smeeth L, Cook C, Fombonne E, et al. MMR vaccination and pervasive developmental disorders: a case-control study. Lancet. 2004 Sep 11-17;364 (9438):963-9. PMID 15364187.

56. Stowe J, Andrews N, Wise L, Miller E. Bell's palsy and parenteral inactivated influenza vaccine. Hum Vaccin. 2006 May-Jun;2 (3):110-2. PMID 17012908.

57. Stowe J, Andrews N, Wise L, Miller E. Investigation of the temporal association of Guillain-Barre syndrome with influenza vaccine and influenzalike illness using the United Kingdom General Practice Research Database. Am J Epidemiol. 2009 Feb 1;169 (3):382-8. PMID 19033158.

58. Tam CC, O'Brien SJ, Petersen I, Islam A, Hayward A, Rodrigues LC. Guillain-Barre syndrome and preceding infection with campylobacter, influenza and Epstein-Barr virus in the general practice research database. PLoS One. 2007;2 (4):e344. PMID 17406668.

59. Tata LJ, West J, Harrison T, Farrington P, Smith C, Hubbard R. Does influenza vaccination increase consultations, corticosteroid prescriptions, or exacerbations in subjects with asthma or chronic obstructive pulmonary disease? Thorax. 2003 Oct;58 (10):835-9. PMID 14514932.

60. Taylor B, Miller E, Farrington CP, et al. Autism and measles, mumps, and rubella vaccine: no epidemiological evidence for a causal association. Lancet. 1999 Jun 12;353 (9169):2026-9. PMID 10376617.

61. Vestergaard M, Hviid A, Madsen KM, et al. MMR vaccination and febrile seizures: evaluation of susceptible subgroups and long-term prognosis. JAMA. 2004 Jul 21;292 (3):351-7. PMID 15265850.

62. Ward KN, Bryant NJ, Andrews NJ, et al. Risk of serious neurologic disease after immunization of young children in Britain and Ireland. Pediatrics. 2007 Aug;120 (2):314-21. PMID 17671057.

63. Williams GW, Steinberg AD, Reinertsen JL, Klassen LW, Decker JL, Dolin R. Influenza immunization in systemic lupus eruthematosus. A double-blind trial. Ann Intern Med. 1978 Jun;88 (6):729-34. PMID 352210.

64. Yih WK, Nordin JD, Kulldorff M, et al. An assessment of the safety of adolescent and adult tetanus-diphtheria-acellular pertussis (Tdap) vaccine, using active surveillance for adverse events in the Vaccine Safety Datalink. Vaccine. 2009 Jul 9;27 (32):4257-62. PMID 19486957.

Rejected for IOM search identified, excluded – 84

1. Allsup S, Gosney M, Haycox A, Regan M. Cost-benefit evaluation of routine influenza immunisation in people 65-74 years of age. Health Technology Assessment (Winchester, England). 2003;7 (24):iii-x, 1-65. PMID 14499051.

2. Allsup S, Haycox A, Regan M, Gosney M. Is influenza vaccination cost effective for healthy people between ages 65 and 74 years? A randomised controlled trial. Vaccine. 2004 Dec 16;23 (5):639-45. PMID 15542184.

3. Allsup SJ, Gosney M, Regan M, Haycox A, Fear S, Johnstone FCW. Side effects of influenza vaccination in healthy older people: A randomised single-blind placebo-controlled trial. Gerontology. 2001 2001;47 (6):311-4. PMID 2001434764 MEDLINE PMID 11721144 (http://www.ncbi.nlm.nih.gov/pubmed/11721144).

4. Arnou R, Icardi G, De Decker M, et al. Intradermal influenza vaccine for older adults: a randomized controlled multicenter phase III study. Vaccine. 2009 Dec 9;27 (52):7304-12. PMID 19849996.

5. Ascherio A, Zhang SM, Hernan MA, et al. Hepatitis B vaccination and the risk of multiple sclerosis. N Engl J Med. 2001 Feb 1;344 (5):327-32. PMID 11172163.

6. Asturias EJ, Dueger EL, Omer SB, et al. Randomized trial of inactivated and live polio vaccine schedules in Guatemalan infants. Journal of Infectious Diseases. 2007 Sep 1;196 (5):692-8. PMID 17674310.

7. Avendano A, Ferreccio C, Lagos R, et al. Haemophilus influenzae type b polysaccharide-tetanus protein conjugate vaccine does not depress serologic responses to diphtheria, tetanus or pertussis antigens when coadministered in the same syringe with diphtheria-tetanus-pertussis vaccine at two, four and six months of age. Pediatric Infectious Disease Journal. 1993 Aug;12 (8):638-43. PMID 8414775.

8. Belshe RB, Ambrose CS, Yi T. Safety and efficacy of live attenuated influenza vaccine in children 2-7 years of age. Vaccine. 2008 Sep 12;26 Suppl 4:D10-6. PMID 18611422.

9. Belshe RB, Gruber WC, Mendelman PM, et al. Efficacy of vaccination with live attenuated, cold-adapted, trivalent, intranasal influenza virus vaccine against a variant (A/Sydney) not contained in the vaccine. J Pediatr. 2000 Feb;136 (2):168-75. PMID 10657821.

10. Belshe RB, Mendelman PM, Treanor J, et al. The efficacy of live attenuated, cold-adapted, trivalent, intranasal influenzavirus vaccine in children. N Engl J Med. 1998 May 14;338 (20):1405-12. PMID 9580647.

11. Belshe RB, Newman FK, Wilkins K, et al. Comparative immunogenicity of trivalent influenza vaccine administered by intradermal or intramuscular route in healthy adults. Vaccine. 2007 Sep 17;25 (37-38):6755-63. PMID 17692438.

12. Benke G, Abramson M, Raven J, Thien FCK, Walters EH. Asthma and vaccination history in a young adult cohort. Australian & New Zealand Journal of Public Health. 2004 Aug;28 (4):336-8. PMID 15704697.

13. Bernsen RMD, van der Wouden JC. Measles, mumps and rubella infections and atopic disorders in MMR-unvaccinated and MMR-vaccinated children. Pediatric Allergy & Immunology. 2008 Sep;19 (6):544-51. PMID 18266826.

14. Black C, Kaye JA, Jick H. MMR vaccine and idiopathic thrombocytopaenic purpura. Br J Clin Pharmacol. 2003 Jan;55 (1):107-11. PMID 12534647.

15. Black SB, Shinefield HR, France EK, et al. Effectiveness of influenza vaccine during pregnancy in preventing hospitalizations and outpatient visits for respiratory illness in pregnant women and their infants. American Journal of Perinatology. 2004 Aug;21 (6):333-9. PMID 15311370.

16. Block SL, Nolan T, Sattler C, et al. Comparison of the immunogenicity and reactogenicity of a prophylactic quadrivalent human papillomavirus (types 6, 11, 16, and 18) L1 virus-like particle vaccine in male and female adolescents and young adult women. Pediatrics. 2006 Nov;118 (5):2135-45. PMID 17079588.

17. Borcic B, Dobrovsak-Sourek V, Kaic B, Ljubicic M. A comparative study of reactogenicity and immunogenicity of an oral and an inactivated polio vaccine. Acta Medica Croatica. 1998;52 (3):155-8. PMID 9818437.

18. Carbone T, McEntire B, Kissin D, et al. Absence of an increase in cardiorespiratory events after diphtheria-tetanus-acellular pertussis immunization in preterm infants: a randomized, multicenter study. Pediatrics. 2008 May;121 (5):e1085-90. PMID 18450851.

19. Chiu SS, Peiris JS, Chan KH, Wong WH, Lau YL. Immunogenicity and safety of intradermal influenza immunization at a reduced dose in healthy children. Pediatrics. 2007 Jun;119 (6):1076-82. PMID 17545373.

20. Chuaychoo B, Wongsurakiat P, Nana A, Kositanont U, Maranetra KN. The immunogenicity of intradermal influenza vaccination in COPD patients. Vaccine. 2010 28;28 (24):4045-51. PMID 2010290747 MEDLINE PMID 20412877 (http://www.ncbi.nlm.nih.gov/pubmed/20412877).

21. Ciszewski A, Bilinska ZT, Brydak LB, et al. Influenza vaccination in secondary prevention from coronary ischaemic events in coronary artery disease: FLUCAD study. Eur Heart J. 2008 Jun;29 (11):1350-8. PMID 18187561.

22. Clements-Mann ML, Dudas R, Hoshino Y, et al. Safety and immunogenicity of live attenuated quadrivalent human-bovine (UK) reassortant rotavirus vaccine administered with childhood vaccines to infants. Vaccine. 2001 Sep 14;19 (32):4676-84. PMID 11535316.

23. De Villiers PJ, Steele AD, Hiemstra LA, et al. Efficacy and safety of a live attenuated influenza vaccine in adults 60 years of age and older. Vaccine. 2009 Dec 10;28 (1):228-34. PMID 19796721.

24. Deinard AS, Ogburn P, Jr. A/NJ/8/76 influenza vaccination program: effects on maternal health and pregnancy outcome. Am J Obstet Gynecol. 1981 Jun 1;140 (3):240-5. PMID 7246624.

25. DeStefano F, Bhasin TK, Thompson WW, Yeargin-Allsopp M, Boyle C. Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan atlanta. Pediatrics. 2004 Feb;113 (2):259-66. PMID 14754936.

26. Dockerty JD, Skegg DC, Elwood JM, Herbison GP, Becroft DM, Lewis ME. Infections, vaccinations, and the risk of childhood leukaemia. Br J Cancer. 1999 Jul;80 (9):1483-9. PMID 10424755.

27. Faden H, Duffy L. Effect of concurrent viral infection on systemic and local antibody responses to live attenuated and enhanced-potency inactivated poliovirus vaccines. American Journal of Diseases of Children. 1992 Nov;146 (11):1320-3. PMID 1415071.

28. Falsey AR, Treanor JJ, Tornieporth N, Capellan J, Gorse GJ. Randomized, double-blind controlled phase 3 trial comparing the immunogenicity of high-dose and standard-dose influenza vaccine in adults 65 years of age and older. J Infect Dis. 2009 Jul 15;200 (2):172-80. PMID 19508159.

29. Ferreccio C, Clemens J, Avendano A, et al. The clinical and immunologic response of Chilean infants to Haemophilus influenzae type b polysaccharide-tetanus protein conjugate vaccine coadministered in the same syringe with diphtheria-tetanus toxoids-pertussis vaccine at two, four and six months of age. Pediatric Infectious Disease Journal. 1991 Oct;10 (10):764-71. PMID 1945579.

30. France EK, Glanz J, Xu S, et al. Risk of immune thrombocytopenic purpura after measles-mumps-rubella immunization in children. Pediatrics. 2008 Mar;121 (3):e687-92. PMID 18310189.

31. Garland SM, Hernandez-Avila M, Wheeler CM, et al. Quadrivalent vaccine against human papillomavirus to prevent anogenital diseases. N Engl J Med. 2007 May 10;356 (19):1928-43. PMID 17494926.

32. Gatchalian S, Palestroque E, De Vleeschauwer I, et al. The development of a new heptavalent diphtheria-tetanus-whole cell pertussis-hepatitis B-Haemophilus influenzae type b-Neisseria meningitidis serogroups A and C vaccine: a randomized dose-ranging trial of the conjugate vaccine components. International Journal of Infectious Diseases. 2008 May;12 (3):278-88. PMID 2008187926 MEDLINE PMID 17981067 (http://www.ncbi.nlm.nih.gov/pubmed/17981067).

33. Giammanco G, Li Volti S, Mauro L, et al. Immune response to simultaneous administration of a recombinant DNA hepatitis B vaccine and multiple compulsory vaccines in infancy. Vaccine. 1991 1991;9 (10):747-50. PMID 1991287091 MEDLINE PMID 1836919 (http://www.ncbi.nlm.nih.gov/pubmed/1836919).

34. Gorse GJ, O'Connor TZ, Young SL, et al. Efficacy trial of live, cold-adapted and inactivated influenza virus vaccines in older adults with chronic obstructive pulmonary disease: A VA cooperative study. Vaccine. 2003 16;21 (17 18):2133-44. PMID 2003156566.

35. Govaert TM, Dinant GJ, Aretz K, Masurel N, Sprenger MJ, Knottnerus JA. Adverse reactions to influenza vaccine in elderly people: randomised double blind placebo controlled trial. BMJ. 1993 Oct 16;307 (6910):988-90. PMID 8241913.

36. Govaert TM, Dinant GJ, Aretz K, Masurel N, Sprenger MJ, Knottnerus JA. Adverse reactions to influenza vaccine in elderly people: randomised double blind placebo controlled trial. BMJ. 1993;307 (6910):988-90.

37. Greco D, Salmaso S, Mastrantonio P, et al. A controlled trial of two acellular vaccines and one whole-cell vaccine against pertussis. Progetto Pertosse Working Group. N Engl J Med. 1996 Feb 8;334 (6):341-8. PMID 8538704.

38. Grimprel E, Scott D, Laudat F, Baker S, Gruber W. Safety and Immunogenicity of a 13-valent Pneumococcal Conjugate Vaccine Given with Routine Pediatric Vaccination to Healthy Infants in France. Vaccine. 2008 PMID WOS:000268750600089.

39. Group FIS. Quadrivalent vaccine against human papillomavirus to prevent high-grade cervical lesions. N Engl J Med. 2007 May 10;356 (19):1915-27. PMID 17494925.

40. Group FIS. Quadrivalent vaccine against human papillomavirus to prevent high-grade cervical lesions - Supplemental Table. N Engl J Med. 2007 May 10;356 (19):1915-27.

41. Haberg SE, Trogstad L, Gunnes N, et al. Risk of Fetal Death after Pandemic Influenza Virus Infection or Vaccination. N Engl J Med. 2013 Jan 16 PMID 23323868.

42. Harper DM, Franco EL, Wheeler C, et al. Efficacy of a bivalent L1 virus-like particle vaccine in prevention of infection with human papillomavirus types 16 and 18 in young women: a randomised controlled trial. Lancet. 2004 Nov 13-19;364 (9447):1757-65. PMID 15541448.

43. Harper DM, Franco EL, Wheeler CM, et al. Sustained efficacy up to 4.5 years of a bivalent L1 virus-like particle vaccine against human papillomavirus types 16 and 18: follow-up from a randomised control trial. Lancet. 2006 Apr 15;367 (9518):1247-55. PMID 16631880.

44. Holland D, Booy R, De Looze F, et al. Intradermal influenza vaccine administered using a new microinjection system produces superior immunogenicity in elderly adults: a randomized controlled trial. J Infect Dis. 2008 Sep 1;198 (5):650-8. PMID 18652550.

45. Hurwitz EL, Morgenstern H. Effects of diphtheria-tetanus-pertussis or tetanus vaccination on allergies and allergy-related respiratory symptoms among children and adolescents in the United States. J Manipulative Physiol Ther. 2000 Feb;23 (2):81-90. PMID 10714532.

46. Khanlou H, Sanchez S, Babaie M, et al. The safety and efficacy of dose-sparing intradermal administration of influenza vaccine in human immunodeficiency virus-positive patients. Arch Intern Med. 2006 Jul 10;166 (13):1417. PMID 16832008.

47. Lasky T, Terracciano GJ, Magder L, et al. The Guillain-Barre syndrome and the 1992-1993 and 1993-1994 influenza vaccines. N Engl J Med. 1998 Dec 17;339 (25):1797-802. PMID 9854114.

48. Leroux-Roels I, Vets E, Freese R, et al. Seasonal influenza vaccine delivered by intradermal microinjection: A randomised controlled safety and immunogenicity trial in adults. Vaccine. 2008 Dec 2;26 (51):6614-9. PMID 18930093.

49. Mallol-Mesnard N, Menegaux F, Auvrignon A, et al. Vaccination and the risk of childhood acute leukaemia: The ESCALE study (SFCE). International Journal of Epidemiology. 2007 February;36 (1):110-6. PMID 2007341402 MEDLINE PMID 17227780 (http://www.ncbi.nlm.nih.gov/pubmed/17227780).

50. Margolis KL, Nichol KL, Poland GA, Pluhar RE. Frequency of adverse reactions to influenza vaccine in the elderly. A randomized, placebo-controlled trial. JAMA. 1990 Sep 5;264 (9):1139-41. PMID 2200894.

51. McKeever TM, Lewis SA, Smith C, Hubbard R. Vaccination and allergic disease: a birth cohort study. Am J Public Health. 2004 Jun;94 (6):985-9. PMID 15249303.

52. Miller C, Miller E, Rowe K, Bowie C, Judd M, Walker D. Surveillance of symptoms following MMR vaccine in children. Practitioner. 1989 Jan;233 (1461):69-73. PMID 2798288.

53. Miller E, Andrews N, Grant A, Stowe J, Taylor B. No evidence of an association between MMR vaccine and gait disturbance. Arch Dis Child. 2005 Mar;90 (3):292-6. PMID 15723921.

54. Miller E, Waight P, Farrington CP, Andrews N, Stowe J, Taylor B. Idiopathic thrombocytopenic purpura and MMR vaccine. Arch Dis Child. 2001 Mar;84 (3):227-9. PMID 11207170.

55. Monto AS, Ohmit SE, Petrie JG, et al. Comparative efficacy of inactivated and live attenuated influenza vaccines. N Engl J Med. 2009 Sep 24;361 (13):1260-7. PMID 19776407.

56. Moriniere BJ, van Loon FP, Rhodes PH, et al. Immunogenicity of a supplemental dose of oral versus inactivated poliovirus vaccine. Lancet. 1993 Jun 19;341 (8860):1545-50. PMID 8099637.

57. Munoz FM, Greisinger AJ, Wehmanen OA, et al. Safety of influenza vaccination during pregnancy. Am J Obstet Gynecol. 2005 Apr;192 (4):1098-106. PMID 15846187.

58. Munoz N, Manalastas R, Jr., Pitisuttithum P, et al. Safety, immunogenicity, and efficacy of quadrivalent human papillomavirus (types 6, 11, 16, 18) recombinant vaccine in women aged 24-45 years: a randomised, double-blind trial. Lancet. 2009 Jun 6;373 (9679):1949-57. PMID 19493565.

59. Murray DL, Imagawa DT, Okada DM, St Geme JW, Jr. Antibody response to monovalent A/New Jersey/8/76 influenza vaccine in pregnant women. J Clin Microbiol. 1979 Aug;10 (2):184-7. PMID 583151.

60. Nichol KL, Margolis KL, Lind A, et al. Side effects associated with influenza vaccination in healthy working adults - A randomized, placebo-controlled trial. Archives of Internal Medicine. 1996 Jul;156 (14):1546-50. PMID WOS:A1996UY33200007.

61. Nichol KL, Mendelman PM, Mallon KP, et al. Effectiveness of live, attenuated intranasal influenza virus vaccine in healthy, working adults: a randomized controlled trial. JAMA. 1999 Jul 14;282 (2):137-44. PMID 10411194.

62. Ohmit SE, Gross J, Victor JC, Monto AS. Reduced reaction frequencies with repeated inactivated or live-attenuated influenza vaccination. Vaccine. 2009 Feb 11;27 (7):1050-4. PMID 19095028.

63. Ohmit SE, Victor JC, Rotthoff JR, et al. Prevention of antigenically drifted influenza by inactivated and live attenuated vaccines. N Engl J Med. 2006 Dec 14;355 (24):2513-22. PMID 17167134.

64. Ohmit SE, Victor JC, Teich ER, et al. Prevention of symptomatic seasonal influenza in 2005-2006 by inactivated and live attenuated vaccines. J Infect Dis. 2008 Aug 1;198 (3):312-7. PMID 18522501.

65. Paavonen J, Jenkins D, Bosch FX, et al. Efficacy of a prophylactic adjuvanted bivalent L1 virus-like-particle vaccine against infection with human papillomavirus types 16 and 18 in young women: an interim analysis of a phase III double-blind, randomised controlled trial. Lancet. 2007 Jun 30;369 (9580):2161-70. PMID 17602732.

66. Paavonen J, Naud P, Salmeron J, et al. Efficacy of human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine against cervical infection and precancer caused by oncogenic HPV types (PATRICIA): final analysis of a double-blind, randomised study in young women. Lancet. 2009 Jul 25;374 (9686):301-14. PMID 19586656.

67. Patja A, Paunio M, Kinnunen E, Junttila O, Hovi T, Peltola H. Risk of Guillain-Barre syndrome after measles-mumps-rubella vaccination. J Pediatr. 2001 Feb;138 (2):250-4. PMID 11174624.

68. Perez G, Lazcano-Ponce E, Hernandez-Avila M, et al. Safety, immunogenicity, and efficacy of quadrivalent human papillomavirus (types 6, 11, 16, 18) L1 virus-like-particle vaccine in Latin American women. Int J Cancer. 2008 Mar 15;122 (6):1311-8. PMID 18000825.

69. Pichichero M, Casey J, Blatter M, et al. Comparative trial of the safety and immunogenicity of quadrivalent (A, C, Y, W-135) meningococcal polysaccharide-diphtheria conjugate vaccine versus quadrivalent polysaccharide vaccine in two- to ten-year-old children. Pediatric Infectious Disease Journal. 2005 Jan;24 (1):57-62. PMID 15665711.

70. Pichichero ME, Blatter MM, Kennedy WA, Hedrick J, Descamps D, Friedland LR. Acellular pertussis vaccine booster combined with diphtheria and tetanus toxoids for adolescents. Pediatrics. 2006 Apr;117 (4):1084-93. PMID 16585302.

71. Pichichero ME, DeTora LM, Johnson DR. An adolescent and adult formulation combined tetanus, diphtheria and five-component pertussis vaccine. Expert Review of Vaccines. 2006 2006;5 (2):175-87. PMID 2006375786 MEDLINE PMID 16608418 (http://www.ncbi.nlm.nih.gov/pubmed/16608418).

72. Reisinger KS, Block SL, Lazcano-Ponce E, et al. Safety and persistent immunogenicity of a quadrivalent human papillomavirus types 6, 11, 16, 18 L1 virus-like particle vaccine in preadolescents and adolescents: a randomized controlled trial. Pediatr Infect Dis J. 2007 Mar;26 (3):201-9. PMID 17484215.

73. Roost HP, Gassner M, Grize L, et al. Influence of MMR-vaccinations and diseases on atopic sensitization and allergic symptoms in Swiss schoolchildren. Pediatr Allergy Immunol. 2004 Oct;15 (5):401-7. PMID 15482514.

74. Rue-Cover A, Iskander J, Lyn SN, et al. Death and serious illness following influenza vaccination: a multidisciplinary investigation. Pharmacoepidemiology and Drug Safety. 2009 Jun;18 (6):504-11. PMID WOS:000267349300010.

75. Shinefield HR, Black SB, Staehle BO, et al. Safety, tolerability and immunogenicity of concomitant injections in separate locations of M-M-R II, VARIVAX and TETRAMUNE in healthy children vs. concomitant injections of M-M-R II and TETRAMUNE followed six weeks later by VARIVAX. Pediatric Infectious Disease Journal. 1998 Nov;17 (11):980-5. PMID 9849978.

76. Spitzer WO. Measles, mumps, and rubella vaccination and autism. N Engl J Med. 2003 Mar 6;348 (10):951-4; author reply -4. PMID 12622119.

77. Takahashi H, Suzumura S, Shirakizawa F, et al. An epidemiological study on Japanese autism concerning routine childhood immunization history. Japanese Journal of Infectious Diseases. 2003 Jun;56 (3):114-7. PMID 12944678.

78. Tam JS, Capeding MR, Lum LC, et al. Efficacy and safety of a live attenuated, cold-adapted influenza vaccine, trivalent against culture-confirmed influenza in young children in Asia.

Pediatr Infect Dis J. 2007 Jul;26 (7):619-28. PMID 17596805.

79. Taylor B, Miller E, Lingam R, Andrews N, Simmons A, Stowe J. Measles, mumps, and rubella vaccination and bowel problems or developmental regression in children with autism: population study. BMJ. 2002 Feb 16;324 (7334):393-6. PMID 11850369.

80. Touze E, Fourrier A, Rue-Fenouche C, et al. Hepatitis B vaccination and first central nervous system demyelinating event: a case-control study. Neuroepidemiology. 2002 Jul-Aug;21 (4):180-6. PMID 12065880.

81. Verstraeten T, Descamps D, David MP, et al. Analysis of adverse events of potential autoimmune aetiology in a large integrated safety database of AS04 adjuvanted vaccines. Vaccine. 2008 Dec 2;26 (51):6630-8. PMID 18845199.

82. Villa LL, Costa RL, Petta CA, et al. Prophylactic quadrivalent human papillomavirus (types 6, 11, 16, and 18) L1 virus-like particle vaccine in young women: a randomised double-blind placebo-controlled multicentre phase II efficacy trial. Lancet Oncol. 2005 May;6 (5):271-8. PMID 15863374.

83. Wilde JA, McMillan JA, Serwint J, Butta J, O'Riordan MA, Steinhoff MC. Effectiveness of influenza vaccine in health care professionals - A randomized trial. Jama-Journal of the American Medical Association. 1999 Mar;281 (10):908-13. PMID WOS:000078950600035.

84. Zhu FC, Wang H, Fang HH, et al. A novel influenza A (H1N1) vaccine in various age groups. N Engl J Med. 2009 Dec 17;361 (25):2414-23. PMID 19846844.

Rejected for No relevant groups (Vaccine and Population) – 28

1. Anderson EL, Belshe RB, Bartram J. Evaluation of rhesus rotavirus vaccine (MMU 18006) in infants and young children. Journal of Infectious Diseases. 1986 1986;153 (5):823-31. PMID 1986148918 MEDLINE PMID 3009633 (http://www.ncbi.nlm.nih.gov/pubmed/3009633).

2. Andrews N, Miller E, Grant A, Stowe J, Osborne V, Taylor B. Thimerosal exposure in infants and developmental disorders: A retrospective cohort study in the United Kingdom does not support a causal association. Pediatrics. 2004 September;114 (3):584-91. PMID 2005485136 MEDLINE PMID 15342825 (http://www.ncbi.nlm.nih.gov/pubmed/15342825).

3. Bernstein DI, Smith VE, Sherwood JR, et al. Safety and immnnogenicity of live, attenuated human rotavirus vaccine 89-12. Vaccine. 1998 Feb;16 (4):381-7. PMID 1998005804.

4. Chotpitayasunondh T, Panpitpat C, Thisyakorn U, et al. Safety and immunogenicity of a Haemophilus influenzae type B polysaccharide-tetanus toxoid conjugate vaccine combined with diphtheria, tetanus and pertussis vaccines in Thai infants. Southeast Asian Journal of Tropical Medicine & Public Health. 1997 Mar;28 (1):91-8. PMID 9322290.

5. Christy C, Madore HP, Treanor JJ. Safety and immunogenicity of live attenuated rhesus

monkey rotavirus vaccine. Journal of Infectious Diseases. 1986 1986;154 (6):1045-7. PMID 1987030898 MEDLINE PMID 3023497 (http://www.ncbi.nlm.nih.gov/pubmed/3023497).

6. Dagan R, Kassis I, Sarov B, et al. Safety and immunogenicity of oral tetravalent human-rhesus reassortant rotavirus vaccine in neonates. Pediatric Infectious Disease Journal. 1992 1992;11 (12):991-6. PMID 1992368170 MEDLINE PMID 1334255 (http://www.ncbi.nlm.nih.gov/pubmed/1334255).

7. Goto N, Kawaguchi T, Watarai Y, et al. A vaccine to prevent herpes zoster in kidney transplantion. American Journal of Transplantation. 2011 April;11 SUPPL. 2:43.

8. Hansen TS, Jess T, Vind I, et al. Environmental factors in inflammatory bowel disease: A case-control study based on a Danish inception cohort. Journal of Crohn's and Colitis. 2011 December;5 (6):577-84. PMID 2011652838 MEDLINE PMID 22115378 (http://www.ncbi.nlm.nih.gov/pubmed/22115378).

9. Harjulehto-Mervaala T, Hovi T, Aro T, Saxen H, Hiilesmaa VK. Oral poliovirus vaccination and pregnancy complications. Acta Obstetricia et Gynecologica Scandinavica. 1995 Apr;74 (4):262-5. PMID 7732798.

10. Joensuu J, Koskenniemi E, Pang XL, Vesikari T. Randomised placebo-controlled trial of rhesus-human reassortant rotavirus vaccine for prevention of severe rotavirus gastroenteritis. Lancet. 1997 Oct 25;350 (9086):1205-9. PMID 9652561.

11. Joensuu J, Koskenniemi E, Vesikaei T. Symptoms associated with rhesus-human reassortant rotavirus vaccine in infants. Pediatric Infectious Disease Journal. 1998 April;17 (4):334-40. PMID 1998151478 MEDLINE PMID 9576390 (http://www.ncbi.nlm.nih.gov/pubmed/9576390).

12. Lanata CF, Midthun K, Black RE, et al. Safety, immunogenicity, and protective efficacy of one and three doses of the tetravalent rhesus rotavirus vaccine in infants in Lima, Peru. Journal of Infectious Diseases. 1996 1996;174 (2):268-75. PMID 1996229392 MEDLINE PMID 8699054 (http://www.ncbi.nlm.nih.gov/pubmed/8699054).

13. Lehmann D, Pomat WS, Combs B, Dyke T, Alpers MP. Maternal immunization with pneumococcal polysaccharide vaccine in the highlands of Papua New Guinea. Vaccine. 2002 Mar 15;20 (13-14):1837-45. PMID 11906773.

14. Losonsky GA, Rennels MB, Kapikian AZ. Safety, infectivity, transmissibility and immunogenicity of rhesus rotavirus vaccine (MMU 18006) in infants. Pediatric Infectious Disease. 1986 1986;5 (1):25-9. PMID 1986099315 MEDLINE PMID 3003715 (http://www.ncbi.nlm.nih.gov/pubmed/3003715).

15. Mrukowicz JZ, Thompson J, Reed GW, et al. Epidemiology of rotavirus in infants and protection against symptomatic illness afforded by primary infection and vaccination. Vaccine. 1999 26;17 (7 8):745-53. PMID 1999058249 MEDLINE PMID 10067679

(http://www.ncbi.nlm.nih.gov/pubmed/10067679).

16. Murphy TV, Gargiullo PM, Massoudi MS, et al. Intussusception among infants given an oral rotavirus vaccine.[Erratum appears in N Engl J Med 2001 May 17;344(20):1564 Note: Livingood, JR [corrected to Livengood, JR]]. New England Journal of Medicine. 2001 Feb 22;344 (8):564-72. PMID 11207352.

17. Perez-Schael I, Blanco M, Garcia D, et al. Evaluation of the antigenicity and reactogenicity of varying formulations of the rhesus rotavirus-based quadrivalent and the M37 rotavirus vaccine candidates. Journal of Medical Virology. 1994 1994;42 (4):330-7. PMID 1994124733 MEDLINE PMID 8046423 (http://www.ncbi.nlm.nih.gov/pubmed/8046423).

18. Perez-Schael I, Guntinas MJ, Perez M, et al. Efficacy of the rhesus rotavirus-based quadrivalent vaccine in infants and young children in Venezuela.[Erratum appears in N Engl J Med 1998 Apr 2;338(14):1002]. New England Journal of Medicine. 1997 Oct 23;337 (17):1181-7. PMID 9337376.

19. Pichichero ME, Losonsky GA. Asymptomatic Infections Due to Wild-Type Rotavirus May Prime for a Heterotypic Response to Vaccination with Rhesus Rotavirus. Clinical Infectious Diseases. 1993 Jan;16 (1):86-92. PMID WOS:A1993KG11700014.

20. Pichichero ME, Losonsky GA, Rennels MB, et al. Effect of dose and a comparison of measures of vaccine take for oral rhesus rotavirus vaccine. Pediatric Infectious Disease Journal. 1990 1990;9 (5):339-44. PMID 1990157488 MEDLINE PMID 2162027 (http://www.ncbi.nlm.nih.gov/pubmed/2162027).

21. Quiambao BP, Nohynek HM, Kayhty H, et al. Immunogenicity and reactogenicity of 23-valent pneumococcal polysaccharide vaccine among pregnant Filipino women and placental transfer of antibodies. Vaccine. 2007 30;25 (22):4470-7. PMID 2007224745 MEDLINE PMID 17442467 (http://www.ncbi.nlm.nih.gov/pubmed/17442467).

22. Scott D, Ruckle J, Dar M, Baker S, Kondoh H, Lockhart S. Phase 1 trial of 13-valent pneumococcal conjugate vaccine in Japanese adults. Pediatrics International. 2008 Jun;50 (3):295-9. PMID 18533940.

23. Stermole BM, Grandits GA, Roediger MP, et al. Long-term safety and serologic response to measles, mumps, and rubella vaccination in HIV-1 infected adults. Vaccine. 2011 Apr 5;29 (16):2874-80. PMID 21352938.

24. Verstraeten T, Baughman AL, Cadwell B, et al. Enhancing vaccine safety surveillance: a capture-recapture analysis of intussusception after rotavirus vaccination. American Journal of Epidemiology. 2001 Dec 1;154 (11):1006-12. PMID 11724716.

25. Vesikari T, Rautanen T, Varis T, Beards GM, Kapikian AZ. Rhesus Rotavirus candidate vaccine. Clinical trial in children vaccinated between 2 and 5 months of age. American Journal of Diseases of Children. 1990 1990;144 (3):285-9. PMID 1990067394 MEDLINE PMID

2154925 (http://www.ncbi.nlm.nih.gov/pubmed/2154925).

26. Vesikari T, Varis T, Green K, Flores J, Kapikian AZ. Immunogenicity and safety of rhesus-human rotavirus reassortant vaccines with serotype 1 or 2 VP7 specificity. Vaccine. 1991 1991;9 (5):334-9. PMID 1991145801 MEDLINE PMID 1651610 (http://www.ncbi.nlm.nih.gov/pubmed/1651610).

27. Vodopija I, Baklaic Z, Vlatkovic R. Combined vaccination with live oral polio vaccine and the bovine rotavirus RIT 4237 strain. Vaccine. 1986 1986;4 (4):233-6. PMID 1987063773 MEDLINE PMID 3026106 (http://www.ncbi.nlm.nih.gov/pubmed/3026106).

28. Wacholder S, Chen BE, Wilcox A, et al. Risk of miscarriage with bivalent vaccine against human papillomavirus (HPV) types 16 and 18: Pooled analysis of two randomised controlled trials. Bmj. 2010;(2010) 340 (7748):696. PMID 2010199167.

Rejected for Correction to rejected study – 8

1. Erratum: Safety and efficacy of high-dose rhesus-human reassortant rotavirus vaccines - Report of the National Multicenter Trial (Pediatrics (1996) 97 (7-13)). Pediatrics. 1996 1996;98 (1):A38. PMID 1996204872.

2. Erratum: Intussusception among infants given an oral rotavirus vaccine (New England Journal of Medicine (Feb. 22, 2001) 344 (564-72)). New England Journal of Medicine. 2001 17;344 (20):1564. PMID 2001174517.

3. Chen J, Heyse JF, Heaton P. Erratum: Age dependence of the risk of intussusception following tetravalent rhesus-human reassortant rotavirus tetravalent vaccine: Is it beyond doubt? (American Journal of Epidemiology (2010) 171: 9 (1046-1054)). American Journal of Epidemiology. 2010 1-jul-2012;172 (1):125. PMID 2012350024.

4. Clark HF. Safety, efficacy, and immunogenicity of a live, quadrivalent human-bovine reassortant rotavirus vaccine in healthy infants (vol 144, pg 184, 2004). Journal of Pediatrics. 2004 Apr;144 (4):558-. PMID WOS:000220760600058.

5. Liang XF. Safety of Influenza A (H1N1) Vaccine in Postmarketing Surveillance in China (vol 364, pg 638, 2011). New England Journal of Medicine. 2011 Apr;364 (15):1481-. PMID WOS:000289467200040.

6. Liang XF, Wang HQ, Wang JZ. Safety and immunogenicity of 2009 pandemic influenza A H1N1 vaccines in China: a multicentre, double-blind, randomised, placebo-controlled trial. (vol 375, pg 56, 2010). Lancet. 2010 May;375 (9727):1694-. PMID WOS:000277890200029.

7. Livengood JR. Intussusception among infants given an oral rotavirus vaccine (vol 344, pg 564, 2001). New England Journal of Medicine. 2001 May;344 (20):1564-. PMID WOS:000168677200027.

8. Rennels, Fries S, Froehlich H. Safety and efficacy of high-dose rhesus-human reassortant rotavirus vaccines - Report of the National Multicenter Trial (vol 97, pg 7, 1996). Pediatrics. 1996 Jul;98 (1):A38-A. PMID WOS:A1996UU13700017.

Rejected for Duplicate publication - abstracted with original pub – 15

1. Ambrose CS, Dubovsky F, Yi T, Belshe RB, Ashkenazi S. The safety and efficacy of live attenuated influenza vaccine in young children with asthma or prior wheezing. European Journal of Clinical Microbiology and Infectious Diseases. 2012.

2. Bernsen RMD, Koes BW, de Jongste JC, van der Wouden JC. Haemophilus influenzae type b vaccination and reported atopic disorders in 8-12-year-old children. Pediatric Pulmonology. 2006 May;41 (5):463-9. PMID 16547964.

3. Buttery J. A rotavirus vaccine for infants prevented rotavirus gastroenteritis with no increase in risk of intussusception. Evidence-Based Medicine. 2006 Aug;11 (4):113. PMID 2006385636.

4. Castellsague X, Munoz N, Pitisuttithum P, et al. End-of-study safety, immunogenicity, and efficacy of quadrivalent HPV (types 6, 11, 16, 18) recombinant vaccine in adult women 24-45 years of age. British Journal of Cancer. 2011 Jun 28;105 (1):28-37. PMID 21629249.

5. Dennehy PH, Goveia MG, Dallas MJ, Heaton PM. The integrated phase III safety profile of the pentavalent human-bovine (WC3) reassortant rotavirus vaccine. International Journal of Infectious Diseases. 2007 Nov;11 Suppl 2:S36-42. PMID 18162245.

6. Ebell M. Oral rotavirus vaccines are safe and effective in children. American Family Physician. 2006 May;73 (10):1814-. PMID WOS:000237676800016.

7. Ehrlich HJ, Berezuk G, Fritsch S, et al. Clinical development of a Vero cell culture-derived seasonal influenza vaccine. Vaccine. 2012 Jun 19;30 (29):4377-86. PMID 22172502.

8. Farrington CP, Miller E, Taylor B. MMR and autism: further evidence against a causal association. Vaccine. 2001 Jun 14;19 (27):3632-5. PMID 11395196.

9. Linhares AC, Velazquez FR, Perez-Schael I, et al. Efficacy and safety of an oral live attenuated human rotavirus vaccine against rotavirus gastroenteritis during the first 2 years of life in Latin American infants: a randomised, double-blind, placebo-controlled phase III study. Lancet. 2008 Apr 5;371 (9619):1181-9. PMID 18395579.

10. Miller EK, Dumitrescu L, Cupp C, et al. Atopy history and the genomics of wheezing after influenza vaccination in children 6-59 months of age. Vaccine. 2011 Apr;29 (18):3431-7. PMID WOS:000290889700009.

11. Palefsky JM, Giuliano AR, Goldstone S, et al. HPV vaccine against anal HPV infection and anal intraepithelial neoplasia. New England Journal of Medicine. 2011 Oct 27;365 (17):1576-85. PMID 22029979.

12. Silfverdal SA, Nilsson L, Blennow M, et al. Vaccination of children-summary and conclusions from a systematic review. Acta Paediatrica, International Journal of Paediatrics. 2010 September;99 (9):1287-9. PMID 2010457259 MEDLINE PMID 20937069 (http://www.ncbi.nlm.nih.gov/pubmed/20937069).

13. Vesikari T, Itzler R, Karvonen A, et al. RotaTeq, a pentavalent rotavirus vaccine: efficacy and safety among infants in Europe. Vaccine. 2009 Dec 11;28 (2):345-51. PMID 19879226.

14. Vesikari T, Karvonen A, Puustinen L, et al. A short report on highlights of world-wide development of RIX4414: An European experience. Vaccine. 2006 1;24 (18):3779. PMID 2006202655 MEDLINE PMID 16581159 (http://www.ncbi.nlm.nih.gov/pubmed/16581159).

15. Virtanen M, Peltola H, Paunio M, Heinonen OP. Day-to-day reactogenicity and the healthy vaccinee effect of measles-mumps-rubella vaccination. Pediatrics. 2000 Nov;106 (5):E62. PMID 11061799.

Rejected for Not about a vaccine – 13

1. Almuneef M, Memish Z, Khan Y, Kagallwala A, Alshaalan M. Childhood bacterial meningitis in Saudi Arabia. Journal of Infection. 1998 Mar;36 (2):157-60. PMID 9570646.

2. Bahl R, Saxena M, Bhandari N, et al. Population-based incidence of intussusception and a case-control study to examine the association of intussusception with natural rotavirus infection among Indian children. Journal of Infectious Diseases. 2009 November;200 (SUPPL. 1):S277-S81. PMID 2010002047 MEDLINE PMID 19817609 (http://www.ncbi.nlm.nih.gov/pubmed/19817609).

3. Chen E, Grimwood K, Beasley S. Operative rates for acute intussusception in New Zealand [2]. New Zealand Medical Journal. 2004;117 (1202) PMID 2005483071.

4. Dennehy PH. Transmission of rotavirus and other enteric pathogens in the home. Pediatric Infectious Disease Journal. 2000 2000;19 (10 SUPPL.):S103-S5. PMID 2000382180 MEDLINE PMID 11052397 (http://www.ncbi.nlm.nih.gov/pubmed/11052397).

5. Gutierrez J, Issacson RS, Koppel BS. Subacute sclerosing panencephalitis: an update. Developmental Medicine & Child Neurology. 2010 Oct;52 (10):901-7. PMID 20561004.

6. Janjua NZ, Skowronski DM, Hottes TS, et al. Seasonal influenza vaccine and increased risk of pandemic A/H1N1-related illness: First detection of the association in British Columbia, Canada. Clinical Infectious Diseases. 2010 1;51 (9):1017-27. PMID 2010591676 MEDLINE PMID 20887210 (http://www.ncbi.nlm.nih.gov/pubmed/20887210).

7. Kale PL, Andreozzi VL, Nobre FF. Time series analysis of deaths due to Diarrhoea in children in Rio de Janeiro, Brazil, 1980-1998. Journal of Health, Population and Nutrition. 2004 March;22 (1):27-33. PMID 2004257452 MEDLINE PMID 15190809

(http://www.ncbi.nlm.nih.gov/pubmed/15190809).

8. Mori M, Kuwabara S, Miyake M, et al. Haemophilus influenzae infection and Guillain-Barre syndrome. Brain. 2000 Oct;123:2171-8. PMID WOS:000089907400018.

9. Neunert C, Lim W, Crowther M, Cohen A, Solberg Jr L, Crowther MA. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. 2011 21;117 (16):4190-207. PMID 2011270705 MEDLINE PMID 21325604 (http://www.ncbi.nlm.nih.gov/pubmed/21325604).

10. Parashar UD, Kilgore PE, Holman RC, Clarke MJ, Bresee JS, Glass RI. Diarrheal mortality in US infants - Influence of birth weight on risk factors for death. Archives of Pediatrics & Adolescent Medicine. 1998 Jan;152 (1):47-51. PMID WOS:000071486300007.

11. Reyes MP, Fisher MW, Lerner AM. Pseudomonas endocarditis: hemagglutinating antibodies to Fisher-Devlin-Gnabasik immunotypes in sera. Journal of Laboratory & Clinical Medicine. 1974 Jun;83 (6):845-52. PMID 4213766.

12. Takeuchi M, Osamura T, Yasunaga H, Horiguchi H, Hashimoto H, Matsuda S. Intussusception among Japanese children: an epidemiologic study using an administrative database. Bmc Pediatrics. 2012 Mar;12 PMID WOS:000304006700001.

13. van der Werf N, Kroese FGM, Rozing J, Hillebrands JL. Viral infections as potential triggers of type 1 diabetes. Diabetes-Metabolism Research and Reviews. 2007 Mar;23 (3):169-83. PMID WOS:000245146800001.

Rejected for Vaccine or formulation not routinely recommended in US today – 134

1. Aaby P, Ravn H, Roth A, et al. Early diphtheria-tetanus-pertussis vaccination associated with higher female mortality and no difference in male mortality in a cohort of low birthweight children: an observational study within a randomised trial. Archives of Disease in Childhood. 2012 Aug;97 (8):685-91. PMID 22331681.

2. Aavitsland P, Bjune G, Aasen S, Halvorsen S. Adverse events following vaccine or placebo injection in an efficacy trial of an outer membrane vesicle vaccine against group B meningococcal disease in Norwegian secondary schools 1988-1991. NIPH Annals. 1991 Dec;14 (2):133-4; discussion 6-7. PMID 1812426.

3. Alami Chentoufi A, Kritzer E, Yu DM, Nesburn AB, Benmohamed L. Towards a rational design of an asymptomatic clinical herpes vaccine: The old, the new, and the unknown. Clinical and Developmental Immunology. 2012;187585 PMID 2012212220.

4. Ali SS, Chandrashekar SR, Singh M, Bansal RK, Sharma DR, Arora D. A multicenter, prospective, open-label, non-comparative study to evaluate the immunogenicity and tolerance of a new, fully liquid pentavalent vaccine (DTwP-HepB-Hib vaccine). Human Vaccines. 2007 Jul-

Aug;3 (4):116-20. PMID 17617743.

5. Anderson EL, Bowers T, Mink CM, et al. Safety and immunogenicity of meningococcal A and C polysaccharide conjugate vaccine in adults. Infection & Immunity. 1994 Aug;62 (8):3391-5. PMID 8039909.

6. Anderson P, Insel RA, Smith DH, Cate TR, Couch RB, Glezen WP. A polysaccharide-protein complex from Haemophilus influenzae type b. III. Vaccine trial in human adults. Journal of Infectious Diseases. 1981 Dec;144 (6):530-8. PMID 7035578.

7. Araujo EC, Clemens SAC, Oliveira CS, et al. Safety, immunogenicity, and protective efficacy of two doses of RIX4414 live attenuated human rotavirus vaccine in healthy infants. Jornal de Pediatria. 2007 May-Jun;83 (3):217-24. PMID 17380232.

8. Atmar RL, Keitel WA, Quarles JM, et al. Evaluation of age-related differences in the immunogenicity of a G9 H9N2 influenza vaccine. Vaccine. 2011 19;29 (45):8066-72. PMID 2011559946 MEDLINE PMID 21864622 (http://www.ncbi.nlm.nih.gov/pubmed/21864622).

9. Atsmon J, Kate-Ilovitz E, Shaikevich D, et al. Safety and immunogenicity of multimeric-001--a novel universal influenza vaccine. Journal of Clinical Immunology. 2012 Jun;32 (3):595-603. PMID 22318394.

10. Baker CJ, Paoletti LC, Rench MA, Guttormsen HK, Edwards MS, Kasper DL. Immune response of healthy women to 2 different group B streptococcal type V capsular polysaccharide-protein conjugate vaccines. Journal of Infectious Diseases. 2004 Mar;189 (6):1103-12. PMID WOS:000220001100019.

11. Baker CJ, Paoletti LC, Wessels MR, et al. Safety and immunogenicity of capsular polysaccharide-tetanus toxoid conjugate vaccines for group B streptococcal types Ia and Ib. Journal of Infectious Diseases. 1999 Jan;179 (1):142-50. PMID 9841833.

12. Barnes GL, Lund JS, Adams L, et al. Phase 1 trial of a candidate rotavirus vaccine (RV3) derived from a human neonate. Journal of Paediatrics & Child Health. 1997 Aug;33 (4):300-4. PMID 9323616.

13. Beam TR, Jr., Crigler ED, Goldman JK, Schiffman G. Antibody response to polyvalent pneumococcal polysaccharide vaccine in diabetics. JAMA. 1980 Dec 12;244 (23):2621-4. PMID 7431608.

14. Belshe RB, Leone PA, Bernstein DI, et al. Efficacy results of a trial of a herpes simplex vaccine. New England Journal of Medicine. 2012 Jan 5;366 (1):34-43. PMID 22216840.

15. Berkowitz CD, Ward JI, Chiu CE, et al. Persistence of antibody and booster responses to reimmunization with Haemophilus influenzae type b polysaccharide and polysaccharide diphtheria toxoid conjugate vaccines in children initially immunized at 15 to 24 months of age. Pediatrics. 1990 Mar;85 (3):288-93. PMID 2304781.

16. Bernsen RMD, Nagelkerke NJD, Thijs C, van der Wouden JC. Reported pertussis infection and risk of atopy in 8- to 12-yr-old vaccinated and non-vaccinated children. Pediatric Allergy & Immunology. 2008 Feb;19 (1):46-52. PMID 18086216.

17. Bernstein DI, Sack DA, Rothstein E, et al. Efficacy of live, attenuated, human rotavirus vaccine 89-12 in infants: a randomised placebo-controlled trial. Lancet. 1999 Jul 24;354 (9175):287-90. PMID 10440305.

18. Bernstein DI, Smith VE, Sherwood JR, et al. Safety and immunogenicity of live, attenuated human rotavirus vaccine 89-12. Vaccine. 1998 Feb;16 (4):381-7. PMID 9607059.

19. Beytout J, Launay O, Guiso N, et al. Safety of Tdap-IPV given one month after Td-IPV booster in healthy young adults: a placebo-controlled trial. Human Vaccines. 2009 May;5 (5):315-21. PMID 19011374.

20. Bhandari N, Sharma P, Glass RI, et al. Safety and immunogenicity of two live attenuated human rotavirus vaccine candidates, 116E and I321, in infants: results of a randomised controlled trial. Vaccine. 2006 Jul 26;24 (31-32):5817-23. PMID 16735085.

21. Black SB, Shinefield HR, Lampert D, et al. Safety and immunogenicity of oligosaccharide conjugate Haemophilus influenzae type b (HbOC) vaccine in infancy. The Northern California Kaiser Permanente Vaccine Study Center Pediatrics Group. Pediatric Infectious Disease Journal. 1991 Feb;10 (2):92-6. PMID 2062620.

22. Bonvehi P, Boutriau D, Casellas J, Weynants V, Feron C, Poolman J. Three doses of an experimental detoxified L3-derived lipooligosaccharide meningococcal vaccine offer good safety but low immunogenicity in healthy young adults. Clinical & Vaccine Immunology: CVI. 2010 Sep;17 (9):1460-6. PMID 20660140.

23. Bresee JS, El Arifeen S, Azim T, et al. Safety and immunogenicity of tetravalent rhesus-based rotavirus vaccine in Bangladesh. Pediatric Infectious Disease Journal. 2001 Dec;20 (12):1136-43. PMID 11740320.

24. Cadranel S, Zeglache S, Jonckheer T, et al. Factors affecting antibody response of newborns to repeated administrations of the rotavirus vaccine RIT 4237. Journal of Pediatric Gastroenterology & Nutrition. 1987 Jul-Aug;6 (4):525-8. PMID 3430259.

25. Cassisi G, Sarzi-Puttini P, Cazzola M. Chronic widespread pain and fibromyalgia: Could there be some relationship with infections and vaccinations? Clinical and Experimental Rheumatology. 2011 2011;29 (6 SUPPL. 69):S118-S26. PMID 2012228348.

26. Castellanos M, Cinza Z, Dorta Z, et al. Immunization with a DNA vaccine candidate in chronic hepatitis C patients is safe, well tolerated and does not impair immune response induction after anti-hepatitis B vaccination. Journal of Gene Medicine. 2010 January;12 (1):107-16. PMID 2010075090 MEDLINE PMID 19866482

(http://www.ncbi.nlm.nih.gov/pubmed/19866482).

27. Castillo-Solorzano C, Reef SE, Morice A, et al. Rubella vaccination of unknowingly pregnant women during mass campaigns for rubella and congenital rubella syndrome elimination, the Americas 2001-2008. Journal of Infectious Diseases. 2011 Sep 1;204 Suppl 2:S713-7. PMID 21954271.

28. Chang EJ, Zangwill KM, Lee H, Ward JI. Lack of association between rotavirus infection and intussusception: implications for use of attenuated rotavirus vaccines. Pediatric Infectious Disease Journal. 2002 Feb;21 (2):97-102. PMID 11840074.

29. Choo S, Seymour L, Morris R, et al. Immunogenicity and reactogenicity of a pneumococcal conjugate vaccine administered combined with a haemophilus influenzae type B conjugate vaccine in United Kingdom infants. Pediatric Infectious Disease Journal. 2000 Sep;19 (9):854-62. PMID 11001109.

30. Clark HF, Bernstein DI, Dennehy PH, et al. Safety, efficacy, and immunogenicity of a live, quadrivalent human-bovine reassortant rotavirus vaccine in healthy infants.[Erratum appears in J Pediatr. 2004 Apr;144(4):558]. Journal of Pediatrics. 2004 Feb;144 (2):184-90. PMID 14760258.

31. Clark HF, Borian FE, Plotkin SA. Immune protection of infants against rotavirus gastroenteritis by a serotype 1 reassortant of bovine rotavirus WC3. Journal of Infectious Diseases. 1990 Jun;161 (6):1099-104. PMID 2161038.

32. Clark HF, Burke CJ, Volkin DB, et al. Safety, immunogenicity and efficacy in healthy infants of G1 and G2 human reassortant rotavirus vaccine in a new stabilizer/buffer liquid formulation. Pediatric Infectious Disease Journal. 2003 Oct;22 (10):914-20. PMID 14551493.

33. Classen JB, Classen DC. Clustering of cases of insulin dependent diabetes (IDDM) occurring three years after hemophilus influenza B (HiB) immunization support causal relationship between immunization and IDDM. Autoimmunity. 2002 Jul;35 (4):247-53. PMID 12482192.

34. Cutts FT, Zaman SMA, Enwere G, et al. Efficacy of nine-valent pneumococcal conjugate vaccine against pneumonia and invasive pneumococcal disease in The Gambia: randomised, double-blind, placebo-controlled trial.[Erratum appears in Lancet. 2005 Jul 2-8;366(9479):28]. Lancet. 2005 Mar 26-Apr 1;365 (9465):1139-46. PMID 15794968.

35. Da Silva ESGR, Camacho LAB, Stavola MS, Lemos XR, De Oliveira CAB, Siqueira MM. Pregnancy outcomes following rubella vaccination: A prospective study in the State of Rio de Janeiro, Brazil, 2001-2002. Journal of Infectious Diseases. 2011 1;204 (SUPPL. 2):S722-S8. PMID 2011546533 MEDLINE PMID 21954273 (http://www.ncbi.nlm.nih.gov/pubmed/21954273).

36. Dagan R, Melamed R, Zamir O, Leroy O. Safety and immunogenicity of tetravalent pneumococcal vaccines containing 6B, 14, 19F and 23F polysaccharides conjugated to either

tetanus toxoid or diphtheria toxoid in young infants and their boosterability by native polysaccharide antigens. Pediatric Infectious Disease Journal. 1997 Nov;16 (11):1053-9. PMID 9384339.

37. Dang DA, Nguyen VT, Vu DT, et al. A dose-escalation safety and immunogenicity study of a new live attenuated human rotavirus vaccine (Rotavin-M1) in Vietnamese children. Vaccine. 2012 Apr 27;30 Suppl 1:A114-21. PMID 22520120.

38. Davis RL, Kolczak M, Lewis E, et al. Active surveillance of vaccine safety: a system to detect early signs of adverse events. Epidemiology. 2005 May;16 (3):336-41. PMID 15824549.

39. de Oliveira LH, Struchiner CJ. Vaccine-associated paralytic poliomyelitis: a retrospective cohort study of acute flaccid paralyses in Brazil. International Journal of Epidemiology. 2000 Aug;29 (4):757-63. PMID 10922356.

40. Dennehy PH. A short report on the highlights of world-wide development of RIX4414: a North American experience. Comparative evaluation of safety and immunogenicity of two dosages of an oral live attenuated human rotavirus vaccine (RIX4414) in infants in the United States and Canada. Vaccine. 2006 1;24 (18):3780-1. PMID 2006202629 MEDLINE PMID 16111790 (http://www.ncbi.nlm.nih.gov/pubmed/16111790).

41. Dennehy PH, Rodgers GC, Jr., Ward RL, Markwick AJ, Mack M, Zito ET. Comparative evaluation of reactogenicity and immunogenicity of two dosages of oral tetravalent rhesus rotavirus vaccine. US Rhesus Rotavirus Vaccine Study Group. Pediatric Infectious Disease Journal. 1996 Nov;15 (11):1012-8. PMID 8933551.

42. Diaz-Ortega JL, Bennett JV, Castaneda D, Martinez D, Fernandez de Castro J. Aerosolized MMR vaccine: Evaluating potential transmission of components to vaccine administrators and contacts of vaccines. SOURCE Biologicals (2012). 2012.

43. Dos Santos BA, Ranieri TS, Bercini M, et al. An evaluation of the adverse reaction potential of three measles-mumps-rubella combination vaccines. Rev Panam Salud Publica. 2002 Oct;12 (4):240-6. PMID 12431355.

44. Eick A, Croll J, Weatherholtz R, Croll L, Santosham M. Safety and immunogenicity of two octavalent pneumococcal conjugate vaccines in American Indian infants. Vaccine. 2004 Mar 12;22 (9-10):1260-4. PMID 15003655.

45. el-Sayed N, el-Gamal Y, Abbassy A-A, et al. Monovalent type 1 oral poliovirus vaccine in newborns. New England Journal of Medicine. 2008 Oct 16;359 (16):1655-65. PMID 18923170.

46. Eskola J, Kayhty H, Gordon LK, et al. Simultaneous administration of Haemophilus influenzae type b capsular polysaccharide-diphtheria toxoid conjugate vaccine with routine diphtheria-tetanus-pertussis and inactivated poliovirus vaccinations of childhood. Pediatric Infectious Disease Journal. 1988 Jul;7 (7):480-4. PMID 3261414.

47. Eskola J, Kayhty H, Takala AK, et al. A randomized, prospective field trial of a conjugate vaccine in the protection of infants and young children against invasive Haemophilus influenzae type b disease. New England Journal of Medicine. 1990 Nov 15;323 (20):1381-7. PMID 2233904.

48. Espinoza F, Tregnaghi M, Gentile A, et al. Primary and booster vaccination in Latin American children with a DTPw-HBV/Hib combination: A randomized controlled trial. BMC Infectious Diseases. 2010;10 (297) PMID 2010614014.

49. Esposito S, Principi N. Influenza vaccination in young children. The Lancet Infectious Diseases. 2011 September;11 (9):656-7. PMID 2011460533.

50. Esteves K. Safety of oral poliomyelitis vaccine: results of a WHO enquiry. Bulletin of the World Health Organization. 1988;66 (6):739-46. PMID 3266113.

51. Farooqi IS, Hopkin JM. Early childhood infection and atopic disorder. Thorax. 1998 Nov;53 (11):927-32. PMID 10193389.

52. Fattom A, Fuller S, Propst M, et al. Safety and immunogenicity of a booster dose of Staphylococcus aureus types 5 and 8 capsular polysaccharide conjugate vaccine (StaphVAX) in hemodialysis patients. Vaccine. 2004 Dec 16;23 (5):656-63. PMID 15542186.

53. Fragapane E, Gasparini R, Schioppa F, Laghi-Pasini F, Montomoli E, Banzhoff A. A heterologous MF59-adjuvanted H5N1 prepandemic influenza booster vaccine induces a robust, cross-reactive immune response in adults and the elderly. Clinical & Vaccine Immunology: CVI. 2010 Nov;17 (11):1817-9. PMID 20810680.

54. Galbraith NS, Crosby G, Barnes JM, Fernandes R. Simultaneous immunization with B.C.G., diphtheria-tetanus, and oral poliomyelitis vaccines in children aged 13-14. British Medical Journal. 1971 Apr 24;2 (5755):193-7. PMID 5575951.

55. Gisselsson-Solen M, Melhus A, Hermansson A. Pneumococcal vaccination in children at risk of developing recurrent acute otitis media - A randomized study. Acta Paediatrica, International Journal of Paediatrics. 2011 October;100 (10):1354-8. PMID 2011518781 MEDLINE PMID 21517964 (http://www.ncbi.nlm.nih.gov/pubmed/21517964).

56. Haber P, Chen RT, Zanardi LR, et al. An analysis of rotavirus vaccine reports to the vaccine adverse event reporting system: more than intussusception alone? Pediatrics. 2004 Apr;113 (4):e353-9. PMID 15060267.

57. Henderson J, North K, Griffiths M, Harvey I, Golding J. Pertussis vaccination and wheezing illnesses in young children: prospective cohort study. The Longitudinal Study of Pregnancy and Childhood Team. BMJ. 1999 May 1;318 (7192):1173-6. PMID 10221941.

58. Hien ND, Luan LT, Huong NT, et al. High immunogenicity of measles AIK-C vaccine produced in Vietnam. Eastern Journal of Medicine. 2011 2011;16 (3):199-207. PMID

2011572623.

59. Jick H, Vasilakis-Scaramozza C, Jick SS. Live attenuated polio vaccine and the risk of intussusception. British Journal of Clinical Pharmacology. 2001 Oct;52 (4):451-3. PMID 11678790.

60. Johnson B, Gargiullo P, Murphy TV, Parashar UD, Patel MM. Sociodemographic and dietary risk factors for natural infant intussusception in the United States. Journal of Pediatric Gastroenterology & Nutrition. 2010 Oct;51 (4):458-63. PMID 20562726.

61. Karsh J, Pavlidis N, Schiffman G, Moutsopoulos HM. Immunization of patients with Sjogren's syndrome with pneumococcal polysaccharide vaccine: a randomized trial. Arthritis & Rheumatism. 1980 Nov;23 (11):1294-8. PMID 7004446.

62. Katial RK, Brandt BL, Moran EE, Marks S, Agnello V, Zollinger WD. Immunogenicity and safety testing of a group B intranasal meningococcal native outer membrane vesicle vaccine. Infection & Immunity. 2002 Feb;70 (2):702-7. PMID 11796602.

63. Kerdpanich A, Warachit B, Kosuwon P, et al. Primary vaccination with a new heptavalent DTPw-HBV/Hib-Neisseria meningitidis serogroups A and C combined vaccine is well tolerated. International Journal of Infectious Diseases. 2008 Jan;12 (1):88-97. PMID 17716936.

64. Ki M, Park T, Yi SG, Oh JK, Choi B. Risk analysis of aseptic meningitis after measles-mumps-rubella vaccination in Korean children by using a case-crossover design. Am J Epidemiol. 2003 Jan 15;157 (2):158-65. PMID 12522023.

65. King JC, Jr., Vink PE, Farley JJ, Smilie M, Parks M, Lichenstein R. Safety and immunogenicity of three doses of a five-valent pneumococcal conjugate vaccine in children younger than two years with and without human immunodeficiency virus infection. Pediatrics. 1997 Apr;99 (4):575-80. PMID 9093301.

66. Kotloff KL, Fattom A, Basham L, Hawwari A, Harkonen S, Edelman R. Safety and immunogenicity of a tetravalent group B streptococcal polysaccharide vaccine in healthy adults. Vaccine. 1996 Apr;14 (5):446-50. PMID 8735558.

67. Kramarz P, France EK, Destefano F, et al. Population-based study of rotavirus vaccination and intussusception. Pediatric Infectious Disease Journal. 2001 Apr;20 (4):410-6. PMID 11332666.

68. Lanata CF, Black RE, Flores J, et al. Immunogenicity, safety and protective efficacy of one dose of the rhesus rotavirus vaccine and serotype 1 and 2 human-rhesus rotavirus reassortants in children from Lima, Peru. Vaccine. 1996 Feb;14 (3):237-43. PMID 8920706.

69. Langley JM, Halperin SA, McNeil S, et al. Safety and immunogenicity of a Proteosome - trivalent inactivated influenza vaccine, given nasally to healthy adults. Vaccine. 2006 Mar 6;24 (10):1601-8. PMID 16303215.

70. Leach A, Ceesay SJ, Banya WA, Greenwood BM. Pilot trial of a pentavalent pneumococcal polysaccharide/protein conjugate vaccine in Gambian infants. Pediatric Infectious Disease Journal. 1996 Apr;15 (4):333-9. PMID 8866803.

71. Lee J, Robinson JL, Spady DW. Frequency of apnea, bradycardia, and desaturations following first diphtheria-tetanus-pertussis-inactivated polio-Haemophilus influenzae type B immunization in hospitalized preterm infants. Bmc Pediatrics. 2006;6:20. PMID 16784533.

72. Lepow ML, Barkin RM, Berkowitz CD, et al. Safety and immunogenicity of Haemophilus influenzae type b polysaccharide-diphtheria toxoid conjugate vaccine (PRP-D) in infants. Journal of Infectious Diseases. 1987 Oct;156 (4):591-6. PMID 3497990.

73. Lewis SA, Britton JR. Measles infection, measles vaccination and the effect of birth order in the aetiology of hay fever. Clin Exp Allergy. 1998 Dec;28 (12):1493-500. PMID 10024220.

74. Li S-TT, Davis RL, Weiss NS. Intussusception and oral poliovirus vaccination: is there an association? American Journal of Epidemiology. 2004 Sep 15;160 (6):576-81. PMID 15353418.

75. Lopez-Macias C, Ferat-Osorio E, Tenorio-Calvo A, et al. Safety and immunogenicity of a virus-like particle pandemic influenza A (H1N1) 2009 vaccine in a blinded, randomized, placebo-controlled trial of adults in Mexico. Vaccine. 2011 Oct 13;29 (44):7826-34. PMID 21816199.

76. Maldonado Y, Hestvik L, Wilson M, et al. Safety and immunogenicity of bovine rotavirus vaccine RIT 4237 in 3-month-old infants. Journal of Pediatrics. 1986 Dec;109 (6):931-5. PMID 3537248.

77. Markwick AJ, Rennels MB, Zito ET, Wade MS, Mack ME. Oral tetravalent rotavirus vaccine can be successfully coadministered with oral poliovirus vaccine and a combined diphtheria, tetanus, pertussis and Haemophilus influenzae type b vaccine. US Rhesus Rotavirus Vaccine Study Group. Pediatric Infectious Disease Journal. 1998 Oct;17 (10):913-8. PMID 9802635.

78. Marshall HS, Richmond PC, Nissen MD, et al. Safety and immunogenicity of a meningococcal B bivalent rLP2086 vaccine in healthy toddlers aged 18 to 36 months: A phase 1 randomized controlled clinical trial. Pediatric Infectious Disease Journal. 2012;20.

79. Matson DO. RotaShield: the ill-fated rhesus-human reassortant rotavirus vaccine. Pediatric Annals. 2006 Jan;35 (1):44-50. PMID 16466075.

80. McElhaney JE, Simor AE, McNeil S, Predy GN. Efficacy and safety of CVT-E002, a proprietary extract of Panax quinquefolius in the prevention of respiratory infections in influenza-vaccinated community-dwelling adults: A multicenter, randomized, double-blind, and placebo-controlled trial. Influenza Research and Treatment. 2011;759051 PMID 2012187058.

81. Menzel M, Muellinger B, Weber N, Haeussinger K, Ziegler-Heitbrock L. Inhalative vaccination with pneumococcal polysaccharide in healthy volunteers. Vaccine. 2005 Oct 17;23 (43):5113-9. PMID 16029914.

82. Mitchell LA, Tingle AJ, MacWilliam L, et al. HLA-DR class II associations with rubella vaccine-induced joint manifestations. J Infect Dis. 1998 Jan;177 (1):5-12. PMID 9419163.

83. Mulholland EK, Byass P, Campbell H, et al. The immunogenicity and safety of Haemophilus influenzae type b-tetanus toxoid conjugate vaccine in Gambian infants. Annals of Tropical Paediatrics. 1994;14 (3):183-8. PMID 7825990.

84. Nachman S, Kim S, King J, et al. Safety and immunogenicity of a heptavalent pneumococcal conjugate vaccine in infants with human immunodeficiency virus type 1 infection. Pediatrics. 2003 Jul;112 (1 Pt 1):66-73. PMID 12837869.

85. Nilsson L, Kjellman NI, Bjorksten B. A randomized controlled trial of the effect of pertussis vaccines on atopic disease. Arch Pediatr Adolesc Med. 1998 Aug;152 (8):734-8. PMID 9701130.

86. Nokleby H, Feiring B. The Norwegian meningococcal group B outer membrane vesicle vaccine: side effects in phase II trials. NIPH Annals. 1991 Dec;14 (2):95-101; discussion -2. PMID 1812440.

87. Obaro SK, Enwere GC, Deloria M, et al. Safety and immunogenicity of pneumococcal conjugate vaccine in combination with diphtheria, tetanus toxoid, pertussis and Haemophilus influenzae type b conjugate vaccine. Pediatric Infectious Disease Journal. 2002 Oct;21 (10):940-7. PMID 12394817.

88. Ornoy A, Arnon J, Feingold M, Ben Ishai P. Spontaneous abortions following oral poliovirus vaccination in first trimester. Lancet. 1990 Mar 31;335 (8692):800. PMID 1969549.

89. Ortega-Barria E, Kanra G, Leroux G, et al. The immunogenicity and reactogenicity of DTPw-HBV/Hib 2.5 combination vaccine: results from four phase III multicenter trials across three continents. Vaccine. 2007 Dec 5;25 (50):8432-40. PMID 17961876.

90. Ouandaogo C-R, Yameogo TM, Diomande FVK, et al. Adverse events following immunization during mass vaccination campaigns at first introduction of a meningococcal A conjugate vaccine in Burkina Faso, 2010. Vaccine. 2012 May 30;30 Suppl 2:B46-51. PMID 22230584.

91. Pardon F, Vilarino M, Barbero P, et al. Rubella vaccination of unknowingly pregnant women during 2006 mass campaign in Argentina. Journal of Infectious Diseases. 2011 1;204 (SUPPL. 2):S745-S7. PMID 2011546540 MEDLINE PMID 21954276 (http://www.ncbi.nlm.nih.gov/pubmed/21954276).

92. Peltola H, Kayhty H, Sivonen A, Makela H. Haemophilus influenzae type b capsular polysaccharide vaccine in children: a double-blind field study of 100,000 vaccinees 3 months to

5 years of age in Finland. Pediatrics. 1977 Nov;60 (5):730-7. PMID 335348.

93. Pichichero ME. Effect of breast-feeding on oral rhesus rotavirus vaccine seroconversion: a metaanalysis. Journal of Infectious Diseases. 1990 Sep;162 (3):753-5. PMID 2167344.

94. Pichichero ME, Marsocci SM, Francis AB, et al. A comparative evaluation of the safety and immunogenicity of a single dose of unbuffered oral rhesus rotavirus serotype 3, rhesus/human reassortant serotypes 1, 2 and 4 and combined (tetravalent) vaccines in healthy infants. Vaccine. 1993;11 (7):747-53. PMID 8393606.

95. Price CS, Thompson WW, Goodson B, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. Pediatrics. 2010 October;126 (4):656-64. PMID 2010559872 MEDLINE PMID 20837594 (http://www.ncbi.nlm.nih.gov/pubmed/20837594).

96. Quiambao B, Van Der Meeren O, Kolhe D, Gatchalian S. A randomized, dose-ranging assessment of the immunogenicity and safety of a booster dose of a combined diphtheria-tetanus-whole cell pertussishepatitis B-inactivated poliovirus-Hemophilus influenzae type b (DTPw-HBV-IPV/Hib) vaccine vs. co-administration of DTPw-HBV/Hib and IPV vaccines in 12 to 24 months old Filipino toddlers. Human Vaccines and Immunotherapeutics. 2012 March;8 (3):337-44. PMID 2012244550.

97. Raman T, Mukhopadhyaya A, Eapen CE, et al. Intussusception in southern Indian children: lack of association with diarrheal disease and oral polio vaccine immunization. Indian Journal of Gastroenterology. 2003 May-Jun;22 (3):82-4. PMID 12839377.

98. Ray P, Black S, Shinefield H, et al. Risk of chronic arthropathy among women after rubella vaccination. Vaccine Safety Datalink Team. JAMA. 1997 Aug 20;278 (7):551-6. PMID 9268275.

99. Rennels MB, Glass RI, Dennehy PH, et al. Safety and efficacy of high-dose rhesus-human reassortant rotavirus vaccines--report of the National Multicenter Trial. United States Rotavirus Vaccine Efficacy Group. Pediatrics. 1996 Jan;97 (1):7-13. PMID 8545227.

100. Richmond PC, Marshall HS, Nissen MD, et al. Safety, immunogenicity, and tolerability of meningococcal serogroup B bivalent recombinant lipoprotein 2086 vaccine in healthy adolescents: A randomised, single-blind, placebo-controlled, phase 2 trial. The Lancet Infectious Diseases. 2012 August;12 (8):597-607. PMID 2012432636.

101. Rigau-Perez JG, Overturf GD, Chan LS, Weiss J, Powars D. Reactions to booster pneumococcal vaccination in patients with sickle cell disease. Pediatric Infectious Disease. 1983 May-Jun;2 (3):199-202. PMID 6346278.

102. Riley ID, Lehmann D, Alpers MP, Marshall TF, Gratten H, Smith D. Pneumococcal vaccine prevents death from acute lower-respiratory-tract infections in Papua New Guinean children. Lancet. 1986 Oct 18;2 (8512):877-81. PMID 2876325.

103. Ruiz-Palacios GM, Guerrero ML, Bautista-Marquez A, et al. Dose response and efficacy of a live, attenuated human rotavirus vaccine in Mexican infants. Pediatrics. 2007 Aug;120 (2):e253-61. PMID 17606534.

104. Saitoh A, Nagai A, Tenjinbaru K, et al. Safety and persistence of immunological response 6 months after intramuscular vaccination with an AS03-adjuvanted H1N1 2009 influenza vaccine: An open-label, randomized trial in Japanese children aged 6 months to 17 years. Human Vaccines and Immunotherapeutics. 2012 June;8 (6):749-58. PMID 2012397534.

105. Salinas B, Perez Schael I, Linhares AC, et al. Evaluation of safety, immunogenicity and efficacy of an attenuated rotavirus vaccine, RIX4414: A randomized, placebo-controlled trial in Latin American infants. Pediatric Infectious Disease Journal. 2005 Sep;24 (9):807-16. PMID 16148848.

106. Salmon-Ceron D, Durier C, Desaint C, et al. Immunogenicity and safety of an HIV-1 lipopeptide vaccine in healthy adults: a phase 2 placebo-controlled ANRS trial. Aids. 2010 Sep;24 (14):2211-23. PMID WOS:000281249200009.

107. Santolaya ME, O'Ryan ML, Valenzuela MT, et al. Immunogenicity and tolerability of a multicomponent meningococcal serogroup B (4CMenB) vaccine in healthy adolescents in Chile: a phase 2b/3 randomised, observer-blind, placebo-controlled study. Lancet. 2012 Feb 18;379 (9816):617-24. PMID 22260988.

108. Santosham M, Letson GW, Wolff M, et al. A field study of the safety and efficacy of two candidate rotavirus vaccines in a Native American population. Journal of Infectious Diseases. 1991 Mar;163 (3):483-7. PMID 1995721.

109. Santosham M, Moulton LH, Reid R, et al. Efficacy and safety of high-dose rhesus-human reassortant rotavirus vaccine in Native American populations. Journal of Pediatrics. 1997 Oct;131 (4):632-8. PMID 9386673.

110. Schmitt HJ, Faber J, Lorenz I, Schmole-Thoma B, Ahlers N. The safety, reactogenicity and immunogenicity of a 7-valent pneumococcal conjugate vaccine (7VPnC) concurrently administered with a combination DTaP-IPV-Hib vaccine. Vaccine. 2003 Sep 8;21 (25-26):3653-62. PMID 12922095.

111. Segaard OS, Lohse N, Harboe ZB, et al. Improving the immunogenicity of pneumococcal conjugate vaccine in HIV-infected adults with a toll-like receptor 9 agonist adjuvant: A randomized, controlled trial. Clinical Infectious Diseases. 2010 1;51 (1):42-50. PMID 2010346742 MEDLINE PMID 20504165 (http://www.ncbi.nlm.nih.gov/pubmed/20504165).

112. Sharma H, Chowdhari S, Raina TR, Bhardwaj S, Namjoshi G, Parekh S. Sero-Surveillance to Assess Immunity to Rubella and Assessment of Immunogenicity and Safety of a Single dose of Rubella Vaccine in School Girls. Indian Journal of Community Medicine. 2010 Jan;35 (1):134-7. PMID 20606938.

113. Sharma H, Patil V, Sharma D, et al. A phase III, randomized controlled study to assess the safety and immunogenicity of a semi-synthetic diphtheria, tetanus and whole-cell pertussis vaccine in Indian infants. Vaccine. 2012.

114. Sharma HJ, Oun SA, Bakr SSA, et al. No demonstrable association between the Leningrad-Zagreb mumps vaccine strain and aseptic meningitis in a large clinical trial in Egypt. Clinical Microbiology & Infection. 2010 Apr;16 (4):347-52. PMID 20222892.

115. Simasathien S, Migasena S, Samakoses R, et al. Vaccination of Thai infants with rhesus-human reassortant tetravalent oral rotavirus vaccine. Pediatric Infectious Disease Journal. 1994 Jul;13 (7):590-6. PMID 7970945.

116. Simonsen L, Viboud C, Elixhauser A, Taylor RJ, Kapikian AZ. More on RotaShield and intussusception: the role of age at the time of vaccination. Journal of Infectious Diseases. 2005 Sep 1;192 Suppl 1:S36-43. PMID 16088803.

117. Slater PE, Ben-Zvi T, Fogel A, Ehrenfeld M, Ever-Hadani S. Absence of an association between rubella vaccination and arthritis in underimmune postpartum women. Vaccine. 1995 Nov;13 (16):1529-32. PMID 8578837.

118. Soares RC, Siqueira MM, Toscano CM, et al. Follow-up study of unknowingly pregnant women vaccinated against rubella in Brazil, 2001-2002. Journal of Infectious Diseases. 2011 Sep 1;204 Suppl 2:S729-36. PMID 21954274.

119. Strebel PM, Ion-Nedelcu N, Baughman AL, Sutter RW, Cochi SL. Intramuscular injections within 30 days of immunization with oral poliovirus vaccine--a risk factor for vaccine-associated paralytic poliomyelitis. New England Journal of Medicine. 1995 Feb 23;332 (8):500-6. PMID 7830731.

120. Sugawara T, Ohsuka Y, Taya K, et al. Diarrhea as a minor adverse effect due to oral polio vaccine. Japanese Journal of Infectious Diseases. 2009 Jan;62 (1):51-3. PMID 19168959.

121. Sur D, Ochiai RL, Bhattacharya SK, et al. A cluster-randomized effectiveness trial of Vi typhoid vaccine in India. New England Journal of Medicine. 2009 Jul 23;361 (4):335-44. PMID 19625715.

122. Tingle AJ, Mitchell LA, Grace M, et al. Randomised double-blind placebo-controlled study on adverse effects of rubella immunisation in seronegative women. Lancet. 1997 May 3;349 (9061):1277-81. PMID 9142061.

123. Tomljenovic L, Shaw CA. Mechanisms of aluminum adjuvant toxicity and autoimmunity in pediatric populations. Lupus. 2012 February;21 (2):223-30. PMID 2012029357.

124. Treanor JJ, Clark HF, Pichichero M, et al. Evaluation of the protective efficacy of a serotype 1 bovine-human rotavirus reassortant vaccine in infants. Pediatric Infectious Disease

Journal. 1995 Apr;14 (4):301-7. PMID 7603812.

125. Turley CB, Rupp RE, Johnson C, et al. Safety and immunogenicity of a recombinant M2e-flagellin influenza vaccine (STF2.4xM2e) in healthy adults. Vaccine. 2011 Jul 18;29 (32):5145-52. PMID 21624416.

126. Ugpo J, Lucero M, Williams G, et al. Reactogenicity and tolerability of a non-adjuvanted 11-valent diphtheria-tetanus toxoid pneumococcal conjugate vaccine in Filipino children. Vaccine. 2009 5;27 (20):2723-9. PMID 2009183639 MEDLINE PMID 18977267 (http://www.ncbi.nlm.nih.gov/pubmed/18977267).

127. Verge CF, Howard NJ, Irwig L, Simpson JM, Mackerras D, Silink M. Environmental factors in childhood IDDM. A population-based, case-control study. Diabetes Care. 1994 Dec;17 (12):1381-9. PMID 7882806.

128. Vesikari T, Isolauri E, D'Hondt E, Delem A, Andre FE, Zissis G. Protection of infants against rotavirus diarrhoea by RIT 4237 attenuated bovine rotavirus strain vaccine. Lancet. 1984 May 5;1 (8384):977-81. PMID 6143964.

129. Vesikari T, Karvonen A, Forrest BD, Hoshino Y, Chanock RM, Kapikian AZ. Neonatal administration of rhesus rotavirus tetravalent vaccine. Pediatric Infectious Disease Journal. 2006 Feb;25 (2):118-22. PMID 16462287.

130. Vesikari T, Karvonen AV, Majuri J, et al. Safety, efficacy, and immunogenicity of 2 doses of bovine-human (UK) and rhesus-rhesus-human rotavirus reassortant tetravalent vaccines in Finnish children. Journal of Infectious Diseases. 2006 Aug 1;194 (3):370-6. PMID 16826486.

131. Wiedermann G, Jovanovic D, Georges AM. Immunogenicity and reactogenicity of new multivalent pneumococcal vaccines. Zentralblatt fur Bakteriologie Mikrobiologie und Hygiene - Abt. 1 Orig. A. 1982 1982;251 (4):494-504. PMID 1983017408 MEDLINE PMID 7201725 (http://www.ncbi.nlm.nih.gov/pubmed/7201725).

132. Wringe A, Fine PEM, Sutter RW, Kew OM. Estimating the extent of vaccine-derived poliovirus infection. PLoS ONE [Electronic Resource]. 2008;3 (10):e3433. PMID 18958288.

133. Zhou W-Z, Koo H-W, Wang X-Y, et al. Revaccination with locally-produced vi typhoid polysaccharide vaccine among chinese school-aged children: safety and immunogenicity findings. Pediatric Infectious Disease Journal. 2007 Nov;26 (11):1001-5. PMID 17984806.

134. Zhu FC, Zhang J, Zhang XF, et al. Efficacy and safety of a recombinant hepatitis E vaccine in healthy adults: a large-scale, randomised, double-blind placebo-controlled, phase 3 trial. Lancet. 2010 Sep;376 (9744):895-902. PMID WOS:000282069100030.

Rejected for H5N1 – 15

1. Beran J, Abdel-Messih IA, Raupachova J, Hobzova L, Fragapane E. A phase III, randomized,

open-label study to assess the tolerability and immunogenicity of an H5N1 influenza vaccine administered to healthy adults with a 1-, 2-, 3-, or 6-week interval between first and second doses. Clinical Therapeutics. 2010 Dec;32 (13):2186-97. PMID 21316535.

2. Cox RJ, Pedersen G, Madhun AS, et al. Evaluation of a virosomal H5N1 vaccine formulated with Matrix MTM adjuvant in a phase I clinical trial. Vaccine. 2011 Oct 19;29 (45):8049-59. PMID 21864624.

3. Diez-Domingo J, Garces-Sanchez M, Baldo J-M, et al. Immunogenicity and Safety of H5N1 A/Vietnam/1194/2004 (Clade 1) AS03-adjuvanted prepandemic candidate influenza vaccines in children aged 3 to 9 years: a phase ii, randomized, open, controlled study. Pediatric Infectious Disease Journal. 2010 Jun;29 (6):e35-46. PMID 20375709.

4. Fragapane E, Gasparini R, Schioppa F, Laghi-Pasini F, Montomoli E, Banzhoff A. A heterologous MF59-adjuvanted H5N1 prepandemic influenza booster vaccine induces a robust, cross-reactive immune response in adults and the elderly. Clinical & Vaccine Immunology: CVI. 2010 Nov;17 (11):1817-9. PMID 20810680.

5. Gillard P, Caplanusi A, Knuf M, et al. An assessment of prime-boost vaccination schedules with AS03(A)-adjuvanted prepandemic H5N1 vaccines: A randomized study in European adults. Influenza and other Respiratory Viruses. 2012.

6. Heijmans S, De Meulemeester M, Reynders P, et al. Immunogenicity profile of a 3.75-(mu)g hemagglutinin pandemic rH5N1 split virion AS03(A)-adjuvanted vaccine in elderly persons: A randomized trial. Journal of Infectious Diseases. 2011 15;203 (8):1054-62. PMID 2011183323 MEDLINE PMID 21450995 (http://www.ncbi.nlm.nih.gov/pubmed/21450995).

7. Hwang S-J, Chang S-C, Yu C-J, et al. Immunogenicity and safety of an AS03(A)-adjuvanted H5N1 influenza vaccine in a Taiwanese population. Journal of the Formosan Medical Association. 2011 Dec;110 (12):780-6. PMID 22248833.

8. Ikeno D, Kimachi K, Kino Y, et al. Immunogenicity of an inactivated adjuvanted whole-virion influenza A (H5N1, NIBRG-14) vaccine administered by intramuscular or subcutaneous injection.[Erratum appears in Microbiol Immunol. 2011 Nov;55(11):822 Note: Dosage error in article text]. Microbiology & Immunology. 2010 Feb;54 (2):81-8. PMID 20377741.

9. Keitel W, Groth N, Lattanzi M, et al. Dose ranging of adjuvant and antigen in a cell culture H5N1 influenza vaccine: safety and immunogenicity of a phase 1/2 clinical trial. Vaccine. 2010 Jan 8;28 (3):840-8. PMID 19835829.

10. Langley JM, Frenette L, Ferguson L, et al. Safety and cross-reactive immunogenicity of candidate AS03-adjuvanted prepandemic H5N1 influenza vaccines: a randomized controlled phase 1/2 trial in adults. Journal of Infectious Diseases. 2010 Jun 1;201 (11):1644-53. PMID 20423222.

11. Langley JM, Risi G, Caldwell M, et al. Dose-sparing H5N1 A/Indonesia/05/2005 pre-

pandemic influenza vaccine in adults and elderly adults: a phase III, placebo-controlled, randomized study. Journal of Infectious Diseases. 2011 Jun 15;203 (12):1729-38. PMID 21606531.

12. Ledgerwood JE, Wei C-J, Hu Z, et al. DNA priming and influenza vaccine immunogenicity: two phase 1 open label randomised clinical trials. The Lancet Infectious Diseases. 2011 Dec;11 (12):916-24. PMID 21975270.

13. Lopez P, Caicedo Y, Sierra A, Tilman S, Banzhoff A, Clemens R. Combined, concurrent, and sequential administration of seasonal influenza and MF59-adjuvanted A/H5N1 vaccines: a phase II randomized, controlled trial of immunogenicity and safety in healthy adults. Journal of Infectious Diseases. 2011 Jun 15;203 (12):1719-28. PMID 21606530.

14. Nagai H, Ikematsu H, Tenjinbaru K, Maeda A, Drame M, Roman FP. A phase II, open-label, multicentre study to evaluate the immunogenicity and safety of an adjuvanted prepandemic (H5N1) influenza vaccine in healthy Japanese adults. BMC Infectious Diseases. 2010;10:338. PMID 21108818.

15. Yang PC, Yu CJ, Chang SC, et al. Safety and immunogenicity of a split-virion AS03(A)-adjuvanted A/Indonesia/05/2005 (H5N1) vaccine in Taiwanese adults. Journal of the Formosan Medical Association. 2012 June;111 (6):333-9. PMID 2012372175.

Rejected for ASO3 adjuvant – 12

1. Andrews N, Stowe J, Al-Shahi Salman R, Miller E. Guillain-Barre syndrome and H1N1 (2009) pandemic influenza vaccination using an AS03 adjuvanted vaccine in the United Kingdom: self-controlled case series. Vaccine. 2011 Oct 19;29 (45):7878-82. PMID 21875631.

2. Bardage C, Persson I, Ortqvist A, Bergman U, Ludvigsson JF, Granath F. Neurological and autoimmune disorders after vaccination against pandemic influenza A (H1N1) with a monovalent adjuvanted vaccine: population based cohort study in Stockholm, Sweden. BMJ. 2011;343:d5956. PMID 21994316.

3. De Wals P, Deceuninck G, Toth E, et al. Risk of Guillain-Barre syndrome following H1N1 influenza vaccination in Quebec. JAMA. 2012 Jul 11;308 (2):175-81. PMID 22782419.

4. Dikow R, Eckerle I, Ksoll-Rudek D, et al. Immunogenicity and efficacy in hemodialysis patients of an AS03(A)-adjuvanted vaccine for 2009 pandemic influenza A(H1N1): a nonrandomized trial. American Journal of Kidney Diseases. 2011 May;57 (5):716-23. PMID 21349617.

5. Hung IFN, Leung AYM, Chu DWS, et al. Prevention of acute myocardial infarction and stroke among elderly persons by dual pneumococcal and influenza vaccination: a prospective cohort study. Clinical Infectious Diseases. 2010 Nov 1;51 (9):1007-16. PMID 20887208.

6. Medical Products Agency. A registry based comparative cohort study in four Swedish

counties of the risk for narcolepsy after vaccination with Pandemrix—a first and preliminary report. 2011. www.mpa.se. 2011.

7. Nohynek H, Jokinen J, Partinen M, et al. AS03 adjuvanted AH1N1 vaccine associated with an abrupt increase in the incidence of childhood narcolepsy in Finland. PLoS ONE [Electronic Resource]. 2012;7 (3) PMID 2012183686.

8. Oppermann M, Fritzsche J, Weber-Schoendorfer C, et al. A(H1N1)v2009: A controlled observational prospective cohort study on vaccine safety in pregnancy. Vaccine. 2012 Jun 22;30 (30):4445-52. PMID 22564554.

9. Pasternak B, Svanstrom H, Molgaard-Nielsen D, et al. Risk of adverse fetal outcomes following administration of a pandemic influenza A(H1N1) vaccine during pregnancy. JAMA. 2012 Jul 11;308 (2):165-74. PMID 22782418.

10. Pasternak B, Svanstrom H, Molgaard-Nielsen D, et al. Vaccination against pandemic A/H1N1 2009 influenza in pregnancy and risk of fetal death: cohort study in Denmark. BMJ. 2012;344:e2794. PMID 22551713.

11. Tavares F, Nazareth I, Monegal JS, Kolte I, Verstraeten T, Bauchau V. Pregnancy and safety outcomes in women vaccinated with an AS03-adjuvanted split virion H1N1 (2009) pandemic influenza vaccine during pregnancy: a prospective cohort study. Vaccine. 2011 Aug 26;29 (37):6358-65. PMID 21596080.

12. Verity C, Stellitano L, Winstone AM, Andrews N, Stowe J, Miller E. Guillain-Barre syndrome and H1N1 influenza vaccine in UK children. Lancet. 2011 Oct 29;378 (9802):1545-6. PMID 22035553.

Rejected for BCG vaccine (tuberculosis) – 9

1. Aaby P, Roth A, Ravn H, et al. Randomized Trial of BCG Vaccination at Birth to Low-Birth-Weight Children: Beneficial Nonspecific Effects in the Neonatal Period? Journal of Infectious Diseases. 2011 Jul;204 (2):245-52. PMID WOS:000292562200013.

2. Behjati M, Ayatollahi J. Post BCG lymphadenitis in vaccinated infants in Yazd, Iran. Iranian Journal of Pediatrics. 2008 2008;18 (4):351-6. PMID 2009150463.

3. Claesson MH. Immunological Links to Nonspecific Effects of DTwP and BCG Vaccines on Infant Mortality. Journal of Tropical Medicine. 2011;2011:706304. PMID 21760811.

4. Faridi MMA, Krishnamurthy S. Abortive reaction and time of scar formation after BCG vaccination. Vaccine. 2008 17;26 (3):289-90. PMID 2008005505 MEDLINE PMID 18093699 (http://www.ncbi.nlm.nih.gov/pubmed/18093699).

5. Kaur S, Faridi MMA, Agarwal KN. BCG vaccination reaction in low birth weight infants. Indian Journal of Medical Research. 2002 1;116 (AUG.):64-9. PMID 2003047252 MEDLINE

PMID 12592992 (http://www.ncbi.nlm.nih.gov/pubmed/12592992).

6. Khemiri M, Bagais A, Becher SB, et al. Tuberculous meningitis in Bacille Calmette-Guerin-vaccinated children: clinical spectrum and outcome. Journal of Child Neurology. 2012 Jun;27 (6):741-6. PMID 22190501.

7. Mohrenschlager M, Haberl VM, Kramer U, Behrendt H, Ring J. Early BCG and pertussis vaccination and atopic diseases in 5- to 7-year-old preschool children from Augsburg, Germany: results from the MIRIAM study. Pediatr Allergy Immunol. 2007 Feb;18 (1):5-9. PMID 17295793.

8. Paterson DL, Patel A. Bacillus Calmette-Guerin (BCG) immunotherapy for bladder cancer: review of complications and their treatment. Australian & New Zealand Journal of Surgery. 1998 May;68 (5):340-4. PMID 9631906.

9. Roth AE, Benn CS, Ravn H, et al. Effect of revaccination with BCG in early childhood on mortality: randomised trial in Guinea-Bissau. British Medical Journal. 2010 Mar;340 PMID WOS:000275931100010.

Rejected for Other – 16

1. Batista-Duharte A, Lindblad EB, Oviedo-Orta E. Progress in understanding adjuvant immunotoxicity mechanisms. Toxicology Letters. 2011 10;203 (2):97-105. PMID 2011235888 MEDLINE PMID 21392560 (http://www.ncbi.nlm.nih.gov/pubmed/21392560).

2. Black S, Klein NP, Shah J, Bedell L, Karsten A, Dull PM. Immunogenicity and tolerability of a quadrivalent meningococcal glycoconjugate vaccine in children 2-10 years of age. Vaccine. 2010 Jan 8;28 (3):657-63. PMID 19895922.

3. Crooks CJ, Prieto-Merino D, Evans SJW. Identifying adverse events of vaccines using a bayesian method of medically guided information sharing. Drug Safety. 2012 2012;35 (1):61-78. PMID 2011677228 MEDLINE PMID 22136183 (http://www.ncbi.nlm.nih.gov/pubmed/22136183).

4. de Vos van Steenwijk PJ, Ramwadhdoebe TH, Lowik MJG, et al. A placebo-controlled randomized HPV16 synthetic long-peptide vaccination study in women with high-grade cervical squamous intraepithelial lesions. Cancer Immunology, Immunotherapy. 2012.

5. Deivanayagam N, Nedunchelian K, Ahamed SS, Ashok TP, Mala N, Ratnam SR. Intramuscular injection as a provoking factor for paralysis in acute poliomyelitis. A case control study. Indian Pediatrics. 1993 Mar;30 (3):335-40. PMID 8365783.

6. Hak E, Grobbee DE, Sanders EAM, et al. Rationale and design of CAPITA: A RCT of 13-valent conjugated pneumococcal vaccine efficacy among older adults. Netherlands Journal of Medicine. 2008 October;66 (9):378-83. PMID 2008509996 MEDLINE PMID 18990781 (http://www.ncbi.nlm.nih.gov/pubmed/18990781).

7. Harrison BJ, Thomson W, Pepper L, et al. Patients who develop inflammatory polyarthritis (IP) after immunization are clinically indistinguishable from other patients with IP. Br J Rheumatol. 1997 Mar;36 (3):366-9. PMID 9133970.

8. Hotopf M, David A, Hull L, Ismail K, Unwin C, Wessely S. Role of vaccinations as risk factors for ill health in veterans of the Gulf war: Cross sectional study. British Medical Journal. 2000 20;320 (7246):1363-7. PMID 2000170967 MEDLINE PMID 10818024 (http://www.ncbi.nlm.nih.gov/pubmed/10818024).

9. Pittman PR, Coonan KM, Gibbs PH, Scott HM, Cannon TL, McKee Jr KT. Long-term health effects of repeated exposure to multiple vaccines. Vaccine. 2004 9;23 (4):525-36. PMID 2004471640 MEDLINE PMID 15530702 (http://www.ncbi.nlm.nih.gov/pubmed/15530702).

10. Svanstrom H, Callreus T, Hviid A. Temporal data mining for adverse events following immunization in nationwide Danish healthcare databases. Drug Safety. 2010 Nov 1;33 (11):1015-25. PMID 20925439.

11. Swingler G, Fransman D, Hussey G. Conjugate vaccines for preventing Haemophilus influenzae type B infections. Cochrane Database of Systematic Reviews. 2007 (2):CD001729. PMID 17443509.

12. Tandale BV, Pawar SD, Mishra AC. Immunogenicity and safety of pandemic H1N1 2009 vaccine among adults in field use, India. Vaccine. 2012 9;30 (12):2043-4. PMID 2012111130 MEDLINE PMID 22001279 (http://www.ncbi.nlm.nih.gov/pubmed/22001279).

13. Verstraeten T, Davis RL, DeStefano F, et al. Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases. Pediatrics. 2003 November;112 (5):1039-48. PMID 2003441819 MEDLINE PMID 14595043 (http://www.ncbi.nlm.nih.gov/pubmed/14595043).

14. Wilson K, Hawken S, Kwong JC, et al. Impact of birth weight at term on rates of emergency room visits and hospital admissions following vaccination at 2 months of age. Vaccine. 2011 Oct;29 (46):8267-74. PMID WOS:000296988500014.

15. Yeh SH, Ward JI, Partridge S, et al. Safety and immunogenicity of a pentavalent diphtheria, tetanus, pertussis, hepatitis B and polio combination vaccine in infants. Pediatric Infectious Disease Journal. 2001 Oct;20 (10):973-80. PMID 11642632.

16. Zhou W, Pool V, DeStefano F, et al. A potential signal of Bell's palsy after parenteral inactivated influenza vaccines: reports to the Vaccine Adverse Event Reporting System (VAERS)--United States, 1991-2001. Pharmacoepidemiol Drug Saf. 2004 Aug;13 (8):505-10. PMID 15317028.

Background - 344

1. From the NIH: Pneumococcal vaccination for patients with Sjogren's syndrome. JAMA. 1981 Jun 12;245 (22):2288. PMID 7230448.

2. Haemophilus influenzae B immunisation. Drug and Therapeutics Bulletin. 1993 1993;31 (1):1-2. PMID 1993037203 MEDLINE PMID 8440158 (http://www.ncbi.nlm.nih.gov/pubmed/8440158).

3. Update: vaccine side effects, adverse reactions, contraindications, and precautions. Recommendations of the Advisory Committee on Immunization Practices (ACIP).[Erratum appears in MMWR Morb Mortal Wkly Rep 1997 Mar 14;46(10):227]. Morbidity & Mortality Weekly Report. Recommendations & Reports. 1996 Sep 6;45 (RR-12):1-35. PMID 8801442.

4. Poliomyelitis prevention: recommendations for use of inactivated poliovirus vaccine and live oral poliovirus vaccine. American Academy of Pediatrics Committee on Infectious Diseases. Pediatrics. 1997 Feb;99 (2):300-5. PMID 9024465.

5. From the Centers for Disease Control and Prevention. Intussusception among recipients of rotavirus vaccine--United States, 1998-1999. JAMA. 1999 Aug 11;282 (6):520-1. PMID 10450702.

6. Rotavirus vaccine for the prevention of rotavirus gastroenteritis among children. Recommendations of the Advisory Committee on Immunization Practices (ACIP). Morbidity & Mortality Weekly Report. Recommendations & Reports. 1999 Mar 19;48 (RR-2):1-20. PMID 10219046.

7. Intussusception among recipients of rotavirus vaccine - US, 1998-1999. Annals of Pharmacotherapy. 1999 Sep;33 (9):1020-1. PMID WOS:000082401100028.

8. Acellular pertussis vaccines. Prescrire International. 2000 2000;9 (45):220-3. PMID 2000044279 MEDLINE PMID 11503804 (http://www.ncbi.nlm.nih.gov/pubmed/11503804).

9. Acellulat pertussis vaccines. New preparation. Better tolerated but less active? Prescrire International. 2000 2000;9 (45):204-7. PMID 2000044272.

10. Haemophilus influenzae type B vaccine safe and effective in early infancy. South African Medical Journal. 2002 2002;92 (1):3. PMID 2002055415.

11. Pneumococcal 7-valent conjugate vaccine protects young children. Drugs and Therapy Perspectives. 2003 2003;19 (7):1-4. PMID 2003282249.

12. Contraindications to vaccination in children. Mainly immunosuppression and a history of severe reactions. Prescrire International. 2003 Jun;12 (65):103-7. PMID 2003226922.

13. Immunization during pregnancy. International Journal of Gynecology and Obstetrics. 2003 1;81 (1):123-8. PMID 2003137411 MEDLINE PMID 12737148 (http://www.ncbi.nlm.nih.gov/pubmed/12737148).

14. Immunization during pregnancy. Obstetrics and Gynecology. 2003 1;101 (1):207-12. PMID 2003021729.

15. MMR vaccine--how effective and how safe? Drug Ther Bull. 2003 Apr;41 (4):25-9. PMID 12724845.

16. Rotavirus vaccine - AVANT Immunotherapeutics/GlaxoSmithKline: 89-12, RIX4414. Drugs in R and D. 2004 2004;5 (2):113-5. PMID 2004205222 MEDLINE PMID 15293874 (http://www.ncbi.nlm.nih.gov/pubmed/15293874).

17. Hepatitis A vaccine recommendations committee on infectious diseases. Pediatrics. 2007 July;120 (1):189-99. PMID 2007328906 MEDLINE PMID 17606579 (http://www.ncbi.nlm.nih.gov/pubmed/17606579).

18. Little evidence that supports a causal link between most vaccines and Guillain-Barre syndrome. Drugs and Therapy Perspectives. 2009 2009;25 (11):21-3. PMID 2009546429.

19. PCV13: Proven efficacy and safety. International Journal of Infectious Diseases. 2010 November;14 (SUPPL. 5):e8. PMID 2010597230.

20. Committee opinion No. 467: Human papillomavirus vaccination. Obstetrics and Gynecology. 2010 September;116 (3):800-3. PMID 2011075974 MEDLINE PMID 20733476 (http://www.ncbi.nlm.nih.gov/pubmed/20733476).

21. Meeting of the Global Advisory Committee on Vaccine Safety,June 2011. Weekly Epidemiological Record. 2011 Jul 22;86 (30):321-4. PMID 21800467.

22. 13-valent pneumococcal conjugate vaccine. Prescrire International. 2011 Jan;20 (112):5-7, 9. PMID 21462782.

23. HPV vaccines and pregnancy: the situation in early 2012. Prescrire International. 2012 Jun;21 (128):154-7. PMID 22822594.

24. Abramson JS, Baker CJ, Fisher MC, et al. Policy statement: Recommendations for the prevention of pneumococcal infections, including the use of pneumococcal conjugate vaccine (Prevnar), pneumococcal polysaccharide vaccine, and antibiotic prophylaxis. Pediatrics. 2000 2000;106 (2 I):362-6. PMID 2000289879.

25. Adler UC. The influence of childhood infections and vaccination on the development of atopy: A systematic review of the direct epidemiological evidence. Homeopathy. 2005 July;94 (3):182-95. PMID 2005298301 MEDLINE PMID 16060204 (http://www.ncbi.nlm.nih.gov/pubmed/16060204).

26. Al-Safi ZA, Shavell VI, Gonik B. Vaccination in pregnancy. Women's Health. 2011 January;7 (1):109-19. PMID 2011000392 MEDLINE PMID 21175395

(http://www.ncbi.nlm.nih.gov/pubmed/21175395).

27. Ambrose CS. Use of intranasal live attenuated influenza vaccine in individuals with asthma or a history of wheezing. Human vaccines & Immunotherapeutics. 2012 Feb;8 (2):279; author reply 80. PMID 22426366.

28. Ambrose CS, Wu XH, Knuf M, Wutzler P. The efficacy of intranasal live attenuated influenza vaccine in children 2 through 17 years of age: A meta-analysis of 8 randomized controlled studies. Vaccine. 2012 Jan;30 (5):886-92. PMID WOS:000301558000011.

29. Ambrose CS, Yi T, Falloon J. An integrated, multistudy analysis of the safety of Ann Arbor strain live attenuated influenza vaccine in children aged 2-17 years. Influenza & Other Respiratory Viruses. 2011 Nov;5 (6):389-97. PMID 21668683.

30. Anderson EJ. Intussusception risk of rotavirus vaccination. New England Journal of Medicine. 2011 Dec 1;365 (22):2137-8; author reply 8. PMID 22129262.

31. Anderson EL. Prevention of pertussis. Seminars in Respiratory Infections. 1989 Dec;4 (4):284-92. PMID 2560581.

32. Avery RK. Vaccination of the immunosuppressed adult patient with rheumatologic disease. Rheumatic Disease Clinics of North America. 1999 1999;25 (3):567-84. PMID 1999298466 MEDLINE PMID 10467629 (http://www.ncbi.nlm.nih.gov/pubmed/10467629).

33. Babl FE, Lewena S, Brown L. Vaccination-related adverse events. Pediatric Emergency Care. 2006 July;22 (7):514-22. PMID 2006367931 MEDLINE PMID 16871116 (http://www.ncbi.nlm.nih.gov/pubmed/16871116).

34. Baggs J, Gee J, Lewis E, et al. The vaccine safety datalink: A model for monitoring immunization safety. Pediatrics. 2011 May;127 (SUPPL. 1):S45-S53. PMID 2011239117 MEDLINE PMID 21502240 (http://www.ncbi.nlm.nih.gov/pubmed/21502240).

35. Balofsky A, Agmon-Levin N, Shoenfeld Y. The new H1N1 and HPV vaccines and old fears. Current Opinion in Rheumatology. 2010 July;22 (4):431-6. PMID 2010329949 MEDLINE PMID 20485175 (http://www.ncbi.nlm.nih.gov/pubmed/20485175).

36. Bar-On ES, Goldberg E, Hellmann S, Leibovici L. Combined DTP-HBV-HIB vaccine versus separately administered DTP-HBV and HIB vaccines for primary prevention of diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae B (HIB).[Update of Cochrane Database Syst Rev. 2009;(3):CD005530; PMID: 19588375]. Cochrane Database of Systematic Reviews. 2012;4:CD005530. PMID 22513932.

37. Barr E, Tamms G. Quadrivalent human papillomavirus vaccine. Clin Infect Dis. 2007 Sep 1;45 (5):609-7. PMID 17682997.

38. Bart KJ, Orenstein WA, Hinman AR. The current status of immunization principles:

Recommendations for use and adverse reactions. Journal of Allergy and Clinical Immunology. 1987 1987;79 (2):296-315. PMID 1987090583 MEDLINE PMID 3819215 (http://www.ncbi.nlm.nih.gov/pubmed/3819215).

39. Battista A, Ruggiero A, Coccia P, Arena R, Attina G, Riccardi R. Vaccination in children with cancer: A debate. Central European Journal of Medicine. 2012 April;7 (2):137-41. PMID 2012265240.

40. Baxter P. Pertussis vaccine encephalopathy: 'Oh! Let us never, never doubt '. Developmental Medicine & Child Neurology. 2010 Oct;52 (10):883-4. PMID 21175453.

41. Bechini A, Tiscione E, Boccalini S, Levi M, Bonanni P. Acellular pertussis vaccine use in risk groups (adolescents, pregnant women, newborns and health care workers): A review of evidences and recommendations. Vaccine. 2012 Jul 27;30 (35):5179-90. PMID 22709953.

42. Beck CR, McKenzie BC, Hashim AB, et al. Influenza vaccination for immunocompromised patients: systematic review and meta-analysis from a public health policy perspective. PLoS ONE [Electronic Resource]. 2011;6 (12):e29249. PMID 22216224.

43. Beeler J, Varricchio F, Wise R. Thrombocytopenia after immunization with measles vaccines: review of the vaccine adverse events reporting system (1990 to 1994). Pediatr Infect Dis J. 1996 Jan;15 (1):88-90. PMID 8684885.

44. Bernstein DI. Live attenuated human rotavirus vaccine, Rotarix. Seminars in Pediatric Infectious Diseases. 2006 Oct;17 (4):188-94. PMID 17055369.

45. Bernstein DI. A live attenuated human rotavirus vaccine. Drugs of Today. 2007 May;43 (5):281-91. PMID 17724495.

46. Beyer WE, Palache AM, Kerstens R, Masurel N. Gender differences in local and systemic reactions to inactivated influenza vaccine, established by a meta-analysis of fourteen independent studies. Eur J Clin Microbiol Infect Dis. 1996 Jan;15 (1):65-70. PMID 8641306.

47. Beyer WEP, Nauta JJP, Palache AM, Giezeman KM, Osterhaus ADME. Immunogenicity and safety of inactivated influenza vaccines in primed populations: a systematic literature review and meta-analysis. Vaccine. 2011 Aug 5;29 (34):5785-92. PMID 21624411.

48. Bigham M, Copes R. Thiomersal in vaccines: Balancing the risk of adverse effects with the risk of vaccine-preventable disease. Drug Safety. 2005 2005;28 (2):89-101. PMID 2005109203 MEDLINE PMID 15691220 (http://www.ncbi.nlm.nih.gov/pubmed/15691220).

49. Bines JE, Kohl KS, Forster J, et al. Acute intussusception in infants and children as an adverse event following immunization: Case definition and guidelines of data collection, analysis, and presentation. Vaccine. 2004 26;22 (5 6):569-74. PMID 2004041838 MEDLINE PMID 14741146 (http://www.ncbi.nlm.nih.gov/pubmed/14741146).

50. Black S, Della Cioppa G, Malfroot A, et al. Safety of MF59-adjuvanted versus non-adjuvanted influenza vaccines in children and adolescents: an integrated analysis. Vaccine. 2010 Oct 21;28 (45):7331-6. PMID 20813217.

51. Blank M, Israeli E, Shoenfeld Y. When APS (Hughes syndrome) met the autoimmune/inflammatory syndrome induced by adjuvants (ASIA). Lupus. 2012;21 (7):711-4. PMID 22635209.

52. Blencowe H, Lawn J, Vandelaer J, Roper M, Cousens S. Tetanus toxoid immunization to reduce mortality from neonatal tetanus. International Journal of Epidemiology. 2010 Apr;39 Suppl 1:i102-9. PMID 20348112.

53. Bliss SJ, O'Brien KL, Janoff EN, et al. The evidence for using conjugate vaccines to protect HIV-infected children against pneumococcal disease. The Lancet Infectious Diseases. 2008 Jan;8 (1):67-80. PMID 17974480.

54. Bonanni P, Cohet C, Kjaer SK, et al. A summary of the post-licensure surveillance initiatives for GARDASIL/SILGARD. Vaccine. 2010 Jul 5;28 (30):4719-30. PMID 20451636.

55. Bonhoeffer J, Heininger U. Adverse events following immunization: Perception and evidence. Current Opinion in Infectious Diseases. 2007 June;20 (3):237-46. PMID 2007219546 MEDLINE PMID 17471032 (http://www.ncbi.nlm.nih.gov/pubmed/17471032).

56. Bonhoeffer J, Siegrist CA, Heath PT. Immunisation of premature infants. Archives of Disease in Childhood. 2006 November;91 (11):929-35. PMID 2006541128 MEDLINE PMID 17056868 (http://www.ncbi.nlm.nih.gov/pubmed/17056868).

57. Borchers AT, Keen CL, Shoenfeld Y, Silva Jr J, Gershwin ME. Vaccines, viruses, and voodoo. Journal of Investigational Allergology and Clinical Immunology. 2002 2002;12 (3):155-68. PMID 2002415477 MEDLINE PMID 12530114 (http://www.ncbi.nlm.nih.gov/pubmed/12530114).

58. Bovier PA. Recent advances with a virosomal hepatitis A vaccine. Expert Opinion on Biological Therapy. 2008 August;8 (8):1177-85. PMID 2008356109 MEDLINE PMID 18613769 (http://www.ncbi.nlm.nih.gov/pubmed/18613769).

59. Brady MT, Bernstein HH, Byington CL, et al. Policy statement - Prevention of varicella: Update of recommendations for use of quadrivalent and monovalent varicella vaccines in children. Pediatrics. 2011 September;128 (3):630-2. PMID 2011490230 MEDLINE PMID 21873692 (http://www.ncbi.nlm.nih.gov/pubmed/21873692).

60. Broder KR, Martin DB, Vellozzi C. Bridging the gap between data and public health needs. In the heat of a signal: Responding to a vaccine safety signal for febrile seizures after 2010-11 influenza vaccine in young children, United States. Vaccine. 2012 2;30 (11):2032-4. PMID 2012104395.

61. Broder KR, Martin DB, Vellozzi C. In the heat of a signal: responding to a vaccine safety signal for febrile seizures after 2010-11 influenza vaccine in young children, United States. Vaccine. 2012 Mar 2;30 (11):2032-4. PMID 22361305.

62. Brunell PA, Bass JW, Daum RS. Hemophilus type b polysaccharide vaccine. Pediatrics. 1985 1985;76 (2):322-4. PMID 1985189925 MEDLINE PMID 3875076 (http://www.ncbi.nlm.nih.gov/pubmed/3875076).

63. Bryant KA, McVernon J, Marchant CD, et al. Immunogenicity and safety of measles-mumps-rubella and varicella vaccines coadministered with a fourth dose of Haemophilus influenzae type b and Neisseria meningitidis serogroups C and Y-tetanus toxoid conjugate vaccine in toddlers: A pooled analysis of randomized trials. Human Vaccines and Immunotherapeutics. 2012 August;8 (8):1036-41. PMID 2012533259.

64. Campion JJ, Casto DT. Haemophilus influenzae type b conjugate vaccine. Journal of Pediatric Health Care. 1988 Jul-Aug;2 (4):215-8. PMID 3404376.

65. Caple J. Pentavalent human-bovine reassortant rotavirus vaccine: a review of its efficacy and safety in preventing acute rotavirus gastroenteritis in healthy infants. Drugs of Today. 2006 May;42 (5):313-9. PMID 16801994.

66. Carter NJ, Curran MP. Live attenuated influenza vaccine (FluMist(registered trademark); Fluenz(trademark)): A review of its use in the prevention of seasonal influenza in children and adults. Drugs. 2011 2011;71 (12):1591-622. PMID 2011471189 MEDLINE PMID 21861544 (http://www.ncbi.nlm.nih.gov/pubmed/21861544).

67. Casey JR, Pichichero ME. Acellular pertussis vaccine safety and efficacy in children, adolescents and adults. Drugs. 2005;65 (10):1367-89. PMID 15977969.

68. Cavassini ML, D'Acremont V, Furrer H, Genton B, Tarr PE. Pharmacotherapy, vaccines and malaria advice for HIV-infected travellers. Expert Opinion on Pharmacotherapy. 2005 June;6 (6):891-913. PMID 2005306629 MEDLINE PMID 15952919 (http://www.ncbi.nlm.nih.gov/pubmed/15952919).

69. Cendes F, Sankar R. Vaccinations and febrile seizures. Epilepsia. 2011 May;52 (SUPPL. 3):23-5. PMID 2011251315 MEDLINE PMID 21542842 (http://www.ncbi.nlm.nih.gov/pubmed/21542842).

70. Centers for Disease C, Prevention. Intussusception among recipients of rotavirus vaccine--United States, 1998-1999. MMWR - Morbidity & Mortality Weekly Report. 1999 Jul 16;48 (27):577-81. PMID 10428095.

71. Centers for Disease C, Prevention. Withdrawal of rotavirus vaccine recommendation. MMWR - Morbidity & Mortality Weekly Report. 1999 Nov 5;48 (43):1007. PMID 10577495.

72. Centers for Disease C, Prevention. Licensure of a high-dose inactivated influenza vaccine

for persons aged >or=65 years (Fluzone High-Dose) and guidance for use - United States, 2010. MMWR - Morbidity & Mortality Weekly Report. 2010 Apr 30;59 (16):485-6. PMID 20431524.

73. Centers for Disease C, Prevention. Preliminary results: surveillance for Guillain-Barre syndrome after receipt of influenza A (H1N1) 2009 monovalent vaccine - United States, 2009-2010. MMWR - Morbidity & Mortality Weekly Report. 2010 Jun 4;59 (21):657-61. PMID 20520590.

74. Centers for Disease C, Prevention. Update: Recommendations of the Advisory Committee on Immunization Practices (ACIP) regarding use of CSL seasonal influenza vaccine (Afluria) in the United States during 2010-11. MMWR - Morbidity & Mortality Weekly Report. 2010 Aug 13;59 (31):989-92. PMID 20703207.

75. Centers for Disease C, Prevention. Licensure of a 13-valent pneumococcal conjugate vaccine (PCV13) and recommendations for use among children - Advisory Committee on Immunization Practices (ACIP), 2010. MMWR - Morbidity & Mortality Weekly Report. 2010 Mar 12;59 (9):258-61. PMID 20224542.

76. Centers for Disease C, Prevention. Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011. MMWR - Morbidity & Mortality Weekly Report. 2011 Aug 26;60 (33):1128-32. PMID 21866086.

77. Centers for Disease C, Prevention. Use of hepatitis B vaccination for adults with diabetes mellitus: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR - Morbidity & Mortality Weekly Report. 2011 Dec 23;60 (50):1709-11. PMID 22189894.

78. Centers for Disease C, Prevention. Updated recommendations for use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine from the Advisory Committee on Immunization Practices, 2010. MMWR - Morbidity & Mortality Weekly Report. 2011 Jan 14;60 (1):13-5. PMID 21228763.

79. Centers for Disease C, Prevention. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) - United States, 2012-13 Influenza Season. MMWR - Morbidity & Mortality Weekly Report. 2012 Aug 17;61:613-8. PMID 22895385.

80. Centers for Disease C, Prevention, American Academy of Pediatrics Committee on Infectious D. Additional recommendations for use of tetanus toxoid, reduced-content diphtheria toxoid, and acellular pertussis vaccine (Tdap). Pediatrics. 2011 Oct;128 (4):809-12. PMID 21949151.

81. Chaithongwongwatthana S, Yamasmit W, Limpongsanurak S, et al. Pneumococcal vaccination during pregnancy for preventing infant infection. Cochrane Database of Systematic Reviews. 2012 (7) PMID WOS:000306280400019.

82. Chambers S. Drug review - Prevenar(registered trademark). Drugs in Context. 2006 2006;2 (11):475-92. PMID 2006314606.

83. Chan R. Cochrane review summary for cancer nursing: Influenza vaccination in children having chemotherapy for cancer. Cancer Nursing. 2010 July-August;33 (4):327-8. PMID 2010363185 MEDLINE PMID 20571381 (http://www.ncbi.nlm.nih.gov/pubmed/20571381).

84. Chen N, Li Q, Zhang Y, Zhou M, Zhou D, He L. Vaccination for preventing postherpetic neuralgia. Cochrane Database of Systematic Reviews. 2011 (3):CD007795. PMID 21412911.

85. Chen RT. Vaccine risks: Real, perceived and unknown. Vaccine. 1999 29;17 (SUPPL. 3):S41-S6. PMID 1999383405 MEDLINE PMID 10559533 (http://www.ncbi.nlm.nih.gov/pubmed/10559533).

86. Chen RT, Mootrey G, DeStefano F. Safety of routine childhood vaccinations: An epidemiological review. Paediatric Drugs. 2000 2000;2 (4):273-90. PMID 2000286458 MEDLINE PMID 10946416 (http://www.ncbi.nlm.nih.gov/pubmed/10946416).

87. Cheuk DK, Chiang AK, Lee TL, Chan GC, Ha SY. Vaccines for prophylaxis of viral infections in patients with hematological malignancies. Cochrane Database of Systematic Reviews. 2011 (3):CD006505. PMID 21412895.

88. Cheuvart B, Friedland LR, Abu-Elyazeed R, Han HH, Guerra Y, Verstraeten T. The human rotavirus vaccine RIX4414 in infants: a review of safety and tolerability. Pediatric Infectious Disease Journal. 2009 Mar;28 (3):225-32. PMID 19209095.

89. Choudhuri D, Huda T, Theodoratou E, et al. An evaluation of emerging vaccines for childhood meningococcal disease. Bmc Public Health. 2011 Apr;11 PMID WOS:000290281000029.

90. Clark HF, Offit PA, Plotkin SA, Heaton PM. The new pentavalent rotavirus vaccine composed of bovine (strain WC3) -human rotavirus reassortants. Pediatric Infectious Disease Journal. 2006 Jul;25 (7):577-83. PMID 16804425.

91. Classen DC., Classen JB. The timing of pediatric immunization and the risk of insulin-dependent diabetes mellitus. Infect Dis Clin Pract. 1997;6 (7):449-54.

92. Clements C, Ball LK, Ball R, Pratt R. Thiomersal in vaccines: Is removal warranted? Drug Safety. 2001 2001;24 (8):567-74. PMID 2001252559 MEDLINE PMID 11480489 (http://www.ncbi.nlm.nih.gov/pubmed/11480489).

93. Clements CJ. The evidence for the safety of thiomersal in newborn and infant vaccines. Vaccine. 2004 7;22 (15 16):1854-61. PMID 2004198021 MEDLINE PMID 15121295 (http://www.ncbi.nlm.nih.gov/pubmed/15121295).

94. Clements CJ, Griffiths E. The global impact of vaccines containing aluminium adjuvants. Vaccine. 2002 31;20 (SUPPL. 3):S24-S33. PMID 2002204913 MEDLINE PMID 12184361 (http://www.ncbi.nlm.nih.gov/pubmed/12184361).

95. Clements CJ, McIntyre PB. When science is not enough - A risk/benefit profile of thiomersal-containing vaccines. Expert Opinion on Drug Safety. 2006 January;5 (1):17-29. PMID 2006018777 MEDLINE PMID 16370953 (http://www.ncbi.nlm.nih.gov/pubmed/16370953).

96. Cohen J. Adverse events following immunisation. Medicine Today. 2006 Apr;7 (4):67-72. PMID 2006207186.

97. Collinson A. Safety in numbers: Anaphylaxis risk in childhood immunisation. Archives of Disease in Childhood. 2012 June;97 (6):485-6. PMID 2012301994.

98. Committee on Infectious D. Policy statement-Prevention of varicella: update of recommendations for use of quadrivalent and monovalent varicella vaccines in children. Pediatrics. 2011 Sep;128 (3):630-2. PMID 21873692.

99. Conti F, Rezai S, Valesini G. Vaccination and autoimmune rheumatic diseases. Autoimmunity Reviews. 2008 Dec;8 (2):124-8. PMID 18700175.

100. Cook IF. Sex differences in injection site reactions with human vaccines. Human Vaccines. 2009 2009;5 (7):441-9. PMID 2009516224 MEDLINE PMID 19377279 (http://www.ncbi.nlm.nih.gov/pubmed/19377279).

101. Cooper B, Detora L, Stoddard J. Menveo(registered trademark): A novel quadrivalent meningococcal CRM(197) conjugate vaccine against serogroups A, C, W-135 and y. Expert Review of Vaccines. 2011 January;10 (1):21-33. PMID 2010701549 MEDLINE PMID 21162617 (http://www.ncbi.nlm.nih.gov/pubmed/21162617).

102. Cunliffe NA, Nakagomi O. A critical time for rotavirus vaccines: a review. Expert Review of Vaccines. 2005 Aug;4 (4):521-32. PMID 16117709.

103. Curlin G, Landry S, Bernstein J, et al. Integrating safety and efficacy evaluation throughout vaccine research and development. Pediatrics. 2011 May;127 (SUPPL. 1):S9-S15. PMID 2011239112 MEDLINE PMID 21502246 (http://www.ncbi.nlm.nih.gov/pubmed/21502246).

104. Dales L, Hammer SJ, Smith NJ. Time trends in autism and in MMR immunization coverage in California. JAMA. 2001 Mar 7;285 (9):1183-5. PMID 11231748.

105. D'Andrilli G, Bovicelli A, Giordano A. HPV vaccines: State of the art. Journal of Cellular Physiology. 2010 September;224 (3):601-4. PMID 2010388484 MEDLINE PMID 20432468 (http://www.ncbi.nlm.nih.gov/pubmed/20432468).

106. D'Angio CT. Active immunization of premature and low birth-weight infants: a review of

immunogenicity, efficacy, and tolerability. Paediatric Drugs. 2007;9 (1):17-32. PMID 17291134.

107. Darkes MJM, Plosker GL. Pneumococcal conjugate vaccine (Prevnar; PNCRM7): a review of its use in the prevention of Streptococcus pneumoniae infection. Paediatric Drugs. 2002;4 (9):609-30. PMID 12175274.

108. De Vos B, Vesikari T, Linhares AC, et al. A rotavirus vaccine for prophylaxis of infants against rotavirus gastroenteritis. Pediatric Infectious Disease Journal. 2004 Oct;23 (10 Suppl):S179-82. PMID 15502699.

109. Dell'Era L, Esposito S, Corona F, Principi N. Vaccination of children and adolescents with rheumatic diseases. Rheumatology. 2011 Aug;50 (8):1358-65. PMID WOS:000292832100004.

110. Delore V, Salamand C, Marsh G, Arnoux S, Pepin S, Saliou P. Long-term clinical trial safety experience with the inactivated split influenza vaccine, Vaxigrip. Vaccine. 2006 Mar 6;24 (10):1586-92. PMID 16271424.

111. Demicheli V, Rivetti A, Debalini MG, Di Pietrantonj C. Vaccines for measles, mumps and rubella in children. Cochrane Database of Systematic Reviews. 2012;2:CD004407. PMID 22336803.

112. Demirjian A, Levy O. Safety and efficacy of neonatal vaccination. European Journal of Immunology. 2009 2009;39 (1):36-46. PMID 2009103530 MEDLINE PMID 19089811 (http://www.ncbi.nlm.nih.gov/pubmed/19089811).

113. DeStefano F. Vaccines and autism: Evidence does not support a causal association. Clinical Pharmacology and Therapeutics. 2007 December;82 (6):756-9. PMID 2007557883 MEDLINE PMID 17928818 (http://www.ncbi.nlm.nih.gov/pubmed/17928818).

114. Destefano F, Pfeifer D, Nohynek H. Safety profile of pneumococcal conjugate vaccines: systematic review of pre- and post-licensure data. Bulletin of the World Health Organization. 2008 May;86 (5):373-80. PMID 18545740.

115. DeStefano F, Thompson WW. MMR vaccine and autism: an update of the scientific evidence. Expert Rev Vaccines. 2004 Feb;3 (1):19-22. PMID 14761240.

116. Dhillon S. Spotlight on DTPa-HBV-IPVHib vaccine (Infanrix hexa((trademark))). BioDrugs. 2010 2010;24 (5):299-302. PMID 2010470987 MEDLINE PMID 20795752 (http://www.ncbi.nlm.nih.gov/pubmed/20795752).

117. Dhillon S. DTPa-HBV-IPVHib vaccine (infanrix hexa(trademark)): A review of its use as primary and booster vaccination. Drugs. 2010 2010;70 (8):1021-58. PMID 2010292020.

118. Dhillon S, Curran MP. Live attenuated measles, mumps, rubella, and varicella zoster virus vaccine (Priorix-Tetra). Paediatric Drugs. 2008;10 (5):337-47. PMID 18754700.

119. Dhillon S, Keam SJ. DTaP-IPV/Hib vaccine (Pentacel(registered trademark)). Pediatric Drugs. 2008 2008;10 (6):405-16. PMID 2008535695 MEDLINE PMID 18998751 (http://www.ncbi.nlm.nih.gov/pubmed/18998751).

120. Dinleyici EC, Yargic ZA. Current knowledge regarding the investigational 13-valent pneumococcal conjugate vaccine. Expert Review of Vaccines. 2009 Aug;8 (8):977-86. PMID 19627181.

121. Duggan ST. Pneumococcal polysaccharide conjugate vaccine (13-Valent, Adsorbed) Prevenar 13((registered trademark)). Drugs. 2010 2010;70 (15):1973-86. PMID 2010559199 MEDLINE PMID 20883054 (http://www.ncbi.nlm.nih.gov/pubmed/20883054).

122. Dull PM, McIntosh ED. Meningococcal vaccine development - from glycoconjugates against MenACWY to proteins against MenB - potential for broad protection against meningococcal disease. Vaccine. 2012 30;30 (SUPPL. 2):B18-B25. PMID 2012287507.

123. Eichelberger MC, Sperber E, Wagner M, et al. Clinical evaluation of a single oral dose of human-bovine (UK) reassortant rotavirus vaccines Wa x UK (P1A[8],G6) and Wa x (DS-1 x UK) (P1A[8],G2). Journal of Medical Virology. 2002 Mar;66 (3):407-16. PMID 11793395.

124. Eldred BE, Dean AJ, McGuire TM, Nash AL. Vaccine components and constituents: Responding to consumer concerns. Medical Journal of Australia. 2006 20;184 (4):170-5. PMID 2006104144 MEDLINE PMID 16489901 (http://www.ncbi.nlm.nih.gov/pubmed/16489901).

125. Etter DJ, Zimet GD, Rickert VI. Human papillomavirus vaccine in adolescent women: A 2012 update. Current Opinion in Obstetrics and Gynecology. 2012;8.

126. Evans G. Vaccine liability and safety: A progress report. Pediatric Infectious Disease Journal. 1996 1996;15 (6):477-8. PMID 1996189560 MEDLINE PMID 8783342 (http://www.ncbi.nlm.nih.gov/pubmed/8783342).

127. Faix RG. Maternal immunization to prevent fetal and neonatal infection. Clinical Obstetrics and Gynecology. 1991 1991;34 (2):277-87. PMID 1991168891 MEDLINE PMID 1907897 (http://www.ncbi.nlm.nih.gov/pubmed/1907897).

128. Farez MF, Correale J. Immunizations and risk of multiple sclerosis: systematic review and meta-analysis. Journal of Neurology. 2011 Jul;258 (7):1197-206. PMID 21431896.

129. Fernandes GC, Camacho LAB, Sa Carvalho M. Surveillance system of vaccine adverse events and local data analysis - The experience in a middle-sized city in Brazil, 1999-2001. Vaccine. 2005 18;23 (17 18):2349-53. PMID 2005114455 MEDLINE PMID 15755626 (http://www.ncbi.nlm.nih.gov/pubmed/15755626).

130. Ferreccio C, Clemens J, Avendano A, et al. The Clinical and Immunological Response of Chilean Infants to Haemophilus-Influenzae Type B-Polysaccharide-Tetanus Protein Conjugate

Vaccine Coadministered in the Same Syringe with Diphtheria-Tetanus Toxoids-Pertussis Vaccine at 2, 4 and 6 Months of Age. Pediatric Infectious Disease Journal. 1991 Oct;10 (10):764-71. PMID WOS:A1991GJ51500010.

131. Fine MJ, Smith MA, Carson CA, et al. Efficacy of pneumococcal vaccination in adults: A meta-analysis of randomized controlled trials. Archives of Internal Medicine. 1994 1994;154 (23):2666-77. PMID 1994374270 MEDLINE PMID 7993150 (http://www.ncbi.nlm.nih.gov/pubmed/7993150).

132. Fiore AE, Uyeki TM, Broder K, et al. Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010.[Erratum appears in MMWR Recomm Rep. 2010 Aug 13;59(31):993], [Erratum appears in MMWR Recomm Rep. 2010 Sep 10;59(35):1147]. Morbidity & Mortality Weekly Report. Recommendations & Reports. 2010 Aug 6;59 (RR-8):1-62. PMID 20689501.

133. Flohr C, Yeo L. Atopic dermatitis and the hygiene hypothesis revisited. SOURCE Current Problems in Dermatology (2011) 41 (1-34). Date of Publication: May 2011 Pathogenesis and Management of Atopic Dermatitis, Book Series Title:. 2011 PMID 2011308604 MEDLINE PMID 21576944 (http://www.ncbi.nlm.nih.gov/pubmed/21576944).

134. Fombonne E, Zakarian R, Bennett A, Meng L, McLean-Heywood D. Pervasive developmental disorders in Montreal, Quebec, Canada: Prevalence and links with immunizations. Pediatrics. 2006 July;118 (1):e139-e50. PMID 2007025041 MEDLINE PMID 16818529 (http://www.ncbi.nlm.nih.gov/pubmed/16818529).

135. Forinash AB, Yancey AM, Pitlick JM, Myles TD. Safety of the HPV bivalent and quadrivalent vaccines during pregnancy. Annals of Pharmacotherapy. 2011 February;45 (2):258-62. PMID 2011107897.

136. Fox KA, Theiler R. Vaccination in pregnancy. Current Pharmaceutical Biotechnology. 2011 June;12 (5):789-96. PMID 2011246833 MEDLINE PMID 21480828 (http://www.ncbi.nlm.nih.gov/pubmed/21480828).

137. Frampton JE, Keating GM. Reduced-antigen, combined diphtheria, tetanus, and acellular pertussis vaccine (boostrix(trademark)): A review of its use as a single-dose booster immunization. BioDrugs. 2006 2006;20 (6):371-89. PMID 2007030567 MEDLINE PMID 17176125 (http://www.ncbi.nlm.nih.gov/pubmed/17176125).

138. Frenck RW, Jr., Seward JF. Varicella vaccine safety and immunogenicity in patients with juvenile rheumatic diseases receiving methotrexate and corticosteroids. Arthritis care & research. 2010 Jul;62 (7):903-6. PMID 20506363.

139. Fritsche PJ, Helbling A, Ballmer-Weber BK. Vaccine hypersensitivity - Update and overview. Swiss Medical Weekly. 2010 30;140 (17 18):238-46. PMID 2010256443 MEDLINE PMID 20349363 (http://www.ncbi.nlm.nih.gov/pubmed/20349363).

140. Galiza EP, Heath PT. Adverse events following immunisation - fact and fiction. Paediatrics and Child Health. 2008 November;18 (11):508-12. PMID 2008478823.

141. Geier DA, Geier MR. A comparative evaluation of the effects of MMR immmunization and mercury doses from thimerosal-containing childhood vaccines on the population prevalence of autism. Medical Science Monitor. 2004 March;10 (3):PI33-PI9. PMID 2004123596 MEDLINE PMID 14976450 (http://www.ncbi.nlm.nih.gov/pubmed/14976450).

142. Ghaffar F. The safety of 7-valent pneumococcal conjugate vaccine. Expert Opinion on Drug Safety. 2005 Jul;4 (4):631-6. PMID 16011442.

143. Girard M. Autoimmune hazards of hepatitis B vaccine. Autoimmunity Reviews. 2005 February;4 (2):96-100. PMID 2005084167 MEDLINE PMID 15722255 (http://www.ncbi.nlm.nih.gov/pubmed/15722255).

144. Gladstone RA, Jefferies JM, Faust SN, Clarke SC. Pneumococcal 13-valent conjugate vaccine for the prevention of invasive pneumococcal disease in children and adults. Expert Review of Vaccines. 2012 August;11 (8):889-902. PMID 2012567216.

145. Glass RI, Patel M, Parashar U. Lessons from the US rotavirus vaccination program. JAMA. 2011 Oct 19;306 (15):1701-2. PMID 22009102.

146. Gleeson TD, Wallace MR, Tasker SA. Vaccination in patients with HIV infection. Current Infectious Disease Reports. 2006 Mar;8 (2):151-61. PMID 2006149208.

147. Glezen WP. Maternal vaccines. Primary Care - Clinics in Office Practice. 2001 2001;28 (4):791-806. PMID 2001417166 MEDLINE PMID 11739030 (http://www.ncbi.nlm.nih.gov/pubmed/11739030).

148. Gluck T, Muller-Ladner U. Vaccination in patients with chronic rheumatic or autoimmune diseases. Clinical Infectious Diseases. 2008 May 1;46 (9):1459-65. PMID 18419456.

149. Gold M, Goodwin H, Botham S, Burgess M, Nash M, Kempe A. Re-vaccination of 421 children with a past history of an adverse vaccine reaction in a special immunisation service. Archives of Disease in Childhood. 2000 2000;83 (2):128-31. PMID 2000310293 MEDLINE PMID 10906018 (http://www.ncbi.nlm.nih.gov/pubmed/10906018).

150. Goldschmidt I, Pfister ED, Becker M, Hackl S, Bott OJ, Baumann U. Acceptance and adverse events of the 2009 H1N1 vaccination in immunosuppressed pediatric liver transplant recipients. Journal of Pediatrics. 2011 Feb;158 (2):329-33. PMID 21163496.

151. Goldstone SE, Vuocolo S. A prophylactic quadrivalent vaccine for the prevention of infection and disease related to HPV-6, -11, -16 and -18. Expert Review of Vaccines. 2012 April;11 (4):395-406. PMID 2012256012.

152. Goveia MG, Ciarlet M, Owen KE, Ranucci CS. Development, clinical evaluation, and

post-licensure impact of RotaTeq, a pentavalent rotavirus vaccine. Annals of the New York Academy of Sciences. 2011 Mar;1222:14-8. PMID 21434938.

153. Goveia MG, Suprun L, Itzler RF, McFetridge R, Dallas MJ, Kuter BJ. Efficacy and safety of pentavalent human-bovine reassortant rotavirus vaccine when administered with greater than 10 weeks between doses. Pediatric Infectious Disease Journal. 2010 Mar;29 (3):263-5. PMID 19949360.

154. Graves PM. Hemophilus vaccine and diabetes. Diabetes Care. 2000 2000;23 (6):872-3. PMID 2000223918.

155. Gray J. Rotavirus vaccines: safety, efficacy and public health impact. Journal of Internal Medicine. 2011 Sep;270 (3):206-14. PMID 21668823.

156. Greenberg DP. Considerations for hepatitis B as part of a combination vaccine. Pediatric Infectious Disease Journal. 2001 2001;20 (11 SUPPL.):S34-S9. PMID 2001402762 MEDLINE PMID 11704722 (http://www.ncbi.nlm.nih.gov/pubmed/11704722).

157. Greenberg HB. Rotavirus vaccination and intussusception--act two. New England Journal of Medicine. 2011 Jun 16;364 (24):2354-5. PMID 21675894.

158. Griffiths UK, Clark A, Gessner B, et al. Dose-specific efficacy of Haemophilus influenzae type b conjugate vaccines: A systematic review and meta- Analysis of controlled clinical trials. Epidemiology and Infection. 2012 August;140 (8):1343-55. PMID 2012418453.

159. Gruber C, Nilsson L, Bjorksten B. Do early childhood immunizations influence the development of atopy and do they cause allergic reactions? Pediatric Allergy and Immunology. 2001 2001;12 (6):296-311. PMID 2002030175 MEDLINE PMID 11846867 (http://www.ncbi.nlm.nih.gov/pubmed/11846867).

160. Gruber WC, Scott DA, Emini EA. Development and clinical evaluation of Prevnar 13, a 13-valent pneumococcal CRM(197) conjugate vaccine. Annals of the New York Academy of Sciences. 2012 Aug;1263 (1):15-26. PMID 22830997.

161. Guidozzi F. The HPV vaccine - What the family practitioner needs to know. South African Family Practice. 2008 July/August;50 (4):22-4. PMID 2008495601.

162. Haber P, DeStefano F, Angulo FJ, et al. Guillain-Barre syndrome following influenza vaccination. JAMA. 2004 Nov 24;292 (20):2478-81. PMID 15562126.

163. Halsey NA, Chesney PJ, Gerber MA, et al. Poliomyelitis prevention: Recommendations for use of inactivated poliovirus vaccine and live oral poliovirus vaccine. Pediatrics. 1997 February;99 (2):300-5. PMID 1997104368 MEDLINE PMID 9024465 (http://www.ncbi.nlm.nih.gov/pubmed/9024465).

164. Heaton PM, Ciarlet M. Vaccines: the pentavalent rotavirus vaccine: discovery to licensure

and beyond. Clinical Infectious Diseases. 2007 Dec 15;45 (12):1618-24. PMID 18198497.

165. Heijstek MW, Ott De Bruin LM, Bijl M, et al. EULAR recommendations for vaccination in paediatric patients with rheumatic diseases. Annals of the Rheumatic Diseases. 2011 October;70 (10):1704-12. PMID 2011496983 MEDLINE PMID 21813547 (http://www.ncbi.nlm.nih.gov/pubmed/21813547).

166. Heijstek MW, Ott de Bruin LM, Borrow R, et al. Vaccination in paediatric patients with auto-immune rheumatic diseases: a systemic literature review for the European League against Rheumatism evidence-based recommendations. Autoimmunity Reviews. 2011 Dec;11 (2):112-22. PMID 21896342.

167. Heininger U. Pertussis immunisation in adolescents and adults. Advances in Experimental Medicine and Biology. 2008 2008;609:72-97. PMID 2009179912 MEDLINE PMID 18193659 (http://www.ncbi.nlm.nih.gov/pubmed/18193659).

168. Heyse JF, Kuter BJ, Dallas MJ, Heaton P, Team RS. Evaluating the safety of a rotavirus vaccine: the REST of the story. Clinical Trials. 2008;5 (2):131-9. PMID 18375651.

169. Huang DB, Wu JJ, Tyring SK. A review of licensed viral vaccines, some of their safety concerns, and the advances in the development of investigational viral vaccines. Journal of Infection. 2004 October;49 (3):179-209. PMID 2004383074 MEDLINE PMID 15337336 (http://www.ncbi.nlm.nih.gov/pubmed/15337336).

170. Huang W-T, Chang S, Miller ER, et al. Safety assessment of recalled Haemophilus influenzae type b (Hib) conjugate vaccines--United States, 2007-2008. Pharmacoepidemiology & Drug Safety. 2010 Mar;19 (3):306-10. PMID 20084617.

171. Hussain H, Omer SB, Manganello JA, et al. Immunization safety in US print media, 1995-2005. Pediatrics. 2011 May;127 (SUPPL. 1):S100-S6. PMID 2011239124 MEDLINE PMID 21502237 (http://www.ncbi.nlm.nih.gov/pubmed/21502237).

172. IOM. Immunization safety review: influenza vaccines and neurological complications. Washington DC: National Academies Press. 2001:78 –9, 88 –9.

173. Iskander J, Broder K. Monitoring the safety of annual and pandemic influenza vaccines: lessons from the US experience. Expert Review of Vaccines. 2008 Feb;7 (1):75-82. PMID WOS:000260047900014.

174. Iskander JK, Gidudu J, Arboleda N, Huang WT. Selected major issues in vaccine safety. Annales Nestle. 2008 July;66 (2):93-102. PMID 2008345556.

175. Izurieta HS, Haber P, Wise RP, et al. Adverse events reported following live, cold-adapted, intranasal influenza vaccine. JAMA. 2005 Dec 7;294 (21):2720-5. PMID 16333007.

176. Jacobson RM. Vaccine safety. Immunology and Allergy Clinics of North America. 2003

November;23 (4):589-603. PMID 2004010558 MEDLINE PMID 14753382 (http://www.ncbi.nlm.nih.gov/pubmed/14753382).

177. Jefferies JMC, Macdonald E, Faust SN, Clarke SC. 13-valent pneumococcal conjugate vaccine (PCV13). Human Vaccines. 2011;7 (10) PMID 2011578238.

178. Jefferson T, Di Pietrantonj C, Al-Ansary LA, Ferroni E, Thorning S, Thomas RE. Vaccines for preventing influenza in the elderly. Cochrane Database of Systematic Reviews. 2010 (2):CD004876. PMID 20166072.

179. Jefferson T, Di Pietrantonj C, Rivetti A, Bawazeer GA, Al-Ansary LA, Ferroni E. Vaccines for preventing influenza in healthy adults. Cochrane Database of Systematic Reviews. 2010 (7):CD001269. PMID 20614424.

180. Jefferson T, Price D, Demicheli V, Bianco E, European Research Program for Improved Vaccine Safety Surveillance P. Unintended events following immunization with MMR: a systematic review. Vaccine. 2003 Sep 8;21 (25-26):3954-60. PMID 12922131.

181. Jeffery DR. The use of vaccinations in patients with multiple sclerosis. Infections in Medicine. 2002 2002;19 (2):73-9. PMID 2002089500.

182. Jick H, Kaye JA. Epidemiology and Possible Causes of Autism. Pharmacotherapy. 2003 December;23 (12 I):1524-30. PMID 2003493362 MEDLINE PMID 14695031 (http://www.ncbi.nlm.nih.gov/pubmed/14695031).

183. Joura EA, Garland SM, Paavonen J, et al. Effect of the human papillomavirus (HPV) quadrivalent vaccine in a subgroup of women with cervical and vulvar disease: Retrospective pooled analysis of trial data. BMJ. 2012;344 (7851) PMID 2012205289.

184. Kaczorowski J. Pneumococcal vaccination and cardiovascular events in men. JAMA. 2010 Aug 18;304 (7):742; author reply 3. PMID 20716734.

185. Kanesa-thasan N, Shaw A, Stoddard JJ, Vernon TM. Ensuring the optimal safety of licensed vaccines: A perspective of the vaccine research, development, and manufacturing companies. Pediatrics. 2011 May;127 (SUPPL. 1):S16-S22. PMID 2011239113 MEDLINE PMID 21502248 (http://www.ncbi.nlm.nih.gov/pubmed/21502248).

186. Kaplan SL. Haemophilus influenzae type B conjugate vaccines. Pediatr Ann. 1990 Dec;19 (12):712-3, 6-8. PMID 2280990.

187. Karande S, Gogtay NJ, Kshirsagar NA. Efficacy and safety of vaccines in Indian children: A review. Paediatric and Perinatal Drug Therapy. 2003 2003;5 (3):124-34. PMID 2003260572.

188. Kaye JA, del Mar Melero-Montes M, Jick H. Mumps, measles, and rubella vaccine and the incidence of autism recorded by general practitioners: a time trend analysis. BMJ. 2001 Feb 24;322 (7284):460-3. PMID 11222420.

189. Keating GM, Noble S, Averhoff FM, et al. Recombinant hepatitis B vaccine (Engerix-B(registered trademark)): A review of its immunogenicity and protective efficacy against hepatitis B. Drugs. 2003 2003;63 (10):1021-51. PMID 2003197841 MEDLINE PMID 12699402 (http://www.ncbi.nlm.nih.gov/pubmed/12699402).

190. Kennedy RC, Byers VS, Marchalonis JJ. Measles virus infection and vaccination: Potential role in chronic illness and associated adverse events. Critical Reviews in Immunology. 2004 2004;24 (2):129-56. PMID 2004535433 MEDLINE PMID 15581394 (http://www.ncbi.nlm.nih.gov/pubmed/15581394).

191. Khromava A, Cohen CJ, Mazur M, Kanesa-Thasan N, Crucitti A, Seifert H. Manufacturers' postmarketing safety surveillance of influenza vaccine exposure in pregnancy. American Journal of Obstetrics and Gynecology. 2012 September;207 (3 SUPPL.):S52-S6. PMID 2012497478.

192. Kohl KS, Marcy SM, Blum M, et al. Fever after immunization: Current concepts and improved future scientific understanding. Clinical Infectious Diseases. 2004 1;39 (3):389-94. PMID 2004342022 MEDLINE PMID 15307007 (http://www.ncbi.nlm.nih.gov/pubmed/15307007).

193. Koppen S, de Groot R, Neijens HJ, Nagelkerke N, van Eden W, Rumke HC. No epidemiological evidence for infant vaccinations to cause allergic disease. Vaccine. 2004 Sep 3;22 (25-26):3375-85. PMID 15308362.

194. Kuo AM, Brown JN, Clinard V. Effect of influenza vaccination on international normalized ratio during chronic warfarin therapy. Journal of Clinical Pharmacy and Therapeutics. 2012.

195. Kwok R. Vaccines: The real issues in vaccine safety. Nature. 2011 26;473 (7348):436-8. PMID 2011293237 MEDLINE PMID 21614053 (http://www.ncbi.nlm.nih.gov/pubmed/21614053).

196. Labrie JE, 3rd, Keiser PB. Whole cell vaccination for meningococcus: Lessons from an idea for which time has gone. Human Vaccines. 2010 Apr;6 (4):360-5. PMID 20372072.

197. Lacroix I, Damase-Michel C, Kreft-Jais C, Castot A, Montastruc JL, French Association of Regional Pharmacovigilance C. 2009 H1N1 influenza vaccines in pregnant women: the French Pharmacovigilance survey. Vaccine. 2011 Feb 4;29 (7):1357-8. PMID 21185422.

198. Lapphra K, Scheifele DW. Can children with minor illnesses be safely immunized? Paediatrics and Child Health. 2011 October;16 (8):463. PMID 2011561841.

199. LaRussa PS, Edwards KM, Dekker CL, et al. Understanding the role of human variation in vaccine adverse events: The clinical immunization safety assessment network. Pediatrics. 2011 May;127 (SUPPL. 1):S65-S73. PMID 2011239119 MEDLINE PMID 21502239 (http://www.ncbi.nlm.nih.gov/pubmed/21502239).

200. Lavelle EC, O'Hagan DT. Delivery systems and adjuvants for oral vaccines. Expert Opinion on Drug Delivery. 2006 November;3 (6):747-62. PMID 2006571316 MEDLINE PMID 17076597 (http://www.ncbi.nlm.nih.gov/pubmed/17076597).

201. Lepage P, Vergison A. Prevention of childhood rotavirus disease through the use of Rotarix and RotaTeq vaccines. Expert Opinion on Biological Therapy. 2007 Dec;7 (12):1881-92. PMID 18034653.

202. Lepage P, Vergison A. Impact of rotavirus vaccines on rotavirus disease. Expert Review of Anti-Infective Therapy. 2012 May;10 (5):547-61. PMID 2012348240.

203. Lepow ML. Pediatric immunizations and adverse events. Current Opinion in Infectious Diseases. 1991 1991;4 (4):463-8. PMID 1991262882.

204. Levavi H. Human papillomavirus vaccination - To adolescents. Pediatric Endocrinology Reviews. 2010 September;8 (1):2-5. PMID 2010694220.

205. Lieu TA, Nguyen MD, Ball R, Martin DB. Health outcomes of interest for evaluation in the Post-Licensure Rapid Immunization Safety Monitoring Program. Vaccine. 2012 Apr 16;30 (18):2824-30. PMID 22394993.

206. Lindblad EB. Aluminium adjuvants - In retrospect and prospect. Vaccine. 2004 9;22 (27 28):3658-68. PMID 2004358343 MEDLINE PMID 15315845 (http://www.ncbi.nlm.nih.gov/pubmed/15315845).

207. Linhares AC, Villa LL. Vaccines against rotavirus and human papillomavirus (HPV). Jornal de Pediatria. 2006 Jul;82 (3 Suppl):S25-34. PMID 16786101.

208. Livengood JR, Mullen JR, White JW, Brink EW, Orenstein WA. Family history of convulsions and use of pertussis vaccine. Journal of Pediatrics. 1989 Oct;115 (4):527-31. PMID 2552066.

209. Lloyd JC, Haber P, Mootrey GT, et al. Adverse event reporting rates following tetanus-diphtheria and tetanus toxoid vaccinations: data from the Vaccine Adverse Event Reporting System (VAERS), 1991-1997. Vaccine. 2003 Sep 8;21 (25-26):3746-50. PMID 12922107.

210. Loebermann M, Winkelmann A, Hartung HP, Hengel H, Reisinger EC, Zettl UK. Vaccination against infection in patients with multiple sclerosis. Nature Reviews Neurology. 2012 March;8 (3):143-51. PMID 2012147137.

211. Lu B, Kumar A, Castellsague X, Giuliano AR. Efficacy and safety of prophylactic vaccines against cervical HPV infection and diseases among women: a systematic review & meta-analysis. BMC Infectious Diseases. 2011;11:13. PMID 21226933.

212. Lucero MG, Dulalia VE, Nillos LT, et al. Pneumococcal conjugate vaccines for preventing

vaccine-type invasive pneumococcal disease and X-ray defined pneumonia in children less than two years of age. Cochrane Database of Systematic Reviews. 2009 (4) PMID WOS:000270687300045.

213. MacDonald NE, Riley LE, Steinhoff MC. Influenza immunization in pregnancy. Obstet Gynecol. 2009 Aug;114 (2 Pt 1):365-8. PMID 19622998.

214. Madaan A, Maddox DE. Vaccine allergy: Diagnosis and management. Immunology and Allergy Clinics of North America. 2003 November;23 (4):555-88. PMID 2004010557 MEDLINE PMID 14753381 (http://www.ncbi.nlm.nih.gov/pubmed/14753381).

215. Mak TK, Mangtani P, Leese J, Watson JM, Pfeifer D. Influenza vaccination in pregnancy: current evidence and selected national policies. Lancet Infect Dis. 2008 Jan;8 (1):44-52. PMID 18156088.

216. Makris MC, Polyzos KA, Mavros MN, Athanasiou S, Rafailidis PI, Falagas ME. Safety of Hepatitis B, Pneumococcal Polysaccharide and Meningococcal Polysaccharide Vaccines in Pregnancy A Systematic Review. Drug Safety. 2012;35 (1):1-14. PMID WOS:000298866400001.

217. Manzoli L, De Vito C, Salanti G, D'Addario M, Villari P, Ioannidis JPA. Meta-analysis of the immunogenicity and tolerability of pandemic influenza A 2009 (H1N1) vaccines. PLoS ONE [Electronic Resource]. 2011;6 (9):e24384. PMID 21915319.

218. Manzoli L, Ioannidis JPA, Flacco ME, De Vito C, Villari P. Effectiveness and harms of seasonal and pandemic influenza vaccines in children, adults and elderly: A critical review and re-analysis of 15 meta-analyses. Human Vaccines and Immunotherapeutics. 2012 July;8 (7):851-62. PMID 2012427206.

219. Marin M, Broder KR, Temte JL, et al. Use of combination measles, mumps, rubella, and varicella vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). Morbidity & Mortality Weekly Report Recommendations & Reports. 2010 May 7;59 (RR-3):1-12. PMID 20448530.

220. Marshall GS. Rotavirus disease and prevention through vaccination. Pediatric Infectious Disease Journal. 2009 Apr;28 (4):355-62, quiz 63-4. PMID 19333083.

221. Marshall GS, Gellin BG. Challenges to vaccine safety. Primary Care - Clinics in Office Practice. 2001 2001;28 (4):853-68. PMID 2001417169 MEDLINE PMID 11739033 (http://www.ncbi.nlm.nih.gov/pubmed/11739033).

222. Martin BL, Nelson MR, Hershey JN, Engler RJM. Adverse reactions to vaccines. Clinical Reviews in Allergy and Immunology. 2003 June;24 (3):263-75. PMID 2003203883 MEDLINE PMID 12721397 (http://www.ncbi.nlm.nih.gov/pubmed/12721397).

223. Mary Healy C. Vaccines in pregnant women and research initiatives. Clinical Obstetrics

and Gynecology. 2012 June;55 (2):474-86. PMID 2012239403.

224. Mathew JL, El Dib R, Mathew PJ, Boxall EH, Brok J. Hepatitis B immunisation in persons not previously exposed to hepatitis B or with unknown exposure status. Cochrane Database of Systematic Reviews. 2008;3 PMID 2008510762.

225. Matson DO. The pentavalent rotavirus vaccine, RotaTeq. Seminars in Pediatric Infectious Diseases. 2006 Oct;17 (4):195-9. PMID 17055370.

226. McCormack PL, Keam SJ. Rotavirus vaccine RIX4414 (Rotarix): a review of its use in the prevention of rotavirus gastroenteritis. Paediatric Drugs. 2009;11 (1):75-88. PMID 19127963.

227. McIntyre P. Vaccines against invasive Haemophilus influenzae type b disease. Journal of Paediatrics and Child Health. 1994 1994;30 (1):14-8. PMID 1994048436 MEDLINE PMID 8148181 (http://www.ncbi.nlm.nih.gov/pubmed/8148181).

228. McKeage K, Romanowski B. AS04-adjuvanted human papillomavirus (HPV) types 16 and 18 vaccine (Cervarix((registered trademark))): A review of its use in the prevention of premalignant cervical lesions and cervical cancer causally related to certain oncogenic HPV types. Drugs. 2011 2011;71 (4):465-88. PMID 2011144419 MEDLINE PMID 21395359 (http://www.ncbi.nlm.nih.gov/pubmed/21395359).

229. McMahon AW, Iskander JK, Haber P, Braun MM, Ball R. Inactivated influenza vaccine (IIV) in children <2 years of age: examination of selected adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) after thimerosal-free or thimerosal-containing vaccine. Vaccine. 2008 Jan 17;26 (3):427-9. PMID 18093701.

230. McPhillips H, Marcuse EK. Vaccine safety. Current Problems in Pediatrics. 2001 Apr;31 (4):91-121. PMID 11330034.

231. McVernon J, Nolan T. Panvax(registered trademark): A monovalent inactivated unadjuvanted vaccine against pandemic influenza A (H1N1) 2009. Expert Review of Vaccines. 2011 January;10 (1):35-43. PMID 2010701546 MEDLINE PMID 21162618 (http://www.ncbi.nlm.nih.gov/pubmed/21162618).

232. Merchant N, Waldrop J. The safety advantages of pentavalent vaccines. Nurse Practitioner. 2012 Apr 15;37 (4):48-53. PMID 22430930.

233. Michiels B, Govaerts F, Remmen R, Vermeire E, Coenen S. A systematic review of the evidence on the effectiveness and risks of inactivated influenza vaccines in different target groups. Vaccine. 2011 15;29 (49):9159-70. PMID 2011662699 MEDLINE PMID 21840359 (http://www.ncbi.nlm.nih.gov/pubmed/21840359).

234. Miravalle A, Biller J, Schnitzler E, Bonwit A. Neurological complications following vaccinations. Neurological Research. 2010 1;32 (3):285-92. PMID 2010237387 MEDLINE PMID 20406607 (http://www.ncbi.nlm.nih.gov/pubmed/20406607).

235. Mirzayeva R, Steele AD, Parashar UD, Zaman K, Neuzil KM, Nelson EAS. Evaluation of rotavirus vaccines in Asia-Are there lessons to be learnt? Vaccine. 2009 20;27 (SUPPL. 5):F120-F9. PMID 2009631221 MEDLINE PMID 19931711 (http://www.ncbi.nlm.nih.gov/pubmed/19931711).

236. Molinaro GA, Lee DA. Rotavirus vaccines [1]. New England Journal of Medicine. 2006 20;354 (16):1747. PMID 2006182386.

237. Monsonego J, Cortes J, Greppe C, Hampl M, Joura E, Singer A. Benefits of vaccinating young adult women with a prophylactic quadrivalent human papillomavirus (types 6, 11, 16 and 18) vaccine. Vaccine. 2010 29;28 (51):8065-72. PMID 2010662131 MEDLINE PMID 20971114 (http://www.ncbi.nlm.nih.gov/pubmed/20971114).

238. Mooi FR, de Greeff SC. The case for maternal vaccination against pertussis. Lancet Infectious Diseases. 2007 September;7 (9):614-24. PMID 2007405927 MEDLINE PMID 17537674 (http://www.ncbi.nlm.nih.gov/pubmed/17537674).

239. Moore MR, O'Brien K, Nuorti JP, Hennessy T. Pitfalls in case-control studies of vaccine effectiveness. Clinical Infectious Diseases. 2007 Nov;45 (9):1241-2. PMID WOS:000249923700020.

240. Moore RA, Wiffen PJ, Lipsky BA. Are the pneumococcal polysaccharide vaccines effective? Meta-analysis of the prospective trials. BMC Family Practice. 2000;1:1-10. PMID 2004473722 MEDLINE PMID 11038265 (http://www.ncbi.nlm.nih.gov/pubmed/11038265).

241. Mu XD. Safety and effectiveness of a 2009 H1N1 vaccine in Beijing [2]. New England Journal of Medicine. 2011 24;364 (12):1181. PMID 2011175441.

242. Muehlhans S, Richard G, Ali M, et al. Safety reporting in developing country vaccine clinical trials-A systematic review. Vaccine. 2012 9;30 (22):3255-65. PMID 2012222588.

243. Muhammad RD, Haber P, Broder KR, et al. Adverse events following trivalent inactivated influenza vaccination in children: Analysis of the vaccine adverse event reporting system. Pediatric Infectious Disease Journal. 2011 January;30 (1):e1-e8. PMID 2011007702.

244. Munoz FM. Vaccination during pregnancy. Women's Health. 2007 March;3 (2):227-41. PMID 2007156609.

245. Munoz FM. Safety of influenza vaccines in pregnant women. American Journal of Obstetrics and Gynecology. 2012 September;207 (3 SUPPL.):S33-S7. PMID 2012497476.

246. Munoz FM, Englund JA. Vaccines in pregnancy. Infectious Disease Clinics of North America. 2001 2001;15 (1):253-71. PMID 2001129004 MEDLINE PMID 11301819 (http://www.ncbi.nlm.nih.gov/pubmed/11301819).

247. Murphy TV, Smith PJ, Gargiullo PM, Schwartz B. The first rotavirus vaccine and intussusception: epidemiological studies and policy decisions. Journal of Infectious Diseases. 2003 Apr 15;187 (8):1309-13. PMID 12696011.

248. Murray D, Jackson C. A conjugate vaccine for the prevention of pediatric pneumococcal disease. Military Medicine. 2002 2002;167 (8):671-7. PMID 2002287476 MEDLINE PMID 12188240 (http://www.ncbi.nlm.nih.gov/pubmed/12188240).

249. Nokleby H. Neurological adverse events of immunization: Experience with an aluminum adjuvanted meningococcal B outer membrane vesicle vaccine. Expert Review of Vaccines. 2007 October;6 (5):863-9. PMID 2007511617 MEDLINE PMID 17931164 (http://www.ncbi.nlm.nih.gov/pubmed/17931164).

250. Noorbakhsh F, Johnson RT, Emery D, Power C. Acute Disseminated Encephalomyelitis: Clinical and Pathogenesis Features. Neurologic Clinics. 2008 August;26 (3):759-80. PMID 2008348848 MEDLINE PMID 18657725 (http://www.ncbi.nlm.nih.gov/pubmed/18657725).

251. Nor Aripin KNB, Choonara I, Sammons HM. Systematic review of safety in paediatric drug trials published in 2007. European Journal of Clinical Pharmacology. 2012 February;68 (2):189-94. PMID 2012091447 MEDLINE PMID 21858432 (http://www.ncbi.nlm.nih.gov/pubmed/21858432).

252. Nunes MC, Madhi SA. Review on the immunogenicity and safety of PCV-13 in infants and toddlers. Expert Review of Vaccines. 2011 July;10 (7):951-80. PMID 2011438482 MEDLINE PMID 21806394 (http://www.ncbi.nlm.nih.gov/pubmed/21806394).

253. Nunes MC, Madhi SA. Safety, immunogenicity and efficacy of pneumococcal conjugate vaccine in HIV-infected individuals. Human Vaccines & Immunotherapeutics. 2012 Feb;8 (2):161-73. PMID 22426374.

254. Obaro SK. The new pneumococcal vaccine. Clinical Microbiology and Infection. 2002 1;8 (10):623-33. PMID 2002397477 MEDLINE PMID 12390280 (http://www.ncbi.nlm.nih.gov/pubmed/12390280).

255. Obaro SK, Pugatch D, Luzuriaga K. Immunogenicity and efficacy of childhood vaccines in HIV-1-infected children. Lancet Infectious Diseases. 2004 1;4 (8):510-8. PMID 2004348576 MEDLINE PMID 15288824 (http://www.ncbi.nlm.nih.gov/pubmed/15288824).

256. Obonyo CO, Lau J. Efficacy of Haemophilus influenzae type b vaccination of children: a meta-analysis. European Journal of Clinical Microbiology & Infectious Diseases. 2006 Feb;25 (2):90-7. PMID 16491301.

257. Offit PA, Jew RK. Addressing Parents' Concerns: Do Vaccines Contain Harmful Preservatives, Adjuvants, Additives, or Residuals? Pediatrics. 2003 December;112 (6 I):1394-401. PMID 2003509020 MEDLINE PMID 14654615 (http://www.ncbi.nlm.nih.gov/pubmed/14654615).

258. O'Hagan DT, Rappuoli R. The safety of vaccines. Drug Discovery Today. 2004 1;9 (19):846-54. PMID 2004413840 MEDLINE PMID 15381137 (http://www.ncbi.nlm.nih.gov/pubmed/15381137).

259. Omer SB. Safety of quadrivalent human papillomavirus vaccine. Journal of Internal Medicine. 2012 Feb;271 (2):177-8. PMID 22077556.

260. Oosterhuis-Kafeja F, Beutels P, Van Damme P. Immunogenicity, efficacy, safety and effectiveness of pneumococcal conjugate vaccines (1998-2006). Vaccine. 2007 Mar 8;25 (12):2194-212. PMID 17267077.

261. Orbach H, Agmon-Levin N, Zandman-Goddard G. Vaccines and autoimmune diseases of the adult. Discovery Medicine. 2010 Feb;9 (45):90-7. PMID 20193633.

262. Orbach H, Tanay A. Vaccines as a trigger for myopathies. Lupus. 2009 2009;18 (13):1213-6. PMID 2009583181 MEDLINE PMID 19880571 (http://www.ncbi.nlm.nih.gov/pubmed/19880571).

263. Ornoy A, Tenenbaum A. Pregnancy outcome following infections by coxsackie, echo, measles, mumps, hepatitis, polio and encephalitis viruses. Reproductive Toxicology. 2006 May;21 (4):446-57. PMID 16480851.

264. Ortqvist A, Blennow M, Carlsson RM, et al. Vaccination of children - A systematic review. Acta Paediatrica, International Journal of Paediatrics. 2010 September;99 (SUPPL. 461):1-192. PMID 2010454253.

265. O'Ryan M. Rotarix (RIX4414): an oral human rotavirus vaccine. Expert Review of Vaccines. 2007 Feb;6 (1):11-9. PMID 17280473.

266. Pai VB, Heyneman CA, Erramouspe J. Conjugated heptavalent pneumococcal vaccine. Annals of Pharmacotherapy. 2002 Sep;36 (9):1403-13. PMID 12196061.

267. Pancharoen C, Ananworanich J, Thisyakorn U. Immunization for persons infected with human immunodeficiency virus. Current HIV Research. 2004 October;2 (4):293-9. PMID 2004400522 MEDLINE PMID 15544450 (http://www.ncbi.nlm.nih.gov/pubmed/15544450).

268. Papaevangelou V, Spyridis N. MenACWY-TT vaccine for active immunization against invasive meningococcal disease. Expert Review of Vaccines. 2012 May;11 (5):523-37. PMID 2012348233.

269. Patel MM, Haber P, Baggs J, Zuber P, Bines JE, Parashar UD. Intussusception and rotavirus vaccination: a review of the available evidence. Expert Review of Vaccines. 2009 Nov;8 (11):1555-64. PMID 19863248.

270. Pavia M, Bianco A, Nobile CGA, Marinelli P, Angelillo IF. Efficacy of Pneumococcal

Vaccination in Children Younger Than 24 Months: A Meta-Analysis. Pediatrics. 2009 Jun;123 (6):E1103-E10. PMID WOS:000266319000050.

271. Peter G, Myers MG, National Vaccine Advisory C, National Vaccine Program O. Intussusception, rotavirus, and oral vaccines: summary of a workshop. Pediatrics. 2002 Dec;110 (6):e67. PMID 12456934.

272. Phua KB, Quak SH, Emmanuel S, et al. A short report on highlights of worldwide development of RIX4414: A Singaporean experience. Vaccine. 2006 1;24 (18):3782-3. PMID 2006202653 MEDLINE PMID 16600443 (http://www.ncbi.nlm.nih.gov/pubmed/16600443).

273. Pichichero ME, Casey JR. Acellular pertussis vaccines for adolescents. Pediatric Infectious Disease Journal. 2005 June;24 (6 SUPPL.):S117-S26. PMID 2005273564 MEDLINE PMID 15931139 (http://www.ncbi.nlm.nih.gov/pubmed/15931139).

274. Plosker GL. Rotavirus vaccine RIX4414 (Rotarix(trademark)): A pharmacoeconomic review of its use in the prevention of rotavirus gastroenteritis in developing countries. PharmacoEconomics. 2011 2011;29 (11):989-1009. PMID 2011571106 MEDLINE PMID 21988293 (http://www.ncbi.nlm.nih.gov/pubmed/21988293).

275. Plosker GL. Rotavirus vaccine RIX4414 (Rotarix(trademark)): A pharmacoeconomic review of its use in the prevention of rotavirus gastroenteritis in developed countries. PharmacoEconomics. 2011 2011;29 (5):439-54. PMID 2011223971 MEDLINE PMID 21504245 (http://www.ncbi.nlm.nih.gov/pubmed/21504245).

276. Plotkin SA. Lessons learned concerning vaccine safety. Vaccine. 2001 15;20 (SUPPL. 1):S16-S9. PMID 2001350388 MEDLINE PMID 11587803 (http://www.ncbi.nlm.nih.gov/pubmed/11587803).

277. Pomfret TC, Gagnon Jr JM, Gilchrist AT. Quadrivalent human papillomavirus (HPV) vaccine: A review of safety, efficacy, and pharmacoeconomics. Journal of Clinical Pharmacy and Therapeutics. 2011 February;36 (1):1-9. PMID 2011016789 MEDLINE PMID 21198715 (http://www.ncbi.nlm.nih.gov/pubmed/21198715).

278. Poorolajal J, Mahmoodi M, Haghdoost A, et al. Booster dose vaccination for preventing hepatitis B. Cochrane Database of Systematic Reviews. 2010 (11) PMID WOS:000284076200027.

279. Principi N, Esposito S. Use of the 13-valent pneumococcal conjugate vaccine in infants and young children. Expert Opinion on Biological Therapy. 2012 May;12 (5):641-8. PMID 22397739.

280. Rasmussen SA. Human teratogens update 2011: Can we ensure safety during pregnancy? Birth Defects Research Part a-Clinical and Molecular Teratology. 2012 Mar;94 (3):123-8. PMID WOS:000301433600001.

281. Rath B, Linder T, Cornblath D, et al. "All that palsies is not Bell's [1]"-The need to define Bell's palsy as an adverse event following immunization. Vaccine. 2007 21;26 (1):1-14. PMID 2007592408 MEDLINE PMID 18037542 (http://www.ncbi.nlm.nih.gov/pubmed/18037542).

282. Ridgway D, Wolff LJ. Active immunization of children with leukemia and other malignancies. Leukemia & Lymphoma. 1993 Feb;9 (3):177-92. PMID 8471977.

283. Rightmier E, Stevens V, Brown J. Streptococcus pneumoniae vaccination in older adults. American Journal of Geriatric Pharmacotherapy. 2011 Dec;9 (6):392-404. PMID 22047941.

284. Rimland B, McGinnis W. Vaccines and autism. Laboratory Medicine. 2002 1;33 (9):708-17. PMID 2002393915.

285. Rivas P, Herrero MD, Puente S, Ramirez-Olivencia G, Soriano V. Immunizations in HIV-infected adults. AIDS Reviews. 2007 July/September;9 (3):173-87. PMID 2007522502 MEDLINE PMID 17982942 (http://www.ncbi.nlm.nih.gov/pubmed/17982942).

286. Rivetti D, Jefferson T, Thomas R, et al. Vaccines for preventing influenza in the elderly. Cochrane Database of Systematic Reviews. 2006 (3):CD004876. PMID 16856068.

287. Rose M, Zielen S. Impact of infant immunization programs with pneumococcal conjugate vaccine in Europe. Expert Review of Vaccines. 2009 October;8 (10):1351-64. PMID 2009537313 MEDLINE PMID 19803758 (http://www.ncbi.nlm.nih.gov/pubmed/19803758).

288. Rosenberg M, Sparks R, McMahon A, Iskander J, Campbell JD, Edwards KM. Serious adverse events rarely reported after trivalent inactivated influenza vaccine (TIV) in children 6-23 months of age. Vaccine. 2009 9;27 (32):4278-83. PMID 2009321262 MEDLINE PMID 19450636 (http://www.ncbi.nlm.nih.gov/pubmed/19450636).

289. Royle J. Meningococcal vaccines. Medicine Today. 2003 1;4 (5):99-100. PMID 2003207635.

290. Rubinstein E. Vaccination and autoimmune diseases: The argument against. Israel Medical Association Journal. 2004 July;6 (7):433-5. PMID 2004327052 MEDLINE PMID 15274538 (http://www.ncbi.nlm.nih.gov/pubmed/15274538).

291. Ruiz LP, Jr. Rotavirus vaccines. New England Journal of Medicine. 2006 Apr 20;354 (16):1747-51; author reply -51. PMID 16625743.

292. Rutschmann OT, McCrory DC, Matchar DB, et al. Immunization and MS: A summary of published evidence and recommendations. Neurology. 2002 24;59 (12):1837-43. PMID 2003029192 MEDLINE PMID 12499473 (http://www.ncbi.nlm.nih.gov/pubmed/12499473).

293. Salemi S, D'Amelio R. Are anti-infectious vaccinations safe and effective in patients with autoimmunity. International Reviews of Immunology. 2010 June;29 (3):270-314. PMID 2010318846 MEDLINE PMID 20521926 (http://www.ncbi.nlm.nih.gov/pubmed/20521926).

294. Salemi S, D'Amelio R. Vaccinations and autoimmune diseases. International Reviews of Immunology. 2010 June;29 (3):239-46. PMID 2010318849 MEDLINE PMID 20521924 (http://www.ncbi.nlm.nih.gov/pubmed/20521924).

295. Sangkomkamhang US, Lumbiganon P, Laopaiboon M. Hepatitis B vaccination during pregnancy for preventing infant infection. Cochrane Database of Systematic Reviews. 2011 (3) PMID WOS:000288457900028.

296. Satterwhite TK. Use of the pneumococcal vaccine. American Family Physician. 1981 Nov;24 (5):209-12. PMID 7293914.

297. Scott LJ. Tdap(5) vaccine (Covaxis(registered trademark)): A review of its use as a single-booster immunization for the prevention of tetanus, diphtheria, and pertussis in children (Aged (greater-than or equal to)4 Years), adolescents, and adults. Biodrugs. 2010 2010;24 (6):387-406. PMID 2010607096.

298. Scott P, Moss WJ, Gilani Z, Low N. Measles vaccination in HIV-infected children: systematic review and meta-analysis of safety and immunogenicity. Journal of Infectious Diseases. 2011 Jul;204 Suppl 1:S164-78. PMID 21666158.

299. Shobha V. Common anti-infective prophylaxis and vaccinations in autoimmune inflammatory rheumatic diseases. Indian Journal of Rheumatology. 2012 March;7 (1):21-8. PMID 2012202945.

300. Shreffler WG. A synthetic conjugate polysaccharide vaccine against Haemophilus influenzae type b. Pediatrics. 2005 2005;116 (2):573. PMID 2006369389.

301. Simonsen L, Viboud C, Taylor RJ, Miller MA, Jackson L. Influenza vaccination and mortality benefits: new insights, new opportunities. Vaccine. 2009 Oct 23;27 (45):6300-4. PMID 19840664.

302. Skowronski DM, De Serres G. Is routine influenza immunization warranted in early pregnancy? Vaccine. 2009 30;27 (35):4754-70. PMID 2009345843 MEDLINE PMID 19515466 (http://www.ncbi.nlm.nih.gov/pubmed/19515466).

303. Small TN, Cowan MJ. Immunization of hematopoietic stem cell transplant recipients against vaccine-preventable diseases. Expert Review of Clinical Immunology. 2011 March;7 (2):193-203. PMID 2011170552 MEDLINE PMID 21426257 (http://www.ncbi.nlm.nih.gov/pubmed/21426257).

304. Smith DH, Madore DV, Eby RJ, Anderson PW, Insel RA, Johnson CL. Haemophilus b oligosaccharide-CRM197 and other Haemophilus b conjugate vaccines: a status report. Advances in Experimental Medicine & Biology. 1989;251:65-82. PMID 2692432.

305. Smith-McCune K. Quadrivalent HPV vaccine administered to women who became

pregnant during trials did not appear to adversely affect pregnancy outcome; however, use during pregnancy is not recommended. Evidence-Based Medicine. 2010 June;15 (3):80-1. PMID 2010346922.

306. Soares-Weiser K, Maclehose H, Bergman H, et al. Vaccines for preventing rotavirus diarrhoea: vaccines in use. Cochrane Database of Systematic Reviews. 2012;2:CD008521. PMID 22336845.

307. Sonneville R, Klein I, de Broucker T, Wolff M. Post-infectious encephalitis in adults: Diagnosis and management. Journal of Infection. 2009 May;58 (5):321-8. PMID 2009198785 MEDLINE PMID 19368974 (http://www.ncbi.nlm.nih.gov/pubmed/19368974).

308. Souayah N, Nasar A, Suri MFK, Qureshi AI. Guillain-Barre syndrome after vaccination in United States. A report from the CDC/FDA Vaccine Adverse Event Reporting System. Vaccine. 2007 20;25 (29):5253-5. PMID 2007307015 MEDLINE PMID 17560693 (http://www.ncbi.nlm.nih.gov/pubmed/17560693).

309. Srivastava VK, Laisram N, Srivastava RK. Immunization status in paralytic poliomyelitis--a hospital based study. Indian Pediatrics. 1989 May;26 (5):430-3. PMID 2599610.

310. Stephenson J. Vaccines pose no diabetes, bowel disease risk. Journal of the American Medical Association. 2000 8;284 (18):2307-8. PMID 2000399302 MEDLINE PMID 11066164 (http://www.ncbi.nlm.nih.gov/pubmed/11066164).

311. Sucher AJ, Chahine EB, Nelson M, Sucher BJ. Prevnar 13, the new 13-valent pneumococcal conjugate vaccine. Annals of Pharmacotherapy. 2011 Dec;45 (12):1516-24. PMID 22045904.

312. Tai JH, Curns AT, Parashar UD, Bresee JS, Glass RI. Rotavirus vaccination and intussusception: can we decrease temporally associated background cases of intussusception by restricting the vaccination schedule? Pediatrics. 2006 Aug;118 (2):e258-64. PMID 16882770.

313. Tamma PD, Ault KA, del Rio C, Steinhoff MC, Halsey NA, Omer SB. Safety of influenza vaccination during pregnancy. Am J Obstet Gynecol. 2009 Dec;201 (6):547-52. PMID 19850275.

314. Tapiainen T, Heininger U. Fever following immunization. Expert Review of Vaccines. 2005 June;4 (3):419-27. PMID 2005315637 MEDLINE PMID 16026253 (http://www.ncbi.nlm.nih.gov/pubmed/16026253).

315. Thjodleifsson B, Davidsdottir K, Agnarsson U, Sigthorsson G, Kjeld M, Bjarnason I. Effect of Pentavac and measles-mumps-rubella (MMR) vaccination on the intestine. Gut. 2002 Dec;51 (6):816-7. PMID 12427783.

316. Toback SL, Beigi R, Tennis P, Sifakis F, Calingaert B, Ambrose CS. Maternal outcomes among pregnant women receiving live attenuated influenza vaccine. Influenza & Other

Respiratory Viruses. 2012 Jan;6 (1):44-51. PMID 21672166.

317. Tom-Revzon C. Rotavirus live, oral, pentavalent vaccine. Clinical Therapeutics. 2007 Dec;29 (12):2724-37. PMID 18201590.

318. Tozzi AE. Field evaluation of vaccine safety. Vaccine. 2004 7;22 (15 16):2091-5. PMID 2004198055 MEDLINE PMID 15121330 (http://www.ncbi.nlm.nih.gov/pubmed/15121330).

319. Tsai TF. MF59((registered trademark)) adjuvanted seasonal and pandemic influenza vaccines. Yakugaku Zasshi - Journal of the Pharmaceutical Society of Japan. 2011 20111201;131 (12):1733-41. PMID 2011666574.

320. Van Assen S, Agmon-Levin N, Elkayam O, et al. EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases. Annals of the Rheumatic Diseases. 2011 March;70 (3):414-22. PMID 2011089272 MEDLINE PMID 21131643 (http://www.ncbi.nlm.nih.gov/pubmed/21131643).

321. Van Assen S, Elkayam O, Agmon-Levin N, et al. Vaccination in adult patients with auto-immune inflammatory rheumatic diseases: A systematic literature review for the European League Against Rheumatism evidence-based recommendations for vaccination in adult patients with auto-immune inflammatory rheumatic diseases. Autoimmunity Reviews. 2011 April;10 (6):341-52. PMID 2011173065 MEDLINE PMID 21182987 (http://www.ncbi.nlm.nih.gov/pubmed/21182987).

322. Van Der Meeren O, Kuriyakose S, Kolhe D, Hardt K. Immunogenicity of Infanrix(trademark) hexa administered at 3, 5 and 11 months of age. Vaccine. 2012 5;30 (17):2710-4. PMID 2012169488.

323. Vesikari T. Rotavirus vaccination: A concise review. Clinical Microbiology and Infection. 2012.

324. Vesikari T, Giaquinto C, Huppertz H-I. Clinical trials of rotavirus vaccines in Europe. Pediatric Infectious Disease Journal. 2006 Jan;25 (1 Suppl):S42-7. PMID 16397428.

325. Wandstrat TL, Kaplan-Machlis B, Temple ME, Nahata MC. Tetravalent rotavirus vaccine. Annals of Pharmacotherapy. 1999 July/August;33 (7 8):833-9. PMID 1999288602 MEDLINE PMID 10466913 (http://www.ncbi.nlm.nih.gov/pubmed/10466913).

326. Watson W. Pneumococcal conjugate vaccines. Pediatric Infectious Disease Journal. 2000 2000;19 (4):331-2. PMID 2000142080 MEDLINE PMID 10783025 (http://www.ncbi.nlm.nih.gov/pubmed/10783025).

327. Weber DJ, Rutala WA. Immunization of immunocompromised persons. Immunology and Allergy Clinics of North America. 2003 November;23 (4):605-34. PMID 2004010559 MEDLINE PMID 14753383 (http://www.ncbi.nlm.nih.gov/pubmed/14753383).

328. Weinberg GA, Granoff DM. Polysaccharide-protein conjugate vaccines for the prevention of Haemophilus influenzae type b disease. Journal of Pediatrics. 1988 Oct;113 (4):621-31. PMID 3050001.

329. Weldeselassie YG, Whitaker HJ, Farrington CP. Use of the self-controlled case-series method in vaccine safety studies: Review and recommendations for best practice. Epidemiology and Infection. 2011 December;139 (12):1805-17. PMID 2011602730 MEDLINE PMID 21849099 (http://www.ncbi.nlm.nih.gov/pubmed/21849099).

330. Wharton M. Vaccine safety: Current systems and recent findings. Current Opinion in Pediatrics. 2010 February;22 (1):88-93. PMID 2010080849 MEDLINE PMID 19952750 (http://www.ncbi.nlm.nih.gov/pubmed/19952750).

331. Wiedermann U, Kollaritsch H. Vaccines against traveler's diarrhoea and rotavirus disease - a review. Wiener Klinische Wochenschrift. 2006;118 (19-20 Suppl 3):2-8. PMID 17131234.

332. Wilson K, Mills E, Ross C, McGowan J, Jadad A. Association of autistic spectrum disorder and the measles, mumps, and rubella vaccine: a systematic review of current epidemiological evidence. Arch Pediatr Adolesc Med. 2003 Jul;157 (7):628-34. PMID 12860782.

333. Wilson ME. Travel-related vaccines. Infectious Disease Clinics of North America. 2001 2001;15 (1):231-51. PMID 2001129003 MEDLINE PMID 11301818 (http://www.ncbi.nlm.nih.gov/pubmed/11301818).

334. Woo EJ, Burwen DR, Gatumu SNM, Ball R. Extensive limb swelling after immunization: Reports to the Vaccine Adverse Event Reporting System. Clinical Infectious Diseases. 2003 1;37 (3):351-8. PMID 2003328908 MEDLINE PMID 12884159 (http://www.ncbi.nlm.nih.gov/pubmed/12884159).

335. Yancey AM, Pitlick JM, Forinash AB. The prophylactic role for the human papillomavirus quadrivalent vaccine in males. Annals of Pharmacotherapy. 2010 Jul-Aug;44 (7-8):1314-8. PMID 20501891.

336. Yates L, Pierce M, Stephens S, et al. Influenza A/HINIv in pregnancy: An investigation of the characteristics and management of affected women and the relationship to pregnancy outcomes for mother and infant. Health Technology Assessment. 2010 2010;14 (34):109-82. PMID 2010418378.

337. Yeh SH. PEDIARIX: clinical trials. Expert Review of Vaccines. 2005 Apr;4 (2):139-45. PMID 15889985.

338. Yih WK, Kulldorff M, Fireman BH, et al. Active surveillance for adverse events: The experience of the vaccine safety datalink project. Pediatrics. 2011 May;127 (SUPPL. 1):S54-S64. PMID 2011239118 MEDLINE PMID 21502252 (http://www.ncbi.nlm.nih.gov/pubmed/21502252).

339. Yin JK, Khandaker G, Rashid H, Heron L, Ridda I, Booy R. Immunogenicity and safety of pandemic influenza A (H1N1) 2009 vaccine: systematic review and meta-analysis. Influenza & Other Respiratory Viruses. 2011 Sep;5 (5):299-305. PMID 21668694.

340. Young F, Marra F. A systematic review of intradermal influenza vaccines. Vaccine. 2011 Nov 8;29 (48):8788-801. PMID 21968444.

341. Zareba G. A new combination vaccine for measles, mumps, rubella and varicella. Drugs of Today. 2006 May;42 (5):321-9. PMID 2006313737 MEDLINE PMID 16801995 (http://www.ncbi.nlm.nih.gov/pubmed/16801995).

342. Zhang L, Prietsch SOM, Axelsson I, Halperin SA. Acellular vaccines for preventing whooping cough in children. Cochrane Database of Systematic Reviews. 2012;3:CD001478. PMID 22419280.

343. Zimmerman RK, Middleton DB, Burns IT, Clover RD. Routine vaccines across the life span, 2003. Journal of Family Practice. 2003 Jan;52 (1 Suppl):S1-21. PMID 12556275.

344. Zuccotti GV. Safety of a virosomal adjuvanted influenza vaccine in children suffering from chronic disease. Open Vaccine Journal. 2010 2010;3 (1):108-13. PMID 2011281638.

Mechanistic Studies – 39

1. . Childhood immunizations and type 1 diabetes: summary of an Institute for Vaccine Safety Workshop. The Institute for Vaccine Safety Diabetes Workshop Panel. Pediatr Infect Dis J. 1999 Mar;18 (3):217-22. PMID 10093941.

2. Agmon-Levin N, Paz Z, Israeli E, Shoenfeld Y. Vaccines and autoimmunity. Nature Reviews Rheumatology. 2009 2009;5 (11):648-52. PMID 2009579139 MEDLINE PMID 19865091 (http://www.ncbi.nlm.nih.gov/pubmed/19865091).

3. Aguilar JC, Rodriguez EG. Vaccine adjuvants revisited. Vaccine. 2007 10;25 (19):3752-62. PMID 2007183669 MEDLINE PMID 17336431 (http://www.ncbi.nlm.nih.gov/pubmed/17336431).

4. Ahmed SS, Plotkin SA, Black S, Coffman RL. Assessing the safety of adjuvanted vaccines. SOURCE Science Translational Medicine (2011) 3:93 Article Number: 93rv2. Date of Publication: 27 Jul 2011. 2011 PMID 2011412590.

5. Anhoury ML, Arickx M, Boon B, et al. Analysis of a bivalent meningococcal vaccine (A + C). Part I. Analytical and safety data. Annales de la Societe Belge de Medecine Tropicale. 1979 Sep;59 (3):259-66. PMID 117760.

6. Annunziata P. Reply to: "Miller Fisher syndrome following vaccination". Infection. 2012 February;40 (1):103-4. PMID 2012126926.

7. Aron-Maor A, Shoenfeld Y. Vaccination and systemic lupus erythematosus: the bidirectional dilemmas. Lupus. 2001;10 (3):237-40. PMID 11315360.

8. Bines JE, Patel M, Parashar U. Assessment of postlicensure safety of rotavirus vaccines, with emphasis on intussusception. Journal of Infectious Diseases. 2009 Nov 1;200 Suppl 1:S282-90. PMID 19817611.

9. Blyth CC, Currie AJ, Wiertsema SP, et al. Trivalent influenza vaccine and febrile adverse events in Australia, 2010: clinical features and potential mechanisms. Vaccine. 2011 Jul 18;29 (32):5107-13. PMID 21640152.

10. Chen RT, Pless R, Destefano F. Epidemiology of autoimmune reactions induced by vaccination. Journal of Autoimmunity. 2001 2001;16 (3):309-18. PMID 2001221056 MEDLINE PMID 11334497 (http://www.ncbi.nlm.nih.gov/pubmed/11334497).

11. Christian LM, Iams JD, Porter K, Glaser R. Inflammatory responses to trivalent influenza virus vaccine among pregnant women. Vaccine. 2011 Nov 8;29 (48):8982-7. PMID 21945263.

12. Clarke JB. Mechanisms of adverse drug reactions to biologics. SOURCE Handbook of Experimental Pharmacology (2010) 196 (453-474). Date of Publication: 2010 Adverse Drug Reactions, Book Series Title:. 2010 PMID 2010034207.

13. Cojocaru M, Cojocaru IM, Radu-Popescu MA, Arsene AL. The relationship between vaccination and the development of autoimmune diseases. Farmacia. 2010 2010;58 (6):677-85. PMID 2011004153.

14. Flanagan KL, Klein SL, Skakkebaek NE, et al. Sex differences in the vaccine-specific and non-targeted effects of vaccines. Vaccine. 2011 Mar;29 (13):2349-54. PMID WOS:000289140500001.

15. Higashi HG, Luna E, Precioso AR, et al. Acellular and "low" pertussis vaccines: Adverse events and the role of mutations. Revista Do Instituto De Medicina Tropical De Sao Paulo. 2009 May-June;51 (3):131-4. PMID 2009339349 MEDLINE PMID 19551286 (http://www.ncbi.nlm.nih.gov/pubmed/19551286).

16. Hilleman MR. Critical overview and outlook: Pathogenesis, prevention, and treatment of hepatitis and hepatocarcinoma caused by hepatitis B virus. Vaccine. 2003 1;21 (32):4626-49. PMID 2003438300 MEDLINE PMID 14585670 (http://www.ncbi.nlm.nih.gov/pubmed/14585670).

17. Huynh W, Cordato DJ, Kehdi E, Masters LT, Dedousis C. Post-vaccination encephalomyelitis: literature review and illustrative case. Journal of Clinical Neuroscience. 2008 Dec;15 (12):1315-22. PMID 18976924.

18. Israeli E, Agmon-Levin N, Blank M, Chapman J, Shoenfeld Y. Guillain-Barre Syndrome-A Classical Autoimmune Disease Triggered by Infection or Vaccination. Clinical Reviews in

Allergy & Immunology. 2012 Apr;42 (2):121-30. PMID WOS:000301569400002.

19. Kapetanovic MC, Roseman C, Jonsson G, Truedsson L, Saxne T, Geborek P. Antibody response is reduced following vaccination with 7-valent conjugate pneumococcal vaccine in adult methotrexate-treated patients with established arthritis, but not those treated with tumor necrosis factor inhibitors. Arthritis and Rheumatism. 2011 December;63 (12):3723-32. PMID 2011657726 MEDLINE PMID 21834061 (http://www.ncbi.nlm.nih.gov/pubmed/21834061).

20. Klein SL, Jedlicka A, Pekosz A. The Xs and Y of immune responses to viral vaccines. The Lancet Infectious Diseases. 2010 May;10 (5):338-49. PMID 2010534658 MEDLINE PMID 20417416 (http://www.ncbi.nlm.nih.gov/pubmed/20417416).

21. Koenig HC, Sutherland A, Izurieta HS, McGonagle D. Application of the immunological disease continuum to study autoimmune and other inflammatory events after vaccination. Vaccine. 2011 Jan;29 (5):913-9. PMID WOS:000287295800009.

22. Lynch M, Shieh W-J, Bresee JS, et al. Intussusception after administration of the rhesus tetravalent rotavirus vaccine (Rotashield): the search for a pathogenic mechanism. Pediatrics. 2006 May;117 (5):e827-32. PMID 16651287.

23. Midthun K, Halsey NA, Jett-Goheen M, et al. Safety and immunogenicity of human rotavirus vaccine strain M37 in adults, children, and infants. Journal of Infectious Diseases. 1991 1991;164 (4):792-6. PMID 1991333507 MEDLINE PMID 1654365 (http://www.ncbi.nlm.nih.gov/pubmed/1654365).

24. Mrozek-Budzyn D, Kieltyka A, Majewska R. Lack of association between measles-mumps-rubella vaccination and autism in children: a case-control study. Pediatr Infect Dis J. 2010 May;29 (5):397-400. PMID 19952979.

25. Murphy BR, Morens DM, Simonsen L, Chanock RM, La Montagne JR, Kapikian AZ. Reappraisal of the association of intussusception with the licensed live rotavirus vaccine challenges initial conclusions. Journal of Infectious Diseases. 2003 Apr 15;187 (8):1301-8. PMID 12696010.

26. Neville B. Dravet syndrome and 'immunization encephalopathy'. Developmental Medicine & Child Neurology. 2010 Jun;52 (6):590-1. PMID 20187876.

27. Perdan-Pirkmajer K, Thallinger GG, Snoj N, et al. Autoimmune response following influenza vaccination in patients with autoimmune inflammatory rheumatic disease. Lupus. 2012 Feb;21 (2):175-83. PMID 22235050.

28. Richmand BJ. Hypothesis: Conjugate vaccines may predispose children to autism spectrum disorders. Medical Hypotheses. 2011 December;77 (6):940-7. PMID 2011619426 MEDLINE PMID 21993250 (http://www.ncbi.nlm.nih.gov/pubmed/21993250).

29. Ronaghy A, de Jager W, Zonneveld-Huijssoon E, et al. Vaccination leads to an aberrant

FOXP3 T-cell response in non-remitting juvenile idiopathic arthritis. Annals of the Rheumatic Diseases. 2011 Nov;70 (11):2037-43. PMID WOS:000295399700027.

30. Rothman KJ, Young-Xu Y, Arellano F. Age dependence of the relation between reassortant rotavirus vaccine (RotaShield) and intussusception. Journal of Infectious Diseases. 2006 Mar 15;193 (6):898; author reply -9. PMID 16479526.

31. Salemi S, D'Amelio R. Could autoimmunity be induced by vaccination? International Reviews of Immunology. 2010 Jun;29 (3):247-69. PMID 20521925.

32. Sejvar JJ. Vaccines and neurologic disease. Seminars in Neurology. 2011 2011;31 (3):338-55. PMID 2011549339 MEDLINE PMID 21964850 (http://www.ncbi.nlm.nih.gov/pubmed/21964850).

33. Shoenfeld Y, Agmon-Levin N. 'ASIA' - Autoimmune/inflammatory syndrome induced by adjuvants. Journal of Autoimmunity. 2011 February;36 (1):4-8. PMID 2011057734 MEDLINE PMID 20708902 (http://www.ncbi.nlm.nih.gov/pubmed/20708902).

34. Siegrist CA. Mechanisms Underlying Adverse Reactions to Vaccines. Journal of Comparative Pathology. 2007 July;137 (SUPPL. 1):S46-S50. PMID 2007305033 MEDLINE PMID 17559869 (http://www.ncbi.nlm.nih.gov/pubmed/17559869).

35. Skowronski DM, Lu H, Warrington R, et al. Does antigen-specific cytokine response correlate with the experience of oculorespiratory syndrome after influenza vaccine? J Infect Dis. 2003 Feb 1;187 (3):495-9. PMID 12552434.

36. Stubgen JP. Neuromuscular disorders associated with Hepatitis B vaccination. Journal of the Neurological Sciences. 2010 May;292 (1-2):1-4. PMID WOS:000276784100001.

37. Tang YW, Li H, Wu H, Shyr Y, Edwards KM. Host single-nucleotide polymorphisms and altered responses to inactivated influenza vaccine. J Infect Dis. 2007 Oct 1;196 (7):1021-5. PMID 17763324.

38. Toubi E. ASIA - autoimmune syndromes induced by adjuvants: Rare, but worth considering. Israel Medical Association Journal. 2012 February;14 (2):121-4. PMID 2012115110 MEDLINE PMID 22693796 (http://www.ncbi.nlm.nih.gov/pubmed/22693796).

39. Vessal S, Kravis LP. Immunologic mechanisms responsible for adverse reactions to routine immunizations in children. Clinical Pediatrics. 1976 Aug;15 (8):688-96. PMID 133013.