Evidence Report/Technology Assessment

Number 215

Safety of Vaccines Used for Routine Immunization in the United States

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Evidence-Based Practice

Evidence Report/Technology Assessment

Number 215

Safety of Vaccines Used for Routine Immunization in the United States

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Addendum

This evidence report summarizes scientific data on the safety of vaccines currently recommended in the United States. High strength of evidence was found for an association of measles-mumps-rubella (MMR) vaccine with febrile seizures in children under age 5 (Key Question 2c). On May 19, 2014 (while this evidence report was in press), an important study investigating the timing of MMR and MMRV (measles-mumps-rubella-varicella) vaccine and risk of febrile seizures[1] was published. We felt this information warranted inclusion in this review of the evidence.

Researchers conducted a self-controlled case series analysis using records from over 300,000 U.S. children from the Vaccine Safety Datalink (VSD). They found timing was unrelated to risk of post-vaccination seizure in infants, but found that delaying measles containing vaccines past 15 months results in a higher risk of seizures.

According to the study's authors, these adverse events are very rare, and occurred at the rate of about 1 per 100,000 person-days at seven months of age, compared to a high of five per 100,000 person-days at 17 months of age.

Reference

1. Hambidge S J, Newcomer SR, Narwaney KJ, et al. Timely versus delayed early childhood vaccination and seizures. Pediatrics. 2014 Jun;133(6):e1492-e1499. PMID: 24843064.

This report is based on research conducted by the Southern California Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10062-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

This report may be used, in whole or in part, as the basis for development of clinical practice guidelines and other quality enhancement tools, or as a basis for reimbursement and coverage policies. AHRQ or U.S. Department of Health and Human Services endorsement of such derivative products may not be stated or implied.

This report may periodically be assessed for the urgency to update. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program Web site at: www.effectivehealthcare.ahrq.gov. Search on the title of the report.

Persons using assistive technology may not be able to fully access information in this report. For assistance, contact EffectiveHealthCare@ahrq.hhs.gov.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The Office of the Assistant Secretary for Health, National Vaccine Program, requested and provided funding for this report.

The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review and public comment prior to their release as a final report.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Safety of Vaccines Used for Routine Immunization in the United States

Structured Abstract

Objectives. To conduct a systematic review of the literature on the safety of vaccines recommended for routine immunization of children, adolescents, and adults in the United States as of 2011.

Data sources. We included placebo-controlled clinical trials and cohort studies comparing vaccinated and unvaccinated patients. We also included the following types of post-licensure analyses: case-control studies, self-controlled case series, and multivariate risk factor analyses. We conducted an electronic search of PubMed® from inception through August 2013, and reviewed Advisory Committee for Immunization Practices statements, vaccine package inserts, and previously published reviews to identify studies. Scientific Information Packets were requested from vaccine manufacturers.

Review methods. We reviewed the methodology of the 2011 Institute of Medicine (IOM) consensus report "Adverse Effects of Vaccines: Evidence and Causality" and accepted their findings. We augmented their work with new studies and additional vaccines. For studies not included in the IOM report, we abstracted data on the presence or absence of adverse health outcomes, characteristics of patients, study design, and vaccine description, including brand, potency, dosage, timing, and formulation, where available. We excluded formulations not used in the United States. The McHarm instrument was used to evaluate the quality of adverse events collection and reporting in each study. We were unable to pool results; we rated the overall strength of evidence (SOE) as high, moderate, low, or insufficient by using guidance suggested by the Agency for Healthcare Research and Quality for its Effective Health Care Program.

Results. A total of 20,478 titles were identified; after title, abstract, and full-text review, 166 studies were accepted for abstraction. The vast majority of studies either did not investigate or could not identify risk factors for adverse events (AEs) associated with vaccination. Similarly, the severity of AEs was inconsistently reported, as was information that would make independent severity determination possible.

SOE was high for the following associations in nonpregnant adults: seasonal influenza vaccine and arthralgia, myalgia, malaise, fever, pain at injection site; 2009 monovalent H1N1 vaccine and Guillain-Barré syndrome (GBS); and a lack of association between influenza and pneumococcal vaccines and cardiovascular events in the elderly. Risk of GBS was estimated at 1.6 excess cases per million persons vaccinated. SOE was high for the following associations in children and adolescents: measles, mumps, rubella (MMR) vaccine and febrile seizures in children under age 5; lack of association between MMR vaccine and autism spectrum disorders; and varicella vaccine and disseminated Oka strain varicella zoster virus with associated complications (i.e., meningitis, encephalitis) in individuals with demonstrated immunodeficiencies. There is moderate SOE that vaccines against rotavirus are associated with intussusception in children; risk was estimated as 1 to 5 cases per 100,000 vaccine doses, depending on brand. Moderate-strength evidence exists regarding human papillomavirus vaccine

and a lack of association with onset of juvenile rheumatoid arthritis, type 1 diabetes, and GBS. Moderate-strength evidence shows no association between inactivated influenza vaccine and serious AEs in pregnant women.

Evidence was insufficient to make conclusions regarding whether several routinely recommended vaccines are associated with serious conditions such as multiple sclerosis, transverse myelitis, and acute disseminated encephalomyelitis.

Conclusions. There is evidence that some vaccines are associated with serious adverse events; however, these events are extremely rare and must be weighed against the protective benefits that vaccines provide. Careful consideration should be given to the investigation of research gaps, including patient risk factors that may be associated with AEs; however, important factors must be taken into account when determining whether studies are warranted, including the severity and frequency of the AE being studied and the challenges of conducting sufficiently powered studies when investigating rare events.

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Executive Summary

Background

Vaccines are considered one of the greatest public health achievements of the last century for their role in eradicating smallpox and controlling polio, measles, rubella, and other infectious diseases in the United States.[1] Despite their effectiveness in preventing and eradicating disease, substantial gaps in vaccine uptake persist. Vaccination rates for young children are high;[2] however, vaccination rates remain well below established Healthy People 2020 targets for many vaccines recommended for adolescents,[3] adults,[4] and pregnant women.[5]

In the United States, vaccine guidelines are set by the Centers for Disease Control and Prevention's Advisory Committee for Immunization Practices (ACIP). The number of routine immunizations recommended for children and adolescents, adults, and pregnant women has expanded considerably over the past 10 years. For example, since 2005, the routine adolescent vaccination schedule has grown to include the following vaccines at ages 11 or 12 years: meningococcal conjugate vaccine; tetanus, diphtheria, and acellular pertussis (Tdap); human papillomavirus (HPV); and influenza (one dose annually). Tables A–C display ACIP recommendations as of October 2011. These recommendations were in effect when this review began.

Table A. Vaccines routinely recommended for children and adolescents, 2011

Vaccine	Age
DTaP (diphtheria, tetanus, and acellular pertussis)	2 months–6 years
Hepatitis A	12 months and older
Hepatitis B	Birth and older
Hib (*Haemophilus influenzae* type b)	6 weeks–59 months
HPV (human papillomavirus)	9 years–21 years (male) 9 years–26 years (female)
Influenza (inactivated)	6 months and older
Influenza (live attenuated)	2 years and older
IPV (inactivated polio vaccine)	6 weeks and older
MCV (meningococcal conjugate vaccine)	2 years and older
MMR (measles, mumps, and rubella)	12 months and older
MPSV (meningococcal polysaccharide vaccine)	2 years and older in specific circumstances
PCV13 (pneumococcal conjugate vaccine)	6 weeks–18 years
Pneumococcal polysaccharide vaccine	2 years and older in specific circumstances
Rotavirus	6 weeks–8 months
Tdap (tetanus, diphtheria, and acellular pertussis)	7 years and older
Varicella	12 months and older

Table B. Vaccines routinely recommended for nonpregnant adults, 2011

Vaccine	Recommendation
Hepatitis A	All adults at increased risk for hepatitis A infection
Hepatitis B	All unvaccinated adults at risk for or requesting protection from hepatitis B infection
HPV (human papillomavirus)	Adults 26 years and younger
Influenza (inactivated)	All adults
Influenza (live attenuated)	All adults 49 years and younger
Meningococcal conjugate vaccine (MCV4) and meningococcal polysaccharide vaccine (MPSV)	Adults at risk of meningococcal disease (MCV4 or MPSV if younger than 55 years; MPSV if 55 years and older)
MMR (measles, mumps, and rubella)	All adults
Pneumococcal polysaccharide vaccine	Adults 64 years and younger with certain conditions and all adults 65 years and older
Td (tetanus, diphtheria)	All adults who are not immune through prior infection
Tdap (tetanus, diphtheria, and acellular pertussis)	All adults 19–64 years old; some adults 65 years and older
Varicella	All adults without evidence of varicella immunity
Zoster	All adults 60 years and older

Table C. Vaccines routinely recommended for pregnant women, 2011

Vaccine	Recommendation
Hepatitis B	Recommended in some circumstances
Influenza (inactivated)	All pregnant women
Td (tetanus, diphtheria)	If indicated
Tdap (tetanus, diphtheria, and acellular pertussis)	All pregnant women at the first trimester if indicated[a]

[a]In 2013, pregnant women were advised to receive Tdap during every pregnancy to protect their newborns from pertussis.

As the number of recommended immunizations has expanded across the population, so too have concerns about the safety of vaccines. Perhaps the most highly publicized safety concern of the last two decades was the proposed link between autism and the measles, mumps, and rubella (MMR) vaccine, first reported in 1998 in *The Lancet* by Dr. Andrew Wakefield.[6] In 2010, *The Lancet* fully retracted the 1998 report,[7] noting that elements of the research had been deliberately falsified. Although multiple large studies have confirmed the lack of association between MMR and autism, parental worries about the safety of vaccines persist. Other parental concerns about childhood vaccines include potential links to multiple sclerosis, sudden infant death syndrome, asthma, and diabetes.[8] Thus, vaccine safety is high on the Nation's public health agenda.

Objectives

The Agency for Healthcare Research and Quality (AHRQ) requested an evidence report on the safety of vaccines recommended for routine immunization of adults (including pregnant women), children, and adolescents as of October 2011. This report, which represents the results of a comprehensive and systematic review of scientific evidence, describes potential associations between vaccines and adverse events (AEs) and will be used by the Office of the Assistant Secretary for Health (OASH) to identify the gaps in evidence. The report was guided by the following Key Questions (KQs):

- **KQ 1.** What is the evidence that vaccines included in the 2011 immunization schedule recommended for U.S. **adults**[9] are safe in the short term (within 30 to 42 days following immunization) or long term (>42 days after immunization)?
    a. What adverse events are collected in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?
    b. What AEs are reported in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?
    c. What AEs are associated with these vaccines?
        1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?
        2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]
        3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether a vaccine is administered individually or in a combination vaccine product, schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

- **KQ 2.** What is the evidence that vaccines included in the immunization schedules recommended for U.S. **children and adolescents** in 2011[10] are safe in the short term (within 30 to 42 days following immunization) or long term (>42 days after immunization)?
    a. What AEs are collected in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?
    b. What AEs are reported in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?
    c. What AEs are associated with these vaccines?
        1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?
        2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]
        3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether a vaccine is administered individually or in a combination vaccine product, schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

- **KQ 3.** What is the evidence that vaccines recommended for **pregnant women**[11] are safe both for the woman and for her fetus/infant?
    a. What AEs are collected in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?
    b. What AEs are reported in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

[a] Level of certainty was operationalized as the 95-percent confidence interval surrounding the risk or odds estimate—i.e., the statistical significance.

c. What AEs are associated with these vaccines in women?
    1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?
    2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]
    3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether the vaccine is administered individually or in a combination vaccine product, the schedule of vaccine administration, adjuvants, and medications administered concomitantly)?
d. What AEs are associated with these vaccines in the fetus/infant?
    1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?
    2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]
    3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether the vaccine is administered individually or in a combination vaccine product, the schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

Methods

In 2011, the Institute of Medicine (IOM) published a consensus report titled "Adverse Effects of Vaccines: Evidence and Causality."[12] That report evaluated the scientific evidence for event-vaccine relationships and covered the following vaccines on the 2011 recommended immunization schedules: varicella, influenza, hepatitis A, hepatitis B, HPV, MMR, meningococcal, tetanus, diphtheria, and pertussis. We report the IOM findings and update them by identifying and evaluating studies published after the IOM searches. We also searched for studies of pneumococcal, rotavirus, *Haemophilus influenzae* type b, inactivated poliovirus, and zoster vaccines; these were not included in the IOM report.

We searched electronic databases such as Medline® for relevant studies; complete search terms are provided in Appendix A of the full report. Databases were searched from inception through August 2013 for the vaccines not covered by the IOM report; for the other vaccines, the searches dated from a year before the IOM search. We also reviewed ACIP statements, package inserts, and Scientific Information Packets requested from vaccine manufacturers by an AHRQ-funded Scientific Resource Center. Finally, we scanned review articles for relevant references.

The following study designs were included:

- **Controlled clinical trial.** Human subjects are assigned prospectively, usually through randomization, to receive an intervention (in this case, a vaccine) or an alternative intervention (another vaccine) or placebo. Clinical trials are used to determine safety and efficacy.[13]

[a] Level of certainty was operationalized as the 95-percent confidence interval surrounding the risk or odds estimate—i.e., the statistical significance.

- **Cohort study.** Cohort studies follow two or more similar groups that differ with respect to whether they received a vaccine (the "exposure") to determine how/whether the vaccination affects rates of one or more AEs (the "outcome").[13,14]
- **Case-control study.** Case-control studies compare people who have a disease or adverse event ("cases") with people who do not have the disease or event ("controls") and look back retrospectively to compare exposure to vaccine in each group to determine the relationship between the vaccine and the disease/event.[13,14]
- **Self-controlled case series (SCCS).** Only cases (individuals who experienced the AE) are included in the analysis. Each individual serves as his or her own control. The analysis inherently controls for covariates that remain stable within a person during the study period—for example, race and sex. SCCSs compare outcome event rates during times when a person is exposed (postvaccination) with those during times when the same person is unexposed (prevaccination) to calculate the relative incidence of AEs.[13,15]
- **Other designs.** We included all active surveillance studies that used regression to control for confounders and test multiple relationships simultaneously. We refer to these as multivariate risk factor analyses. Data sources may include medical records, health insurance claims, and government registries.[13]

Studies that use passive surveillance, such as the U.S. Vaccine Adverse Event Reporting System,[16] are crucial in identifying signals regarding AEs postlicensure. However, because by definition they do not consider the rate of such events in nonvaccinated populations, they are not designed to assess a statistical association between a vaccine and an adverse event, so such studies were excluded from this project. We also excluded studies of vaccine formulations never used or no longer available in the United States. Examples include whole-cell pertussis vaccine, oral polio vaccine, and PCV7 pneumococcal vaccine. The recent IOM report "The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies"[17] makes recommendations for future research on childhood vaccination schedules and cumulative effect, so this report focuses on assessing the association between AEs and specific vaccines rather than the cumulative effect of vaccines.

Two researchers independently reviewed the titles and abstracts identified. The union of their selections was retrieved. Two researchers also independently reviewed the full text of study reports and met to reach consensus regarding exclusion/inclusion. Disputes were settled by the lead investigators and team physician experts. Patient and study characteristics were abstracted by single researchers and confirmed by the principal investigator.

If a study reported severity or if adequate information was provided for our investigators to categorize severity, we used the Common Terminology Criteria for Adverse Events classification system[18] to characterize AEs. The definition of "serious" differs by AE type; each category of AE (e.g., fever, headache) is rated on a scale of 1 to 5, with 1 being very mild and 5 being death due to the event.

The McHarm instrument[19] was used to evaluate the quality of the studies with regard to assessment of adverse events. Studies that reported timing and severity and that defined AEs using standard precise definitions were rated higher than those that did not. (Many studies provided data on a list of AEs but did not address severity.) Epidemiological studies that used medical records to ascertain vaccination and health outcomes were rated higher than those that relied on patient or parent report.

We assessed the overall strength of evidence using guidance suggested by AHRQ for its Effective Health Care Program.[20] This method is based on one developed by the GRADE

(Grading of Recommendations Assessment, Development and Evaluation) Working Group[21] and classifies the evidence according to the following criteria:

- **High.** High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- **Moderate.** Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- **Low.** Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.
- **Insufficient.** Evidence either is unavailable or does not permit a conclusion.

The evidence grade is based on four primary (required) domains and four optional domains. The required domains are risk of bias, consistency, directness, and precision, as described in the Methods section of the full report. The additional domains are dose response, plausible confounders that would decrease the observed effect, strength of association, and publication bias.

It is important to note that the 2011 IOM report used different terminology; evidence was classified as either "convincingly supports," "favors acceptance," "inadequate to accept or reject," or "favors rejection" of a causal association. The IOM included mechanistic studies and individual case reports to assess the biological plausibility of AEs and considered this information in addition to any statistical association. For each vaccine discussed in the IOM report, we started with the IOM findings and modified them, if needed, based on any additional evidence identified. If the IOM found that evidence "convincingly supports" an association, we rated the strength of evidence as "high" unless additional evidence was identified. Similarly, if the IOM found evidence "favors acceptance" we started with by rating as "moderate" strength of evidence and evidence rated as "inadequate to accept or reject" was considered "insufficient" in our grading system. If new evidence was identified for vaccines evaluated by the IOM, ratings could be adjusted up or down according to our assessment of the new studies. If the IOM found that evidence "favors rejection" of a causal relationship we choose between moderate and high based on our review of the IOM evidence plus any studies published after their search.

Results

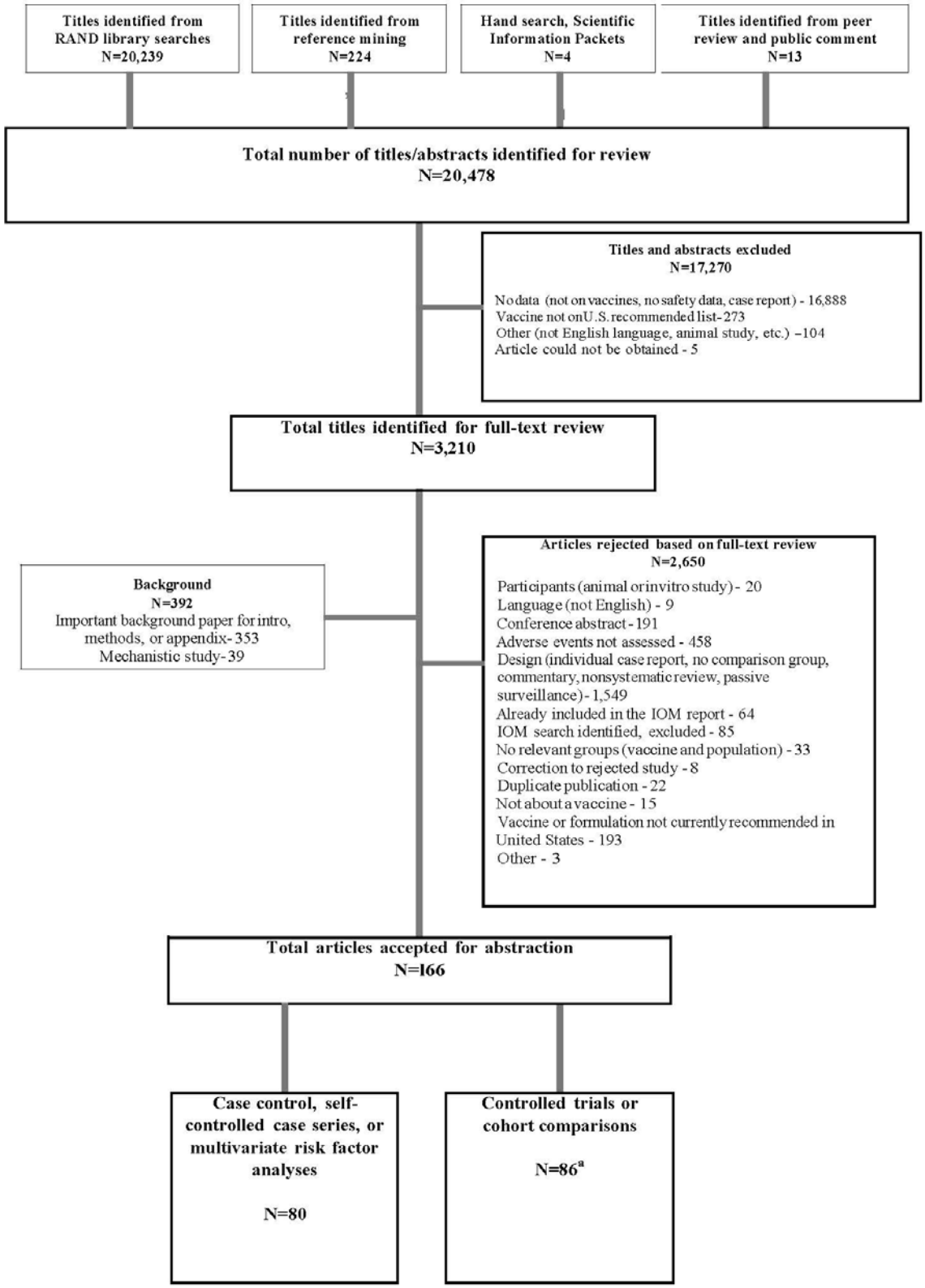
As presented in Figure A, a total of 20,478 titles were identified through electronic literature searches; review of product inserts; review of Food and Drug Administration, ACIP, and other Web sites; reference mining; and requests for Scientific Information Packets from drug manufacturers. Of those, 17,270 were excluded upon review of abstract or title, mostly due to lack of data on safety of vaccines. Other reasons for exclusion included use of vaccines not within the scope of this project (e.g., not formulations available in the United States, recommended only for travel), publication in languages other than English, and study not conducted on humans. Five reports could not be obtained; based on their titles, we do not think this affected the project.

Based on abstract screening, 3,210 articles were selected for full-text review. Of those, 392 were identified as relevant background/theoretical materials and set aside as potential references. A total of 2,650 other articles were excluded. The most common reason for exclusion was lack of suitable study design (1,549): individual case reports, nonsystematic reviews, and studies using passive surveillance were excluded. Many publications (458) discussed vaccines on the recommended schedule but did not report or assess AEs.

Studies using formulations never available or discontinued in the United States were excluded at full-text review (e.g., H5N1 vaccine, vaccines with the squalene adjuvant ASO3, and BCG vaccine against tuberculosis). Determining whether the potency or formulation was the one approved for clinical use in the United States was often difficult; the process involved comparing the potency, dosage, and ingredients listed on product materials and in Food and Drug Administration filings with the information reported in the study.

Based on full-text screening, 166 studies were accepted for abstraction. These include 86 controlled trials or cohort studies directly comparing a group that received a vaccine with an unvaccinated group. (Five of the 86 studies also reported a multivariate analysis.) We also abstracted 80 case-control studies, SCCSs, or multivariate risk factor analyses that met our inclusion criteria. These studies are in addition to those included in the 2011 IOM consensus report "Adverse Effects of Vaccines: Evidence and Causality," which were not abstracted.

Figure A. Study/literature flow diagram



IOM = Institute of Medicine
[a]Five studies also contributed multivariate risk factor analyses.

Table D displays a summary of our results. The second column displays the strength of evidence regarding statistical association of vaccines with AEs. Where we identified no additional studies on a vaccine, our conclusions are based entirely upon the 2011 IOM report. It is important to recognize that the strength of evidence refers to the chances the vaccine is truly associated with a particular AE, rather than the **rate** of that AE or **severity**. Strength of evidence may be high for an AE that is extremely rare, very mild, or without long-term consequences. Further details on the scientific evidence behind the findings are available in the full report and its appendices.

Importantly, the vast majority of studies did not report potential risk factors for AEs that were statistically associated with vaccination. Similarly, the severity of AEs was inconsistently reported, as was information that would make independent severity determination possible.

Table D. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
		Adults	
Diphtheria Toxoid, Tetanus Toxoid, and Acellular Pertussis Vaccines (Td, Tdap)	**High:** Anaphylaxis	Evidence **"convincingly supports"** a causal relationship between the tetanus toxoid vaccine and anaphylaxis.	We identified 2 additional trials in adults. No AEs were associated with vaccine.
Hepatitis A Vaccine	**Insufficient:** Acute disseminated encephalomyelitis, transverse myelitis, MS, GBS, chronic inflammatory demyelinating polyneuropathy, Bells' palsy, anaphylaxis, and autoimmune hepatitis	Evidence is **"inadequate to accept or reject"** any causal relationships with AEs the committee was tasked with investigating: acute disseminated encephalomyelitis, transverse myelitis, MS, GBS, chronic inflammatory demyelinating polyneuropathy, Bells' palsy, anaphylaxis, and autoimmune hepatitis.	We identified 1 additional postlicensure study; there was no association of the vaccine with any AEs or onset of medical conditions.
Hepatitis B Vaccine	**Insufficient:** Optic neuritis, first demyelinating event, GBS, SLE, onset or exacerbation of vasculitis, polyarteritis nodosa, and onset or exacerbation of rheumatoid arthritis **Moderate:** No association with MS onset or exacerbation **Moderate:** Anaphylaxis in patients allergic to yeast	Although no epidemiological studies were identified on anaphylaxis, mechanistic evidence **"favors acceptance"** of a causal relationship between the vaccine and anaphylaxis in yeast-sensitive individuals. Epidemiological studies of the following AEs in adults had evidence **"inadequate to accept or reject"** a causal relationship: optic neuritis, first demyelinating event, GBS, SLE, onset or exacerbation of vasculitis, polyarteritis nodosa, and onset or exacerbation of rheumatoid arthritis. A 2002 IOM review on Hep B vaccine and demyelinating neurological disorders concluded that the evidence "**favors rejection**" of a causal relationship with incident MS or MS relapse.	No additional studies met our inclusion criteria.

Table D. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Hepatitis B Vaccine (continued)		No epidemiological studies of the following AEs in adults were found and evidence is also **"inadequate to accept or reject"** a causal relationship: encephalitis, encephalopathy, ADEM, transverse myelitis, neuromyelitis optica, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, erythema nodosum, onset or exacerbation of psoriatic arthritis, onset or exacerbation of reactive arthritis, and fibromyalgia.	
Influenza Vaccines	**High:** Arthralgia, myalgia, malaise, fever, pain at injection site. Anaphylaxis in allergic persons. **High:** 2009 monovalent H1N1 vaccine with GBS **High:** No association with cardiovascular events in the elderly **Insufficient:** MS onset and exacerbation	Two forms of influenza vaccine were studied: live attenuated form, administered intranasally (LAIV), and inactivated form (TIV), administered intramuscularly. Evidence **"convincingly supports"** a causal relationship between influenza vaccines and anaphylaxis in people allergic to egg or gelatin. However, in recent years, manufacturers have reduced the egg protein content.	Many clinical trials reported that influenza vaccines are associated with arthralgia, myalgia, malaise, fever, and pain in the short term in adults. These AEs were not considered serious; severity was graded mild to moderate. Odds of experiencing these events were 1.5 to 2 times higher in vaccinated patients than in unvaccinated people. Risk factors were not discussed in the trials. A high-quality meta-analysis found an association between 2009 monovalent H1N1 vaccine and GBS in the 42 days postvaccination; results translate to about 1.6 excess cases per million vaccinated. Postlicensure studies have found inconsistent evidence associating influenza vaccines with onset or exacerbation of MS in adults. Postlicensure studies have found influenza vaccines are NOT associated with increased risk of cardiovascular or cerebrovascular events in the elderly. Postlicensure studies have shown that influenza vaccines are NOT associated with increased risk of serious AEs in renal patients.

Table D. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
MMR Vaccine	**Moderate:** No association with Type 1 diabetes **Moderate:** Transient arthralgia in women **Insufficient:** MS onset, GBS, chronic arthralgia in women, and chronic arthritis and arthropathy in men	Evidence **"favors acceptance"** of a causal relationship with transient arthralgia in women. Evidence is **"inadequate to accept or reject"** a causal relationship with MS onset, GBS, chronic arthralgia in women, and chronic arthritis and arthropathy in men.	MMR was NOT associated with onset of type 1 diabetes in adults in 1 large high-quality epidemiological study: RR=0.71 (95% CI, 0.61 to 0.83).
Pneumococcal Polysaccharide Vaccine	**High:** No association with cardiovascular or cerebrovascular events in the elderly	Not covered.	We found no placebo-controlled trials of the current formulation that reported AE data. (We found trials of the current formulation that reported pneumonia or mortality; these were considered efficacy outcomes.) Postlicensure studies of pneumococcal polysaccharide vaccine found vaccination was not associated with increased risk of cardiovascular events in older adults.
Zoster Vaccine	**Moderate:** Injection site reactions, allergic reactions, cellulitis possibly related to allergy	Recommended for U.S. adults 60 years and older; AEs specific to this age group were not covered.	In some reports of clinical trials, AEs were reported only in categories such as "injection-related adverse events," "systematic adverse events," or "serious adverse events." Vaccination was associated with injection site reactions. In postlicensure studies, vaccination was associated with cellulitis possibly related to allergy and allergic reactions such as redness and swelling 1 to 7 days postvaccination. These mild AEs occurred in less than 1% of patients and were more likely in the younger (aged 50-59) vaccinees.

Table D. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Children and Adolescents			
Diphtheria Toxoid, Tetanus Toxoid, and Acellular Pertussis-Containing Vaccines (DTap, Td, Tdap)	**Moderate:** No association with type 1 diabetes **Insufficient:** Infantile spasms, seizures, cerebellar ataxia, autism, ADEM, transverse myelitis, MS relapse, serum sickness, immune thrombocytopenic purpura, and SIDS	Evidence **"favors rejection"** of a causal relationship between vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens and type 1 diabetes. Evidence is **"inadequate to accept or reject"** causal relationships between vaccination and the following: infantile spasms, seizures, cerebellar ataxia, autism, ADEM, transverse myelitis, MS relapse in children, serum sickness, immune thrombocytopenic purpura, and SIDS.	We found no additional studies that met our inclusion criteria.
Hepatitis B Vaccine	I**nsufficien**t: Food allergy **Moderate:** No association with MS	Although no epidemiological studies were identified by the IOM, mechanistic evidence "**favored acceptance"** of a causal relationship between the vaccine and anaphylaxis in yeast-sensitive individuals. The IOM found evidence **"inadequate to accept or reject"** a causal relationship with any other AEs. A 2002 IOM report **"favors rejection"** of a causal relationship with MS onset or exacerbation.	Hep B vaccine in the first 6 months of life was associated with elevated total IgE in a postlicensure study of children with a family history of food allergy, but not with clinical allergy.
Hib Vaccine	**Moderate:** No association with serious AEs in short term	Not covered.	No serious AEs were associated in 3 high-quality clinical trials.

Table D. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
HPV Vaccine	**Moderate:** No association with juvenile rheumatoid arthritis, type 1 diabetes, appendicitis, GBS, seizures, stroke, syncope, venous thromboembolism **Moderate:** Anaphylaxis in persons with allergies, fever, headache, mild gastrointestinal AEs, skin infection **High:** Pain at injection site **Insufficient:** ADEM, transverse myelitis, neuromyelitis optica, MS, onset of Hashimoto's disease, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, amyotrophic lateral sclerosis, transient arthralgia, pancreatitis, thromboembolic events, spontaneous abortion, and hypercoagulable states	Evidence **"favors acceptance"** of a causal relationship between the HPV vaccine and anaphylaxis. Evidence is **"inadequate to accept or reject"** causal relationships between HPV vaccines and the following: ADEM, transverse myelitis, neuromyelitis optica, MS, GBS, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, amyotrophic lateral sclerosis, transient arthralgia, pancreatitis, thromboembolic events, and hypercoagulable states.	A large postlicensure study found HPV vaccine was not associated with onset of juvenile rheumatoid arthritis or type 1 diabetes. This study reported an IRR of 1.29 (95% CI, 1.08 to 1.56) of onset of Hashimoto's disease. However, investigation of a temporal relationship and biological plausibility revealed no consistent evidence of a safety signal. A large postlicensure study found HPV vaccine was NOT associated with GBS, seizures, stroke, syncope, or venous thromboembolism. Several clinical trials found HPV vaccination associated with short-term severe pain at injection site. Trials also found vaccine associated with fever, headache, nausea, and stomach ache. A secondary analysis including only Black women who became pregnant within 3 to 4 years of receiving HPV vaccine in 2 trials reported a higher rate of spontaneous abortion in vaccinated subjects.
Inactivated Polio Vaccine	**Insufficient:** Food allergy	Not covered.	One postlicensure study reported association between polio vaccine in newborns and sensitivity to food allergens.

Table D. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Influenza Vaccines	**Moderate:** Mild gastrointestinal disorders, febrile seizures **Low:** No association with any serious AEs in the short term in children with cancer or who have received organ transplants **Low:** Influenza-like symptoms **Insufficient:** Asthma exacerbation (with live vaccine), ADEM, transverse myelitis	The IOM committee studied seasonal influenza vaccines. The influenza vaccine is administered in 2 forms: a live attenuated form, administered intranasally, and an inactivated form, administered intramuscularly. Evidence was **"inadequate to accept or reject"** a causal relationship in the pediatric population between seasonal influenza vaccines and the following: seizures, ADEM, and transverse myelitis. Evidence was **"inadequate to accept or reject"** a causal relationship between LAIV and asthma exacerbation or reactive airway disease episodes.	In postlicensure studies, seasonal influenza vaccines were NOT associated with any serious adverse events in the short term in children with malignancy, inflammatory bowel disease, or urea cycle disorders, or children who had received organ transplants. Both seasonal influenza vaccines and monovalent H1N1 vaccine were associated with mild gastrointestinal disorders, such as vomiting and diarrhea, in children in the short term in several large postlicensure studies. One large study found that younger vaccinated children (aged 5 to 8 years) were more likely to experience these symptoms than older vaccinated children (aged 9 to 17 years). (Children under 5 years of age were not included in that study). Both live and inactivated seasonal influenza vaccines were associated with influenza-like symptoms in children in the short term in multiple studies, while not associated in others. A large U.S. postlicensure study of children under age 5 years found TIV associated with febrile seizures. Risk was increased if PCV13 was administered concomitantly.

Table D. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
MMR Vaccine	**High:** No association with autism spectrum disorders **High:** Anaphylaxis in children with allergies, febrile seizures **Moderate:** Transient arthralgia **Moderate:** Thrombocytopenic purpura **Insufficient:** Encephalitis, encephalopathy, afebrile seizures, meningitis, cerebellar ataxia, acute disseminated encephalomyelitis, transverse myelitis, optic neuritis, neuromyelitis optica, MS onset, and chronic arthropathy	Evidence **"convincingly supports"** causal relationships with febrile seizures and anaphylaxis. Evidence **"convincingly supports"** a causal relationship with measles inclusion body encephalitis in immunocompromised patients. Evidence **"favors acceptance"** of a causal relationship between MMR and transient arthralgia Evidence **"favors rejection"** of a causal relationship between MMR and autism. Evidence is **"inadequate to accept or reject"** a causal relationship with encephalitis, encephalopathy, afebrile seizures, cerebellar ataxia, acute disseminated encephalomyelitis, transverse myelitis, optic neuritis, neuromyelitis optica, MS onset, and chronic arthropathy.	Four additional postmarketing studies were identified. Vaccination was associated with thrombocytopenic purpura in the short term. MMR vaccination was associated with increased emergency department visits within 2 weeks; this is indirect support of the IOM's findings that MMR vaccine is associated with febrile seizures.
Meningococcal Vaccines (MCV4, MPSV)	**Moderate:** Anaphylaxis in children with allergies **Insufficient:** Encephalitis, encephalopathy, ADEM, transverse myelitis, MS, GBS, CIDP, chronic headache	Evidence **"convincingly supports"** a causal relationship with anaphylaxis in children who may be allergic to ingredients. Evidence is **"inadequate to accept or reject"** causal relationships between meningococcal vaccine (unspecified) and the following: encephalitis, encephalopathy, ADEM, transverse myelitis, MS, GBS, CIDP, and chronic headache.	Two new trials of quadrivalent meningococcal conjugate vaccines found no association with any AEs assessed.

Table D. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Miscellaneous and Combination Vaccines	**Moderate:** DTaP-IPV-Hib vaccination with febrile seizures **High:** No association of childhood leukemia with MMR, DTaP, Td, Hib, Hep B, and polio vaccines **Moderate:** Hepatitis A, MMR, and varicella vaccine with purpura	Not covered.	Association of DTaP-IPV-Hib vaccination with febrile seizures in children was found in a very large high-quality postlicensure study. Rate for first dose was estimated as 5.5 cases per 100,000 person/days. Rate for second dose was estimated as 5.7 cases per 100,000 person/days. Multiple large epidemiological studies have assessed MMR, DTaP, Td, Hib, Hep B, and polio vaccine and have found no association with childhood leukemia. In a large postlicensure study of over 1.8 million vaccine recipients, purpura was associated with vaccination against hepatitis A in children aged 7 to 17 years, vaccination against varicella in children aged 11 to 17, and MMR in children from 12 to 19 months of age. These results were based on 1 or 2 cases per vaccine type/age group. According to the authors most cases were mild and acute.
Pneumococcal Conjugate (PCV13)	**Moderate:** Febrile seizures	Not covered.	A recent study using the U.S. Vaccine Safety Datalink (VSD) found an association with febrile seizures. Estimated rate for 16-month-old patients is 13.7 cases per 100,000 doses for PCV13 without concomitant TIV and 44.9 per 100,000 doses for concomitant TIV and PCV13.

Table D. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Rotavirus Vaccines: RotaTeq and Rotarix	**Moderate:** Intussusception	Not covered.	In clinical trials, there was no association between either of the 2 currently available vaccines (RotaTeq and Rotarix) and any serious AEs, including intussusception, in the long or short term. A high-quality epidemiological study in Australia found RotaTeq was associated with intussusception 1 to 21 days following the first of 3 required doses in infants 1 to 3 months of age. Two case-control studies conducted in Latin America found an association of Rotarix with intussusception in children following the first of 2 required doses. Although 1 U.S. epidemiological study found no association, a recent analysis of the U.S. Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program found both RotaTeq and Rotarix associated with intussusception in the short term. Estimated rate was 1.1 to 1.5 cases per 100,000 doses of RotaTeq and 5.1 cases per 100,000 doses of Rotarix.
Varicella Vaccine	**High:** Anaphylaxis; disseminated Oka VZV without other organ involvement; disseminated Oka VZV with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies; vaccine strain viral reactivation without other organ involvement; vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis	Evidence **"convincingly supports"** causal relationships between varicella virus vaccine and the following: disseminated Oka VZV without other organ involvement; disseminated Oka VZV with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies; vaccine strain viral reactivation without other organ involvement; vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis; and anaphylaxis. The evidence is **"inadequate to accept or reject"** a causal relationship between the vaccine and seizures, ADEM, transverse myelitis, GBS, small fiber neuropathy, onset or exacerbation of arthropathy, and thrombocytopenia.	We identified 1 small trial in children with SLE; the trial reported no association with AEs.

Table D. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Varicella Vaccine (continued)	**Insufficient:** Seizures, ADEM, transverse myelitis, GBS, small fiber neuropathy, onset or exacerbation of arthropathy, thrombocytopenia		
Pregnant Women			
Influenza Vaccines	**Moderate:** No association with serious adverse events	Results not specific to pregnant women.	Both monovalent H1N1 vaccine and seasonal influenza vaccine (inactivated) containing H1N1 strains were not associated with serious adverse events in pregnant women or their offspring in multiple trials and postlicensure studies. Studies report an association with lower risk of adverse pregnancy outcomes.

ADEM = acute disseminated encephalomyelitis; AE = adverse event; CI = confidence interval; CIDP = chronic inflammatory demyelinating polyneuropathy; DTaP = diphtheria, tetanus, and pertussis vaccine; EPC = Evidence-based Practice Center; GBS = Guillain-Barré syndrome; Hep B = hepatitis B; Hib = *Haemophilus influenzae* type B; HPV = human papillomavirus; IgE = immunoglobulin E; IOM = Institute of Medicine; LAIV = live attenuated influenza vaccine; MMR = measles, mumps, rubella vaccine; MS = multiple sclerosis; SIDS = sudden infant death syndrome; SLE = systemic lupus erythematosus; Td = tetanus-diphtheria; TIV = trivalent influenza vaccine; IPV = inactivated polio vaccine; IRR = incidence rate ratio; MCV = meningococcal conjugate vaccine; MPSV = meningococcal polysaccharide vaccine; PCV = pneumococcal conjugate vaccine; RR = relative risk; Tdap = tetanus, diphtheria, and acellular pertussis vaccine; VZV = varicella-zoster virus

Discussion

In 2011, the IOM released "Adverse Effects of Vaccines: Evidence and Causality." At the request of AHRQ and OASH, we assessed the additional evidence on the safety of vaccines recommended for routine use among adults, children, and pregnant women as of 2011. We conducted an extensive literature search for clinical trials and observational studies with strong study designs and analysis methods: cohort studies comparing vaccinated and unvaccinated groups, case-control studies, self-controlled case series, and designs using multivariate risk factor analyses. Our results support most findings of the IOM report, add conclusions on some adverse events for which new evidence was identified, and include findings on additional vaccines.

Our findings may allay some patient, caregiver, and health care provider concerns. Strength of evidence is high that vaccines against pneumonia and influenza are not associated with cardiovascular or cerebrovascular events in the elderly; many studies reported a decreased risk for vaccinated patients. Strength of evidence is high that MMR vaccine is not associated with the onset of autism in children; this conclusion supports findings of all previous reviews on the topic. There is moderate-strength evidence that HPV vaccine is not associated with appendicitis, stroke, seizures, syncope, venous thromboembolism, onset of juvenile arthritis, or onset of type 1 diabetes and high-strength evidence that MMR, DTaP (diphtheria, tetanus, and pertussis), Td (tetanus-diphtheria), Hib (*Haemophilus influenzae* type B), and hepatitis B vaccines are not associated with childhood leukemia.

Evidence of association with vaccines was found for several serious AEs; however, these events were extremely rare. Absolute risk is extremely rare. Strength of evidence is high that 2009 monovalent H1N1 influenza vaccine was associated with Guillain-Barré syndrome (GBS), but results translate to about 1.6 additional cases per million persons vaccinated. Since 2010, U.S. seasonal influenza vaccines have contained an H1N1 strain. No association with GBS has been found for inactivated seasonal vaccine (TIV). Strength of evidence is moderate for association of vaccines against rotavirus with intussusception. Although one U.S. epidemiological study found no association, a recent analysis of the U.S. Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program[22] found both RotaTeq and Rotarix associated with intussusception in the short term. Estimated rate was 1.1 to 1.5 cases per 100,000 doses of RotaTeq and 5.1 cases per 100,000 doses of Rotarix.

Evidence is insufficient to make conclusions regarding whether several routinely recommended vaccines are associated with serious conditions much as multiple sclerosis (MS), transverse myelitis, and acute disseminated encephalomyelitis (ADEM). This leaves an important research gap.

We identified a recent secondary analysis of data on Black women who participated in two placebo-controlled trials of quadrivalent HPV vaccine (Gardasil) conducted in several countries. In women who became pregnant in the 4 years following the trial, there was a significantly higher rate of spontaneous abortion for women who were vaccinated.[23] The authors state that the rate of "fetal loss" was statistically similar for vaccinees and nonvaccinees; however, "fetal loss" included planned abortion. In the vaccine group, 19 of 307 pregnancies resulted in spontaneous abortion, compared with 7 of 393 pregnancies in the control group. Databases such as the Vaccine Safety Datalink (VSD) could be used to further investigate this signal in a much larger population.

Conclusions must be viewed in light of the important caveats below.

Literature search procedures were extensive; however, some unpublished trial results may not have been identified. An independent Scientific Resource Center under contract with AHRQ requested Scientific Information Packets from vaccine manufacturers. (The research team was prohibited from contacting manufacturers directly.) Only two companies responded.

We included trials of the formulations currently on the market in the United States. We tried to exclude Phase II studies that used dosages that were never licensed and/or formulations available only in foreign countries. Some studies reported the potency or formulation of the vaccines in a different manner or unit than reported in the product materials. Large epidemiological studies sometimes included any available formulation of vaccines against a particular disease and did not stratify results by dosage or formulation. For example, the relationship between the "seasonal influenza vaccine" and an AE could be studied over several years of data without addressing the changes in formulation over the seasons.

Our findings are based on only the most rigorous study designs to assess potential statistical associations; however, these designs have limitations that must be considered. Controlled trials often have insufficient sample size to identify very rare AEs and do not have extended followup to identify long-term sequelae. In addition, trials may purposely exclude subjects such as the elderly, pregnant women, and people with medical conditions who could be more susceptible to AEs. For this reason, any comprehensive review of vaccine safety also includes postlicensure studies, but these are not without limitations. People who avoid vaccinations (whether purposely or not) may differ from those who receive vaccinations in terms of race, sex, age, socioeconomic status, and preexisting medical conditions, and these differences may be associated with health outcomes. Observational studies attempt to control for such potential confounders by using matched cohorts or multivariate regression analysis; still, some factors such as environmental exposures may be unmeasured or challenging to adequately control for. The self-controlled case series was developed specifically to assess the safety of vaccines; this method eliminates confounding by all time-independent variables by using cases as their own controls and predefined "time windows" before and after vaccination. This design has been used to study purpura, febrile seizures, intussusception, and autism in children. The SCCS assumption of no temporal shifts is difficult to justify in very young children, as any patient characteristics that change with time will not be adequately controlled for.

There may be important AE signals not identified in this report that warrant future research. Passive surveillance systems such as the U.S. Vaccine Adverse Event Reporting System[16] are crucial in identifying signals regarding AEs postlicensure, but they are not designed to assess a statistical association so were excluded from this project. The research gaps below are based on the study designs that met our inclusion criteria.

Research Gaps

Adults

There was insufficient evidence to determine whether influenza vaccines are associated with onset or exacerbation of MS.

The unknown association regarding MS and GBS and vaccines for MMR and hepatitis A also presents a research gap; the IOM found evidence inadequate to accept or reject a causal relationship. As these medical conditions are extremely rare, "insufficient" evidence determination may be unavoidable despite additional research.

A recent meta-analysis on 2009 monovalent H1N1 vaccine provided high-strength evidence of association with GBS in adults. As the vaccine is associated with only 1.6 excess cases per million vaccinated, it will be very difficult to assess risk factors.

Some published vaccine trials were not specific in reporting AEs. Broad categories such as "injection-related adverse events," "systemic adverse events," "one or more adverse events," or "serious adverse events" were reported rather than specific AEs. In addition, many studies reported on a list of predefined AEs but did not rate the severity or provide enough information for our investigators to determine severity. Future studies of vaccines should report results with more granularity.

Children and Adolescents

There is insufficient evidence to determine any potential association between trivalent inactivated vaccine and asthma exacerbation, acute disseminated encephalomyelitis, and transverse myelitis.

Febrile seizures were associated with MMR, influenza, and pneumococcal conjugate vaccines. Younger age was associated with increased risk in several studies. Large-scale epidemiological studies could determine other patient risk factors.

A large U.S. postlicensure study found associations between both Rotarix and RotaTeq and intussusception in the short term following vaccination; patient risk factors were not reported.

Strong evidence for a lack of association of HPV vaccines with several serious medical conditions (juvenile rheumatoid arthritis, type 1 diabetes, GBS) has been found in large postlicensure studies. However, there is insufficient evidence regarding other serious conditions such as MS, chronic inflammatory demyelinating polyneuropathy, amyotrophic lateral sclerosis, and pancreatitis. Importantly, a recent analysis of long-term followup data from Black women enrolled in two trials of Gardasil showed a possible increased risk of miscarriage of pregnancies within 4 years of vaccination. Large datasets from U.S. managed care organizations include medical records on both immunization and pregnancy, so they could be used to investigate any potential association.

There is insufficient evidence to determine the possible association, if any, between vaccines such as DTaP, meningococcal vaccine, and varicella vaccine and the onset of nervous system conditions such as ADEM, transverse myelitis, MS, and GBS. Large-scale epidemiological studies could provide additional data; however, as these medical conditions are extremely rare, it may not be possible to reach a level of evidence beyond "insufficient."

Pregnant Women

There is moderate strength of evidence that inactivated influenza vaccine is not associated with serious adverse events in pregnant women or their offspring. Given the 2013 recommendation to administer the Tdap vaccine during every pregnancy, passive surveillance systems should be monitored regularly for AEs in this population.

A reliable system of tracking when in pregnancy the vaccine was given is extremely important. In addition, in any study of vaccines and pregnancy, followup of newborns should be sufficiently long, as not all adverse effects may be apparent immediately after birth. The need for large numbers of pregnant exposures is particularly important given the relatively low frequency of some birth defects and the need to define which are associated with vaccine. In addition, little is known about the patient factors that may influence the effect of the vaccine. Another unknown is how vaccination in pregnancy may affect the newborn's immune system/reaction to newborn

vaccinations. The Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) has components to monitor safety of maternally administered vaccines and their effect on recipients and their offspring. VAMPSS is a collaboration of the American Academy of Allergy, Asthma & Immunology; the Organization of Teratology Information Specialists (OTIS) Research Center at the University of California San Diego; and the Slone Epidemiology Center (SEC) at Boston University. The U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority contracted VAMPSS to perform safety monitoring of H1N1 influenza vaccine administered during the 2009 pandemic. As this report was being finalized, a VAMPSS study on the safety of H1N1 was released;[24,25] the authors found no meaningful evidence of increased risk of major birth defects, miscarriage, or low birth weight for gestational age. Existing Federal systems such as the VSD and/or PRISM could potentially be used as well.

General Methodological Observations

Advanced health information technology systems that contain both vaccination and health outcome records can be used to conduct high-quality epidemiological studies. In the United States, the VSD contains data obtained through such systems at nine very large managed care organizations. The FDA's Mini-Sentinel program PRISM system also conducts active surveillance using electronic health care databases from managed care organizations. Nations with single-payer health care systems often have electronic registries that allow very large epidemiological studies of entire populations. Studies using these databases have greater validity than studies that rely on surveys that use patient/parent recall for ascertainment of vaccination or health outcome. Not only are such surveys subject to recall bias, but there may be no way of determining the formulation or brand of vaccination.

Observational studies should be powered adequately to determine risk factors such as demographic and health characteristics of patients. Analysis should be stratified by formulation and brand of vaccine, if possible. This is especially true for influenza vaccine, which differs from season to season.

Independent abstraction and systematic reassessment of the studies included in the IOM consensus report "Adverse Effects of Vaccines: Evidence and Causality" may be a useful future endeavor. Odds ratios could be calculated for each event reported in each trial and postlicensure study and, where appropriate, meta-analysis conducted to calculate overall odds ratios for each AE and each vaccine type. If the additional studies were abstracted, the totality of data abstracted could be statistically analyzed to explore additional hypotheses and issues beyond the scope of the current report.

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Introduction

Background

Vaccines are considered one of the greatest public health achievements of the last century for their role in eradicating smallpox and controlling polio, measles, rubella, and other infectious diseases in the United States.[1] Despite their effectiveness in preventing and eradicating disease, substantial gaps in vaccine uptake exist. Vaccination rates for young children are high;[2] however, vaccination rates remain well below established Healthy People 2020 targets for many vaccines recommended for adolescents,[3] adults,[4] and pregnant women.[5]

Increasing vaccination rates remains critically important, as vaccine-preventable diseases such as influenza, pertussis, and human papillomavirus (HPV)-associated cervical cancer continue to take a heavy toll despite the widespread availability of effective vaccines. The health and productivity costs of influenza infection alone in adults are have been estimated to be as high as $87 billion per year.[6] The recent pertussis outbreaks in California, Washington, Minnesota, and Wisconsin highlight the importance of protecting vulnerable infants by vaccinating their pregnant mothers, caregivers, and other contacts. HPV is the most common sexually transmitted infection. HPV-16 and HPV-18— two strains included in the HPV vaccine —are thought to be responsible for approximately 70 percent of incident cervical cancer. Nationally, in 2005, there were nearly 12,000 new cases of cervical cancer reported, with 4,000 cervical cancer-related deaths.[7] Despite the availability of an HPV vaccine that could prevent a substantial proportion of these cases of cervical cancer, completion of the three-dose series was only 34.8 percent among adolescent females in 2011.[3]

The shortfall in vaccination coverage rates occurs in the context of a rapidly changing immunization schedule. Routine immunizations recommended as of October, 2011 for children (Table 1), adolescents (Table 1), adults (Table 2), and pregnant women (Table 3) are presented below. Since 2005, the routine adolescent vaccination schedule has grown to include these vaccines at ages 11 or 12 years: meningococcal conjugate vaccine; tetanus, diphtheria, and acellular pertussis (Tdap); HPV; and influenza (one dose annually). In 2013, pregnant women were advised to receive Tdap during every pregnancy to protect their newborns from pertussis regardless of prior history of receiving Tdap.[8]

Table 1. Vaccines routinely recommended for children and adolescents, 2011

Vaccine	Age
DTaP (diphtheria, tetanus, and acellular pertussis)	2 months–6 years
Hepatitis A	12 months and older
Hepatitis B	Birth and older
Hib (*Haemophilus influenzae* type b)	6 weeks–59 months
HPV (human papillomavirus)	9 years–21 years (male) 9 years–26 years (female)
Influenza (inactivated)	6 months and older
Influenza (live attenuated)	2 years and older
IPV (inactivated polio vaccine)	6 weeks and older
MCV (meningococcal conjugate vaccine)	2 years and older
MMR (measles, mumps, and rubella)	12 months and older
MPSV (meningococcal polysaccharide vaccine)	2 years and older, in specific circumstances
PCV13 (pneumococcal conjugate vaccine)	6 weeks–18 years
Pneumococcal polysaccharide vaccine	2 years and older, in specific circumstances
Rotavirus	6 weeks–8 months
Tdap (tetanus, diphtheria, and acellular pertussis)	7 years and older
Varicella	12 months and older

Table 2. Vaccines routinely recommended for nonpregnant adults, 2011

Vaccine	Recommendation
Hepatitis A	All adults at increased risk for hepatitis A infection
Hepatitis B	All unvaccinated adults at risk for or requesting protection from Hepatitis B infection
HPV (human papillomavirus)	Adults 26 years and younger
Influenza (inactivated)	All adults
Influenza (live attenuated)	All adults 49 years and younger
Meningococcal conjugate vaccine (MCV4) and meningococcal polysaccharide vaccine (MPSV)	Adults at risk of meningococcal disease (MCV4 or MPSV if younger than 55 years; MPSV if older than 55 years)
MMR (measles, mumps, and rubella)	All adults who are not immune through prior infection
Pneumococcal polysaccharide vaccine	Adults 64 years and younger with certain conditions, and all adults 65 years and older
Td (tetanus, diphtheria)	All adults
Tdap (tetanus, diphtheria, and acellular pertussis)	All adults 19–64 years old; some adults 65 years and older
Varicella	All adults without evidence of varicella immunity
Zoster	All adults 60 years and older

Table 3. Vaccines routinely recommended for pregnant women, 2011

Vaccine	Recommendation
Hepatitis B	Recommended in some circumstances
Influenza (inactivated)	All pregnant women
Td (tetanus, diphtheria)	Should be used if indicated
Tdap (tetanus, diphtheria, and acellular pertussis)	All pregnant women after first trimester if indicated*

*In 2013, pregnant women were advised to receive Tdap during pregnancy to protect their newborns from pertussis.

As the number of recommended immunizations has expanded across the population, so too have concerns about the safety of vaccines, despite the rigorous processes new vaccines must undergo before receiving approval from the U.S. Food and Drug Administration (FDA). Vaccine development and commercialization are complex processes, and the regulatory review process is overseen by the Center for Biologics Evaluation and Research of the FDA.[9] Vaccines are unique when compared with many other medications because they are administered to a large population of mostly young healthy people to prevent rather than treat disease. Vaccines must meet stringent criteria for safety, efficacy, and potency. Preclinical studies are conducted in the early stages of vaccine development and are meant to be sufficient to rule out overt toxicity and identify potential toxic effects that might occur during the clinical trial. Once a vaccine is ready for clinical evaluation, an Investigational New Drug application must be submitted so the FDA can monitor the safety of clinical trial subjects and ensure that the study design is appropriate to assess the vaccine's effectiveness and safety.

The clinical evaluation of a vaccine typically consists of three phases.[9] Phase I studies—which typically enroll 20 to 80 subjects—are designed to evaluate vaccine safety and tolerability and to generate preliminary immunogenicity data. Phase II studies evaluate the immunogenicity of the vaccine and provide preliminary estimates on the rates of common adverse events, typically enrolling several hundred subjects. Phase III trials provide the information on a vaccine's safety and efficacy that is required to support licensure. After a vaccine is licensed and in use, multiple systems are in place to ensure ongoing assessments of safety,[10] including post licensure safety surveillance conducted by sponsors as postmarketing commitments or requirements to the FDA,[11] the FDA's Post-Licensure Rapid Immunization Monitoring (PRISM) system,[12-14] FDA surveillance using databases of Federal Partners such as the Centers for Medicare and Medicaid Services (CMS),[15] the Vaccine Adverse Event Reporting System (VAERS) co-administered by the FDA and the Centers for Disease Control and Prevention (CDC),[16] CDC's Vaccine Safety Datalink,[17] and CDC's Clinical Immunization Safety Assessment project.[18]

Despite the stringent regulation and evaluation of vaccines, public concerns about vaccine safety continue to persist. Perhaps the most highly publicized safety concern of the last two decades has been the alleged link between autism and the MMR vaccine, first reported in *The Lancet* by Dr. Andrew Wakefield.[19] Vaccination rates for measles, mumps, and rubella plummeted in the United Kingdom leading to measles outbreaks[20] and concern about vaccines and autism spread globally. In 2010, *The Lancet* fully retracted the 1998 publication,[21] noting that elements of the manuscript had been deliberately falsified. Subsequently, Dr. Wakefield was barred from practicing medicine in the United Kingdom. Although multiple large studies have confirmed the lack of association between MMR and autism, parental worries about the safety of the vaccine persist. In addition to autism, other parental concerns about childhood vaccines include possible links to multiple sclerosis, sudden infant death syndrome, asthma, and diabetes.[22] Though no systematic data exist on the safety concerns of pregnant women, this is likely to be an active focus given the relatively recent introduction of the recommendation to administer the Tdap vaccine during pregnancy.

The Agency for Healthcare Research and Quality (AHRQ) requested an evidence report on the safety of vaccines used for routine immunization of adults (including pregnant women), children, and adolescents that will, based on a comprehensive and systematic review of the scientific literature, describe associations between vaccines and adverse events (AEs) and help to outline the gaps in evidence. This report focuses on the adverse events (AEs) potentially

associated with vaccines as opposed to the benefits, as all of these vaccines are already recommended.

Our work expands upon the consensus report "Adverse Effects of Vaccines: Evidence and Causality," published by the Institute of Medicine (IOM) in late 2011. That report evaluated the scientific evidence for event-vaccine relationships and covered many vaccines included in the 2011 U.S. recommended immunization schedules (varicella, influenza, Hepatitis A, Hepatitis B, HPV, MMR, meningococcal, tetanus, diphtheria, and pertussis). Our work builds upon the IOM report in a number of important ways. In addition to vaccines covered by the IOM report, our systematic review covers pneumococcal, rotavirus, *Haemophilus influenzae* type b, inactivated poliovirus, and zoster vaccines. We report the 2011 IOM conclusions, update the literature with more recent studies, and conduct original searches for the recommended vaccines that were not included; we provide an assessment of AEs reported.

Methods

Original Proposed Key Questions

AHRQ provided following original Key Questions (KQs). Not all questions were answerable through a systematic review of the published research; we discuss important research gaps later in this report.

- **KQ 1.** What is the evidence that vaccines included in the 2011 immunization schedule recommended for U.S. **adults**[23] are safe in the short term (within 30–42 days following immunization) or long term (>42 days after immunization)?
    a. What adverse events (AEs) are collected in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?
    b. What AEs are reported in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?
    c. What AEs are associated with these vaccines?
        1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?
        2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]
        3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether a vaccine is administered individually or in a combination vaccine product, schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

- **KQ 2.** What is the evidence that vaccines included in the immunization schedules recommended for U.S. **children and adolescents** in 2011[24] are safe in the short term (within 30–42 days following immunization) or long term (>42 days after immunization)?
    a. What AEs are collected in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?
    b. What AEs are reported in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?
    c. What AEs are associated with these vaccines?
        1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?
        2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]
        3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether a vaccine is administered individually or in a combination vaccine product, schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

[a] Level of certainty was operationalized as the 95-percent confidence interval surrounding the risk or odds estimate—i.e., the statistical significance.

- **KQ 3.** What is the evidence that vaccines recommended for **pregnant women**[25] are safe both for the woman and for her fetus/infant?
    a. What AEs are collected in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?
    b. What AEs are reported in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?
    c. What AEs are associated with these vaccines in women?
        1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?
        2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]
        3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether the vaccine is administered individually or in a combination vaccine product, the schedule of vaccine administration, adjuvants, and medications administered concomitantly)?
    d. What AEs are associated with these vaccines in the fetus/infant?
        1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?
        2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]
        3. For each AE associated with a particular vaccine, what are risk factors for the AE (including age, gender, race/ethnicity, genotype, underlying medical condition, whether vaccine administered individually or in a combination vaccine product, vaccine schedule of administration, adjuvants, medications administered concomitantly)?

Technical Expert Panel

For each Agency for Healthcare Research and Quality (AHRQ) systematic review, a Technical Expert Panel (TEP) is assembled to provide clinical expertise and context. A distinguished group of scientists and clinicians were invited to participate in the TEP for this report. Potential members submitted conflict of interest disclosure forms; any current or prior relationship with a vaccine manufacturer was grounds for disqualification per AHRQ. A list of members is included in the front matter.

TEP conference calls were held on June 18, June 19, and July 19, 2012; they were attended by project staff and Task Order Officers (TOO) from AHRQ and the Office of the Assistant Secretary for Health (OASH). The TEP informed staff of recent developments in the field, gave input on which AEs and issues were most important, and emphasized we should only include studies which use the same dosage and formulation as currently used in the U.S . Vaccines with adjuvants not currently used in the U.S. (for example, ASO3) or strengths that were never licensed in the U.S. (for example, those used in Phase II studies that did not advance to Phase III)

[a] Level of certainty was operationalized as the 95-percent confidence interval surrounding the risk or odds estimate—i.e., the statistical significance.

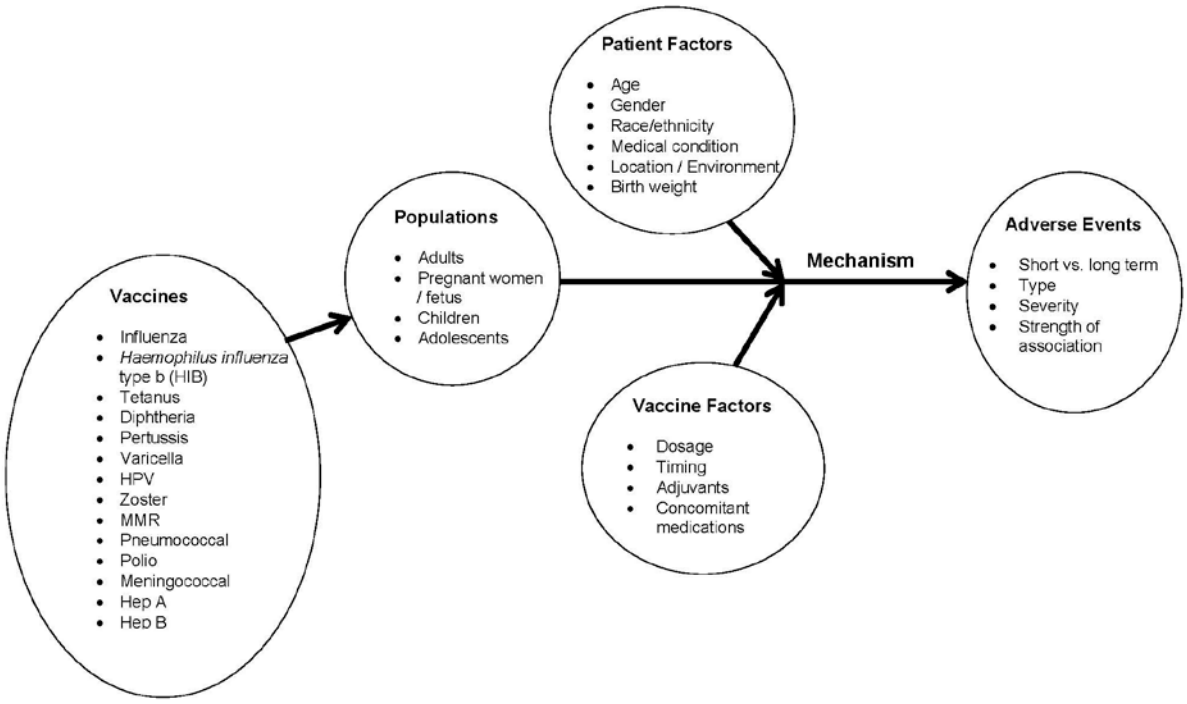
should be excluded. They also advised that, given resource limitations, minor AEs such as crying and injection site redness need not be discussed in the report.

Panel members were invited to review the draft version of this report and provide feedback.

Analytic Framework

The analytic framework for the project is displayed in Figure 1. Vaccinations recommended by the Centers for Disease Control and Prevention (CDC) are listed in the large oval. Various subsets are administered annually to children, adolescents, and adults, including pregnant women (next circle), according to a schedule developed by the Advisory Committee on Immunization Practices (ACIP). Both patient factors (i.e., age, pre-existing conditions) and vaccine factors (i.e., formulation, dosage, and timing) may be risk factors for potential AEs.

Figure 1. Analytic framework



Hep A = hepatitis A; Hep B = hepatitis B; HPV = human papillomavirus; MMR = measles, mumps, rubella

Literature Search

The following databases were searched to identify relevant studies: DARE, the Cochrane Database of Systematic Reviews, CENTRAL, PubMed®, EMBASE®, CINAHL®, TOXLINE®, and TOXFILE®. The Institute of Medicine (IOM) report, ACIP statements, and vaccine package inserts were reviewed. Review articles were mined for references.

Our search strategy built upon the recent IOM report for the eight vaccines contained therein. Using the IOM keyword search strategy, we updated their searches on varicella, influenza, Hepatitis A, Hepatitis B, HPV, MMR, meningococcal, diphtheria, pertussis, and tetanus vaccines to identify more recently published studies. The following structure was used in the IOM keyword search strategy: "vaccine term" AND "health term," where vaccine terms include the technical vaccine name, general descriptions of the vaccine of interest (e.g., rotavirus AND

vaccine), or manufacturer names; health terms include a list of AEs potentially associated with the vaccine. We also added more general AE keywords to the list of health terms such as "safe" or "safety," "side effect" or "harm." We searched from a year before the publication of the IOM report through August, 2013.

Using this approach, we developed new search strategies for the vaccines not originally included in the IOM report: pneumococcal, rotavirus, *H. influenzae* type b, inactivated poliovirus, and zoster. We searched each of the databases mentioned above from their inception to August, 2013.

Searches were based on AEs reported in systems such as the Vaccine Injury Compensation Program (VICP), Vaccine Adverse Event Reporting System (VAERS) and the FDA's Mini-Sentinel Program. The Technical Expert Panel (TEP) reviewed the draft list of AEs and suggested additional AEs of interest. Appendix A contains the detailed search strategy and a list of AEs included in the searches.

Article Review

Two researchers independently reviewed the titles and abstracts identified. The union of their selections was retrieved. Two researchers also independently reviewed the full text of study reports, entered data into an electronic form, and met to reach consensus on any conflicts regarding exclusion/inclusion. Disputes were settled by the lead investigators and team physician experts.

Data were entered directly by researchers into DistillerSR software (Evidence Partners Inc., Ottawa, Ontario, Canada),[26] which is designed specifically for systematic reviews and meta-analyses, and exported to SAS (SAS Institute Inc., Cary, NC) for analysis.

Study Inclusion

We **included** the following study designs:

- **Controlled clinical trial—**A study where human subjects are assigned prospectively, usually through randomization, to receive an intervention (in this case a vaccine) or an alternate intervention (another vaccine) or placebo. Clinical trials are used to determine safety and efficacy.[27]
- **Cohort study—**Follows two or more groups who differ with respect to whether they received a vaccine (the "exposure"), over time to determine how/whether the vaccination affects rates of one or more adverse events (the "outcome").[27,28]
- **Case-control study—**A study that compares persons who have a disease or adverse event (AE) (cases) with persons who do not have the disease or AE (the "outcome"), and looks back retrospectively to compare exposure to vaccine in each group to determine the relationship between the vaccine and the disease / AE.[27,28]
- **Self-controlled case series (SCCS)—**Only cases (individuals who experienced the AEs) are included in the analysis. With SCCS, each individual serves as their own control. The analysis inherently controls for covariates that remain stable within a person during the study period; for example, race and gender. SCCS compares outcome event rates during times when a person is exposed (post-vaccination) with those during times when the same person is unexposed (pre-vaccination) to calculate the relative incidence of AEs.[27,29]
- **Other designs—**We included all active surveillance studies that used regression to control for confounders and test multiple relationships simultaneously. We refer to these

as multivariate risk factor analyses. Data sources may include medical records, health insurance claims, and government registries.[27]

Studies using passive surveillance such as the U.S. Vaccine Adverse Event Reporting System (VAERS)[16] are crucial in identifying signals regarding adverse events post-licensure. However, because by definition they do not consider the rate of such events in non-vaccinated populations, they are not designed to assess a statistical association between a vaccine and an adverse event, so they were excluded from this project. We also excluded studies of vaccines not on the current U.S. recommended schedules. These include brands and formulations never available in the United States and or no longer used. Examples include whole cell pertussis vaccine, oral polio vaccine, and PCV7 pneumococcal vaccine.

The following publication types/studies were **excluded:**

- Letters
- Editorials
- Individual case reports
- Animal studies
- Mechanistic/in vitro studies
- Conference abstracts
- Vaccine efficacy studies that did not report the presence or absence of AEs
- Observational studies which use passive surveillance for AEs
- Non–English-language studies. (Given the focus of this review and the corresponding literature base, we concluded the risk of language bias to be low and that it was thereby acceptable to limit the inclusion criteria to English studies only.)
- Studies of vaccines not on the U.S.-recommended schedules, including brands/formulations never available in the United States, or no longer used.

Data Abstraction and Synthesis of Results

Based on our experience conducting systematic reviews of the evidence on other health care interventions, we developed a structured approach to assessing AEs instead of relying on a random post hoc grouping. We used a tested and standardized form to extract AEs. If a study reported severity, or if adequate information was provided for our investigators to categorize severity, we used the Common Terminology Criteria for Adverse Events (CTCAE) classification system[30] to characterize AEs. Serious adverse events (SAE) were defined and coded. The definition of "serious" differs by AE type; each category of AE (i.e. fever, headache) is rated on a scale of 1 to 5, with 1 being very mild and 5 being death due to the event.

Clinical trials and cohort comparisons were abstracted using an electronic form which contained items for sample size, population description (age, gender, race/ethnicity, country, any co-morbidities), items on study quality (described below), vaccine description (name, manufacturer, dosage, formulation, adjuvants, preservatives, timing, mode of administration), and AEs (exact description, severity, timing, number) for each group. Odds ratios of AEs for vaccination and comparison arms were computed for each study, along with the 95% confidence interval. Studies were included for analysis if the total number of people in each group and the number of people with events in each group were reported. Occasionally, this information was missing, or the number of AEs and number of doses (rather than number of persons) was provided. Since AEs are generally rare, conditional pooling using exact methods provided a fixed effects estimate of the odds ratio. Analyses were conducted with StatXact® Procs for

SAS.[31] Subgroup analyses are narrative in order to be able to make comparisons between study designs and other variables in the heterogeneous dataset.

The case-control, self-controlled case series, and multivariate risk factor analyses were abstracted onto a different electronic form containing similar items; however, the statistical findings were abstracted directly. These types of studies generally do not include enough information for researchers to re-calculate the statistics independently, as they are not simple comparisons of a vaccinated group with an unvaccinated group. To assess the reliability and validity of the findings, we abstracted how vaccination status and health outcomes were ascertained (self-report, national registry, parent interview, medical record, etc.); potential sources of bias due to selection, participation, attrition, and non-response of subjects; amount of missing data; funding source; and how potential confounders were handled. The abstraction forms are presented in Appendix B.

We created detailed evidence tables displaying critical data for each included study. Multiple publications of the same study are noted and counted (extracted, assessed for quality, and analyzed) as one study to ensure that the same participants do not enter the analyses multiple times. Multiple publications were defined by the investigated patients.

Assessment of Methodological Quality

For controlled trials and cohort comparisons, we used a quality-rating instrument Santaguida and colleagues (2008)[32] developed for evaluating studies reporting adverse events. Called McHarm, the tool was developed from quality rating items generated by a review of the literature on harms and from previous quality assessment instruments. Scores range from 0 to 15; a copy of the instrument and scoring instructions are included in Appendix B. McHarm was tested for reliability and face, construct, and criterion validity and includes important factors such as:

- Were AEs predefined using standard, precise definitions?
- Was the mode of harms collection active (participants are asked about the occurrence of specific AEs) or passive (participants are not specifically asked about or tested for the occurrence of AEs; patient reports of AEs are made on their own initiative)?
- Did the study specify who collected the AE data?
- Did the study specify the timing of AEs?
- Was the number of participants who withdrew or were lost to follow up reported?

Grading the Evidence for Each Key Question

We assess the overall strength of evidence by using guidance suggested by AHRQ for its Effective Health Care Program.[33] This method is based on one developed by the GRADE Working Group[34] and classifies the grade of evidence according to the following criteria:

- **High.** High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- **Moderate.** Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- **Low.** Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.
- **Insufficient.** Evidence either is unavailable or does not permit a conclusion.

The evidence grade is based on four primary (required) domains and four optional domains. The required domains are risk of bias, consistency, directness, and precision, as described in Table 4 below. The additional domains are dose-response, plausible confounders that would decrease the observed effect, strength of association, and publication bias.

It is important to note that the 2011 IOM report used different terminology; evidence was classified as either "convincingly supports," "favors acceptance," inadequate to accept or reject" or "favors rejection" of a causal association. They included mechanistic studies and individual case reports to assess the biological plausibility of AE and considered this in addition to any statistical association. For each vaccine discussed in the IOM report, we started with the IOM findings and modified them, if needed, based on any additional evidence identified. For example, if the IOM found that evidence "convincingly supports" an association, we rated the strength of evidence as "high" unless additional evidence was identified. Similarly, if the IOM found evidence "favors acceptance" we started with by rating as "moderate" strength of evidence and evidence rated as "inadequate to accept or reject" was considered "insufficient" in our grading system. If new evidence was identified for vaccines evaluated by the IOM, ratings could be adjusted up or down according to our assessment of the new studies. If the IOM found that evidence "favors rejection" of a causal relationship we choose between moderate and high based on our review of the IOM evidence plus any studies published after their search.

Table 4. Grading the strength of a body of evidence: required domains and their definitions

Domain	Definition and Elements	Score and Application
Risk of Bias	Risk of bias is the degree to which the included studies for a given outcome or comparison have a high likelihood of adequate protection against bias (i.e., good internal validity), assessed through two main elements: • Study design (e.g., RCTs or observational studies) • Aggregate quality of the studies under consideration Information for this determination comes from the rating of quality (good/fair/poor) done for individual studies.	Use one of three levels of aggregate risk of bias: • Low risk of bias • Medium risk of bias • High risk of bias

Table 4. Grading the strength of a body of evidence: required domains and their definitions (continued)

Domain	Definition and Elements	Score and Application
Consistency	The principal definition of consistency is the degree to which reported effect sizes from included studies appear to have the same direction of effect. This can be assessed through two main elements: • Effect sizes have the same sign (that is, are on the same side of "no effect"). • The range of effect sizes is narrow.	Use one of three levels of consistency: • Consistent (i.e., no inconsistency) • Inconsistent • Unknown or not applicable (e.g., single study) As noted in the text, single-study evidence bases (even mega-trials) cannot be judged with respect to consistency. In that instance, use "Consistency unknown (single study)."
Directness	The rating of directness relates to whether the evidence links the interventions directly to health outcomes. For a comparison of two treatments, directness implies that head-to-head trials measure the most important health or ultimate outcomes. Two types of directness, which can coexist, may be of concern: Evidence is indirect if: • It uses intermediate or surrogate outcomes instead of health outcomes. In this case, one body of evidence links the intervention to intermediate outcomes and another body of evidence links the intermediate to most important (health or ultimate) outcomes. • It uses two or more bodies of evidence to compare interventions A and B—e.g., studies of A vs. placebo and B vs. placebo, or studies of A vs. C and B vs. C but not A vs. B. Indirectness always implies that more than one body of evidence is required to link interventions to the most important health outcomes. Directness may be contingent on the outcomes of interest. EPC authors are expected to make clear the outcomes involved when assessing this domain.	Score dichotomously as one of two levels directness • Direct • Indirect If indirect, specify which of the two types of indirectness account for the rating (or both, if that is the case) — namely, use of intermediate/ surrogate outcomes rather than health outcomes, and use of indirect comparisons. Comment on the potential weaknesses caused by, or inherent in, the indirect analysis. The EPC should note if both direct and indirect evidence was available, particularly when indirect evidence supports a small body of direct evidence.
Precision	Precision is the degree of certainty surrounding an effect estimate with respect to a given outcome (i.e., for each outcome separately). If a meta-analysis was performed, this will be the confidence interval around the summary effect size.	Score dichotomously as one of two levels of precision: • Precise • Imprecise A precise estimate is an estimate that would allow a clinically useful conclusion. An imprecise estimate is one for which the confidence interval is wide enough to include clinically distinct conclusions. For example, results may be statistically compatible with both clinically important superiority and inferiority (i.e., the direction of effect is unknown), a circumstance that will preclude a valid conclusion.

Peer Review and Public Commentary

A draft of this report was submitted in May, 2013. The AHRQ Effective Healthcare Program Scientific Resource Center (SRC) located at Portland VA Research Foundation coordinated peer review by experts and stakeholders. The report was posted on AHRQ's web site for a month for public comment. Resulting comments were considered by the authors in preparation of the final report**. Synthesis of the scientific literature presented here does not necessarily represent the views of individual reviewers, and service as a peer reviewer or member of the Technical Expert Panel cannot be construed as endorsement of the report's findings.**

Results

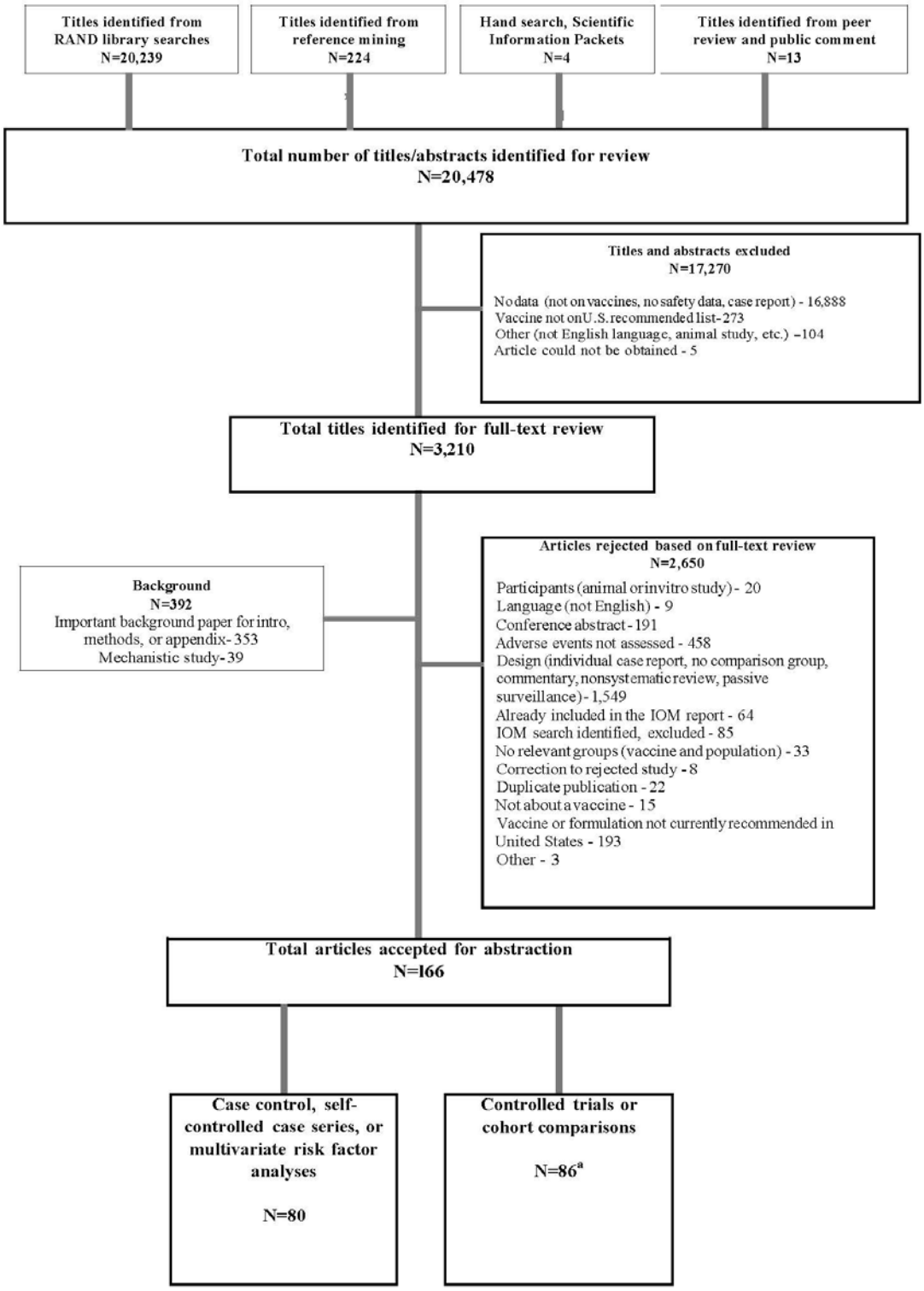
A total of 20,478 titles were identified through electronic literature searches; suggestions from TEP members; review of product inserts; review of FDA, ACIP, and other web sites; reference mining; and finally, Scientific Information Packets (SIPs) requested from vaccine manufacturers by the AHRQ-funded Scientific Resource Center (SRC). Of those, 17,270 were excluded upon review of abstract (where available) or title, mostly due to lack of data on safety of vaccines (see Figure 2). Other reasons for exclusion included use of vaccines not within the scope of this project (i.e. not routinely recommended in the United States, recommended only for travel, no longer used in the United States), publication in languages other than English, and study not conducted on humans. Five could not be obtained; based on their titles, we do not think this affected the project. A list of excluded studies and corresponding reasons for exclusion is provided as Appendix D.

Based on title/abstract screenings, 3,210 articles were selected for full text review. Of those, 392 were identified as relevant background/theoretical materials and set aside as potential references. A total of 2,650 other articles were excluded. The most common reason for exclusion was lack of suitable study design (1,549): Individual case reports, non-systematic reviews, and studies using passive surveillance (for example, reports from VAERS) were not included. Many publications (458) discussed vaccines on the recommended schedule, but did not assess adverse events.

One hundred and ninety-three studies using formulations not currently or routinely recommended in the United States were excluded at full text review. For example, studies of H5N1 vaccine, BCG vaccine, and vaccines using the adjuvant ASO3, or BCG vaccine were excluded. Identifying strength / formulation was often difficult; this process involved comparing product materials and/or FDA filings with formulations reported in the studies.

Based on full text screening, 166 studies were accepted for abstraction, including 86 controlled trials or cohort studies directly comparing a group who received a vaccine with an unvaccinated group. Five of these 86 studies also conducted a multivariate analysis. We also included 80 case-control studies, self-controlled case series, or multivariate risk factor analyses that met our inclusion criteria. These studies are in addition to the studies included in the 2011 IOM consensus report “Adverse Effects of Vaccines: Evidence and Causality”; we summarize their conclusions for each population and vaccine, we did not abstract those studies. The results are presented by population: adults, children and adolescents, and pregnant women.

Figure 2. Study/literature flow diagram



IOM = Institute of Medicine
[a]Five studies also contributed multivariate risk factor analyses.

Key Question 1: What is the evidence that vaccines included in the 2011 immunization schedule recommended for U.S. **adults**[23] are safe in the short term (within 30–42 days following immunization) or long term (>42 days after immunization)?

a. What adverse events (AEs) are collected in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?

b. What AEs are reported in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?

Table 5 lists all AEs collected or reported in placebo-controlled trials and vaccinated/unvaccinated cohort comparisons of adults, abstracted verbatim. We interpreted "collected" to mean those specified a priori by investigators, while "reported" were any AEs reported by participants. The list does not imply an association with vaccination; it displays reported AEs regardless of whether they were reported in vaccinated or unvaccinated study participants, and whether or not the number reported was zero. (In the latter case, a study could "collect" data on a specific serious AE, but "report" zero cases.) Later in this report, we describe the studies and assess association.

Table 5. Adverse events collected or reported in trials of adults

Vaccine	Adverse Event
HPV*	• Acute appendicitis • Arthralgia • Fatigue • Fever • GI symptoms • Headache • Lymph node tuberculosis • Myalgia • Pain (Grade 3) • Rash • Redness (>50 mm) • Swelling (>50 mm) • Urticaria

Table 5. Adverse events collected or reported in trials of adults (continued)

Vaccine	Adverse Event
Influenza inactivated	• Arthralgia • Bruising • Burning/stinging nose (Grade2/3) • Burning/stinging throat (Grade 2/3) • Chills • Conjunctival hemorrhage • Cough • Death • Fatigue • Fever • Fits (seizures) • Gingival bleeding • Headache • Hyperhidrosis • Itching nose/throat/eyes (Grade 2/3) • Joint pain • Lightheadedness/Dizziness (Grade2/3) • Lump formation • Malaise • Muscle pain • Myalgia • Nausea • Nosebleeds • Oropharyngeal pain • Pain • Posttraumatic elbow hematoma • Pyrexia • Redness • Rigors (muscle cramp) • Seizures • Shivering or chills • Shortness of breath (Grade 2/3) • Sweating (mild-moderate) • Swelling • Withdrawal after AE
Influenza—monovalent H1N1	• Any systemic AE • Chills • Fever • Headache • Malaise • Myalgia • Nausea • Vomiting
Td	• Hypoesthesia • “Serious adverse events”

Table 5. Adverse events collected or reported in trials of adults (continued)

Vaccine	Adverse Event
Varicella/Zoster	• Adenopathy • Anaphylaxis • Blood/Lymphatic disorders • Cardiac disorders • Chest pain • Death • Discontinued due to a vaccine-related AE • Fever • GI disorders • Hospitalization related to herpes zoster • Influenza-like illness • Injection-site reaction • Liver enzyme elevation • Neoplasms • Nervous system • Nose bleed • Oka VZV with or without other organ involvement • "Overall - Vaccine related AEs" • Pruritus • Psychiatric • Rash • Respiratory/Thoracic • "Serious adverse events" • "Systemic adverse events" • Systemic rash (non-zosteriform) • "Vaccine-related systemic adverse events"

AE = adverse events; GI = gastrointestinal; HPV = human papillomavirus; VZV = varicella-zoster virus
*For HPV, Table 5 includes trials in adults age 18 to 35; adverse events in trials of younger patients appear in the children & adolescents section.

Table 6 lists all AEs and medical conditions assessed in the post-licensure studies of adults. The majority of these studies were designed to assess the association of a specific AE with vaccination. Again, appearance on the list does not imply an association.

Table 6. Adverse events investigated in postmarketing studies of adults

Vaccine	Adverse Event
Influenza vaccines: H1N1	• Allograft loss in kidney patients • Chronic obstructive pulmonary disease – exacerbation • Guillain–Barré Syndrome (GBS) • Hematologic diseases • Immune thrombocytopenia • Mortality • Multiple Sclerosis • Myocardial infarction • Sickle cell disease – exacerbation • Spasmodic dysphonia • Stroke
Influenza vaccines: LAIV or TIV	• Anaphylaxis • Asthma exacerbation • Death • Hospitalization • Oculorespiratory syndrome

Table 6. Adverse events investigated in postmarketing studies of adults (continued)

Vaccine	Adverse Event
Influenza with 23-valent pneumococcal vaccine	• Cardiac failure • COPD • Hospitalization for influenza • Hospitalization for pneumococcal diseases • Mortality due to pneumonia • Myocardial infarction • Stroke
Hepatitis B	• Anaphylaxis • Demyelinating Event, First • Guillain-Barré Syndrome • Multiple Sclerosis – Onset • Multiple Sclerosis – Relapse • Optic Neuritis • Rheumatoid Arthritis • Systemic Lupus Erythematosus • Vasculitis
MMR	• Arthropathy in men • Autism • Multiple sclerosis • Transient Arthralgia • Type 1 diabetes
Meningococcal Vaccines	• Encephalitis • Encephalopathy • Guillain-Barré Syndrome
Pneumococcal vaccines	• Acute coronary syndrome • Death • Major vascular events • Myocardial infarction • Stroke
Studies of multiple vaccines, including Hepatitis A, Hepatitis B, MMR, IPV	• Graves' disease • Hashimoto's thyroiditis • Psoriatic arthritis • Type 1 diabetes
Zoster	• Acute myocardial infarction • Acute myocarditis • Acute pericarditis • Allergic reactions • Bell's palsy • Cardiomyopathy • Cellulitis • Encephalopathy • Hospitalization for meningitis or encephalitis • Inflammatory bowel disease • Meningitis encephalitis • Pain • Psoriasis • Psoriatic arthritis • Ramsay-Hunt syndrome • Rheumatoid arthritis

COPD = chronic obstructive pulmonary disease; GBS = Guillain–Barré syndrome; IPV = polio vaccine; LAIV = live attenuated influenza vaccine; MMR = measles, mumps, rubella; TIV = trivalent inactivated vaccine

Key Question 1 – Adults (continued):

c. What AEs are associated with these vaccines?

1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?

2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]

3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether a vaccine is administered individually or in a combination vaccine product, schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

Our primary focus is the statistical association of AEs with vaccination. The severity of AEs was inconsistently reported. Where reported, or where possible for our researchers to categorize, severity is displayed in the summary tables in this section. Some clinical trials reported severity; most simply provided a list of AEs along with the number of patients in each group reporting them. Postmarketing studies tended to combine all cases of a particular AE, as severity details were often unavailable or inadequate.

Results are organized by vaccine type. For each vaccine, we first describe the findings of the 2011 Institute of Medicine (IOM) report "Adverse Events of Vaccine: Evidence and Causality," where available. (Not all recommended vaccines are covered in that report.) We then describe the findings from studies published after the IOM report that met our inclusion criteria: clinical trials and cohort studies that included an unvaccinated group, followed by the results of postmarketing studies. The results for all reported AEs, including those not statistically associated with vaccination, are displayed in the right-hand column of tables in this section. The 95% confidence intervals reflect the level of certainty.

We summarize and critique the evidence, taking into consideration the number and size of studies, study methodology and quality, and applicability.

Influenza Vaccines

The seasonal influenza vaccine is administered in two forms: a live attenuated form, administered intranasally (LAIV), and an inactivated form (TIV), administered intramuscularly. Monovalent H1N1 or "swine flu" vaccine was administered widely during the winter of 2009-2010; we were encouraged by our expert panel to include it, as seasonal vaccines developed after 2009 include an H1N1 strain.

[a] Level of certainty was operationalized as the 95-percent confidence interval surrounding the risk or odds estimate—i.e., the statistical significance.

The IOM committee studied the two forms of seasonal influenza vaccines. They found that evidence[35] "convincingly supports" a causal relationship between influenza vaccine and anaphylaxis. The committee found that evidence[36-39] "favors acceptance" of a causal relationship between two particular influenza vaccines used in Canada and oculorespiratory syndrome. The IOM committee found the evidence[40-45] "favors rejection" of a causal relationship between TIV and asthma exacerbation or reactive airway disease episodes in adults. Finally, despite finding some studies of influenza vaccine and the following AEs, the IOM found evidence was "inadequate to accept or reject" a causal relationship: encephalitis, encephalopathy, optic neuritis, multiple sclerosis (MS) onset or relapse, Guillain-Barré Syndrome (GBS), chronic inflammatory demyelinating polyneuropathy, Bell's Palsy, onset of exacerbation of systemic lupus erythematosus (SLE), onset or exacerbation of vasculitis, polyarteritis nodosa, onset or exacerbation of arthropathy, ischemic stroke, myocardial infarction, and all-cause mortality.

One comparative cohort study and eight trials of influenza vaccine in adults were published after the IOM search dates. All trials administered inactivated vaccine. One trial studied monovalent H1N1 vaccine; all other trials studied seasonal vaccine. All but one study of seasonal vaccine included an H1N1 strain. The results are summarized in Table 7.

A trial in Canada[46] included 1,348 adults (54.2% female) who received inactivated trivalent influenza vaccine at study start and 14 days later. Odds ratios were not calculated because the study reported AEs per dose rather than per patient.

A controlled clinical trial in the United States[47] included 7,250 adults aged 18 to 49 who received one dose of inactivated influenza vaccine. Compared to the control group, vaccinated individuals were more likely to experience arthralgia (OR 2.10, 95% CI 1.67-2.66), chills (OR 2.24, 95% CI 1.77-2.84), fatigue (OR 1.58, 95% CI 1.38-1.80), headache (OR 1.40, 95% CI 1.23-1.59), hyperhidrosis (OR 1.68, 95% CI 1.31-2.16), malaise (OR 2.02, 95% CI 1.74-2.36), myalgia (OR 3.28, 95% CI 2.80-3.85), oropharyngeal pain (OR 1.63, 95% CI 1.06-2.50), and pyrexia (OR 2.27, 95% CI 1.54-3.36).

A controlled clinical trial in the United States, Finland, and Poland[48] included 11,404 adults (55% female) separated into two vaccine groups that receive one dose inactivated influenza vaccine and one placebo group. Group 1 received Agrippal and Group 2 received Optaflu. Compared to the control group, Group 1 was more likely to experience mild to moderate fever (OR 2.01, 95% CI 1.16-3.49), mild to moderate malaise (OR 1.27, 95% CI 1.06-1.52), and mild to moderate myalgia (OR 1.31, 95% CI 1.11-1.55). A trial in Italy[49] included 104 adults (45.1% female) who received inactivated influenza vaccine (Fluad) at study start and 42 days later. No statistically significant differences in AEs between vaccinated and unvaccinated groups were reported. A trial in the United States[50] included 7,611 adults (60% female, 0.7% pregnant) who received one dose of inactivated influenza vaccine (Flulaval). Compared to the unvaccinated group, vaccinated individuals were more likely to experience fever (OR 1.79, 95% CI 1.28-2.50) and myalgia/arthralgia (OR 1.98, 95% CI 1.73-2.26).

A controlled clinical trial in the United States[51] included 4,648 adults (59% female, 0.8% pregnant) who received one dose of inactivated trivalent influenza vaccine (Flublok). Compared to the unvaccinated group, vaccinated individuals were more likely to experience any pain (OR 6.69, 95% CI 5.62-7.95) and muscle pain (OR 1.59, 95% CI 1.28-1.96).

Regarding monovalent H1N1, a trial in the United States[52] included 1,313 adults (57.1% female) who were divided into two groups receiving different doses (7.5 mg [Group 1] or 15 mg [Group 2]) of at study baseline and 21 days later. The only statistically significant finding was fewer systemic AEs in Group 2 (OR 0.56, 95% CI 0.32-0.99).

A controlled clinical trial in South Africa[53] included 189 HIV+ adults (84% female) who received inactivated influenza vaccine (Mutagrip). No statistically significant differences in AEs between vaccinated and unvaccinated groups were reported. This vaccine did not include an H1N1 strain.

The cohort study[54] compared vaccinated vs. unvaccinated patients with End Stage Renal Disease (ESRD) who were undergoing dialysis. The study was conducted in Taiwan; vaccine was inactivated. Vaccinees were older and more likely to have conditions such as cardiac disease and COPD. The elderly in the vaccine cohort had a lower hospitalization rate (adjusted HR 0.73, 95% CI 0.64-0.82). The time-dependent Cox model revealed an overall adjusted Hazard Ratio for mortality of 0.30 (95% CI 0.26–0.35) after counting vaccination for multi-years.

Table 7. Vaccinated versus unvaccinated adults: influenza vaccines

Author-Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Barrett P. N. et al.,2011[47] U.S.	Controlled Clinical Trial	4	Sample size : 7,250, Mean age: NR, Age range: 18 - 49	Influenza (inactivated), Baxter, Austria, contain 15 µg of hemagglutinin 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	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[48] U.S., Finland, Poland	Controlled Clinical Trial	4	Sample size : 11,404, 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: 0 Days	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)
Iorio A. et al.,2010[49] Italy	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 (influenza B), Adjuvant: Other adjuvant, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days Dose2: 42 Days	Nosebleeds: OR 0.743 (0.162-3.403)

Table 7. Vaccinated versus unvaccinated adults: influenza vaccines (continued)

Author-Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Jackson L. A. et al.,2010[50] U.S.	Controlled Clinical Trial	7	Sample size : 7,611, Mean age: 32.7, Age range: 18 - 49, Percent female: 60%, Percent Pregnant: 0.7%	Influenza (inactivated), Flulaval, ID Biomedical Corporation of Quebec (trademarked, 15 lg 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	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)
Langley J. M. et al.,2011[46] Canada	Controlled Clinical Trial	4	Sample size : 1,348, 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. meningitiis serogroup B strain 8047 at an initial ratio of OMP to hemaglutinin (HA) of 4:1. After filtration to removed 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/Shandong/7/97 [H1N1, Adjuvant: Not Reported, Preservative: Thimerosal, Delivery: Intranasal	Dose1: 0 Days Dose2: 14 Days	Not calculable

Table 7. Vaccinated versus unvaccinated adults: influenza vaccines (continued)

Author-Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Talaat K. R. et al.,2010[52] United States	Controlled Clinical Trial	5	Sample size : 1,313, Mean age: 56.5, Age range: 18 – 93, Percent female: 57.1%	Influenza – monovalent H1N1, CSL Limited, The 7.5-mg doses 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: 0 Days Dose2: 21 Days	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)
Treanor J. et al.,2011[51] USA	Controlled Clinical Trial	3	Sample size : 4,648, Mean age: 32.5, Age range: 18 – 55, Percent female: 59%, 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 sodium phosphate buffer pH 7.0 ± 0.4 without a preservative, Adjuvant: Not Reported, Preservative: Preservative Free, Delivery: Intramuscular	Dose1: 0 Days	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)
Madhi S. A. et al.,2011[53] South Africa	Controlled Clinical Trial	3	Sample size : 189, Mean age: 36.3, Percent female: 84%, Condition: 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	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)

Table 7. Vaccinated versus unvaccinated adults: influenza vaccines (continued)

Author-Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Wang, I.K. et al. 2013[54] Taiwan	Cohort	5	Sample size : 4018, Mean age: 70/59 (vaccinated/unvaccinated, Age range: 18 – 80+ Percent female: 51%, Conditions: End Stage Renal Disease (ESRD)	Influenza (inactivated) , Not specified , NR , Not reported , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Not reported	Dose1: 0 Days	Intensive care unit admission-hospitalization: OR 0.341 (0.206-0.564)** Respiratory Failure-hospitalization: OR 0.963 (0.727-1.276) Septicemia, bacteremia, and viremia-hospitalization: OR 1.158 (0.916-1.464) Total hospitalization: OR 1.096 (0.94-1.277)

AE = adverse event; CI = confidence interval; HA = hemagglutinin; NR = not reported; OMPs = outer membrane proteins; OR = odds ratio

ADDITIONAL STUDY DETAILS PRESENTED IN APPENDIX C EVIDENCE TABLES

We identified 19 postmarketing studies of influenza vaccines in adults published after the IOM report; they are displayed in Table 8. The vast majority assessed the relationship between vaccination and one adverse event or medical condition of particular interest. A few assessed whether the vaccine was associated with fewer cardiovascular events in the elderly. Finally, some studied the effect of vaccine in adults with pre-existing conditions such as MS, renal disease or COPD.

Guillain–Barré Syndrome (GBS) and Other Autoimmune Disorders

Several studies evaluated whether H1N1 vaccine was associated with an increased risk of developing Guillain-Barré Syndrome. Baxter[55] studied 415 cases of GBS among managed care enrollees in California. Odds of TIV vaccination in both 6 and 10 week intervals before GBS onset were not significant. (Inactivated polio vaccine, PPV, Tdap, Td, and vaccinations against hepatitis A and B were not associated statistically with GBS onset.) Greene et al. 2012[56] performed separate self-controlled risk interval and case-centered analyses among members of eight managed care organizations (MCOs) in the United States who received 1.48 million doses of monovalent inactivated pandemic H1N1 vaccine (MIV) and 1.72 million doses of TIV. Altogether thirteen confirmed cases of Guillain-Barré Syndrome were identified after receipt of MIV and 16 after receipt of TIV. Statistically significant increases in GBS risk following receipt of MIV were suggested by the self-controlled risk interval analysis (RR = 4.4 95% CI: 1.3, 14.2 risk difference = 5.0 per million MIV doses (95% CI: 0.5 per million, 9.5 per million). The case-centered analysis found that the OR 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), but this was not statistically significant. The risk difference was 3.4 per million MIV doses (95% CI: -6.4 per million, 7.6 per million). No increased risk for developing GBS was associated with receipt of seasonal trivalent inactivated influenza vaccine (RR 1.3, 95% CI: 0.5, 3.8), so case-centered analysis was not conducted. A meta-analysis of data from six U.S. surveillance systems established or enhanced during the 2009 H1N1 pandemic[57] found an association with GBS (IRR 2.35, 95% CI 1.42.4.01), equivalent to about 1.6 excess cases per million monovalent H1N1 vaccines administered.

In contrast, in a prospective case-control study of 1,225 subjects in France, Grimaldi-Bensouda et al. 2011[58] were unable to demonstrate any statistically significant association between receipt of monovalent H1N1 and/or seasonal influenza vaccine and the development of GBS in eight separate analyses (see Table 8 for statistics). As formulation and brand of vaccines were not reported, it is possible that AS03 adjuvant (not used in the United States) was contained in some vaccines. In Australia, Crawford[59] conducted a self-controlled case series to assess the potential relationship between monovalent H1N1 vaccine (Panvax) and GBS. No statistically significant association was found, after multiple sensitivity analyses for time period and use of season influenza vaccine. Lee[60] conducted a study of over 4.5 million doses of monovalent H1N1, TIV, and LAIV administered to enrollees in 8 U.S. MCOs. In a self-controlled case series analysis, a statistical association for monovalent H1N1 vaccine and Bell's palsy was found. However, a subsequent case-centered logistic regression controlling for seasonality found the association not statistically significant (OR 1.26, 95% CI 0.97-1.63). No significant associations were noted during sequential analyses for Guillain–Barré syndrome, most other neurological outcomes, and allergic and cardiac events.

In Europe, Isai and colleagues[61] compared the rate of autoimmune disorders reported to the EUdraVigilance database after vaccination with adjuvanted vs. unadjuvanted H1N1 vaccine. They used MedDRA classifications; autoimmune disorders included GBS, rheumatoid arthritis, type 1 diabetes, onset and exacerbation of MS, and over a dozen other conditions. The rate difference

between adjuvanted and non-adjuvanted H1N1 vaccines was not statistically significant. Using the estimated number of vaccinees as the denominator, they calculated the reporting rate as 9.98 (6.81-13.16) cases per million vaccinees for non-adjuvanted vaccines and 6.87 (6.06-7.68) cases per millionvaccinees for adjuvanted vaccines.

Neurological sequelae following MIV vaccination were evaluated in two other studies. Using a self-controlled case series method, Farez et al. 2012[62] assessed whether receipt of MIV was associated with relapses of MS. No significant relationship was found in this study of 137 patients (98% of whom were receiving interferon-beta and 25% glatiramer acetate) with previously diagnosed MS (for 30-day risk period, OR 0.86, 95% CI: 0.20, 3.62). Tanner et al. 2012[63] performed a case-control study of 150 patients with spasmodic dysphonia (cases) and 136 patients with other structural, neurological, and functional voice disorders (controls). There was no difference in post-vaccine incidence of spasmodic dysphonia among persons who did or did not self-report receipt of swine influenza vaccine (OR 2.1, 95% CI 0.9, 5.0), whereas persons who did not know whether they had received swine influenza vaccine were more likely to have spasmodic dysphonia than were persons who reported not receiving the vaccine.

Cardiovascular

The relationship between receipt of influenza vaccination and cardiovascular and cerebrovascular complications was assessed in three studies. In a matched case-control study of 16,012 persons with myocardial infarction and 62,964 controls, Siriwardena et al. 2010[64] found that receipt of influenza vaccine within the previous year was significantly associated with lower odds of acute myocardial infarction (OR 0.83, 95% CI 0.80, 0.88). A multi-center study including 40 countries[65] following 31,546 subjects, aged 55 and above, with a history of vascular disease or diabetes with documented end-organ damage between 2004 and 2007 concluded that although initial analyses suggested that influenza vaccination was associated with reduced risk of major adverse vascular events during influenza seasons when the influenza vaccine matched the circulating virus, sensitivity analyses revealed that risk of bias remained. The primary outcomes were a composite of death resulting from cardiovascular causes, and a composite of death from other causes during these four influenza seasons. Data were modeled using logistic regression and adjusted using propensity scores for influenza vaccination (demographics, body mass index, vitamin use, smoking history, alcohol use, history of pneumococcal vaccination, and use of a variety of medications).

Hedlund et al. 2003[66] compared one-year outcomes among 100,242 persons vaccinated with influenza and/or 23-valent pneumococcal vaccine versus 159,385 unvaccinated individuals; all subjects were aged 65 years or older. Among the vaccinated subjects, 76,177 had both vaccines, 23,224 received only the influenza vaccine, and 841 received only the pneumococcal vaccine. The incidence of hospital admissions for influenza, pneumonia, and invasive pneumococcal disease during one year after vaccination was significantly lower in the vaccinated than in the unvaccinated cohort. The vaccinated cohort had significantly lower rates of in-hospital mortality for pneumonia, COPD, and cardiac failure. The benefits of vaccination were greater during influenza season (December - May) than at other times of the year (June - November). No harms from vaccination were noted among the reported outcomes. Finally, in a self-controlled case series analysis, Gwini et al. 2011[67] found that the incidence of post vaccination myocardial infarction was reduced at time intervals extending up to 59 days after receipt of vaccine.

Hematological

Two studies addressed the relationship between receipt of influenza vaccine and the development of hematologic diseases. In a self-controlled case series conducted by Garbe et al. 2012,[68] two different statistical models revealed a significant association between prior influenza vaccination and new onset immune thrombocytopenia (OR 4.0, 95% CI 1.5, 9.6) in a model adjusted for age, sex, and multiple medications). In a self-controlled case series, Hambidge et al. 2011[69] found no relationship between receipt of influenza vaccine by adults with sickle cell disease and subsequent hospitalization for complications of sickle cell disease (OR 0.92, 95% CI 0.66, 1.28).

Regarding vaccination of dialysis patients, Gilbertson et al. (2011)[70] studied 118,533 adult U.S. Medicare patients who initiated hemodialysis before August 1, 2003 and were alive through October 31, 2005. Subjects were followed between 2005 and 2006 for data on health outcomes. The analysis adjusted for patient demographics, primary cause of end stage renal disease, duration of dialysis, existing comorbidities, and influenza vaccination. Results indicate that vaccination with influenza (RR 0.77, 95% CI 0.73, 0.81) or pneumococcal (RR 0.94, 95% CI 0.90, 0.98) vaccines was associated with lower mortality. In a retrospective cohort analysis of 51,730 adult Medicare patients with renal transplants, Hurst et al. 2011[71] found that influenza vaccination in the first year after transplant was associated with lower risk of both subsequent allograft loss (adjusted hazard ratio, 0.77, 95% CI 0.69, 0.85) and death (adjusted hazard ratio, 0.82, 95% CI 0.76, 0.89).

Other

In a single retrospective matched cohort study of patients with chronic obstructive pulmonary diseases (COPD), Ting; 2011[72] found no change in the frequency of COPD exacerbations during the 14 days following vaccination.

General

One study of the safety of live attenuated influenza vaccine (LAIV) was identified (Baxter et al. 2012).[73] In this retrospective cohort study of 21,340, 18,316, and 21,340 adults aged 18 to 49 years who received LAIV, TIV, or no vaccine, respectively, the rate of hospitalization or death due to any condition within 180 days of vaccination with LAIV was significantly lower than with TIV or no vaccine. The incidence rate for any serious adverse event within 21 days and 42 days of vaccination with LAIV was lower than for no vaccination. The pattern of medically attended events did not suggest any safety signal associated with LAIV.

Summary

Based on the entire body of available evidence, including the IOM report, clinical trials, and post-licensure studies that met our inclusion criteria, we make the following conclusions regarding key adverse events.

There is high strength of evidence that influenza vaccines currently used in the United States are associated with arthralgia, myalgia, malaise, fever, and pain in the short-term in adults; these associations were consistently reported in randomized, placebo-controlled clinical trials conducted in the U.S. and abroad. These AEs are not considered serious; thus, they are rarely investigated in post-marketing epidemiological studies. Risk factors are not discussed in the trials. Clinical trials have found no association between influenza vaccines currently used in the United States and serious adverse events (SAEs).

There is high strength evidence of an association between 2009 monovalent H1N1 and Guillain-Barré Syndrome (GBS). This conclusion is based on a meta-analysis of data from six large U.S.

surveillance systems established or enhanced during the 2009 H1N1 pandemic[57]. However, this adverse event is extremely rare; the authors estimate about 1.6 excess cases per million doses of monovalent H1N1 vaccine administered.

Based on our review of the IOM report and its conclusion that evidence "convincingly supports" a causal relationship between influenza vaccines and anaphylaxis in persons who may be allergic to egg, we rated the strength of evidence high for this AE. Anaphylactic reactions can be severe if not treated immediately. Manufacturers have decreased the amount of egg protein significantly in recent years.

The IOM conclusion favoring acceptance of a causal relationship between influenza vaccines and oculorespiratory syndrome was based on a specific vaccine used in Canada from 2001 to 2003; there is no basis for current concern in the United States

Post-licensure studies with strong study designs have found inconsistent evidence associating influenza vaccines with onset or exacerbation of MS in adults. Strength of evidence is insufficient to determine an association.

Strength of evidence is high that influenza vaccines do not lead to cardiovascular and cerebrovascular events in the elderly; several high quality post-licensure studies have shown a decreased risk among vaccinees.

Two large post-licensure studies with strong study designs have shown that influenza vaccines are not associated with increased risk of SAEs in renal patients. Strength of evidence is moderate.

Table 8. Postmarketing studies of influenza vaccines in adults

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Greene et al. 2012[56] Self-controlled risk interval and case-centered analysis	N=1.48 million doses Monovalent inactivated H1N1 and 1.72 million doses TIV; 8 U.S. MCOs	Monovalent inactivated influenza vaccine (MIV) and seasonal trivalent inactivated influenza vaccine (TIV) during the 2009-2010 season	Case-centered analyses by stratum of onset date, age, sex, site	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 illness onset inside of the 42-day risk period versus outside of that period was 2.0 (95% CI: 0.5, 8.1).	Not reported
Grimaldi-Bensouda et al. 2011[58] Prospective case-control	N=1,225; Location=France; Age=Cases/Controls, Mean (SD): 48.6 (18.0)/50.7 (18.1); Setting=Guillain-Barré cases drawn from all university and major regional hospital centers in metropolitan France known to have a large neurology clinic and centers treating neurological disease in children; Controls from registry of general practice patients across France	Influenza vaccines (seasonal and A/H1N1), brand and formulations unclear	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 months.	OR, Guillain-Barré Syndrome 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 reported

Table 8. Postmarketing studies of influenza vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Farez et al. 2012[62] Self-controlled case series	N=137 Multiple Sclerosis patients;Location=Argentina;Age=37 +/-8 years (mean)	Monovalent H1N1 or trivalent vaccine containing both H1N1 and seasonal influenza strains	None reported	OR for MS relapse 30-day risk period: 0.86 (95% CI 0.20–3.62) 60-day risk period: 0.61 (95% CI 0.18–2.02) 90-day risk period: 0.51 (95% CI 0.18–1.47)	Not reported
Tanner et al. 2012[63] Case-control	N=286; Location=Utah; Age=20.4 to 92.5; Setting=The University of Utah Voice Disorders Center	Swine flu of any type from any year	Age, sex, race/ethnicity	OR (95%) CI for Spasmodic Dysphonia Vaccinated v. Non-vaccinated: 2.1 (0.9-5.0) Don't Know v. Non-vaccinated: 2.3 (1.3-4.1)	Not reported
Johnstone et al. 2012[65] Prospective cohort	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	Seasonal Influenza, 2003-2004, 2004-2005, 2006-2007 pneumococcal	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	Association Between Influenza Vaccination and Risk of Major Adverse Vascular Events During the Influenza Season Cohort OR, (95% CI) 2003-2004: 0.96 (0.73–1.27) 2004-2005: 0.62 (0.50–0.77) 2005-2006: 0.69 (0.53–0.91) 2006-2007: 0.52 (0.42–0.65) Association Between Influenza Vaccination and Risk of the Major Adverse Vascular Events During the Non-influenza Season Cohort 2003-2004: 0.81 (0.61–1.09) 2004-2005: 0.64 (0.50–0.83) 2005-2006: 0.74 (0.56–0.98) 2006-2007: 0.50 (0.38–0.67) Association Between Influenza Vaccination and Risk of Non-cardiovascular Death During the	Not reported

Table 8. Postmarketing studies of influenza vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				Influenza Season Cohort 2004-2005 Non-cardiovascular deaths: 0.26 (0.16–0.40) Cancer deaths: 0.20 (0.10–0.39) Deaths resulting from other causes: 0.33 (0.18–0.60) 2005–2006 Non-cardiovascular deaths: 0.21 (0.10–0.46) Cancer deaths: 0.27 (0.10–0.69) Deaths resulting from other causes: 0.14 (0.03–0.58) 2006-2007 Non-cardiovascular deaths: 0.27 (0.18–0.41) Cancer deaths: 0.17 (0.10–0.31) Deaths resulting from other causes: 0.47 (0.25–0.86)	
Siriwardena et al. 2010[64] Matched case-control	N=78,706 (16,012 cases of myocardial infarction (MI), 62,964 controls); Location=UK; Age=40 to >=65; Setting=United Kingdom General Practice Research Database (GPRD), an extensively validated computerized database, representative of and comprising 5% of the population of England and Wales.	Influenza; pneumococcal (unspecified; did not stratify by formulation or year)	Model 1 adjusted for asthma or chronic obstructive pulmonary disease, chronic heart disease, stroke or transient ischemic attack, diabetes, splenectomy, chronic liver disease, chronic renal failure, immunosuppression and HIV, hyperlipidemia, family history of acute myocardial infarction, peripheral vascular disease, hypertension, smoking status, treatment with acetylsalicylic acid, treatment with statins, treatment with	OR (95% CI) of acute MI Influenza vaccination within previous year: Model 1: 0.81 (0.77-0.85) Model 2: 0.83 (0.80–0.88)	Influenza 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: 0.82 (0.76–0.89) Model 2: 0.86 (0.85–0.99)

Table 8. Postmarketing studies of influenza vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
			antihypertensives, 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		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) 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) 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)

Table 8. Postmarketing studies of influenza vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Gwini et al. 2011[67] Self-controlled case series	N=8,180 cases of first acute myocardial infarction; Location=UK; Age=>=40 years;	Seasonal influenza, unspecified, 2002-2008	Seasonality	Incidence Rate Ratio, Acute MI 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) 121-180 days: 1.02 (0.95–1.10)	Not reported
Garbe et al. 2012[68] Case-control	N=1,200 (outpatient + inpatient). Influenza results presented just for outpatients, N=861; Location=Berlin, Germany; Age=18-92; Setting=Berlin hospitals, hematological practices, and laboratories	Influenza vaccine, unspecified (Pneumococcal and poliomyelitis vaccine also assessed as causing 1 case each but ORs were not reported.)	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")	OR (95% CI) idiopathic thrombocytopenic purpura (ITP) Influenza, outpatient cases and controls: Model 1: 3.8 (1.5–9.1) Model 2: 4.0 (1.5–9.6)	Not reported
Hambidge et al. 2011[69] Case-control and Self-controlled case series	N=348 adults with sickle cell disease in 8 MCOs in the U.S. (Vaccine Safety Datalink (VSD) cohort)	TIV, 1999-2006	Stratification by sex and age, adjustment for month within season	Incidence rate ratios for sickle cell hospitalization All: 0.92 (0.66, 1.28)	Males: 1.00 (0.59, 1.72) Females 0.87 (0.57, 1.31) 18-49 yrs.: 0.84 (0.57, 1.22) 50-64 yrs.: 1.51 (0.72, 3.18) >=65 yrs.: 0.94 (0.10, 8.55)
Gilbertson et al. (2011)[70] Cohort: Multivariate analysis	N=118,533 Medicare patients who initiated hemodialysis before August 1, 2003 and were alive through October 31, 2005; Location= U.S. Age=>=18 years;	Influenza, unspecified 2003-2004, 2004-2005	Patient demographics, doesn't specify but variables assessed include age, sex, race, primary cause of end-stage renal disease, dialysis duration, comorbid conditions.	Relative risk of mortality Influenza vaccine (both seasons): 0.77 (0.73–0.81)	Vaccine associated with lower mortality. Higher risk of mortality if older, longer on dialysis, or comorbid conditions.

Table 8. Postmarketing studies of influenza vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Hurst et al. 2011[71] Cohort: Multivariate analysis	N=51,730 adult Medicare patients with renal transplant; Location=U.S.; Age=>=65 years; 9,678 had claims for influenza vaccine in the first year post transplant	Influenza, unspecified, January 2000 – September 2006	Factors known to be independently associated with allograft loss (recipient age, black race, PRA 20%, dialysis vintage, diabetes 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	Vaccination in the first year after transplant was associated with lower risk of subsequent allograft loss and death Adjusted hazard ratio Allograft loss: 0.77 (0.69-0.85) Death: 0.82 (0.76-0.89) 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), Rejection in first 12 mo: 0.97 (0.89-1.07)	Not reported
Ting et al. 2011[72] Matched cohort	586 patients with moderate to severe COPD identified in COPD Registers of 6 general practices in North Derbyshire UK. Age range 37-89 (median 68)	Influenza, unspecified, Fall 2005	Environmental factors (weather, prevalence of respiratory viral pathogens)	In the 14 days following vaccination, the control group had 21 COPD exacerbations cf. 11 in the vaccinated group OR 0.52 (95% CI 0.29, 1.14)	Not reported

Table 8. Postmarketing studies of influenza vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Baxter et al. 2012[73]	Sample size: 60,996; Location: U.S.; Age: 18-49; Setting: Kaiser Permanente Managed Care Health Plans	Ann Arbor Strain LAIV	Adjusted for: Matching factors, seasonal changes in background rates	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) or no vaccine (1.46 vs. 3.36). 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.	Not reported
Isai et al., 2012[61], cohort	N=50,221 adverse events; Location=European Union; Age=Unknown; Setting=EudraVigilance database	Monovalent H1N1 vaccines: Cantgrip, Celtura, Celvapan, Fluval, Focetria, Pandemrix, Panenza	None	Analysis 1 included all autoimmune disorder cases as reported. Analysis 2 used cases assessed as certain, probable or possible according to WHO Causality assessment and available Brighton Collaboration definitions Using analysis 1, the reporting ratio calculated as the percentage of autoimmune ADRs amongst all reported ADRs shows comparable results for non adjuvanted (0.94% [0.64–1.24]) and adjuvanted (0.60% [0.53–0.67]) vaccines. The calculation using analysis 2 (restricted analysis) included 15 cases of autoimmune disorders for non adjuvanted vaccines and121 cases for adjuvanted ones. The reporting ratio was 0.37% (0.18–0.56) and 0.26% (0.22–0.31), respectively. For the calculation of reporting rates using the estimated number of vaccinees as the denominator, analysis 1 resulted in a reporting rate of 9.98 (6.81–13.16) per million for non adjuvanted vaccines and of 6.87 (6.06–	None

Table 8. Postmarketing studies of influenza vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				7.68) per million for adjuvanted vaccines. Using analysis 2, the reporting rates were respectively 3.94 (1.95–5.94) and 3.01 (2.47–3.55) per million.	
Crawford, et al., 2012[59], Self-controlled case series	N=44 Location=Victoria, Australia Age=48 (median); 7-95 years (range) Setting=An active surveillance system for GBS was established in 10 hospitals in Victoria	Monovalent H1N1 vaccine (Panvax, CSL Limited) TIV (Fluvax, CSL Limited; Vaxigrip, Sanofi Pasteur; Influvac, Abbott)	None, self-controlled design	Pandemic (H1N1) 2009 influenza A immunisation and Guillain-Barré syndrome: relative incidence (RI) estimates from the self-controlled case series with a 42-day postvaccination risk window Base: 3.41 (0.78–14.97) No seasonal trivalent influenza vaccine: 3.39 (0.77–14.91) No period adjustment: 2.92 (0.75–11.31) Three 2-week periods 0–13 days: 3.74 (0.41–34.05) 14–27 days: 3.35 (0.38–29.64) 28–41 days: 3.19 (0.35–28.67) Only Brighton level 1–2 cases: 3.99 (0.82–19.55) Include unconfirmed cases: 2.71 (0.62–11.85) Include incomplete vaccine history: 3.25 (0.75–14.21) Include incomplete vaccine history and second episode: 3.34 (0.76–14.59) Include all: 2.25 (0.54–9.37)	None

Table 8. Postmarketing studies of influenza vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Baxter, et al. 2013,[55] Case-centered and cohort	N=415 cases; Location=California; Age=48.5 years (mean), 5-87 years (range); Setting=Kaiser Permanente Northern California (KPNC)	Influenza (TIV), 23-valent pneumococcal polysaccharide, IPV, Tdap, I-typhoid, Hepatitis A, Hepatitis B, Td	Case-centered: Age and sex matching for expected odds Cohort: age	Odds Ratio of Vaccination in a 6- or 10-Week Risk Interval Before Onset of Guillain-Barre Syndrome, Using a Case-Centered Analysis Design OR, 95% CI 6-week Risk Interval IPV: 7.19 (0.18-281.03) Tdap: None (0.16 to NE) PPV-23: 0.72 (0.11-2.87) Hep A: 2.22 (0.30-10.63) Hep B: 0.43 (0.02-2.56) Td: 1.43 (0.33-4.56) TIV: 1.11 (0.39-3.08) 10-week Risk Interval IPV: 4.15 (0.11-163.38) Tdap: None (.09 to NE) PPV-23: 0.44 (0.07-1.72) Hep A: 2.00 (0.39-8.74) Hep B: 0.24 (0.01-1.46) Td: 1.14 (0.32-3.29) TIV: 0.99 (0.33-2.70)	None

Table 8. Postmarketing studies of influenza vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Hedlund et al. 2003[66] Prospective cohort	N=100,242 vaccinated with influenza or pneumococcal vaccines, 159,385 unvaccinated controls, in Stockholm County, Sweden; Age=>=65 years;	TIV and 23-valent pneumococcal vaccine (PV), December 1998-November 1999	Age and gender	Hospital admissions/100,000 individuals between 1 December 1998 and 30 November 1999 Influenza 0.68 (0.53-0.88) Pneumonia 0.78 (0.71-0.86) IPD: 0.46 (0.25-0.87) COPD: 1.04 (0.92-1.17) Cardiac failure: 0.95 (0.87-1.05) 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) Pneumonia 0.55 (0.43-0.71) IPD: 0.53 (0.06-5.10) COPD: 0.53 (0.29-0.98) Cardiac failure: 0.72 (0.59-0.87) Hospital admissions/100 000 individuals per year between 1 December 1998 and 31 May 1999 Influenza: 0.66 (0.52-0.82) Pneumonia: 0.72 (0.65-0.79) IPD: 0.47 (0.24-0.93) COPD: 1.07 (0.94-1.23) Cardiac failure: 0.90 (0.80-1.01) Hospital admissions/100 000 individuals per year between 1 June and 30 November 1999 Influenza: 1.36 (0.58-3.17) Pneumonia: 0.88 (0.77-1.00) IPD: 0.45 (0.15-1.32) COPD: 1.00 (0.87-1.15) Cardiac failure: 1.02 (0.93-1.11)	Not reported

Table 8. Postmarketing studies of influenza vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Lee et al. 2011, Self-controlled case series and multivariate logistic regression [60]	N=4,512,366 flu doses in eight U.S. managed care organizations; Age=6 mos to >=65 years;	H1N1 monovalent inactivated (MIV trivalent inactivated (TIV), and live, attenuated (LAIV) influenza vaccines	Case-centered logistic regression: case date, age group, gender, and site.	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 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).	None

AE = adverse event; CI = confidence interval; COPD = chronic obstructive pulmonary disease; GBS = Guillain-Barré syndrome; GPRD = general practice research database; HLA = human leukocyte antigens; ITP = thrombocytopenic purpura; LAIV = live attenuated influenza vaccine; MCOs = managed care organizations; MI = myocardial infarction; MIV = monovalent inactivated influenza vaccine; MMR = measles, mumps, rubella vaccine; Mo = month; MS = multiple sclerosis; OR = odds ratio; PRA = plasma renin activity; SAE = serious adverse events; SD = standard deviation; TIV = trivalent inactivated influenza vaccine; VAESCO = vaccine adverse events surveillance and communication; VSD = vaccine safety datalink; Yr(s) = year(s)

Note: Additional study details presented in Appendix C evidence tables.

Pneumococcal Vaccines

Pneumococcal vaccines were not covered by the IOM report. We found no placebo controlled trials of the currently available pneumococcal polysaccharide vaccine (PVC23) that reported adverse events data. (If a study did not explicitly state that no adverse events took place, it was excluded.) We found several trials of PPV23 that reported community-acquired pneumonia and associated mortality; however, these were considered efficacy outcomes. We also found trials of PVC 23 versus old versions (i.e. PCV13, PCV7); however those studies were excluded because they had no unvaccinated comparison group.

Five postmarketing studies in adults were identified; all studied the relationship between pneumococcal polysaccharide vaccine and occurrence of cardiovascular or cerebrovascular disease. Results are displayed in Table 9. No other case-control study, self-controlled case series, or multivariate analysis focused on pneumococcal vaccine alone.

Cardiovascular and Cerebrovascular

In a prospective cohort study of 84,170 men aged 45 to 69 years, Tseng et al. 2010[74] found that administration of pneumococcal vaccine (unspecified) was not associated with reduced risk adjusted for propensity score of stroke (OR 1.14, 95% CI 1.00, 1.31) and of myocardial infarction (OR 1.09, 95% CI 0.98, 1.21). In contrast, in a prospective cohort of 6,171 subjects, Eurich et al. 2012[75] showed that administration of pneumococcal polysaccharide vaccine was associated with a decreased rate of acute coronary syndrome-related hospitalization. Other studies did not show a lower risk of myocardial infarction (Siriwardena et al. 2010; Vila-Corcoles et al. 2012; [64,76,77] Hedlund et al. 2003[66] compared one-year outcomes among 100,242 persons vaccinated with influenza and/or 23-valent pneumococcal vaccine versus 159,385 unvaccinated individuals; all subjects were aged 65 years or older.(Study details are displayed in Table 8 in the influenza section.) Among the vaccinated subjects, 76,177 had both vaccines, 23,224 received only the influenza vaccine, and 841 received only the pneumococcal vaccine. No harms from vaccination were noted among the reported outcomes. Administration polysaccharide pneumococcal vaccination was not associated with any subsequent change in the age-adjusted rates of first and recurrent myocardial infarction or stroke.

Summary

Pneumococcal vaccines were not covered by the IOM report. We found no placebo-controlled trials of PCV23 which assessed adverse events. Post-licensure studies focused on association of pneumococcal polysaccharide vaccines with cardiovascular and cerebrovascular events in older adults. As results of four high quality post-licensure studies conducted in the US, UK, Canada, and Spain consistently found vaccination was not associated with increased risk of these events in persons age 65 and older, the strength of evidence is rated as high. The studies have low risk of bias, as the analyses adjusted for subject characteristics that would make them more at risk for these adverse events, such as pre-existing medical conditions, demographics, and behavioral risks. The US and UK studies had high statistical power, with about 80,000 subjects each. Results were inconsistent as to whether these vaccines decrease risk of these events.

Table 9. Postmarketing studies of pneumococcal vaccines in adults

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Tseng et al. 2010[74] Prospective cohort	N=84,170; Location=CA; Age=45-69 years; Setting=Kaiser Permanente Northern and Southern California health plans (California Men's Health Study)	Pneumococcal, any	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, history of stroke, history of acute MI, and the log scale transformed number of outpatient visits in last 5 years	Adjusted hazard ratio, Pneumococcal Vaccination and Incidence of MI and Stroke Acute MI All men: 1.09 (0.98-1.21) Stroke All men: 1.14 (1.00-1.31)	Association of Pneumococcal Vaccination and Incidence of MI and Stroke Age, years <65: 1.23 (1.08-1.40) >=65: 0.89 (0.80-1.01) High-risk groups Current smokers: 1.11 (0.83-1.47) Diabetes: 1.04 (0.87-1.24) Hypertension: 1.10 (0.97-1.25) Low-risk group: 0.98 (0.35-2.73) Influenza vaccine 0: 1.10 (0.70-1.72) 1-10: 1.10 (0.97-1.26) >10: 1.00 (0.83-1.21)
Eurich et al. 2012[75] Prospective cohort	N=6,171; Location=Edmonton (Alberta, Canada); Age=mean 59 years; Setting=Population-based cohort of adults presenting with community-acquired pneumonia (CAP) in Edmonton	Pneumococcal polysaccharide vaccination (PPV)	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	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) Death: 0.92 (0.32 to 2.63) Hospitalization due to ACS: 0.35 (0.21 to 0.57) Propensity score analysis Death or ACS-related Hospitalization: 0.46 (0.28 to 0.73) Death: 1.51 (0.42 to 5.34) Hospitalization due to ACS: 0.36 (0.21 to 0.61)	Not reported

Table 9. Postmarketing studies of pneumococcal vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Siriwardena et al. 2010[64] Matched case-control	N=78,706 (16,012 cases of myocardial infarction (MI), 62,964 controls); Location=UK; Age=40 to >=65; Setting=United Kingdom General Practice Research Database (GPRD), an extensively validated computerized database, representative of and comprising 5% of the population of England and Wales.	Influenza; pneumococcal, any	Model 1 adjusted for asthma or chronic obstructive pulmonary disease, chronic heart disease, stroke or transient ischemic attack, diabetes, splenectomy, chronic liver disease, chronic renal failure, immunosuppression and HIV, hyperlipidemia, family history of acute myocardial infarction, peripheral vascular disease, hypertension, smoking status, treatment with acetylsalicylic acid, treatment with statins, treatment with antihypertensives, 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	Pneumococcal vaccination within previous year, OR for MI Model 1: 0.96 (0.91–1.02) Model 2: 0.98 (0.93-1.04)	Not reported, but subgroup results shows for the following categories: Pneumococcal Age < 65: Model 1: 0.83 (0.73–0.95) Model 2: 0.91 (0.79–1.05) Age ≥ 65: Model 1: 0.88 (0.83–0.93) Model 2: 0.97 (0.91–1.03)

Table 9. Postmarketing studies of pneumococcal vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Vila-Corcoles et al. 2012[76] Prospective cohort	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 urban area in the Mediterranean coast of Catalonia, Spain)	Pneumococcal (PPV23)	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 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: Community Acquired Pneumonia (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 Acute Myocardial Infarction (AMI): Adjusted for age, sex, number of outpatient visits in prior year, influenza vaccination in prior year, history of coronary artery disease, chronic heart disease, diabetes mellitus, hypercholesterolemia, smoking (confounder) and nursing-home resident Ischemic Heart Disease: Adjusted for age, sex, number of outpatient visits in prior year, influenza vaccination in	Multivariate hazard ratio (95% CI) CAP: 0.85 (0.62-1.15) AMI: 0.83 (0.56-1.22) Ischemic Stroke: 0.65 (0.42-0.99) Death from any cause: 0.88 (0.75-1.03)	Not reported

Table 9. Postmarketing studies of pneumococcal vaccines in adults (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
			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, diabetes mellitus, cancer, chronic nephropathy, dementia, hypertension, hypercholesterolemia, obesity, smoking, and nursing home-resident		

ACS = acute coronary syndrome; AMI = acute myocardial infarction; CAP = community-acquired pneumonia; CI = confidence interval; GPRD = general practice research database; IHD = ischemic heart disease; OR = odd ratio; MI = myocardial infarction; PPV = pneumococcal polysaccharide vaccination; PSI = pneumonia severity index

**Statistically significant association.

Note: Additional study details presented in Appendix C evidence tables.

Zoster

We identified six trials of Zostavax; results are summarized in Table 10.

One trial conducted in Brazil, Costa Rica, Colombia, Mexico, Peru, Venezuela, and the Philippines[78] studied the vaccine in varicella-zoster virus sero-negative or low sero-positive adults. This trial included only 21 persons: 18 received the vaccine, while three received placebo. There were no AEs reported in the placebo group; thus, odds ratios could not be calculated. There were no serious AEs in the vaccine group.

Some publications reported only broad categories of AEs. A controlled clinical trial in North America and Europe[79] included 22,439 adults (62% female) who received one dose of the zoster (Zostavax) vaccine at baseline. Compared to the control group, vaccinated individuals were more likely to experience one or more injection-site AEs (OR 10.38, 95% CI 9.72-11.08), vaccine-related AEs (OR 8.39, 95% CI 7.88-8.92), and one or more systemic adverse events (OR 1.09, 95% CI 1.03-1.15).

A smaller trial in the United States and Netherlands[80] included 210 older adults (63% female) who received two doses of Zostavax, one at baseline (Dose 1) and another 42 days later (Dose 2). Compared to the control group, vaccinated individuals were more likely to experience one or more adverse events post dose 1 (OR 3.06, 95% CI 1.73-5.41), systemic adverse events post dose 1 (OR 14.70, 95% CI 1.89-114.53), vaccine-related adverse events post dose 1 (OR 8.53, 95% CI 4.18-17.39), one or more adverse events post dose 2 (OR 4.06, 95% CI 2.28-7.24), and vaccine-related adverse events post dose 2 (OR 11.17, 95% CI 5.46-22.87). A crossover trial in the United States[81] randomized 101 adults (59% female) to Zostavax or placebo at study start. The groups were switched at 28 days; those who received placebo on Day 1 were given Zostavax and vice-versa. The study reported overall results and also results according to different subgroups. The only AE associated with vaccination in the overall study population was injection-site AE (OR 19.84, 95% CI 6.77-58.12). The vaccine was associated with "one or more adverse event" in patients over 60 years old (OR 5.37, 95% CI 2.61-11.05).

A controlled clinical trial in the United States included 38,546 older adults (41% female) who received one dose of zoster vaccine. No statistically significant differences in serious adverse events between vaccinated and unvaccinated groups were reported. An Adverse Events Monitoring Substudy of this trial [82] reported on over 6,600 of the subjects. Compared to the control group, vaccinated individuals were more likely to experience one or more adverse events at the injection site (OR 4.67, 95% CI 4.16-5.24) and one or more vaccine-related systemic adverse events (OR 1.30, 95% CI 1.05-1.60). There were no significant differences in cardiovascular, endocrine, digestive, metabolic, musculoskeletal, or nervous system AEs.

Lastly, a controlled clinical trial conducted in the United States, Canada, Spain, Germany, and the UK[83] included almost 12,000 older adults (59% female) who received one dose of Zostavax. This study reported on cardiac, GI, psychiatric, and other categories of serious adverse events. No statistically significant differences in adverse events between vaccinated and unvaccinated groups were reported.

Table 10. Vaccinated versus unvaccinated adults: zoster vaccine

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Macaladad N. et al.,2007[78] also Brazil, Costa Rica, Colombia, Mexico, Peru and Venezuela and the Philippines	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 Days	Not calculated
Mills R. et al.,2010[81] U.S.	Controlled Clinical Trial – Crossover on Day 28	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	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) **
Murray A. V. et al.,2011[83] U.S., Canada, Spain, Germany, UK	Controlled Clinical Trial	4	Sample size : 11,999, Mean age: 70.4, Age range: 60 - 99, Percent female: 58.6%	Zoster, Zostavax, Merck, Lyophilized ZV, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Subcutaneous	Dose1: 0 Days	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)

Table 10. Vaccinated versus unvaccinated adults: zoster vaccine (continued)

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Simberkoff M. S. et al.,2010[82] U.S.	Controlled Clinical Trial	7	Sample size : 38,546,, Adverse events substudy N = 6,660 Median age: 69 years; Age range: 60 - > 80	Zoster, Merck, Median potency, 24600 plaque-forming units per dose, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Subcutaneous	Dose1: 0 Days	# 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 - Skin: OR 0.903 (0.542-1.506) Diagnostic group - Cancer: OR 1.131 (0.76-1.683) Diagnostic group - Vascular (functional): OR 1.155 (0.752-1.774)
Schmader K. E. et al.,2012[79] North America and Europe	Controlled Clinical Trial	4	Sample size : 22,439, 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 Days	1 or more Injection-site AEs: OR 10.379 (9.722-11.081) ** SAE with death: OR 0.334 (0.035-3.209) 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) **

Table 10. Vaccinated versus unvaccinated adults: zoster vaccine (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Vermeulen J. N. et al.,2012[80] U.S. and Netherlands	Controlled Clinical Trial	5	Sample size : 210, Mean age: 68.7 (Tx); 70.7 (Placebo), Age range: 58–90, Percent female: 62.85% Conditions: Arthritis, hyperlipidemia, hypertension	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	1 or more AEs (Post Dose 1): OR 3.062 (1.732-5.412) ** # of patients with any AE Dose 2: OR 4.203 (2.348-7.522) ** 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) ** Vaccine-related AEs (Post Dose 1): OR 8.525 (4.179-17.389) ** 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) **

AEs = adverse events; D = day; GI = gastrointestinal; NR = not reported; OR = odds ratio; PD = post dose; PFU = plaque forming units; SAE = serious adverse events; Y = year; ZV = zoster vaccine

** Statistically significant.

Note: Additional study details presented in Appendix C evidence tables.

Three post-licensure studies evaluated adverse events following administration of adult herpes zoster vaccine. They are displayed in Table 11. Zhang et al. 2012[84] evaluated the efficacy and safety of zoster vaccine among Medicare beneficiaries 60 years and older who had inflammatory bowel disease, psoriatic arthritis, psoriasis or rheumatoid arthritis. Receipt of zoster vaccine was not associated with increased cases of varicella or herpes zoster within 42 days in the cohort as a whole and specifically in individuals who were receiving biologic immunodulatory agents (principally agents targeted against Tumor Necrosis Factor). The authors also evaluated the relationship between vaccination and hospitalization for meningitis or encephalitis; no such cases were identified. With a median follow-up of two years, receipt of the zoster vaccine was associated with a decreased rate of incident cases of zoster. Lower rates were associated with vaccination in all patient subgroups

Using both a case-centered approach and a self-controlled case series analysis, Tseng et al 2012,[85] examined the relationship between receipt of zoster vaccine and various adverse events among a cohort of adults age 50 and above receiving care from eight U.S. managed-care organizations. Five specific groupings of events were examined: cerebrovascular events (Group 1); acute myocardial infarction, acute pericarditis, acute myocarditis, cardiomyopathy, heart failure (Group 2); meningitis encephalitis and encephalopathy (Group 3); Ramsay-Hunt syndrome and Bell's palsy (Group 4); and medically attended events, including cellulitis, pain and allergic reactions (Group 5). No increased risk was found for Groups 1 – 4 as a whole or for the any of the individual entities within these groups. An increased rate of cellulitis on days 1 – 7 was found using only the case-centered method (RR 1.30, 95% CI 1.18, 1.44) and an increase in allergic reactions was found by both the case centered analysis (RR 2.13, 95% CI 1.87, 2.40) and the self-controlled case series method (RR 2.32 95% CI 1.85, 2.91). No cases of anaphylaxis occurred with vaccine administration. The authors state the increased rate of cellulitis may be due to patient allergy or inflammatory reactions.

Baxter[86] compared rates of medical events resulting in emergency room visits or hospitalization in a 42-day time period following vaccination with rates in the same cohort in a subsequent comparison time period. Of the 386 comparisons performed, four conditions (systemic lupus erythematous, angioplasty, coronary atherosclerosis, and other heart disease) had a statistically significant increased relative risk. However, after medical records review, the timing of these conditions was found to often be prior to vaccination, and no clear increase in health events was observed in the risk period following vaccination compared to later.

Summary

Zostavax is recommended for U.S. adults over age 60; adverse events specific to this population were not covered by the IOM report. In the clinical trials we identified, potency varied from 18,700 to 89,000 PFU (plaque-forming units) per dose. (Two of the six trials did not report potency.) The formulation currently licensed in the United States contains a minimum of 19,400 PFU per 0.65 ml dose.

Adverse events were sometimes reported using broad categories such as "injection–related adverse events," "systematic adverse events," or "one or more adverse events;" the quality of adverse events reporting in these trials was thus considered poor. Two trials reported events using more specific categories such as "psychiatric" or "respiratory/thoracic;" in these two trials, the vaccine was not associated with any adverse events other than injection site reaction. Strength of evidence is moderate for this non-serious adverse event based on high quality of these trials. We found three post-licensure studies; the only adverse events associated with Zoster

vaccine were allergic reactions and cellulitis possibly due to inflammatory or allergic reactions. No cases of anaphylaxis were reported; the events are non-serious. The strength of evidence is moderate; studies used appropriate designs, had low risk of bias, and high statistical power due to sample size.

Table 11. Postmarketing studies of zoster vaccine

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Zhang et al. 2012[84] Retrospective cohort	N=463,541(4,026 with ankylosing spondylitis, 66,751 with inflammatory bowel disease, 11,030 with psoriatic arthritis, 89,565 with psoriasis, and 292,169 with RA); Location=U.S.; Age=74 years (mean at study start); Setting=U.S. Medicare beneficiaries	Zostavax	Sex, race, immune-mediated disease, time varying concurrent medications, and time-varying health care utilization (hospitalization and physician visits)	HR (95% CI) for Herpes Zoster Incidence Using ICD-9-CM diagnosis code+pharmacy claim definition for HZ case (Definition 1) HZ vaccination: 0.61 (0.52-0.71) Using ICD-9-CM diagnosis code only for HZ case (Definition 2) HZ vaccination: 0.67 (0.59-0.75)	Sex Men [Reference] Women Definition 1: 1.22 (1.17-1.28) Definition 2: 1.21 (1.17-1.26) Race White [Reference] Black Definition 1: 0.67 (0.62-0.73) Definition 2: 0.69 (0.64-0.74) Other Definition 1: 0.89 (0.81-0.97) Definition 2: 0.89 (0.83-0.95) Immune-mediated disease Rheumatoid arthritis [Reference] Ankylosing spondylitis Definition 1: 0.98 (0.77-1.25) Definition 2: 0.94 (0.77-1.13) Inflammatory bowel diseases Definition 1: 1.03 (0.97-1.10) Definition 2: 1.02 (0.97-1.07) Psoriatic arthritis Definition 1: 0.92 (0.80-1.05) Definition 2: 0.92 (0.83-1.02) Psoriasis Definition 1: 0.99 (0.93-1.05) Definition 2: 0.97 (0.93-1.02) Hospitalized in the previous 6 mo No [Reference] Yes

Table 11. Postmarketing studies of zoster vaccine (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
					Definition 1: 1.00 (0.95-1.05) Definition 2: 1.25 (1.20-1.29) No. of physician visits in the previous 6 mo Definition 1: 1.04 (1.04-1.0 4) Definition 2: 1.04 (1.04-1.04)

Table 11. Postmarketing studies of zoster vaccine (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Tseng et al. 2010[85] Case-centered and Self-controlled case series	N=193,083 recipients of zoster vaccine in 8 U.S. MCOs; Age≥50;	Zostavax	No additional confounders controlled for in models	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 <u>Day 1-14</u> Stroke: 1.03 (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) <u>Day 15-28</u> Stroke: 0.92 (0.73–1.16) Acute myocardial infarction: 1.04 (0.81–1.34) 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) <u>Day 29-42</u> Stroke: 1.06 (0.85–1.31) Acute myocardial infarction: 0.97 (0.75–1.26) Acute pericarditis: 1.04 (0.13–8.05) 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) <u>Day 1-42</u> Stroke: 1.00 (0.87–1.15) Acute myocardial infarction: 1.07 (0.92–1.26) Acute pericarditis: 0.27 (0.03–2.22) Cardiomyopathy: 0.94 (0.77–1.14) Heart failure: 0.91 (0.68–1.21)	Not reported

				Meningitis, encephalitis, and encephalopathy: 0.66 (0.37–1.16) Mortality: 0.31 (0.23–0.40) <u>Day 1-7</u> Cellulitis and infection: 1.30 (1.18–1.44) Allergic Reaction: 2.13 (1.87–2.40) Self-controlled case series <u>Day 1-14</u> Cerebrovascular diseases: 0.94 (0.70–1.28) 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) <u>Day 15-28</u> 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) <u>Day 29-42</u> 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) Cardiomyopathy: 0.86 (0.57–1.29) Heart failure: 0.64 (0.36–1.16) Meningitis, encephalitis, and encephalopathy: 0.80 (0.21–2.98) <u>Day 1-42</u> 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) 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) <u>Day 1-7</u> Cellulitis and infection: 1.10 (0.95–1.26) Allergic Reaction: 2.32 (1.85–2.91)	

Table 11. Postmarketing studies of zoster vaccine (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Baxter, et al. 2012,[86] Retrospective cohort	N=29,000; Location=California Age=60+ years; Setting=Kaiser Permanente Northern California (KPNC), a U.S. managed care organization	Zostavax	Self-controlled	Health outcomes with elevated RR and statistically significant unadjusted p-value ($p<0.05$)(N=29,010). After medical records review. The timing of these conditions was found to be prior to vaccination. Coronary atherosclerosis and other heart disease 1.86 (1.09–3.15) Coronary atherosclerosis (ATS) 1.97 (1.11–3.49) Percutaneous transluminal coronary angioplasty (PTCA) 2.26 (1.19–4.27) Systemic lupus, erythematosus and connective tissue disorders 8.57 (1.08–212.11)	None

CI = confidence interval; CM = clinical modification; HR = hazard ratio; HZ = herpes zoster; ICD = International Classification of Diseases; MCOs = managed care organizations; Mo = month; RA = rheumatoid arthritis; RR = relative risk

Note: Additional study details presented in Appendix C evidence tables.

Varicella

We identified only one study comparing varicella-vaccinated and unvaccinated adults, published after the IOM search. A U.S. trial[87] randomized 67 HIV positive adults to either varicella vaccine (Varivax) or placebo at baseline and 12 weeks. No statistically significant differences in AEs between vaccinated and unvaccinated groups were reported. Data are presented in Table 12.

Table 12. Vaccinated versus unvaccinated adults: varicella vaccine

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Weinberg, A., et al. 2010[87] U.S. (No direct mentions)	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 Days Dose2: 12 Weeks	Dose 1: Influenza-like illness: OR 1.55 (0.242-9.94) Dose 1: Pruritus: 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)

CI = confidence interval; HIV = human immunodeficiency virus; NR = not reported; OR = odds ratio

Note: Additional study details presented in Appendix C evidence tables.

HPV

The IOM committee found the evidence "favors acceptance" of a causal relationship with anaphylaxis and "convincingly supports" no other causal relationships with AEs. The IOM committee found the evidence is "inadequate to accept or reject" a causal relationship between HPV vaccine and the following AEs: ADEM, transverse myelitis, neuromyelitis optica, MS, Guillain-Barré Syndrome, chronic inflammatory demyelinating d polyneuropathy, brachial neuritis, amyotrophic lateral sclerosis, transient arthralgia, pancreatitis, thromboembolic events, and hypercoagulable states. In the United States, HPV vaccine is generally administered to patients between the ages of 9 and 26. Thus, the post-licensure studies are discussed in the section on children and adolescents.

We identified two double blind randomized trials of HPV vaccine in women aged 18 to 35. Both were administered Cervarix at baseline, one month, and six months. The results are summarized in Table 13. A controlled trial in Hong Kong[88] included 300 women; compared to the control group, women who were vaccinated were more likely to experience the non-serious AEs, fatigue (OR 1.69, 95% CI 1.05 -2.72) and myalgia (OR 1.71, 95% CI 1.03-2.82). A controlled trial in India[89] included 337 adult women; compared to the placebo group, women who were vaccinated were more likely to experience Grade 3 (severe) pain (OR 6.19, 95% CI 2.63-14.54). Grade 3 pain was defined as that which limited typical daily activity; 20.5% of the HPV group and 4.0% of the placebo group reported this level of pain. We do not consider this a SAE.

We summarize the totality of the evidence on HPV in the section on children and adolescents.

Table 13. Vaccinated versus unvaccinated adults: HPV vaccine

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Bhatla N. et al.,2010[89] India	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 Days Dose2: 1 Month Dose3: 6 Month	Pain (Grade 3): OR 6.189 (2.634-14.54) ** Redness (>50 mm): OR 1 (0.063-15.882)
Ngan H. Y. S. et al.,2010[88] Hong Kong	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 contained 20 µg each of HPV-16 and -18 L1 (structural protein of HPV) virus-like particle (VLP) and adjuvanted with a proprietary AS04 (3-O-desacyl-4'-monophosphoryllipid [50 µg] adsorbed on aluminum hydroxide [Al(OH)3, 500 µg]), Adjuvant: ASO 4, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days Dose2: 1 Month Dose3: 6 Month	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)

CI = confidence interval; GI = gastrointestinal; HPV = human papillomavirus; MPL = monophosphoryl lipid; OR = odds ratio; VLP = virus-like particle
**Statistically significant.
Note: Additional study details presented in Appendix C evidence tables.

Diphtheria Toxoid, Tetanus Toxoid, and Acellular Pertussis

The IOM studied diphtheria toxoid, tetanus toxoid, and acellular pertussis-containing vaccines alone and in combination; they are administered to both children and adults. Except where noted below, studies did not report specific AEs by age. The IOM committee found the evidence "convincingly supports" a causal relationship in the adult population between the tetanus toxoid vaccine and anaphylaxis.

We identified only one trial of adults published after the IOM search dates. A trial in Korea[90] included only 20 individuals, all male, who received one dose of SK Td vaccine. No statistically significant differences in AEs between vaccinated and unvaccinated groups were reported. Data are displayed in Table 14.

We identified no post-license studies of vaccines against diphtheria, tetanus, or pertussis in adults published after the IOM searches. Thus, we rate the strength of evidence as high for association of tetanus toxoid with anaphylaxis among persons allergic to ingredients, per the IOM findings.

Table 14. Vaccinated versus unvaccinated adults: Td (tetanus/diphtheria) vaccine

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Lee S. et al.,2011[90] Korea	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	Hypoesthesia: OR 3.857 (0.326-45.572)

CI = confidence interval; IU = international unit; OR = odds ratio; NR = not reported; Td = tetanus/diphtheria
Note: Additional study details presented in Appendix C evidence tables.

Miscellaneous Other Vaccines

Postmarketing Studies of Multiple Vaccines

We found three postmarketing studies of multiple vaccines in adults not included in the IOM report, as presented in Table 15.

In a case-control study of 159 cases of psoriatic arthritis and 159 persons with psoriasis alone, Eder et al. 2011[91] found vaccination against any of the following diseases was not associated with onset of psoriatic arthritis: Hepatitis A, Hepatitis B, influenza, and pneumonia.

In a multivariate analysis of records from the Defense Medical Surveillance System, Duderstadt and colleagues[92] found that military personnel vaccinated for MMR were less likely to have new onset of Type 1 diabetes (RR 0.71, 95% CI 0.61, 0.83) than those who were not vaccinated. The same was true for military personnel who had received Hep B vaccine (RR. 0.83, 95% CI 0.72, 0.83).

In a case control study of 355 Graves' disease cases, 418 Hashimoto's thyroiditis cases, and 1,102 controls, Yu et al. 2007[93] found that vaccination against Hepatitis B, influenza, MMR, Hepatitis A, or polio was not associated with an increase rate of Graves' disease or Hashimoto's thyroiditis.

The IOM report made the following conclusions regarding other vaccines in adults.

MMR Vaccine

The evidence[94-97] "favors acceptance" of a causal relationship with transient arthralgia in women. The IOM committee found the evidence "inadequate to accept or reject" a causal relationship in the adult population between MMR vaccine and MS onset, Guillain-Barré Syndrome, chronic arthralgia in women, and chronic arthritis and arthropathy in men.

Hepatitis A

No epidemiological studies of the following AEs in adults were found: acute disseminated encephalomyelitis, transverse myelitis, MS, Guillain-Barré Syndrome, chronic inflammatory demyelinating polyneuropathy, Bells' Palsy, anaphylaxis, and autoimmune hepatitis. The IOM thus states that the evidence is "inadequate to accept or reject" a causal relationship with these AEs. We found no additional trials of MMR, vaccine in adults published after the IOM searches. We concur with the IOM findings and rate the strength of evidence as insufficient for association of vaccination against Hepatitis A with these potential sequelae.

Hepatitis B

Although no epidemiological studies were identified, mechanistic evidence "favored acceptance" of a causal relationship between the vaccine and anaphylaxis in yeast-sensitive individuals. Epidemiological studies of the following AEs in adults had evidence "inadequate to accept or reject" a causal relationship: optic neuritis, first demyelinating event, Guillain-Barré Syndrome, SLE, onset or exacerbation of vasculitis, polyarteritis nodosa, and onset or exacerbation of rheumatoid arthritis. A 2002 IOM review on Hep B vaccine and demyelinating neurological disorders concluded that the evidence "favors rejection" of a causal relationship with incident MS or MS relapse. [98] No epidemiological studies of the following AEs in adults were found: encephalitis, encephalopathy, ADEM, transverse myelitis, neuromyelitis optica, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, erythema nodosum, onset

or exacerbation of psoriatic arthritis, onset or exacerbation of reactive arthritis, and fibromyalgia. The IOM thus states that the evidence is "inadequate to accept or reject" a causal relationship with these AEs. We found no controlled trials of Hepatitis B vaccine in adults published after the IOM searches. The only post-licensure study that met our inclusion criteria investigated several vaccines and is described above.

Summary

MMR. Upon our review of the IOM report, we concur and rate the strength of evidence as moderate for association of MMR and transient arthralgia in women, and insufficient for association with the other investigated adverse events. Strength of evidence is moderate that MMR is not associated with onset of type 1 diabetes in adults, per results of a very large recent high quality epidemiological study.

Hepatitis A. There is insufficient evidence regarding association of this vaccine with any adverse events or onset of medical conditions, per evidence presented in the IOM report and recent post-licensure studies.

Hepatitis B. Per evidence presented in the IOM report and recent post-licensure studies, there is insufficient evidence regarding association of this vaccine with any short-term adverse events other than anaphylaxis in yeast-sensitive individuals. This event is considered serious. Hepatitis B vaccine is not associated with onset of type 1 diabetes in adults; strength of evidence is moderate, per results of a very large recent high quality epidemiological study. There is insufficient evidence regarding the association of Hepatitis B vaccine and onset of any other medical conditions.

Table 15. Postmarketing studies of multiple vaccines in adults

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Dudderstadt et al. 2012[92] Retrospective cohort	N=2,385,102 active military personnel, including 1,074 cases of type 1 diabetes; Location=U.S.; Age=17-35 years;	Hepatitis B, MMR, smallpox, typhoid, yellow fever	Receipt of multiple vaccines, age, race, sex, service branch, military grade, occupation, deployment, and calendar year	Risk Ratios for Diabetes Type 1 Hepatitis B: 0.83 (0.72, 0.95) MMR: 0.71 (0.61, 0.83)	Not reported
Yu et al. 2007[93] Case-control	N=1,875 (355 Graves' disease cases, 418 Hashimoto's thyroiditis cases, 1,102 controls); Vaccine Safety Datalink Project: Age=18–69 years; Setting=Three health maintenance organizations (HMOs) In U.S.	Hepatitis B vaccine, influenza, MMR, Hepatitis A, polio	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	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) Polio: 1.17 (0.73–1.86)	Not reported

ASD = autism spectrum disorders; CI = confidence interval; COPD = chronic obstructive pulmonary disease; DPT = diphtheria–pertussis–tetanus vaccine; HMO = health maintenance organization; IPD = invasive pneumococcal disease; MMR = measles, mumps, rubella; PV = pneumococcal vaccine; YPDC = Yokohama Psycho-Developmental Clinic

**Statistically significant association.

Note: Additional study details presented in Appendix C evidence tables.

Key Question 2: What is the evidence that vaccines included in the immunization schedules recommended for U.S. children and adolescents in 2011[24] are safe in the short term (within 30–42 days following immunization) or long term (>42 days after immunization)?

a. What AEs are collected in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?

b. What AEs are reported in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?

Table 16 lists all AEs collected or reported in trials of vaccines on the U.S. routine recommended schedule for children and adolescents. We interpreted "collected" to mean those specified a priori by investigators, while "reported" were any AEs reported by participants. The list does not imply an association with vaccination, as it contains AEs regardless of whether they were reported in vaccinated or unvaccinated study participants. Also, a study could "collect" data on a specific serious AE, but "report" zero cases. Later in this report, we describe the studies further and assess association.

Table 16. Adverse events collected or reported in trials in children and adolescents

Vaccine	Adverse Event
***Haemophilus influenzae* type b (Hib) protein conjugate**	• Areas of swelling measuring less than 2.54 cm in diameter • Areas of redness measuring less than 2.54 cm in diameter • Conjunctivitis • Fever greater than or equal to 38 C • Hospitalizations 30 days after vaccination • Serious adverse reactions • Viral infections
Human papillomavirus (HPV)	• Injection site reactions • Ear and eye and respiratory system • "Laboratory abnormality" • Pruritus, severe • Serious AE (any) • Serious AE (vaccine-related) • Systemic AE (any) • Systemic AE (vaccine-related)
Influenza (inactive)	• Abnormal crying • Allograft rejection, acute • Appetite decrease • Death • Drowsiness • Emesis • Febrile illness, acute • Fever >=38C • Flu virus infection • Irritability
Influenza (live)	• Chills • Cough • Febrile neutropenia • Fever >=100F • Headache • Irritability • Muscle ache • Rash • Runny nose • Sore throat • Tiredness • Vomiting
Pneumococcal conjugate	• Febrile seizure • Fever • Kawasaki Disease • Local AE • Otitis media

Table 16. Adverse events collected or reported in trials in children and adolescents (continued)

Vaccine	Adverse Event
Rotavirus	• Accidental drowning • Anal fissure • Anemia • "Any AE" • Abdominal pain • Apneic attack (extreme preemie) • Asthma • Bronchiolitis • Bronchopneumonia • Constipation • Convulsions • Cough/runny nose • Death • Death due to SIDS • Death (Outside of 42 day safety window and not associated with vaccine) • Decreased appetite • Dehydration • Diarrhea • Eczema • Femur fracture • Fever • Gastroenteritis • Gastrointestinal disorders • General Body • General disorders and administration site conditions • GERD • Head injury • Hematochezia • Hospitalization • Hypovolemia/dehydration • Infections • Influenza • Intussusception • Intussusception related Death • Irritability • Kawasaki disease • Kidney cyst • Leukocytosis • Meningitis • Meningitis, pneumococcal • Mesenteric adenitis • Nasal congestion • Nasopharyngitis • Nervous system disorders • Oral candidiasis - Grade 3 • Otitis media, acute • Partial seizures • Pertussis • Pneumonia • Pyelonephritis • Pyrexia • Reproductive system and breast disorders • Respiratory • SAE (extreme preemie) • Sepsis

Table 16. Adverse events collected or reported in trials in children and adolescents (continued)

Vaccine	Adverse Event
	• SIDS • Serious Adverse Event • Umbilical infection • "Unsolicited symptoms" • Upper respiratory infection • Urinary Tract Infection • Vaccine-related serious adverse event • Viral infections • Vomiting • Wheezing Withdrawal due to AE
Studies of multiple vaccines	• Apnea/collapse/cyanosis/pallor • Convulsion/fit/seizure • Crying • Diarrhea • Feeding Problem • Fever • "Vaccine reaction" • Vomiting

AE = adverse events; GERD = gastroesophageal reflux disease; Hib = *Haemophilus influenzae* type B; HPV = human papillomavirus; SAE = severe adverse event; SIDS = sudden infant death syndrome; Tdap = tetanus, diphtheria, and acellular pertussis vaccine

Table 17 lists all AEs and medical conditions investigated in the case-control, self-controlled case series, and multivariate risk factor analyses in children and adolescents. The majority of these studies were designed to assess the association of a specific AE with vaccination. Again, the list does not imply an association.

Table 17. Adverse events investigated in postmarketing studies of children and adolescents

Vaccine	Adverse Event
Influenza vaccines: H1N1	• Convulsion • Flu-like symptoms • Hospitalization or ER visit
HPV	• Guillain-Barré Syndrome • Hashimoto's Disease • Rheumatoid Arthritis • Seizures • Stroke • Syncope • Type 1 diabetes • Venous thromboembolism
Hepatitis B	• Anaphylaxis (in yeast sensitive children) • Demyelinating Event, First • Multiple Sclerosis – Onset • Multiple Sclerosis – Relapse • Seizures
MMR	• Anaphylaxis • Autism • Febrile seizures • Hospitalization or ER visit • Measles Inclusion Body Encephalitis • Purpura • Transient Arthralgia

Table 17. Adverse events investigated in postmarketing studies of children and adolescents (continued)

Vaccine	Adverse Event
Rotavirus vaccines	• Intussusception
TIV	• GI event, acute • Respiratory infection, acute • Sickle cell disease, exacerbation • Urea cycle disorders

ER = emergency room; GI = gastrointestinal; HPV = human papillomavirus; MMR = measles, mumps, rubella; TIV = trivalent influenza vaccine

Key Question 2 – Children and Adolescents (continued):

c. What AEs are associated with these vaccines?

1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?

2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]

3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether a vaccine is administered individually or in a combination vaccine product, schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

Influenza Vaccines

The IOM committee studied seasonal influenza vaccines in children and adolescents. Such vaccines are administered in two forms: a live attenuated form, administered intranasally, and an inactivated form, administered intramuscularly. The IOM committee did not find evidence that "convincingly supports" causal relationships in the pediatric population for any conditions. They found the evidence is "inadequate to accept or reject" a causal relationship between influenza vaccine and the following: seizures, acute disseminated encephalomyelitis (ADEM), and transverse myelitis. The IOM committee also found evidence is "inadequate to accept or reject" a causal relationship between live attenuated influenza vaccine (LAIV) and asthma exacerbation or reactive airway disease (RAD) episodes in children younger than 5 years of age and 5 years of age or older.[99-104]

We identified five trials[105-109] of children published after the IOM search and one cohort study.[110] These are displayed in Table 18. Four studies looked at special populations: children with cancer,[106] transplant patients,[110] children with HIV[108] and children with egg allergy.[109] The studies were set in the United States, South Africa and Japan. In four trials and the cohort study,

[a] Level of certainty was operationalized as the 95-percent confidence interval surrounding the risk or odds estimate—i.e., the statistical significance.

participants received 1-2 doses of either live[106] or inactivated[105,108-110] seasonal influenza vaccines which included an H1N1 strain. The fifth trial studied monovalent H1N1 vaccine.

In the studies of healthy patients, both inactivated seasonal influenza vaccine (including a strain of H1N1)[105] and 2009 monovalent H1N1[107] were associated with no AEs. Similarly, in the studies of children with cancer[106] and transplant patients,[110] inactivated seasonal influenza vaccine (including a strain of H1N1) was associated with no AEs. The study of HIV positive children reported no serious adverse events.[108] Finally, Fluzone[109] was not associated with urticaria, angioedema, wheezing, throat itch or swelling in children with egg allergy.

Table 18. Vaccinated versus unvaccinated children or adolescents: influenza vaccines

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Englund J. A. et al.,2010[105] U.S.	Controlled Clinical Trial	6	Sample size : 1,375, 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	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)
Gotoh K. et al.,2011[110] Japan	Cohort	1	Sample size : 101, Mean age: 9.8, Percent female: 51.5%, Conditions: Transplant	Influenza (inactivated), NR, 15 lg hemagglutinin per 0.5 mL of 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/Solomon Islands/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	Acute febrile illness: OR 0.421 (0.16-1.11) Flu virus infection: OR 0.819 (0.143-4.703)

Table 18. Vaccinated versus unvaccinated children or adolescents: influenza vaccines (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Halasa N. et al.,2011[106] U.S.	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 TCID 50per 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	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)
Mallory R. M. et al.,2010[107] U.S.	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: 0 Days Dose2: 29 Days	# 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 2: OR 1.821 (0.404-8.219) Injury, poisoning, procedural complications Dose 2: OR 0.759 (0.078-7.414)
Madhi, S.A. et al. 2013[108] South Africa	Controlled Clinical Trial	4	Sample size : 410, Mean age: 23.8, Age range: 6 – 59 months, Percent female: 59% Condition: HIV	Influenza (inactivated) , VAXIGRIP, Sano-Aventis, Adjuvant: Adjuvant Free, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days Dose2: 1 month	Incalculable – No serious adverse events

Table 18. Vaccinated versus unvaccinated children or adolescents: influenza vaccines (continued)

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Greenhawt, M.J. et al. 2012[109] U.S.	Controlled Clinical Trial	1	Sample size : 143, Mean age: NR, Age range: 14 - 17, Percent female: 36.7%, Conditions: Egg allergy	Influenza (inactivated) , Fluzone , Sanofi , Formulation had ovo-albumin content of 0.1 microgram per 0.5 ml dose , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Not reported	Dose1: 0 Days Dose2: 30 mins NR	Dyspnea: OR 0.117 (0.02-0.693)** Hypotension: OR 0.577 (0.047-7.119) Localized urticaria: OR 1.019 (0.232-4.466) Oro-facial angioedema: OR 1.8 (0.407-7.957) Stridor: OR 0.577 (0.047-7.119) Systemic urticaria: OR 0.494 (0.116-2.105) Throat itching: OR 1.273 (0.214-7.582) Throat swelling: OR 2.667 (0.216-32.961) Wheezing: OR 2.667 (0.216-32.961)

CI = confidence interval; GI = gastrointestinal; HA = hemagglutinin; OR = odds ratio; TCID = tissue culture infective dose

**Statistically significant.

Note: Additional study details presented in Appendix C evidence tables.

We found eight post marketing studies of influenza vaccines in children or adolescents; they are displayed in Table 19.

Convulsions

Stowe et al. (2011)[111] studied 2,366 cases of convulsions in children (age <10 years) between May 2000 and April 2010 using the UK's General Practice Research Database (GPRD). The monovalent H1N1 vaccine (MIV) was studied during the 2009/10 influenza season and the TIV vaccine was studied during other seasons. Both vaccination status and health outcomes were ascertained by a review of medical records. The children were followed up for an average of 5.1 years each (range 0.3–10.0 years). The analysis adjusted for age, period, and season. For both the monovalent H1N1 and TIV vaccines, the onset of a convulsion episode was not significantly associated with vaccine at any time point. In contrast, Tse[112] analyzed data on over 200,000 U.S. children under age 5 who received TIV in autumn of 2010 and found a signal for febrile seizures was found. In a self-controlled case series including febrile seizures confirmed through medical record, incidence rate ratio was significant for first dose (IRR 4.0; 95% CI 2.1 – 6.2). Vaccine against pneumonia (PCV13) was also associated with febrile seizures; importantly, administration of both vaccines at the same visit was associated with increased risk. For example, for 16 month old children, estimated rate was 12.5 per 100,000 doses for TIV without concomitant PCV13, 13.7 per 100,000 doses for PCV13 without concomitant TIV, and 44.9 per 100,000 doses for concomitant TIV and PCV13. Risk difference estimates varied by age due to the varying baseline risk for seizures in young children.

Influenza-Like Illness

A case-control analysis studied 683 children and adolescents (age 1 month - 18 years) who were hospitalized through the emergency departments of eight hospitals in Italy between November 2009 and August 2010.[113] Vaccination for H1N1 was ascertained via parental report, and health outcomes were collected through active surveillance of both clinically defined and laboratory confirmed hospitalizations for Influenza-Like Illness (ILI) events. AEs were confirmed using parental reports. Data were modeled using logistic regression that adjusted for age, chronic conditions, and other seasonal influenza vaccines. Results indicate that children vaccinated with any influenza vaccine (OR 2.7, 95% CI 1.6, 4.7) or seasonal vaccine (OR 2.1, 95% CI 1.1, 4.1) were significantly more likely to show symptoms of ILI, while those vaccinated for H1N1 were not (OR 1.3, 95% CI 0.6, 3.1).

Gastrointestinal

Baxter et al. (2012)[114] examined 43,702 LAIV recipients, 43,702 TIV recipients, and 53,366 matched unvaccinated controls, 5-17 years of age between October 2003 and March 2008. Immunization status and health outcomes were confirmed by a review of Kaiser Permanente's electronic medical records. Data were analyzed using Cox proportional hazards model, and relative risks (RR) were calculated as the ratio of the incidence rates without adjustment for any covariate. Hazard ratios (HR) were also calculated adjusting for matching factors and seasonal changes in background rates. Results were significant in children aged 5 to 8 years vaccinated with LAIV — for acute GI event within 21 days (HR 1.36, 95% CI 1.05, 1.76) and 42 days (HR 1.30, 95% CI 1.08, 1.78) and for acute respiratory tract event in 21 days (HR 1.12, 95% CI 1.00, 1.25) and 42 days (HR 1.15, 95% CI 1.06, 1.24) compared to the unvaccinated same age cohort. The incidence

rates of SAEs overall and by specific diagnosis were not significantly higher or lower in the LAIV recipients relative to control groups in any comparison.

In another self-controlled case series, Glanz et al. (2011)[115] studied 66,283 children aged 24-59 months who received TIV vaccine between 2002 and 2006 in the United States. Immunization status and health outcomes were ascertained by a review of medical records. Data were modeled using conditional Poisson regression adjusted for calendar month (indicating influenza season) and age. The results showed that influenza vaccination was significantly associated with medically confirmed GI tract disorders (RR 7.70, 95% CI 1.11, 53.52), fever (RR 1.71, 95% CI 1.64, 1.80), and GI tract symptoms like vomiting and diarrhea (RR 1.18, 95% CI 1.10, 1.25) in the risk windows of 0-2, 1-14, and 1-42 days after vaccination.

Benchim et al[116] analyzed data from an Ontario, Canada, registry of over 25,000 pediatric patients with Inflammatory Bowel Disease (IBD). Data were collected from 1999 to 2010. Patients with IBD were matched with controls according to gender, region, and age. The researchers studied receipt of any seasonal influenza vaccine; results were not stratified by type or season. Receipt of influenza vaccination was not associated with health services utilization (hospitalizations, ED visits, outpatient visits). A self-controlled case series analysis of patients with IBD-related health services utilization also found no association with influenza vaccination at any time period within six of months of receipt.

Urea Cycle Disorders

In a self-controlled case series, Morgan et al. (2011)[117] studied whether hyperammonemic episodes (HAE) were associated with vaccination in 169 U.S. children with urea cycle disorders.. The study included numerous vaccines but reported only results for the influenza vaccines. Vaccination status and health outcomes were ascertained from clinical records. Data were analyzed used conditional Poisson regression that was adjusted for age. Results indicate that the influenza vaccination was not associated with HAE at any post vaccination risk period.

Sickle Cell Disease

In a matched case-control study, Hambidge et al. (2011)[69] studied 1,294 (269 cases, 1,025 controls) children and adolescents (age 6 months to 17 years) in the United States using data from the 1999-2006 Vaccine Safety Datalink program. This study also included a self-controlled case series analysis. Cases were identified as children who had received the TIV and had been hospitalized due to sickle cell crisis. Medical records were reviewed to confirm vaccination and hospitalization. Data were modeled using a conditional logistic regression and cases and controls were matched on age, gender, location, and influenza season. Results from both the case-control study and the self-controlled case series indicated that TIV is not associated with hospitalizations due to sickle cell crises. The authors noted that children classified as not receiving vaccine may have received vaccine from an outside provider.

Summary

Seasonal influenza vaccines were not associated with SAEs in the short term in children with cancer or who have received organ transplants. Due to small number and size of trials, the strength of evidence is low.

Seasonal influenza vaccines were not associated with events requiring medical attention in IBD patients; strength of evidence is moderate due to a high quality epidemiological study including all children with IBD in a Canadian province.

In clinical trials of healthy children, seasonal influenza vaccines were not associated with SAEs in the short term. However, a recent study using the U.S. Vaccine Safety Datalink (VSD) found an association with febrile seizures, which increases with concomitant administration of PCV13. In the highest risk age group (16 months) estimated rate was 12.5 per 100,000 doses for TIV without concomitant PCV13, 13.7 per 100,000 doses for PCV13 without concomitant TIV, and 44.9 per 100,000 doses for concomitant TIV and PCV13. Strength of evidence is moderate for this AE, given the large number of subjects / statistical power of the study and the low risk of bias given that all vaccination and AE data was obtained through medical records.

Our review of the IOM findings that evidence is "inadequate to accept or reject" an association between influenza vaccines and ADEM, transverse myelitis, asthma exacerbation, or RAD in children, due to the dearth of studies on these issues, leads us to rate the evidence as insufficient to determine an association between influenza vaccines and these potential sequelae.

In large, high quality post-licensure studies, both LAIV and TIV were associated with mild gastrointestinal disorders, such as vomiting and diarrhea in children in the short-term. Strength of evidence is moderate for these AEs. One large study found that younger vaccinated children (aged 5 to 8 years) were more likely to experience these symptoms than older vaccinated children (aged 9 to 17 years). (Children under 5 years of age were not included in that study).

Seasonal influenza vaccines were associated with influenza-like symptoms in children in the short term, but strength of evidence is low, given the inconsistency of results.

Table 19. Postmarketing studies of influenza vaccines in children and adolescents

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Stowe et al., 2011[111] Self-controlled case series	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	Age, period and season	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) 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)	Not reported

Table 19. Postmarketing studies of influenza vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Italian Multicenter Study Group for Drug and Vaccine Safety in Children, 2011[113] Case-control	N=683 children aged 1 month to 18 years, hospitalized through the emergency departments of eight pediatric hospitals/wards in Italy	2009 Monovalent H1N1, Seasonal influenza unspecified	Age and chronic diseases; the ORs of A-H1N1 and seasonal vaccine were each adjusted for the other influenza vaccine	OR of influenza-like illness Any flu vaccine 2.7 (1.6 to 4.7) A-H1N1 1.3 (0.6 to 3.1) Seasonal vaccine 2.1 (1.1 to 4.1)	Not reported
Baxter, 2012[114] Retrospective cohort	43,702 LAIV recipients, 53,366 matched unvaccinated controls, 43,702 TIV recipients Age: 5 to 17 years, Setting: Kaiser Permanente health system	LAIV, TIV, October 2003 – March 2008	Relative risks (RR) were calculated as the ratio of the incidence rates of the two comparison groups without adjustment for any covariate. Hazard ratios (HR) were also calculated adjusting for matching factors and seasonal changes in background rates.	The incidence rates of 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 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.

Table 19. Postmarketing studies of influenza vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Glanz et al. 2011[115] Self-controlled case series	N=66,283 who received trivalent inactivated influenza vaccine (TIV); Location=U.S.; Age=24-59 months; Setting=Seven U.S. managed care organizations (Vaccine Safety Datalink)	TIV, October 2002 to March 2006	Calendar month (season) and age	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), Cardiac event: 3.56 (0.55-22.89) Hypotension: 5.52 (0.71-43.07) Gastrointestinal tract disorder: 2.75 (1.07-7.09) Cellulitis and skin reaction: 3.06 (0.89-10.53) Potentially less serious and common Rash: 2.33 (0.68-7.93) Limb soreness: 3.56 (1.30-9.75) Fever: 1.40 (1.09-1.80) Gastrointestinal tract symptoms (vomiting and diarrhea): 1.52 (1.18-1.95) Medical Record–Confirmed Cases Potentially serious Gastrointestinal tract disorder: 7.70 (1.11-53.52) Cellulitis and skin reaction: 3.27 (0.36-29.70) Potentially less serious and common Rash: 1.94 (0.44-8.63) Fever: 1.71 (1.64-1.80) Gastrointestinal tract symptoms (vomiting and diarrhea): 1.18 (1.10-1.25)	Not reported
Morgan et al. 2011[117] Self-controlled case series	N= 169 children with urea cycle disorders (USD); Location=U.S. Age=0-18 years;	A number of vaccines were analyzed but influenza (unspecified) was only vaccine reported on	Age	Hyperammonemic episodes (HAE): Relative Incidences 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 reported

Table 19. Postmarketing studies of influenza vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Hambidge et al. 2011[69] Matched case-control (and self-controlled case series)	N=1,294 (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 , 1999-2006	Cases/controls matched on age category, gender, Vaccine Safety Datalink site, and season	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) Boys: 1.07 (0.50–2.28) Girls: 1.33 (0.72–2.44) 6-23 months: 1.23 (0.25–6.04) 60 mo to 17 yr: 1.38 (0.83–2.29)	Not reported
Benchimol, et al. 2013,[116] Self-controlled case series	N=26602; Location=Ontario, Canada; Age=< 19 years; Setting=Ontario Crohn's and Colitis Cohort (OCCC), a population-based registry of pediatric IBD patients derived from provincial health administrative data	Influenza, unspecified, 1999-2010	Self-controlled and also matched controls. Each IBD case was matched to 5 (or 4 where a fifth could not be found) controls according to gender, provincial administrative health region in which the subject resided, and date of birth.	SCCS Analysis to Assess Risk of Increased Health Services Utilization in the Postvaccine Period in Children With IBD and Non-IBD Matched Controls Overall all-cause health services utilization (hospitalizations + ED visits + outpatient visits) RI in IBD Patients, (95 CI) Days 3–14: 1.19 (0.88–1.59) . Days 15–30: 0.83 (0.61–1.13) Days 31–45: 0.96 (0.71–1.29) Days 46–60: 0.81 (0.58–1.12) Days 61–75: 0.94 (0.69–1.26) . Days 76–90: 0.79 (0.57–1.09) Days 91–180: 0.99 (0.85–1.16) . Pooled day 3–180: 0.95 (0.84–1.07) . Pooled day 15–180: 0.92 (0.82–1.04) RI in Controls, (95 CI) Days 3–14: 0.64 (0.47–0.89) Days 15–30: 0.95 (0.75–1.20) Days 31–45: 0.68 (0.52–0.91) Days 46–60: 0.93 (0.73–1.19) Days 61–75: 0.87 (0.68–1.11) Days 76–90: 0.91 (0.71–1.16)	None

Table 19. Postmarketing studies of influenza vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				Days 91–180: 0.96 (0.85–1.09) Pooled day 3–180: 0.90 (0.82–0.98) Pooled day 15–180: 0.91 (0.83–1.00) RIR of Cases Versus Controls, (95 CI) Days 3–14: 1.60 (1.05–2.44) .03 Days 15–30: 0.74 (0.51–1.08) .12 Days 31–45: 1.18 (0.79–1.76) .42 Days 46–60: 0.73 (0.49–1.08) .12 Days 61–75: 0.91 (0.63–1.33) .64 Days 76–90: 0.74 (0.50–1.09) .13 Days 91–180: 0.85 (0.71–1.02) .09 Pooled day 3–180: 0.89 (0.78–1.02) .09 Pooled day 15–180: 0.85 (0.74–0.97) .02 Hospitalizations (all causes) RI in IBD Patients, (95 CI) Days 3–14: 0.79 (0.18–3.37) .75 Days 15–30: 1.14 (0.39–3.31) .82 Days 31–45: 0.60 (0.14–2.55) .49 Days 46–60: 0.59 (0.14–2.49) .47 Days 61–75: 2.01 (0.86–4.69) .11 Days 76–90: 0.57 (0.13–2.43) .40 Days 91–180: 0.69 (0.35–1.36) .43 ED visits (all causes) RI in IBD Patients, (95 CI) Days 3–14: 0.73 (0.27–2.03) Days 15–30: 0.89 (0.41–1.95) Days 31–45: 0.72 (0.29–1.80) Days 46–60: 1.57 (0.81–3.07) Days 61–75: 0.98 (0.42–2.26) Days 76–90: 0.99 (0.43–2.31) Days 91–180: 1.12 (0.73–1.72) RI in Controls, (95 CI) Days 3–14: 0.58 (0.21–1.58) Days 15–30: 1.12 (0.58–2.16)	

Table 19. Postmarketing studies of influenza vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				Days 31–45: 0.94 (0.45–1.94) Days 46–60: 1.35 (0.73–2.47) Days 61–75: 0.98 (0.50–1.96) Days 76–90: 0.76 (0.35–1.64) Days 91–180: 1.02 (0.72–1.45) RIR of Cases Versus Controls, (95 CI) Days 3–14: 1.21 (0.30–4.94) Days 15–30: 0.83 (0.31–2.24) Days 31–45: 0.80 (0.26–2.50) Days 46–60: 1.09 (0.46–2.59) Days 61–75: 0.88 (0.31–2.52) Days 76–90: 1.17 (0.38–3.55) Days 91–180: 0.94 (0.57–1.56) SCCS Analysis of IBD-Related Health Services Utilization (Hospitalizations + ED Visits + Outpatient Visits) RI, 95 CI, Days 3–14: 1.05 (0.68–1.63) Days 15–30: 0.45 (0.26–0.80) Days 31–45: 0.68 (0.42–1.11) Days 46–60: 0.89 (0.58–1.36) Days 61–75: 0.68 (0.43–1.10) Days 76–90: 0.81 (0.52–1.26) Days 91–180: 0.87 (0.70–1.09) Pooled days 3–180: 0.81 (0.68–0.96) Pooled days 15–180: 0.78 (0.66–0.94)	

Table 19. Postmarketing studies of influenza vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Tse et al. 2012, Self-controlled risk interval, current vs. historical vaccine design[112]	N=206,174 children vaccinated with TIV in 8 U.S. MCOs ; Age=6-59 months;	TIV, PCV13, Fall 2010	Adjustment for TIV or PCV13	Febrile seizures, 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

CI = confidence interval; ED = emergency department; GPRD = general practice research database; HR = hazard ratio; IRR = incidence rate ratio; LAIV = live attenuated influenza vaccine; Mo = month; OR = odds ratio; RR = relative risk; SAEs = serious adverse events; TIV = trivalent influenza; USD = urea cycle disorders; Yr = year
Note: Additional study details presented in Appendix C evidence tables.

Haemophilus Influenza Type B (Hib) Vaccine

We identified three trials of the *Haemophilus influenza* type B (Hib) vaccine in children;[118-120] one was set in the United States, the other two in Asia. Details are presented in Table 20. Results of the U.S. trial (N = 5,190) indicated that vaccination agents Hib was associated with redness (OR 2.71, 95% CI 1.57, 4.67) and swelling (OR 9.44, 95% CI 4.90, 18.19), but not associated with hospitalizations. Vaccination was not associated with high fever in either the U.S. trial or a trial in the Philippines. A trial in Vietnam[118] found the vaccine was not associated with any serious adverse events, including convulsion, diarrhea, fungal infection or GERD. No other AEs were associated with vaccination. In sum, strength of evidence is moderate that no serious AEs are associated with Hib vaccine in the short term. Regarding long term, we identified no post-licensure studies that met our inclusion criteria.

Table 20. Vaccinated versus unvaccinated children or adolescents: Hib vaccine

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Capeding M. R. Z. et al.,1996[120] Philippines	Controlled Clinical Trial	3	Sample size : 174, Mean age: 6.9 months, Age range: 5 – 8 months, Percent female: 37%	*Haemophilus 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	Fever greater than or equal to 38 C: OR 1.246 (0.467-3.323)
Santosham M. et al.,1991[119] United States	Controlled Clinical Trial	4	Sample size : 5,190, Mean age: 54.6 days, Age range: 35 – 196 days, Percent female: 49.4%	*Haemophilus Influenza* type b (Hib) protein conjugate, Routine Vaccines, Pedvax HIB, Merck, OMPC lots 1072, 1080, and 1085. After reconstitution with 0.1ml of diluent, each 0.5m of vaccine contained 15 micrograms of H. influenzae polysaccharide and 131 to 272 micrograms of group B meningococcal OMPC., Adjuvant: Aluminum, Preservative: Thimerosal, Delivery: Intramuscular	Dose1: 42-90 Days Dose2: 70-146 Days	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)**

Table 20. Vaccinated versus unvaccinated children or adolescents: Hib vaccine (continued)

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Huu, T.N. et al. 2013[118] Vietnam	Controlled Clinical Trial	7	Sample size : 300, Mean age: 8.7, Age range: 6 - 12, Percent female: 43.3%	*Haemoph. Influen.* type b (Hib) protein conjugate, Routine Vaccines , Experimental: Synflorix Routine: Infanrix hexa , GlaxoSmithKline , PHiD-CV (Synflorix™, GlaxoSmithKline, Rixensart, Belgium) contained 1µg of each capsular polysaccharide of pneumococcal serotypes 1, 5, 6B, 7F, 9V, 14, and 23Fand 3µg of serotype 4 capsular polysaccharide conjugated individually to NTHi protein D; 3µg of serotype18C capsular polysaccharide conjugated to tetanus toxoid; and 3µg of serotype 19F capsular polysaccharide conjugated to diphtheria toxoid. Routine: DTPa-HBV-IPV/Hib vaccine (Infanrix hexa™,GlaxoSmithKline, Rixensart, Belgium) contained=30 IU of diphtheria toxoid,=40 IU of tetanus toxoid, 25µgofpertussis t , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Days Dose2: 28-42 Days Dose3: 28-42 Days	SAE- convulsion: OR 0.332 (0.055-2.017) SAE- diarrhea: OR 0.503 (0.07-3.621) SAE- fungal infection: OR 0.25 (0.022-2.791) SAE- gastro-esophageal reflux disease: OR 0.505 (0.031-8.159) SAEs (total): OR 0.75 (0.259-2.169)

CI = confidence interval; Hib = *Haemophilus influenza* Type b; OR = odds ratio;
Note: Additional study details presented in Appendix C evidence tables.

Measles-Mumps-Rubella (MMR)

The IOM committee found the evidence "convincingly supports" causal relationships in the pediatric population between MMR and the following: measles inclusion body encephalitis in immunocompromised patients; febrile seizures;[121-128] and anaphylaxis. The IOM committee found the evidence "favors acceptance" of a causal relationship between MMR and transient arthralgia in the pediatric population.[129-135] They found the evidence "favors rejection" of a causal relationships between MMR and autism in the pediatric population.[136-140] Finally, the IOM committee found the evidence is "inadequate to accept or reject" a causal relationship in the pediatric population between MMR and the following: encephalitis, encephalopathy, afebrile seizures, cerebellar ataxia, acute disseminated encephalomyelitis, transverse myelitis, optic neuritis, neuromyelitis optica, MS onset, and chronic arthropathy.

In addition, a causal relationship between the Urabe Strain of mumps and aseptic meningitis has been shown; there is no evidence to link Jeryl Lynn™ strain, commonly used in the United States, to this adverse event.

We identified no additional trials and four postmarketing studies of MMR in children published after the IOM searches. Study designs included self-controlled case series and case-control. The studies were conducted in England, Denmark, Italy, Canada, and the United States. Data are displayed in Table 21.

Purpura

Andrews et al. (2012)[141] studied 343 cases of thrombocytopenic purpura (TP) in children aged 12 to 23 months between 1990 and 2007. Vaccination status was ascertained using review of the immunization registry and health outcomes from hospital discharge data. This study presented data from both a case-control design and a self-controlled case series. The self-controlled case series was adjusted for age only. The results indicate that the relative risk of TP was significant 14-27 days (England: RR 3.13, 95% CI 1.44, 6.79; Denmark: RR 2.75, 95% CI 1.61, 4.69) after immunization and 0- 42 days after immunization in both England (RR 1.92, 95% CI 1.02, 3.59) and Denmark (RR 2.01, 95% CI 1.34, 2.99). The data from Denmark were used in a model adjusting for age (1-month intervals), calendar period (one year intervals), gender, place of birth, ethnicity of mother (Danish or not), and maternal age at birth. Similar results were obtained with a significant relative risk of TP at 14-27 days (RR 2.54, CI 95% 1.47, 4.37) and 0-42 days (RR 1.85, 95% CI 1.23, 2.78) after immunization with MMR.

Bertuola et al. (2010)[142] studied 2,311 children from four pediatric hospitals in Italy between November 1999 and December 2007. The sample included 387 cases (mean age: 4.9 years) of idiopathic thrombocytic purpura (ITP) and 1,924 controls (mean age: 5.7 years) who had gastroduodenal lesions or neurological disorders. Vaccination with MMR was confirmed using physician self-report, and health outcomes were ascertained using emergency department and hospital records. Analysis adjusted for age and use of NSAIDs, acetaminophen, antibacterials, mucolytics, and corticosteroids. There was a statistically significant association between vaccination with MMR and ITP (OR 2.4, 95% CI 1.2, 4.7). Results were also significant for use of each medication except corticosteroids.

The VSD was used to study the association between several vaccines and ITP.[143] (Details are displayed in Table 29 on studies of multiple vaccines.) MMR was associated with ITP in infants 12 to 19 months old (OR 5.48, 95% CI 1.61, 18.64).

Hospitalization or ER visits

In a self-controlled case series study, Wilson et al. (2011)[144] studied 413,957 Canadian children who were vaccinated against MMR at 12-18 months of age between 2006 and 2009. Vaccination status was ascertained by a review of records from the Ontario Health Insurance Plan database. Health outcomes were verified using national databases like the Discharge Abstract Database and the National Ambulatory Care Registration System. Data were analyzed using a fixed effects Poisson regression model. The results show that the relative risk of hospitalization/ED use was significant on days 4-12 (RR 1.33, 95% CI 1.29–1.38) following the 12-month vaccination, and during days 10 to 12 after the 18-month vaccination.

Autism

In a case-control study of 189 young adults with Autism Spectrum Disorder and 224 controls, Uno et al. 2012[145] found that childhood receipt of mumps-measles-rubella (MMR) vaccine was not associated with an increased rate of new onset autism (OR 1.10, 95% CI 0.64, 1.90).

Summary

The IOM found that evidence "convincingly supports" a causal relationship between MMR and anaphylaxis in children allergic to ingredients, and an association of MMR vaccine with febrile seizures. We reviewed and agree with these determinations; thus, we rate the strength of evidence as high.

MMR vaccination was associated with thrombocytopenic purpura in children in the short term after vaccination. Strength of evidence is moderate, as findings have been consistent and odds ratios similar in three European countries, Canada and the United States.

A large post-licensure study found that MMR vaccination is associated with increased emergency department visits within two weeks. This is consistent with the IOM's findings that MMR vaccine is associated with febrile seizures.

The IOM found that the evidence is "inadequate to accept or reject" a causal relationship in the pediatric population between MMR and the following: encephalitis, encephalopathy, afebrile seizures, meningitis, cerebellar ataxia, acute disseminated encephalomyelitis, transverse myelitis, optic neuritis, neuromyelitis optica, MS onset, and chronic arthropathy. We reviewed the IOM evidence and agree that evidence is insufficient to determine an association. The IOM findings favor rejection of a causal relationship between MMR vaccination and autism. We judge the strength of evidence as high based on a review of their findings and later published case-control study which reported no association.

Table 21. Postmarketing studies of measles-mumps-rubella (MMR) vaccine in children and adolescents

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Andrews et al., 2012[141] Prospective cohort, also analyzed as self-controlled case series	N=343 cases of thrombocytopenic purpura (TP); Location=England, Denmark; Age=12–23 months;	MMR	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)	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 (1.34–2.99) 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)	Not reported

Table 21. Postmarketing studies of measles-mumps-rubella (MMR) vaccine in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Bertuola et al., 2010[142] Case-control	N=2,311 (387 cases, 1924 controls); Location=Italy; Age=Mean (SD) case/control: 4.9 (3.5) / 5.7 (4.9); Setting=Four pediatric hospitals: Department of Paediatrics, University of Padua; Giannina Gaslini Pediatric Hospital, Genoa; Bambino Gesu Hospital, Rome; Santobono-Pausilipon Pediatric Hospital, Naples	MMR	Age and use of multiple medications	OR 95% CI for idiopathic thrombocytopenic purpura (ITP): MMR 2.4 (1.2-4.7)	Not reported

Table 21. Postmarketing studies of measles-mumps-rubella (MMR) vaccine in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Wilson et al.,2011[144] Self-controlled case series	N=413,957; Location=Ontario, Canada; Age=12 and 18 months;	Live MMR	None in the model	Relative incidence of combined endpoint (hospital admission or emergency room visit) following 12 month vaccination, comparison is 20 to 28 days after vaccination. Risk interval: Relative Incidence (95% CI) Day 4: 1.15 (1.06–1.25) Day 5: 1.19 (1.10–1.29) Day 6: 1.20 (1.11–1.31) Day 7: 1.20 (1.10–1.30) Day 8: 1.62 (1.50–1.74) Day 9: 2.04 (1.91–2.17) Day 10: 1.84 (1.72–1.97) Day 11: 1.72 (1.60–1.84) Day 12: 1.32 (1.22–1.43) Days 4 to 12** (Combined risk interval): 1.33(1.29–1.38) Relative incidences of 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)	Not reported

Table 21. Postmarketing studies of measles-mumps-rubella (MMR) vaccine in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Uno et al. 2012[145] Case-control	N=413 (189 Autism Spectrum Disorder (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.	Maternal hypertension, low Apgar score, obstetrical vacuum extraction or forceps delivery Cases/controls matched by sex and year of birth	Odds ratio for ASD: 1.10 (0.64–1.90)	Maternal hypertension: 4.19 (0.46–38.57) Low Apgar score: 2.06 (0.18–22.12) Obstetrical vacuum extraction or forceps delivery: 0.98 (0.50–1.92)

CI = confidence interval; ITP = idiopathic thrombocytopenic purpura; MMR = measles-mumps-rubella; OR = odd ratio; SCCS = self-controlled case series; SD = standard deviation; TP = thrombocytopenic purpura

Note: Additional study details presented in Appendix C evidence tables.

Rotavirus Vaccines: RotaTeq and Rotarix

Vaccines against rotavirus were not included in the 2011 IOM report on adverse effects of vaccines. We identified 35 eligible trials of rotavirus vaccine.[146-177] We excluded several trials because the dosage was not comparable to that of the current product. We also excluded studies of Rotashield, which was withdrawn from the market in 1999 because of concerns regarding risk of intussusception.

Participants in the accepted studies received 2-3 oral administered doses of Rotarix (18 studies) or RotaTeq (15 studies). Most participants were between 4 and 20 months of age. Studies were conducted in North America, South America, Europe, and Asia. The number of participants ranged from 100 to over 60,000. In general, neither Rotarix nor RotaTeq was associated with increased risk of AEs other than cough, runny nose or irritability. The only exception was an association of RotaTeq with respiratory and thoracic disorders in a trial of children with HIV in Sub-Saharan Africa.[157] Data from the studies are displayed in Table 22.

Table 22. Vaccinated versus unvaccinated children: rotavirus vaccines

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Armah G. E. et al.,2010[146] Ghana, Kenya, Mali	Controlled Clinical Trial	5	Sample size: 5,560, 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	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)
Block S. L. et al.,2007[147] United States, Finland	Controlled Clinical Trial	5	Sample size: 1,312, Age range: 6 - 13, Percent female: 47.8%	Rotavirus, RotaTeq, Merck, ©1.1X10 infectious U per dose. Pentavalent (G1–G4, and P[8]) human bovine(WC3) reassortant rotavirus vaccine (PRV), Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 4-10 Weeks Dose3: 8-20 Weeks	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) Pneumonia: OR 3.056 (0.317-29.453) 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[148] Taiwan	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 Days Dose2: 4-10 Weeks Dose3: 8-20 Weeks	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)

Table 22. Vaccinated versus unvaccinated children: rotavirus vaccines (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Christie C. D. C. et al.,2010[149] Jamaica	Controlled Clinical Trial	4	Sample size: 1,804, 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 Days Dose2: 2 Month Dose3: 2 Month	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)
Dennehy P. H. et al.,2005[150] United States, Canada	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 Days Dose2: 2 Month	Bronchiolitis: OR 0.502 (0.1-2.532) Hypovolemia/dehydration: OR 0.507 (0.031-8.187)
Goveia M. G. et al.,2007[151] 11 countries	Controlled Clinical Trial	8	Sample size: 2,074, 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	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)
Grant L. R. et al.,2012[152] United States	Controlled Clinical Trial	5	Sample size: 1,003, Age range: 6 - 12	Rotavirus, RotaTeq, Merck, PRV is a live, pentavalent, vaccine that contains human bovine (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 Days Dose2: 4-10 Weeks Dose3: 8-20 Weeks	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)

Table 22. Vaccinated versus unvaccinated children: rotavirus vaccines (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Kawamura N. et al.,2011[153] Japan	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 Days Dose2: 1 Month	# 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)
Kerdpanich A. et al.,2010[154] Thailand	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 Days Dose2: 2 Month	Loss of appetite: OR 0.487 (0.205-1.16) SAE - UTI: OR 0.145 (0.009-2.384)
Kim D. S. et al.,2008[155] Korea	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 Days Dose2: 4-10 Weeks Dose3: 8-20 Weeks	One or more serious adverse events: OR 0.44 (0.141-1.373)

Table 22. Vaccinated versus unvaccinated children: rotavirus vaccines (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Kim J. S. et al.,2012[156] South Korea	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	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) nasopharyngitis (unsolicited/31d): OR 0.563 (0.301-1.051)
Laserson K. F. et al.,2012[157] Kenya	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	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 Dose 2: 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)**
Madhi S. A. et al.,2010[158] South Africa and Malawi	Controlled Clinical Trial	3	Sample size: 4,939, Mean age: 6.4 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	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)

Table 22. Vaccinated versus unvaccinated children: rotavirus vaccines (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Narang A. et al.,2009[159] India	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 Days Dose2: 1 Month	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)**
Omenaca F. et al.,2012[160] France, Portugal, Poland and Spain	Controlled Clinical Trial	6	Sample size: 1,009, 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	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)
Phua K. B. et al.,2005[161] Singapore	Controlled Clinical Trial	3	Sample size: 2,464, 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 89–12 vaccine 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	Severe Vomiting (Dose 1): OR 1 (0.312-3.203) Severe Vomiting (Dose 2): OR 1 (0.312-3.203)

Table 22. Vaccinated versus unvaccinated children: rotavirus vaccines (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Phua K. B. et al.,2009[162] Hong Kong, Singapore, Thailand	Controlled Clinical Trial	8	Sample size: 10,708, 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 Days Dose2: 1-2 Month	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)
Phua K. B. et al.,2012[163] Singapore, Hong Kong, Taiwan	Controlled Clinical Trial	1	Sample size: 8,407, 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: 0 Days Dose2: 1-2 Month	Intussusception: OR 1.983 (0.18-21.878) gastroenteritis (failed treatment?): OR 1.487 (0.248-8.905)
Rodriguez Z. M. et al.,2007[164] United States	Controlled Clinical Trial	1	Sample size: 1,358, 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	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)
Ruiz-Palacios G. M. et al.,2006[165] Finland, Argentina, Brazil, Chile, Colombia, the Dominican Republic, Honduras, Mexico,Nicaragua, Panama, Peru, Venezuela	Controlled Clinical Trial	6	Sample size: 63,225, 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	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)**

Table 22. Vaccinated versus unvaccinated children: rotavirus vaccines (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Sow S. O. et al.,2012[166] Vietnam, Bangladesh, Ghana, Kenya, Mali	Controlled Clinical Trial	5	Sample size: 1,960, 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	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)
Steele A. D. et al.,2010[167] South Africa	Controlled Clinical Trial	4	Sample size: 475, Mean age: 6.3	Rotavirus, Rotarix, GlaxoSmithKline, RIX4414 developed from 89-12 parent vaccine strain that was cloned and passaged on Vero cells. Viral concentration of 1 dose contained at least 1x10*6.0 medial cell culture infective dose and lyophilized vaccine was reconstituted with calcium carbonate as buffer, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 10 Weeks Dose2: 14 Weeks	Serious adverse events (any): OR 1.011 (0.336-3.046)
Steele A. D. et al.,2011[168] South Africa	Controlled Clinical Trial	5	Sample size: 100, Mean age: 7, Age range: 6 - 10, Percent female: 53%, Conditions: HIV	Rotavirus, Rotarix, GlaxoSmithKline, Each dose of the vaccine contained at least 106.0 median cell culture infective dose (CCID 50) of the active virus strain. Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 1 Month Dose3: 1 Month	At least 1 Grade 3 unsolicited symptom w/in 31 d): OR 1 (0.425-2.352) Bronchopneumonia: OR 1.872 (0.512-6.848) Bronchopneumonia - Grade 3: OR 1 (0.236-4.242) Cough: OR 1.43 (0.622-3.286) Fatality: OR 0.621 (0.203-1.899) GE: OR 2.136 (0.503-9.068) GE - Grade 3: OR 2.087 (0.365-11.949) Irritability: OR 1.17 (0.39-3.515) Oral candidiasis - Grade 3: OR 2.087 (0.365-11.949)
Tregnaghi M. W. et al.,2011[169] Argentina, Brazil, Colombia, Dominican Republic, Honduras, and Panama	Controlled Clinical Trial	4	Sample size: 6,568, Mean age: 8.6, Age range: 6 - 12	Rotavirus, Rotarix, 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	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)

Table 22. Vaccinated versus unvaccinated children: rotavirus vaccines (continued)

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Vesikari T. et al.,2004[170] Finland	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	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)
Vesikari T. et al.,2006[171] Finland	Controlled Clinical Trial	5	Sample size: 1,946, Age range: 2 - 8	Rotavirus, NR, Low-potency pentavalent RotaTeq G1, G2, G3, G4, P1A 2.41×106., Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 4-8 Weeks Dose3: 8-16 Weeks	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)
Vesikari T. et al.,2006[172] 11 countries	Controlled Clinical Trial	8	Sample size: 69,274, 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	Not calculable
Vesikari T. et al.,2011[173] Finland	Controlled Clinical Trial	3	Sample size: 250, 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	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)

Table 22. Vaccinated versus unvaccinated children: rotavirus vaccines (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Vesikari T. et al.,2004[174] Belgium, Germany	Controlled Clinical Trial	5	Sample size: 59, Age range: 1 - 44	Rotavirus, Rotarix, GlaxoSmithKline, Derived from the parent strain 89-12 single 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	Not calculable
Zaman K. et al.,2009[175] Bangladesh	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	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)
Zaman K. et al.,2010[176] Bangladesh and Vietnam	Controlled Clinical Trial	8	Sample size: 2,035, 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	Death: OR 0.75 (0.167-3.36)
Zaman K. et al.,2012[177] Bangladesh	Controlled Clinical Trial	5	Sample size: 1,136, 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	Accidental drowning: OR 1 (0.062-16.027) Acute diarrhea: OR 1 (0.062-16.027) All Serious Adverse Events: OR 0.939 (0.47-1.878) Death, All causes: OR 3.011 (0.312-29.031) Pneumonia: OR 0.728 (0.331-1.599)
Sow, S.O. et al. 2012[178] Sub-Saharan Africa (Ghana, Kenya and Mali)	Controlled Clinical Trial	2	Sample size: 1960, Mean age: 48, Age range: 0 - 14, Percent female: 48%	Rotavirus, RotaTeqTM , Merck, Not reported , Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 6 Weeks Dose2: 10 Weeks Dose3: 14 Weeks	Bronchiolitis: OR 1.002 (0.063-16.044) Pneumonia: OR 0.667 (0.111-4.003) Total deaths: OR 0.6 (0.143-2.518)

Table 22. Vaccinated versus unvaccinated children: rotavirus vaccines (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Lau, Y.L. et al. 2013[179] China	Controlled Clinical Trial	1	Sample size: 3025, Mean age: 11.6, Age range: 6 - 12, Percent female: Not reported%	Rotavirus, RotarixTM , GlaxoSmithKline , Each dose of the lyophilized formulation of RIX4414 (RotarixTM, GlaxoSmithKline, Belgium) vaccine contained at least 106.0 median cell culture infectious dose (CCID50) of live, attenuated human G1P rotavirus. The RIX4414 vaccine was reconstituted in a calcium carbonate buffer before oral administration. , Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 2 Month Dose2: 4 Month	Gastroenteritis-related symptoms requiring <=1 hospitalization: OR 0.793 (0.616-1.021) Intussusception: OR 2.001 (0.366-10.943)
Zaman, K. et al. 2012[180] Bangladesh	Controlled Clinical Trial	2	Sample size: 1136, Mean age: NR, Age range: 4 - 12	Rotavirus, RotaTeq, Merck, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Oral	Dose1: 0 Days Dose2: 4 Weeks Dose3: 4 Weeks	Acute diarrhea: OR 1 (0.062-16.027) Death: OR 1 (0.201-4.976) Pneumonia: OR 0.728 (0.331-1.599)

AE = adverse event; CCID = cell culture infective dose; CI = confidence interval; FFU = focus forming unit; H = Hour; HIV = human immunodeficiency virus; IU = international unit; OR = odds ratio; PRV = pentavalent rotavirus vaccine; SAE = serious adverse events

Note: Additional study details presented in Appendix C evidence tables.

We found five post-licensure studies of vaccines against rotavirus (Buttery, 2011; Yih, 2013; Velazquez, 2012; Patel, 2011; Shui, 2012).[181-185] The studies were set in Australia (Buttery, 2011), United States (Shui, 2012; Yih, 2013), Mexico (Velazquez, 2012; Patel, 2011) and Brazil (Patel, 2011). All studied intussusception, as an earlier brand of rotavirus vaccine (Rotashield) was withdrawn from the market in 1999 due to concerns about this AE. Studies are displayed in Table 23.

Intussusception

Buttery et al. (2011)[181] studied children under the age of 24 months who received either RotaTeq (N=296,023) or Rotarix (N=302,455) between July 2007 and December 2008. Vaccination status was ascertained through a national vaccination registry. Health outcomes were collected using active surveillance: the Australian Pediatric Surveillance Unit (APSU), the Pediatric Active Enhanced Disease Surveillance (PAEDS), and from the active surveillance of four major tertiary pediatric hospitals. Relative risk ratios were estimated to compare observed and expected cases of intussusception by age. For the RotaTeq vaccine, in the 1-7 days post vaccination period, the risk of intussusception was significant after the first dose (RR 5.26, 95% CI 1.09, 15.4) but insignificant after the second and third doses. The overall relative risk of intussusception was insignificant (RR 1.15, 95% CI 0.37, 2.68) during this period. There was a similar decreasing trend in the risk of intussusception with each dose in the 21-day period after vaccination; only dose one had a significant association (RR 3.51, 95% CI 1.29, 7.64). In children vaccinated with Rotarix, risk of intussusception was insignificant for all doses; the overall relative risk was 1.58 (95% CI 0.51, 3.69) for the 7-day post vaccination period and 1.37 (95% CI 0.73, 2.34) for the 21-day period.

In a self-controlled case series, Velazquez et al. (2012)[182] studied 698 infants (age< 1 year) with intussusception between January 2008 and October 2010 in Mexico. Use of the Rotarix vaccine was confirmed using immunization cards or a review of all available medical records. In the absence of medical records, vaccination status was ascertained using parent/guardian reported data. Active surveillance identified cases of intussusception through reviews of admission and discharge logs from hospitals, emergency departments, pediatric, surgery and radiology wards. Episodes of intussusception were confirmed using radiography, surgery, or post mortem examination. Data were modeled using a conditional Poisson regression and adjusted for age as a potential confounder. The relative incidence of intussusception was significant after dose 1 during the 0-6 days (RR 6.49, 95% CI 4.17, 10.09), 0-15 days (RR 3.24, 95% CU 2.15, 4.87), and 0-30 days (RR 1.75, 95% CI 1.24, 2.48) post vaccination periods. The risk of intussusception after dose 2 was not significant for all three post vaccination periods studied.

Patel et al. (2011)[183] studied 2,665 infants (615 cases of intussusception, 2,050 controls), 45-245 days of age from 53 hospitals in seven states in Brazil and from 16 hospitals in 10 states in Mexico. This study reports two sets of results, one as a case-control study and the other as a self-controlled case series. Vaccination with Rotarix was ascertained by a review of medical records, and cases of intussusception were verified by a review of clinical records. Data were analyzed using a conditional logistic regression model that was matched by date of birth, and also controlled for age and sex. For the children studied in Mexico, the likelihood of intussusception in the case-control analysis was significant (OR 5.8, 95% CI 2.6, 13.0) at 1-7 days but not at 8-14 days or 15-21 days after vaccination. After the second dose, the likelihood of intussusception was significant 8-14 days (OR 2.3, 95% CI 1.2, 4.4) days after vaccination but not in the other periods. The case-control analysis of data from the children in Brazil showed no significant relationship between vaccine and

intussusception at any time period after dose 1, but showed a significant association (OR 1.9, 95% CI 1.1, 3.4) within 1-7 days after dose 2.

The results of Patel's self-controlled case series analyses[183] showed a significant association of Rotarix with intussusception in 1-7 days after the first dose (OR 5.3, 95% CI 3.0, 9.3) and 8-14 days (OR 2.2, 95% CI 1.2, 4.2) and 15-21 days (OR 2.2, 95% CI 1.2, 4.0) after the second dose in children in Mexico. In Brazil, the association with intussusception after the first dose of Rotarix was insignificant at each time period, but significant (OR 2.6, 95% CI 1.3, 5.2) 1-7 days after the second dose.

Two post-licensure studies were recently conducted in the U.S. Shui, 2012[184] analyzed VSD data on 786,725 doses of RotaTeq and found no association with intussusception at any time after vaccination. However, a recent analysis of data from the U.S. Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program[185] found that RotaTeq was associated with intussusception after Dose 1 and Rotarix associated with this AE after Dose 2. The RotaTeq analysis had higher statistical power, as that vaccine was administered to orders of magnitude more children than Rotarix. Estimated rate of intussusception was 1.1 to 1.5 cases per 100,000 doses of RotaTeq and 5.1 cases per 100,000 doses of Rotarix.

Summary

Vaccines against rotavirus were not included in the 2011 IOM report.

Both RotaTeq and Rotarix were associated with cough, runny nose and irritability in children. There is moderate strength evidence from several RCTs for these mild, short-term adverse events.

In clinical trials, there was no association between either of the two currently available vaccines (RotaTeq and Rotarix) and any serious adverse events, including intussusception.

A high quality epidemiological study (N = 296,023) conducted in Australia found RotaTeq associated with intussusception in children 1 to 21 days following the first of three required doses. While a study of the U.S. VSD found no association, a large high quality U.S. study also found RotaTeq associated with intussusception after the first dose. Estimated rate of intussusception was 1.1 to 1.5 cases per 100,000 doses.

Two case-control studies conducted in Latin America found an association with intussusception in children following the first of two required doses of Rotarix. One study estimated Rotarix increases risk by 3.7 (95% CI 1.2, 7.3) additional cases per 100,000 person/years in Mexico. The other Latin American study estimated risk as one case per 51,000 vaccines in Mexico and one case per 68,000 vaccines in Brazil. A large high quality study in the United States found Rotarix associated with intussusception after Dose 2; rate was 5.1 cases per 100,000 doses.

Given the totality of scientific findings, the strength of evidence is moderate for an association of intussusception with both Rotateq and Rotarix. Although no cases were reported in over 30 well-designed clinical trials conducted around the world, such trials are not powered to detected adverse events that occur so infrequently. The most recent post-licensure study used the strongest design yet and included all cases from eight large U.S. HMOs. This study supports findings from the 2011 epidemiological study of over 500,000 children in Australia and two small studies conducted in Latin America.

Table 23. Postmarketing studies of rotavirus vaccines in children

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Buttery et al., 2011[181] Observed /expected analysis	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	No control for confounders	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) Dose 2: 0.88 (0.29, 2.05) Total: 1.37 (0.73, 2.34)	Not reported
Velázquez et al., 2012[182] Self-controlled case-series	N=698 infants < 1 year old in Mexico with intussusception Active surveillance across hospitals in Mexico from the Mexican Institute of Social Security	Rotarix	Age	Relative Incidence Dose and risk period (days after vaccination) Dose 1, 0-30 days: 1.75 (1.24–2.48) Dose 2, 0-30 days: 1.06 (0.75–1.48) Dose 1, 0-15 days: 3.24 (2.15–4.87) Dose 2, 0-15 days: 1.06 (0.69–1.61) Dose 1, 0-6 days: 6.49 (4.17–10.09) Dose 2, 0-6 days: 1.29 (0.80–2.11)	Not reported

Table 23. Postmarketing studies of rotavirus vaccines in children (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Patel et al., 2011[183] Case-control (also did self-controlled case-series)	N=2,665 (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	Matched by date of birth, also controlled for age, sex	OR (95% CI) for intussusception (Case-control) 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 (0.1–2.2) 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 (Self-controlled case-series) 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)	Not reported

Table 23. Postmarketing studies of rotavirus vaccines in children (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				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) 15–21 days: 0.9 (0.4–2.0)	
Shui I. M. et al.,2012[184] Cohort	Children receiving RotaTeq in U.S. (N=786,725 total doses, which included 309,844 first doses) Mean age: NR Age range: 4 – 34 weeks	RotaTeq		RR (95% CI) for intussusception vs. concurrent comparison group administered any other vaccine. All doses 1 to 7 days 0.90 (0.10 – 11.08) 1 to 30 days 0.95 (0.37 – 2.63) Dose 1 1 to 7 days Undefined (0.01, Undefined) 1 to 30 days Undefined (0.22, Undefined) Dose 2 1 to 7 days 0.00 (0.00 – 17.30) 1 to 30 days 0.36 (0.07 – 1.65) Dose 3 1 to 7 days 1.57 (0.08 – 92.75) 1 to 30 days 1.57 (0.34 – 9.72)	
Yih, et al. 2013,[185]Self-controlled risk interval (SCRI) and a cohort design	N=124 total cases, 613,000 infant-years; Location=U.S.; Age=5-36.9 weeks; Setting=Post-Licensure Rapid Immunization Safety Monitoring program (PRISM), participants were members of Mini-Sentinel Data Partners Aetna, HealthCore, or Humana	RotaTeq, Rotarix	SCRI: age Cohort: age, sex, Data Partner, and exposure status	Case counts and risk estimates (RR, 95% CI) for Brighton Level 1 confirmed intussusception after RotaTeq, risk estimates incorporate a correction factor for cases lacking charts (which make up 22% of the total by dose, study design, and age adjustment. Attributable potential cases ascertained). Pre-specified: Tate age-adjustment Post-hoc: PRISM age-adjustment SCRI, Risk Window 1-7 days Dose 1 Pre-specified: 9.1, 2.2-39 Post-hoc: 7.0, 1.7-29 Dose 2 Pre-specified: 1.8, 0.4-7.2	Not reported

Table 23. Postmarketing studies of rotavirus vaccines in children (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				Post-hoc: 1.8, 0.4-7.2 Dose 3 Pre-specified: 2.2, 0.5-9.7 Post-hoc: 2.3, 0.5-10 All Pre-specified: 3.3, 1.5-7.4 Post-hoc: 3.0, 1.4-6.8 SCRI, Risk Window 1-21 days Dose 1 Pre-specified: 4.2, 1.1-16 Post-hoc: 3.4, 0.9-13 Dose 2 Pre-specified: 1.0, 0.3-3.1 Post-hoc: 1.0, 0.3-3.1 Dose 3 Pre-specified: 1.0, 0.2-3.9 Post-hoc: 1.0, 0.2-4.0 All Pre-specified: 1.6, 0.8-3.3 Post-hoc: 1.5, 0.7-3.1 Cohort Dose 1 Pre-specified: 2.6, 1.2-5.8 Post-hoc: 2.9, 1.4-6.0 Dose 2 Pre-specified: 0.9, 0.4-2.2 Post-hoc: 0.8, 0.3-2.0 Dose 3 Pre-specified: 0.9, 0.4-2.2	

Table 23. Postmarketing studies of rotavirus vaccines in children (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				Post-hoc: 0.9, 0.4-2.2 All Pre-specified: 1.3, 0.8-2.1 Post-hoc: 1.3, 0.8-2.1 Table 3. Case counts and risk estimates for Brighton Level 1 confirmed intussusception after Rotarix, by dose, study design, and age adjustment. Pre-specified: Tate age-adjustment Post-hoc: PRISM age-adjustment SCRI, Risk Window 1-7 days Dose 1 Pre-specified: infinity Post-hoc: none Dose 2 Pre-specified: 3.5, 0.5-25 Post-hoc: 3.6, 0.5-25 Dose 3 Pre-specified: 5.7, 0.9-34 Post-hoc: 5.5, 0.9-33 SCRI, Risk Window 1-21 days Dose 1 Pre-specified: infinity Post-hoc: none Dose 2 Pre-specified: 1.7, 0.3-10 Post-hoc: 1.7, 0.3-10	

Table 23. Postmarketing studies of rotavirus vaccines in children (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				Dose 3 Pre-specified: 2.3, 0.4-13 Post-hoc: 2.3, 0.4-13 Cohort Dose 1 Pre-specified: 2.9, 0.4-22 Post-hoc: 3.2, 0.4-23 Dose 2 Pre-specified: 5.1, 1.6-16 Post-hoc: 4.6, 1.5-15 Dose 3 Pre-specified: 3.8, 1.4-10 Post-hoc: 3.7, 1.4-10	

CI = confidence interval; OR = odds ratio

Note: Additional study details presented in Appendix C evidence tables.

Hepatitis B Vaccine

Although no epidemiological studies were identified by the IOM, mechanistic evidence "favored acceptance" of a causal relationship between the vaccine and anaphylaxis in yeast-sensitive individuals. The IOM found insufficient evidence to accept or reject a causal relationship with any other AEs. A 2002 IOM review on Hepatitis B vaccine and demyelinating neurological disorders concluded that the evidence "favors rejection" of a causal relationship with incident MS or MS relapse. [98]

We found no trials and one postmarketing study of Hepatitis B vaccine in children or adolescents. Data from this study are displayed in Table 24.

Autism

Gallagher and Goodman (2010)[186] conducted a secondary analysis of 7,074 boys, age 3 to 17 years, born prior to 1999, using the National Health Interview Survey through 2002. Vaccination status and health outcomes were reported by parents in an interview with trained interviewers who asked them to gather vaccination records in advance. Data were analyzed using a logistic regression adjusted for race/ethnicity, two-parent household, and maternal education. Result was significant for the risk of autism in children who received their first dose of Hepatitis B vaccine during the first month of life (OR 3.00, 95% CI 1.11, 8.13), compared with those who received the vaccination after the first month of life or not at all. Significant protective factors included non-Hispanic white ethnicity (OR 0.36, 95% CI 0.15, 0.88), and belonging to a household with two parents (OR 0.30, 95% CI 0.12, 0.75). It is unclear why the authors selected "first month of life" as the only vaccination time period studied, without presenting analyses for other time periods or comparing "ever vaccinated" with "never vaccinated."

The IOM found "insufficient" evidence of association of Hepatitis B vaccine with any short or long term adverse events in children. Our findings support that conclusion. Based on the newly identified study discussed above, there is insufficient evidence of an association of the Hepatitis B with autism in children.

Table 24. Postmarketing study of Hepatitis B vaccine in children and adolescents

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Gallagher and Goodman, 2010[186] Cross-sectional	N=7,074 (30 with autism, 7,044 without autism); Location=U.S.; Age=boys 3 through 17 years born prior to 1999; Used National Health Interview Survey data	Hepatitis B	Race/ethnicity, two-parent household, maternal education	OR (95% CI) of autism diagnosis Received first dose of Hepatitis B vaccine during first month of life, compared with receipt after first month of life or not at all OR=3.00 (1.11-8.13)	Non-Hispanic white: 0.36 (0.15-0.88) Two-parent household 0.30 (0.12-0.75) Maternal education, high school or higher 2.32 (0.85-6.30)

CI = confidence interval; OR = odds ratio

Note: Additional study details presented in Appendix C evidence tables.

HPV

The IOM committee studied the HPV vaccine, which is administered to adolescents and young adults in the United States. Except where noted below, studies did not report specific AEs by age. The IOM committee found the evidence "favors acceptance" of a causal relationship between the HPV vaccine and anaphylaxis. The IOM committee found the evidence is "inadequate to accept or reject" causal relationships between the HPV vaccine and the following: ADEM, transverse myelitis, neuromyelitis optica, MS, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, amyotrophic lateral sclerosis, transient arthralgia, pancreatitis, thromboembolic events, and hypercoagulable states.

We found thirteen additional reports of trials of the HPV vaccine in children and adolescents; eleven[187-193] were original trials, and two[194,195] were longitudinal follow ups of clinical trials. Data from these studies are displayed in Table 25. Participants were between 7 and 27 years of age and received either placebo or three doses of vaccine (either Cervarix or Gardasil). The trials were conducted in North America, South America, Asia, Europe, Australia, and Africa. Most participants were female; one trial[187] with a later follow-up[193] was conducted in males. That trial found a significant association between vaccination with Gardasil and respiratory and thoracic disorders in the 15 days post-vaccination (OR 20.78, 95% CI 7.09, 60.89). One study of Gardasil[190] included only children with HIV; that trial found no AEs associated with vaccination.

A trial of 208 females in Korea[191] found an association between Cervarix and medically significant adverse conditions (OR 1.94, 95% CI 1.23, 3.07). Cervarix was associated with the following Grade 3 (severe) adverse events: arthralgias (OR 2.68, 95% CI 1.29, 5.59), fatigue (OR 1.96, 95% CI 1.39, 2.77), GI symptoms (OR 2.41, 95% CI 1.39, 4.19), and rash (OR 2.67, 95% CI 1.23, 5.80). (In this study, Grade 3 events were defined as severe enough to prevent normal daily activity.)

A Cervarix trial conducted in Taiwan, Germany, Honduras, Panama, and Columbia[196] followed girls aged 10 to 14 for 48 months post-vaccination. The vaccine was not associated with serious adverse events in the short or long term. However, only girls who had received the vaccine were followed long term; therefore, there is no control group for the follow-up phase of the study, and long-term safety could not be evaluated versus control. A trial conducted in West Africa[197] did not find an association between Cervarix and onset of chronic disease (OR 0.49, 95% CI 0.29-1.23). A small trial (N = 67) in Bangladesh [198] found Cervarix associated with "any adverse event" in the five days after each of the three doses. Adverse events included fever, headache, GI symptoms, and injection site issues. The most common AE was pain at the injection site; this was reported by 50% of vaccinees after Dose 1 and 72% after Dose 2.

A strong association between Gardasil and "vaccine related adverse events" was found in a Korean trial.[199] during seven months follow-up. There was no difference in rate of serious AEs between vaccine and placebo group. Again, the most common AE was pain at injection site, reported by 72.6% of vaccinees.

We identified a secondary analysis[200] of data on young black women enrolled in two double-blind placebo-controlled trials of Gardasil (N = 706) in North America, South America, and Europe. This report presented results separately for women who became pregnant within the follow-up period that ranged from three to four years; they comprised one quarter of the study participants. Receipt of vaccine was associated with spontaneous abortion (miscarriage): in the vaccine group 19 of 307 pregnancies resulted in spontaneous abortion, compared to seven of 393 pregnancies in the placebo groups. Of note, HPV vaccine is not recommended for pregnant

women. Study participants were required to be on birth control and were tested for pregnancy before each of the three required vaccinations. Anyone testing positive was excused from the study.

Table 25. Vaccinated versus unvaccinated adolescents: HPV vaccine

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Block S. L. et al.,2010[188] Asia, Europe, Latin America, North America	Controlled Clinical Trial	7	Sample size : 21,480, 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: 0 Days Dose2: 2 Month Dose3: 6 Month	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)
De Carvalho N. et al.,2010[194] Brazil	Controlled Clinical Trial, Follow-up	3	Sample size : 433, Mean age: 26.5, Percent female: 100%, 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 Days Dose2: 1 Month Dose3: 6 Month	Medically significant adverse event (any): OR 1.344 (0.641-2.816)

Table 25. Vaccinated versus unvaccinated adolescents: HPV vaccine (continued)

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Giuliano A. R. et al.,2011[193] 18 countries	Controlled Clinical Trial, follow-up	4	Sample size : 3,895, 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. Adjuvant: Aluminum, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days Dose2: 2 Month Dose3: 6 Month	Death (entire study period): OR 0.3 (0.082-1.091)
Khatun S. et al.,2012[192] Bangladesh	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	Not calculable

Table 25. Vaccinated versus unvaccinated adolescents: HPV vaccine (continued)

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Kim S. C. et al.,2011[191] Korea	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 aluminum hydroxide [AI(OH)3, 500 mcg]), Adjuvant: ASO 4-Aluminum, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days Dose2: 1 Month Dose3: 6 Month	Medical significant adverse condition: OR 1.942 (1.227-3.073)** New onset chronic diseases: OR 0.41 (0.199-0.846)** Solicited - Arthralgias (Grade 3): OR 2.682 (1.287-5.591)** Solicited - Fatigue (Grade 3): OR 1.959 (1.388-2.766)** Solicited - Fevers (Grade 3): OR 1.725 (0.355-8.377) Solicited - GI symptoms (Grade 3): OR 2.405 (1.381-4.19)** Solicited - Headache (Grade 3): OR 1.633 (1.101-2.422)** Solicited - Myalgia (Grade 3): OR 2.275 (1.582-3.272)** Solicited - Rash (Grade 3): OR 2.668 (1.228-5.8)** Solicited - Urticaria (Grade 3): OR 2.156 (0.608-7.651) Unsolicited - Breast and reproductive system: OR 2.651 (0.763-9.208) Unsolicited - Infections and infestations: OR 2.149 (0.927-4.983) Unsolicited - any AE (Grade 3): OR 0.078 (0.026-0.232)**
Levin M. J. et al.,2010[190] U.S. (not stated explicitly)	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 Days Dose2: 8 Weeks Dose3: 24 Weeks	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[189] China	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: 0 Days Dose2: 2 Month Dose3: 6 Month	Systemic AE (any): OR 1.122 (0.81-1.553) Systemic AE (vaccine-related): OR 1.066 (0.747-1.522)

Table 25. Vaccinated versus unvaccinated adolescents: HPV vaccine (continued)

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Moreira Jr E. D. et al.,2011[187] 18 countries including Brazil, Germany, Mexico, U.S., South Africa, Australia, Canada	Controlled Clinical Trial	7	Sample size : 4,065, 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 hydroxyphosphate sulfate (AAHS) adjuvant, Adjuvant: Aluminum, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days Dose2: 2 Month Dose3: 6 Month	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[195] Brazil	Controlled Clinical Trial, follow-up	NC	Sample size : 436, Mean age: 26.5, Age range: 15 - 25, Percent female: 100%, Percent Pregnant: 17%	Human papillomavirus (HPV), HPV-16/18, GlaxoSmithKline, Described in another study, Adjuvant: ASO 4, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days Dose2: 1 Month Dose3: 6 Month	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)

Table 25. Vaccinated versus unvaccinated adolescents: HPV vaccine (continued)

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Schwarz, T.F. et al. 2012[196] Taiwan, Germany, Honduras, Panama, and Colombia	Controlled Clinical Trial	NC	Sample size : 588, Mean age: 12, Percent female: 100%, Percent pregnant: Percent Pregnant: 5%	Human papillomavirus (HPV) , HPV-16/18 AS04-adjuvanted vaccine, GlaxoSmithKline, Each dose of the HPV-16/18 vaccine consisted of 20 ®g each of HPV-16 and HPV-18 L1 proteins, self-assembled as virus-like particles, adjuvanted with the Adjuvant System AS04 (comprising 500 ®g of aluminum hydroxide and 50®g of MPL), Adjuvant: ASO4, Preservative: Not reported, Delivery: Not reported	Dose1: 0 Days Dose2: 1 Month Dose3: 6 Month	New onset chronic disease: OR 2.822 (1.818-4.38)**
Sow, P. S. et al. 2013[197] Senegal, Tanzania	Controlled Clinical Trial	5	Sample size : 676, Mean age: 16.9, Age range: 10 - 25, Percent female: 100%	Human papillomavirus (HPV) , Cervarix , GlaxoSmithKline, Each dose of HPV-16/18 AS04-adjuvanted vaccine Cervarix ® (GlaxoSmithKline Vaccines) contained 20 µg each of HPV-16 and HPV-18 L1 virus like particles, 50 µ g of 3-O-desacyl-4 ' - monophosphoryl lipid A, and 500 µ g of Al(OH)3, Adjuvant: Aluminum, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days Dose2: 1 Month Dose3: 5 Month	Medically significant condition: OR 0.745 (0.518-1.07) New onset autoimmune disease: OR 0.5 (0.07-3.573) New onset chronic disease: OR 0.49 (0.209-1.148) SAE: OR 0.595 (0.288-1.229)

Table 25. Vaccinated versus unvaccinated adolescents: HPV vaccine (continued)

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Khatun, S. et al. 2012[198] Bangladesh	Controlled Clinical Trial	4	Sample size : 67, Mean age: NR, Age range: 9 - 13, Percent female: 100%	Human papillomavirus (HPV), Cervarix , GlaxoSmithKline , In this preparation, the L1protein of each HPV type is expressed via a recombinant baculo virus vector. The VLPs of each HPV type are produced separately and consist of purified L1 VLPs ofHPV-16/18 at 20/20-g per dose formulated on AS04 adjuvant comprising 500 gm of aluminum hydroxide and 50 gmof 3-deacylated monopods phage lipid ., Adjuvant: ASO 4 , Preservative: Not reported, Delivery: Not reported	Dose1: 0 Days Dose2: 1 Dose3: 6	Any AE after 1st dose: OR 16 (4.043-63.326)** Any AE after 2nd dose: OR 53.778 (9.89-292.432)** Any AE after 3rd dose: OR 81 (12.938-507.104)**
Kang, S. et al. 2008[199] Korea	Controlled Clinical Trial	4	Sample size : 176, Mean age: 16.6, Age range: 9 - 23, Percent female: 100%	Human papillomavirus (HPV) , Gardasil , Merck , Mixture of four recombinant HPV type-specific VLPs consisting of the L1 major capsid proteins of HPV 6,11, 16, and 18 synthesized in Saccharomyces cerevisiae. The four VLP types were purified and adsorbed onto amorphous aluminum hydroxyphosphate sulfate adjuvant. , Adjuvant: Aluminum , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Days Dose2: 1 Month Dose3: 6 Month	Vaccine related AE: OR 154.063 (20.474-1159.27)**

Table 25. Vaccinated versus unvaccinated adolescents: HPV vaccine (continued)

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Clark, L.R. et al. 2013[200] Europe, Latin America, North America	Controlled Clinical Trial. Long-term follow-up	3	Sample size : 700, Mean age: 20, Age range: 16 - 24, Percent female: 100%, Percent pregnant: Percent Pregnant: 25%	Human papillomavirus (HPV) , Not reported. Quadrivalent vaccine targeting HPV-6/11 , Gardasil, Merck Sharp & Dohme, Corp. , Quadrivalent vaccine targeting HPV-6/11/16/18 , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Days Dose2: Month 2 Dose3: Month 6	Abnormal live birth: OR 0.766 (0.182-3.23) Congenital or other anomaly - live birth: OR 1.281 (0.08-20.564) Number of fetal losses: OR 7.876 (2.694-23.025)** One or more injection-site AE: OR 1.384 (1.024-1.871)** One or more systemic AE: OR 1.362 (0.988-1.876) Spontaneous abortion: OR 0.798 (0.44-1.447) Vaccine-related systemic AE: OR 1.414 (0.977-2.046)

AAHS = amorphous aluminum hydroxyphosphate sulfate; AE = adverse event; $Al(OH)_3$ = aluminium hydroxide; CI = confidence interval; GI = gastrointestinal; HIV = human immunodeficiency virus; HPV = human papillomavirus; MPL = monophosphoryl lipid; OR = odds ratio; QHPV = quadrivalent human papillomavirus; SAE = serious adverse events

**Statistically significant.

Note: Additional study details presented in Appendix C evidence tables.

We found three postmarketing studies of HPV in adolescents / young adults published after the IOM report and one long-term follow-up of trial participants. Data from the studies are presented in Table 26.

Various Illnesses

Between August 2006 and March 2008, Chao et al. (2012)[201] followed 189,629 females, aged 9 to 26 years, who had received the HPV vaccine from two MCOs. Immunization with HPV vaccine was ascertained by a review of health records and health outcomes were identified through electronic health records followed by in-depth case review by a panel of experts. Data were analyzed to generate incidence rate ratio (IRR) estimates of onset of select autoimmune conditions in the vaccinated group compared to unvaccinated female populations of similar age. Vaccinated patients had a significantly lower incidence of juvenile rheumatoid arthritis (IRR 0.36, 95% CI 0.14, 0.71) and Type 1 diabetes (IRR 0.54, 95% CI 0.45, 0.70), they had a higher incidence of Hashimoto's disease (IRR 2.02, 95% CI 1.65, 2.60); the authors report that an investigation of a temporal relationship and biological plausibility revealed no consistent evidence of a safety signal.

Gee et al. (2011)[202] studied the administration of 600,558 doses of HPV4 in females age 9 to 26 years in seven large MCOs between August 2006 and October 2009. Vaccination status and health outcomes were confirmed using weekly standardized data files from participating MCOs. Case ascertainment was limited to the first episode in a particular time period. Data were analyzed using Poisson based maximized sequential probability ratio test (MaxSPRT) and a logistic regression model (appendicitis only). The logistic regression was adjusted for sex, age, and seasonality. No statistically significant increased risk for any of the pre-specified adverse events (appendicitis, Guillain Barré Syndrome, seizures, stroke, syncope, venous thromboembolism) was detected after vaccination.

Klein and colleagues[203] analyzed data from enrollees in a California MCO who had received either Gardasil or Cervarix. Over 44,000 females received all three recommended doses. Fifty medical categories had significantly elevated ORs during at least one risk interval. Patient chart review found that most diagnoses existed before vaccination or that diagnostic workups were initiated at vaccine visit. Experts judged that only skin infections within two weeks of vaccine (OR, 1.8; 95% CI, 1.3-2.4) and syncope on day of vaccination (OR, 6.0; 95% CI, 3.9-9.2) were likely associated with the vaccine.

Summary

Short term adverse events including fever, headache, GI symptoms, and injection site issues were associated with HPV vaccine consistently in double-blind placebo-controlled trials. The most common adverse event was pain at the injection site; strength of evidence is high for this association due to the overwhelming consistency of results. Strength of evidence is moderate for the others listed.

A large high quality post-licensure study conducted in the U.S. found that HPV vaccine was associated with skin infection within two weeks and syncope on day of vaccination. SOE is moderate due to low risk of bias and strong study design.

The IOM found evidence "favors acceptance" of a causal relationship between the HPV vaccine and anaphylaxis in children and adolescents who may be allergic to ingredients. Our review of the IOM supports this finding; thus, strength of evidence is rated moderate.

We found moderate strength evidence that HPV vaccine is not associated with onset of juvenile rheumatoid arthritis or Type 1 diabetes. Although we identified only one post-licensure study on these diseases, the study included hundreds of thousands of doses and used computerized medical records to confirm vaccination and outcomes. We found insufficient evidence that HPV vaccine may be associated with onset of Hashimoto's disease, as the one study that investigated a temporal relationship and biological plausibility revealed no consistent evidence of a safety signal.

Strength of evidence is moderate that HPV vaccine is not associated with appendicitis, Guillain Barré Syndrome, seizures, stroke, or venous thromboembolism, based on a well-designed study of over 600,000 doses administered to patients in US HMOs.

A secondary analysis of long-term follow-up data on young black women who participated in two controlled trials of HPV vaccine reported an association with spontaneous abortion of pregnancies within three to four years of vaccination. There is insufficient evidence to conclude causality; however, this signal should be investigated in other data sets.

The IOM found that the evidence is "inadequate to accept or reject" causal relationships between HPV vaccine and the following: ADEM, transverse myelitis, neuromyelitis optica, MS, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, amyotrophic lateral sclerosis, transient arthralgia, pancreatitis, thromboembolic events, and hypercoagulable states. We reviewed their findings and agree with their conclusions. Thus, strength of evidence is rated insufficient to determine association of these sequelae with vaccination.

Table 26. Postmarketing studies of HPV vaccine in children and adolescents

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Chao et al. 2012[201] Prospective cohort	N=189,629 females who received HPV Age=9–26 years; Setting=Two managed care organizations in California	HPV4 - Gardasil	Not reported	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 hemolytic anemia - 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 (0.38–2.13) Optic neuritis: 1.45 (1.00–2.91) Uveitis: 1.28 (0.53–6.39)	Not reported
Gee et al. 2011[202] Prospective cohort	N=600,558 doses of HPV4; Females age 9-26 years in7 large managed care organizations (MCOs)in U.S.	HPV4 - Gardasil	Logistic regression: sex, age, and seasonality	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.	Not reported

Table 26. Postmarketing studies of HPV vaccine in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Klein, et al. 2012,[203], Retrospective cohort	N=189,629; Location=California; Age=9-26 years; Setting=Kaiser Permanente in California	HPV4 - Gardasil	None	ORs Following HPV4 Vaccination in the Combined ED/Hospital Setting, All Doses Combined Viral infection Days 1-60 Risk Interval: 1.1 (0.9-1.3) Days 1-14 Risk Interval: 1.5 (1.2-2.0) Attention-deficit, conduct, and disruptive behavior disorders Days 1-60 Risk Interval: 1.5 (1.2-2.0) Days 1-14 Risk Interval: 1.5 (1.0-2.3) Disease of nervous system and sense organs Days 1-60 Risk Interval: 1.0 (0.9-1.1) Days 1-14 Risk Interval: 1.2 (1.0-1.3) Ear conditions Days 1-60 Risk Interval: 1.2 (1.0-1.5) Days 1-14 Risk Interval: 1.5 (1.1-1.9) Disorders of peripheral nervous system Days 1-60 Risk Interval: 2.1 (1.0-4.2) Days 1-14 Risk Interval: 2.1 (0.8-5.7) Diseases of circulatory system Days 1-60 Risk Interval: 1.1 (1-1.3) Days 1-14 Risk Interval: 1.2 (1.0-1.5) Diseases of heart Days 1-60 Risk Interval: 1.1 (0.1-1.3) Days 1-14 Risk Interval: 1.3 (1.0-1.6) COPD and bronchiectasis Days 1-60 Risk Interval: 1.5 (1-2.2) Days 1-14 Risk Interval: 1.8 (1.1-3.2)	None

Table 26. Postmarketing studies of HPV vaccine in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				Asthma Days 1-60 Risk Interval: 1.2 (1.1-1.4) Days 1-14 Risk Interval: 1.21 (1-1.47) Disease of skin and subcutaneous tissue Days 1-60 Risk Interval: 1.0 (0.8-1.1) Days 1-14 Risk Interval: 1.5 (1.2-1.9) Skin and subcutaneous tissue infections Days 1-60 Risk Interval: 1.1 (0.9-1.4) Days 1-14 Risk Interval: 1.8 (1.3-2.4) Cellulitis and abscess Days 1-60 Risk Interval: 1.1 (0.8-1.4) Days 1-14 Risk Interval: 1.6 (1.2-2.3) Diseases of musculoskeletal system and connective tissue Days 1-60 Risk Interval: 1.1 (1-1.2) Days 1-14 Risk Interval: 1.2 (1.0-1.4) Spondylosis, disc intervertebral disorders, back problems Days 1-60 Risk Interval: 1.1 (0.9-1.3) Days 1-14 Risk Interval: 1.4 (1.0-1.8) Congenital anomalies Days 1-60 Risk Interval: 1.6 (1.1-2.3) Days 1-14 Risk Interval: 2.5 (1.6-4.0) Other congenital anomalies Days 1-60 Risk Interval: 1.8 (1.1-3.0) Days 1-14 Risk Interval: 3.6 (2.0-6.3) Fever of unknown origin Days 1-60 Risk Interval: 1.1 (0.9-1.4) Days 1-14 Risk Interval: 1.5 (1.0-2.1)	

Table 26. Postmarketing studies of HPV vaccine in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				Lymphadenitis Days 1-60 Risk Interval: 1.0 (0.6-1.8) Days 1-14 Risk Interval: 2.3 (1.2-4.4) Diabetes mellitus Days 1-60 Risk Interval: 2.2 (1.1-4.4) Days 1-14 Risk Interval: 2.5 (1.0-6.4) Attention-deficit disorder Days 1-60 Risk Interval: 1.7 (1.1-2.8) Days 1-14 Risk Interval: 2.1 (1.1-4.1) Personality disorders Days 1-60 Risk Interval: 1.8 (0.9-3.4) Days 1-14 Risk Interval: 2.8 (1.3-6.4) Disorders of teeth and jaw Days 1-60 Risk Interval: 1.1 (0.6-2.1) Days 1-14 Risk Interval: 2.6 (1.2-5.6) Congenital anomalies Days 1-60 Risk Interval: 1.7 (1.0-2.8) Days 1-14 Risk Interval: 2.7 (1.4-5.3) Other congenital anomalies Days 1-60 Risk Interval: 2.3 (1.1-5.0) Days 1-14 Risk Interval: 5.1 (2.2-11.9)	

CI = confidence interval; HPV = human papillomavirus; IRR = incidence rate ratio; MCOs = managed care organizations
Note: Additional study details presented in Appendix C evidence tables.

Varicella

The IOM committee found evidence "convincingly supports" causal relationships in children between varicella virus vaccine and the following: disseminated Oka VZV without other organ involvement; disseminated Oka VZV with subsequent infection resulting in pneumonia,[204] meningitis, or hepatitis in individuals with demonstrated immunodeficiencies; vaccine strain viral reactivation without other organ involvement; vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis;[205] and anaphylaxis.[204]

The IOM committee found the evidence is "inadequate to accept or reject" a causal relationship between the varicella virus vaccine and the following: seizures, ADEM, transverse myelitis, Guillain-Barré syndrome, small fiber neuropathy, onset or exacerbation of arthropathy, and thrombocytopenia.

We found one new study in children (Table 27). Barbosa, 2012[206] randomized 54 Brazilian children with systemic lupus erythematosus (SLE) to placebo or vaccine, and also vaccinated 28 healthy children who were matched controls. The authors reported no difference in AEs between placebo and control groups. Data on specific AEs was not provided.

Summary

Based on our review of the IOM findings, there is high strength evidence that vaccination of immunocompromised children against varicella is associated with disseminated Oka VZV with or without subsequent infection resulting in pneumonia,[204] meningitis, or hepatitis. There is insufficient evidence regarding association of varicella virus vaccine and seizures, ADEM, transverse myelitis, Guillain-Barré syndrome, small fiber neuropathy, onset or exacerbation of arthropathy, and thrombocytopenia.

Based on one small controlled trial of vaccine in Brazilian children, there is insufficient evidence to determine whether varicella vaccine is safe in children with SLE.

Table 27. Vaccinated versus unvaccinated children and adolescents: varicella vaccine

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Barbosa, C.M..et al. 2012[206] Brazil	Controlled Clinical Trial	4	Sample size : 134, Mean age: 15, Age range: 5 - 18, Percent female: 78%	Varicella, Biken, Aventis Pasteur, >=1000 plaque forming units of virus/0.5 mL. Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days	Incalculable. Authors stated no difference in AEs

CI = confidence interval; HIV = human immunodeficiency virus; OR = odds ratio; NR = not reported

Note: Additional study details presented in Appendix C evidence tables.

Diphtheria Toxoid, Tetanus Toxoid, and Acellular Pertussis-Containing Vaccines

The IOM studied diphtheria toxoid, tetanus toxoid, and acellular pertussis-containing vaccines alone and in combination, in both children and adults. The IOM committee did not find evidence that "favors acceptance" of causal relationships for any conditions. They found the evidence "favors rejection" of a causal relationship between type 1 diabetes and vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens.[207-211] The IOM committee found the evidence is "inadequate to accept or reject" causal relationships between diphtheria toxoid-, tetanus toxoid- or acellular pertussis-containing vaccine and the following: infantile spasms; seizures; cerebellar ataxia; autism; ADEM; transverse myelitis; MS relapse in children; serum sickness; immune thrombocytopenic purpura; and SIDS.

We found no additional studies in children published after the IOM search date; our review of their findings leads to a rating of moderate strength of evidence for each of the associations they investigated.

Meningococcal Vaccine

The IOM found the evidence "convincingly supports" a causal relationship with anaphylaxis in children who may be allergic to ingredients. The committee found the evidence "inadequate to accept or reject" causal relationships between meningococcal vaccine and the following: encephalitis, encephalopathy, ADEM, transverse myelitis, MS, Guillain-Barré syndrome, CIDP, and chronic headache. The IOM conclusion does not differentiate between meningoccal conjugate or meningococcal polysaccharide vaccine.

We found two studies of quadrivalent meningococcal conjugate vaccine in children (Table 28)[212,213] published after the IOM report. A trial in Saudi Arabia found no statistical association with Grade 2 or 3 fever, malaise, myalgia or headache in the short term. A trial in the United States and South America[213] found vaccination was not associated with severe change in eating habits, severe irritability, severe persistent crying, severe sleepiness or urticaria in the year following vaccination. Per the findings of the IOM, strength of evidence is moderate that meningococcal vaccine may cause anaphylaxis in children who are allergic to ingredients. Strength of evidence is insufficient to determine an association between meningococcal vaccine and the serious adverse events encephalitis, encephalopathy, ADEM, transverse myelitis, MS, Guillain-Barré syndrome, CIDP, and chronic headache. Strength of evidence is insufficient to determine association with less serious events such as headache, irritability, and urticaria.

Table 28. Vaccinated versus unvaccinated studies of meningococcal vaccines in children and adolescents

Author-Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Khalil, M. et al. 2012[212] Saudi Arabia	Controlled Clinical Trial	4	Sample size : 238, Mean age: 6.3, Age range: 5 - 8, Percent female: 55.0%	Meningococcal conjugate , Menactra, PA , Sanofi , Quadrivalent (A, C, Y, and W-135) meningococcal diphtheria toxoid-conjugate vaccine , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Days	Grade 2-3 Fever: OR 1.508 (0.389-5.842) Grade 2-3 Headache: OR 1.113 (0.099-12.453) Grade 2-3 Malaise: OR 4.027 (0.487-33.3) Grade 2-3 Myalgia: OR 2.255 (0.248-20.507) SAE - Headache (unsolicited AE): OR 0.553 (0.034-8.949)
Klein, N.P. et al. 2012[213] U.S., Colombia, Argentina	Controlled Clinical Trial	2	Sample size : 1508, Mean age: 65.5, Age range: 55 - 89, Percent female: 47.8%	Meningococcal conjugate, Routine Vaccines , NR (likely Novartis, the trial sponsor) , Lyophilized Men A component with liquid MenCWY component, Each dose contained 10micrograms of MenA oligosaccharides and 5microgram each of MenC, MenW-135, and MenY conjugated to CRM197 (~50microgram) , Adjuvant: Not Reported, Preservative: Not reported, Delivery: Intramuscular	Dose1: 0 Days Dose2: 2 Month Dose3: 2 Month	Severe change in eating habits (12m): OR 3.574 (0.439-29.129) Severe change in eating habits (6m): OR 0.507 (0.102-2.519) Severe irritability (12m): OR 0.675 (0.233-1.955) Severe irritability (6m): OR 3.06 (0.367-25.49) Severe persistent crying (12m): OR 0.761 (0.214-2.707) Severe sleepiness (12m): OR 0.507 (0.102-2.519) Severe sleepiness (6m): OR 3.06 (0.367-25.49) Urticaria (12m): OR 0.507 (0.102-2.519) Urticaria (6m): OR 0.888 (0.259-3.048)

CI = confidence interval; NR = not reported; OR = odds ratio

Note: Additional study details presented in Appendix C evidence tables.

Studies of Multiple Vaccines

Allergies/Asthma

We identified five postmarketing studies on allergic symptoms, wheezing, or asthma, that were not included in the IOM report. These, along with all studies of multiple vaccines in children, are displayed in Table 29. A study in the Netherlands using parent questionnaires to ascertain vaccination status and health outcomes found no association between receipt of a combined DTP-IPV vaccine and asthma, hay fever, eczema, food allergy or atopic disorders (Bernsen, 2006).[214] A case-control study of over 2,000 children with atopic dermatitis and a family history of allergy in twelve Western countries (Gruber, 2008)[215] found newborns immunized against polio had higher odds (OR 2.60, 95% CI 1.08, 6.25) of sensitivity to food allergens. This relationship did not hold for those immunized against polio later in life. The study also found that a significant relationship between Hepatitis B vaccine in the first 6 months of life with elevated total IgE (OR 1.48, 95% CI 1.03, 2.13). Varicella vaccine seemed to have a protective effect against elevated total IgE. A German study (Mommers, 2004)[216] found no relationship between vaccination against pertussis, measles, rubella, or Hib and atopic disease. A self-controlled case series of premature infants born in the United States (Mullooly, 2007)[217] found no increased risk of wheezing and lower respiratory syndrome associated with DTaP, inactivated polio virus (IPV), Hib, varicella, PCV7, MMR, or TIV vaccination. In fact, some of the vaccines had a protective effect in the week after vaccination. Finally, Thomson[218] found no association of MMR vaccine with asthma in an Australian cohort. (Two diphtheria-tetanus vaccines not currently used in the United States were also studied; no association with asthma was found.)

Seizures

Sun, 2012[219] examined national registry data on over 378,000 children who received a combined DTaP-IPV-Hib vaccine in Denmark from 2003-2009. They assessed the association of vaccination with febrile seizures, controlling for birth circumstances, demographics, and family history of epilepsy. In both a cohort analysis and self-controlled case series (SCCS), risk of febrile seizures on the day of vaccination was significant (cohort – first vaccination, HR 6.02, 95% CI 2.86, 12.65; cohort – second vaccination, HR 3.94, 95% CI 2.18, 7.10; SCCS - first vaccination, HR 6.49, 95% CI 3.10, 13.61; SCCS – second vaccination, HR 3.97, 95% CI 2.20, 7.16). An American study (Chen, 1997)[220] investigated the relationship between DTP and MMR vaccines and seizures in children from four HMOs in the United States. For DTP, the relative risk for seizures was elevated on the day of vaccination (RR 2.20, 95% CI 1.50, 3.40). For MMR, the risk was elevated on days 4 to 7 (RR 1.80, 95% CI 1.20, 2.70) and 8 to 14 (RR 2.50, 95% CI 2.20, 3.30) after vaccination. The authors also investigated the relationship between Td vaccination and emergency department visit or hospitalization. They found that risk of emergency department visit was elevated within 14 days of vaccination.

Gold, 2010[221] also studied the relationship between DTP and MMR vaccines and seizures. They used Australian registry data and medical records to ascertain vaccination status and health outcomes. For MMR, the risk for seizures was elevated between days 6 to 11 after exposure (IRR 2.11 95% CI 1.43, 3.10). For DTP, the risk was not elevated during any time period studied.

Bell's Palsy

A small self-controlled case series of 233 Bell's Palsy cases in Northern California (Rowhani, 2012)[222] found no association with vaccination with TIV or Hepatitis B vaccine.

Guillain-Barre Syndrome (GBS)

Velentgas and colleagues[223] were tasked with investigating the association between meningococcal conjugate vaccine and GBS in children and adolescents enrolled in five MCOs in the United States. Between March 2005 and August 2008, there were no reported cases of GBS within 42 days following vaccination with MCV4. The same was true for Tdap, Td, and Tetanus vaccination. There was one case each for MPSV4 and HPV; there were two cases reported for TIV and Hepatitis B vaccine. The authors calculated the attributable risks per one million vaccinations as displayed in Table 29 below.

Leukemia

Groves and colleagues[224] included 439 children in nine Midwest and Mid-Atlantic states with lymphoblastic leukemia in a case-control analysis to investigate any possible relationship with oral or injected polio vaccine, diphtheria-tetanus pertussis vaccine, MMR, Hib, or Hepatitis B vaccine. Controls were selected using random-digit dialing, which resulted in controls of higher SES then the 439 cases. Analysis controlled for age at censoring, year of birth, sex, race, family income, parental education and attendance at daycare and/or preschool. Data collection forms were completed by mothers using vaccination records. None of the vaccines were associated with leukemia.

The relationship between vaccination and leukemia was also assessed in a case-control study of children enrolled in a large HMO in Northern California. (Ma, 2005)[225] Cases were matched on date of birth, sex, and race / ethnicity. Analysis also controlled for maternal education and family income. Vaccination and diagnosis were ascertained through medical records. None of the vaccines investigated (DPT, polio vaccine, MMR, Hib, Hepatitis B vaccine) were associated with increased risk of leukemia.

The Cross-Canada Childhood Leukemia Study (MacArthur, 2008)[226] was a case control study which found no association between vaccines against mumps, measles, rubella, diphtheria, tetanus, pertussis, polio, or Hepatitis B and leukemia. Vaccinations were administered from 1990 to 1994. Data was acquired through population registries. Analysis adjusted for 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, gender, and age.

Finally, a case-control study of over 14,000 children born in Texas (Pagaoa, 2011)[227] found no association between DTaP, IPV, MMR, Hib, Hepatitis B, and Varicella vaccines and acute lymphoblastic leukemia using data from cancer registry and medical records. Analysis adjusted for sex, child's birth year, child's ethnicity, child's birth weight, mother's age at child's birth.

Diabetes

Hummel[228] conducted a secondary analysis of data from the BABYDIAB study in Germany to investigate the possible association of many factors (breast feeding, vaccinations, environmental, infections) and development of islet antibodies before the age of two. They included vaccines for Hib, measles, mumps, and rubella (separately) in their analyses; no association with the vaccines was found.

Purpura

A recent analysis investigated possible relationships between Hib, PCV, MMR, DTaP, TIV, Hepatitis A, varicella, and meningococcal vaccines and immune thrombocytopenic purpura (ITP) in children enrolled in five U.S. HMOs. (O'Leary, 2012)[143] In children from 12 to 19 months of age, MMR vaccine was associated with purpura (IRR 5.48, 95% CI 1.61, 18.64). None of the vaccines were associated with purpura in children aged two to six years. Purpura was associated with vaccination against Hepatitis A in children aged 7 to 17 years (IRR 23.14, 95% CI 3.59, 149.30) and a vaccination against varicella in children aged 11 to 17 years (IRR 12.14, 95% CI 1.10, 133.96).

Encephalitis

Pahud, 2012 investigated whether various factors were associated with encephalitis in California children and adolescents.[229] Of 1,434 cases, immunization records were requested for over 800 and received for only 246. Of these, 136 were excluded due to incomplete records or no vaccinations in the one-year observation period. In the 110 encephalitis cases included, there was no association with either measles virus-containing vaccines or pertussis antigen-containing vaccines.

Summary

Strength of evidence is insufficient to determine an association between polio vaccine in newborns and sensitivity to food allergens. Strength of evidence is also insufficient to determine an association between Hepatitis B vaccine in the first 6 months of life and elevated total IgE. Strength of evidence is based on associations reported in one medium size study (N = 2,173) of children with a family history of food allergy living in 12 countries in multiple continents.

Strength of evidence of association of DTaP-IPV-Hib vaccination with febrile seizures in children in the short-term is moderate, based on a very large, high quality study.

There is high strength evidence that MMR, DTaP, Td, Hib, Hepatitis B, and polio vaccine vaccinations are not associated with childhood leukemia.. This rating is based on four high quality case-control studies that consistently found no association. All studies had low risk of bias and adjusted for important confounders in their analyses.

In the short-term, purpura was associated with vaccination against Hepatitis A in children aged 7 to 17 years, vaccination against varicella in children aged 11 to 17, and MMR in children from 12 to 19 months of age. Strength of evidence is moderate. Cases were rare (one or two per age group), and the majority were mild.

Table 29. Postmarketing studies of multiple vaccines in children and adolescents

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Bernsen et al. 2006[214] Retrospective Cohort	N=1,875; Location=Netherlands; Age=8-12 years; Setting=Orthodox Reformed (Protestant) primary schools	DTP-IPV (diphtheria-tetanus-pertussis-(inactivated) poliomyelitis vaccination)	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 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; 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) wholegrain bread (yes/no); Frequent (at least 1 day/week) consumption of fish; Frequent exercise (school gym 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	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 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)	Not reported

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
			walking or cycling from home to school vice versa for at least 1 h a day); Body mass index; Hib vaccination.		
Gruber et al. 2008[215] Retrospective cohort	N=2,173 (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 influenzae* Type B, Hepatitis B, mumps, measles, rubella, varicella, BCG, meningococci and pneumococci	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	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) Hepatitis B immunization later on in life: NS OR (95% CI) for sensitivity to food allergens Newborns immunized against polio: 2.60 (1.08–6.25,) 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), (0.12–0.93)	Not reported
Mommers et al. 2004,[216] Case-control	N=510; Location=Dutch-German borderland; Age=7-8 years; Setting=Study on respiratory health in children conducted in the Dutch-German borderland, involving the Municipal Health Services of Kreis Heinsberg,	Bacille Calmette-Guérin (BCG), pertussis, measles/mumps, rubella, and Haemophilus influenza type b (Hib)	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.	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	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

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
	Germany and of the Westelijke Mijnstreek, the Netherlands			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) 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)	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 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 .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)

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				Allergic sensitization Pertussis: 1.04 (0.73–1.47) Measles: 1.59 (0.61–4.17) Rubella: 0.80 (0.54–1.19) Hib: 0.94 (0.67–1.32)	Sensitized against HDM 0.29 (0.05–1.71)
Mullooly et al. 2007[217] Case-control	N=1,074 (844 atopy cases, 230 controls); Location=West Coast; Age=6-16 years; Setting=Kaiser Permanente Northwest (KPNW) HMO	DTP, MMR, HBV, IPV, HIB	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 (1978–93, 1994–99, 2000–01)	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 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)	Not reported

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Thomson et al. 2010[218] Prospective cohort	N=488; Location=Australia; Age=2-6 years (outcomes ascertained at 6 years); Setting=Melbourne Atopy Cohort Study (MACS), an ongoing prospective cohort study initiated in 1989	Triple antigen [diphtheria, tetanus and pertussis (DTP)], combined diphtheria and tetanus (CDT), measles mumps rubella (MMR)	Parental socio-demographics, allergic disease, parental smoking history; parental education; gender of child and older siblings, pet ownership of at least one dog and/or cat	RR (95% CI) for Asthma Triple antigen (DTP) 1st year: 4.75 (0.88, 25.58) 2nd year: 0.74 (0.56, 0.96) 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)	RR (95% CI) for Asthma Socio-demographics child Gender (male) 1.61 (1.21, 2.14) Older siblings (at least 1) 1.27 (1.17, 1.38) Characteristics mother Asthma 1.43 (1.07, 1.90) Eczema 1.32 (1.02, 1.72) Drug allergy 1.33 (1.02, 1.74) Characteristics father Asthma 1.34 (1.01, 1.79) Allergic rhinitis 1.37 (1.04, 1.81) Parent's education, parents' marital status, pet ownership: NS
Sun et al. 2012[219] Prospective cohort study and self-controlled case series	N=378,834 (cohort study), 7,811 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	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	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	Differences between boys and girls not significant.

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				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 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)	
Chen et al. 1997[220] Prospective cohort	N=~242,000 Location=U.S.; Age=0-6 years; Setting=Vaccine Safety Datalink (VSD) project (4 HMOs, Group Health Cooperative (GHC) of Puget Sound in Washington, Northwest Kaiser Permanente (NWK) in Oregon, Northern California Kaiser (NCK), and Southern California Kaiser (SCK) Permanente	DTP, MMR,	stratified by HMO and birth date, adjusted for other vaccines	Relative risk (and 95% confidence interval) of seizures and persistent seizure disorders 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 (0.50-1.00) 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 MMR. After adjustment the association with MMR persisted (2.42 (1.8-3.2)).	Not reported

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Gold et al. 2010[221] Self Controlled Case Series	N= 323 cases of febrile seizures Location=South Australia; Age=0-7 years;	MMR, DTP	SCCS method accounted for exposure period and age	IRR for febrile seizures MMR vaccine Exposure period −1 to −14 days: 0.58 (0.33–1.02) Exposure period 6 to 11 days: 2.11 (1.43–3.10) Exposure period 15 to 35 days: 0.90 (0.65–1.25) DTP vaccine Exposure period −1 to −14 days: 0.56 (0.33–0.94) Exposure period 0 to 3 days: 0.59 (0.24–1.45) Exposure period 4 to 7 days: 0.94 (0.46–1.91) Exposure period 8 to 14 days: 0.93 (0.54–1.62)	Not reported
Rowhani-Rahbar et al. 2012[222] Case-centered	N=233 cases of Bell's Palsy; Age=<=18 years; Setting=Kaiser Permanente Northern California population	TIV, Hepatitis B	Not reported	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)	Not reported

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Groves et al. 1999[224] Case-control	N=878; Location=nine Midwestern and Mid-Atlantic states; Age=0-14 years; Setting=Patients with acute lymphoblastic leukemia (ALL), diagnosed between 1989 and 1993. Subjects who resided in Illinois, Indiana, Iowa, Michigan, Minnesota, New Jersey, Ohio, Pennsylvania, or Wisconsin at the time of diagnosis were eligible for the vaccination component of the study.	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 influenzae* group b (Hib) vaccines, Hepatitis B virus vaccine and other vaccines	Age at censoring, year of birth, sex, race, family income, parental education and attendance at day-care and/or preschool	Effect of vaccination (ever vs. never) on subsequent risk of childhood acute lymphoblastic leukemia (439 matched pairs) OR (95% CI) 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 influenzae b* (Hib): 0.73 (0.50–1.06) (Presumptive) polysaccharide vaccine: 1.13 (0.64–1.98) (Presumptive) conjugate vaccine: 0.57 (0.36–0.89)	Not reported
Ma et al. 2005,[225] Case-control	N=732; Location=California; Age=0-14 years; Setting=Northern California Childhood Leukemia Study (major pediatric clinical centers)	DPT, polio, MMR, Hib, Hepatitis B	Matched on date of birth, sex, mother's race and Hispanic status Adjusted for maternal education and annual household income	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)	Not reported

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				ALL: 0.81 (0.66, 0.98) Hepatitis B Leukemia: 0.97 (0.77, 1.23) ALL: 1.01 (0.78, 1.31)	
MacArthur et al. 2008[226] Case-control	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)	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, gender, and age.	Vaccinations in childhood and risk of childhood leukemia, the Cross-Canada Childhood Leukemia Study, 1990–1994 OR (95% CI) 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) Hepatitis 1.09 (0.34-3.52) Other vaccine 0.81 (0.58-1.13)	Not reported
Pagaoa et al. 2011[227] Case-control	N=14,000 (2,800 cancer cases, 11,200 controls); Location=Texas; Age=2 to 17 years; Setting=Texas Cancer Registry combined with birth certificate data to identify eligible participants	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 Hib), 4-3-1-3-3, 4-3-1-3-3-1	Stratified analyses with infant sex, race/ethnicity, maternal age at birth, birth weight, and parity. Subjects matched on sex and birth year Adjusted for sex, child's birth year, child's ethnicity, child's birth weight, mother's age at child's birth	No associations found between any vaccine and any type of cancer.	Not reported

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Hummel et al. 2000[228] Prospective cohort	N=823; Location=Germany; Age=0-2 years; Setting=German BABYDIAB Study	Bacille Calmette-Guérin [BCG]); Haemophilus influenzae (HIB); diphtheria, tetanus, and pertussis (DTP); poliomyelitis; tick-born encephalitis (TBE); and measles, mumps, and rubella (MMR)	Not reported	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)	Not reported
O'Leary et al. 2012[143] Retrospective cohort	N=1.8 million from 5 managed care organizations; Location=Colorado, Hawaii, Georgia, Northern CA, Massachusetts; Age=6 weeks to 17 years;	MMR, Hepatitis A, varicella, Tdap, Hib	Not reported	IRR for immune thrombocytopenic purpura (ITP) 6 wk to 11 mo Hib, PCV: Not significant (NS) 6 to 23 mo TIV: NS 12 to 19 mo MMR: 5.48 (1.61, 18.64) MMRV, DTaP, Hib, PCV: NS 12 to 23 mo Hep A: NS 2 to 6 years TIV, Hep A: NS 4 to 6 years MMR, VAR, DTaP, IPV: NS 7 to 17 years Hep A: 23.14 (3.59, 149.30) TIV: NS 11 to 17 years VAR: 12.14 (1.10, 133.96) Tdap: 20.29 (3.12, 131.83) HPV, MCV: NS	Not reported

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Pahud et al. 2012 Case-centered method	N=110 encephalitis cases; Location=CA; Age= 6 months to 18 years	Many analyzed, measles virus-containing vaccines and pertussis antigen containing vaccines reported	Not reported	Association with pre-defined risk windows Measles virus-containing vaccines 5–15 days: OR=1.31 (0.30–5.77) Pertussis antigen-containing vaccines 0–3 days: OR=1.37 (0.33–5.78)	Not reported
Velentgas et al. 2012,[223] Retrospective cohort study	N=12.6 million; Location=U.S.; Age=11 to 21 years Setting: Five U.S. health plans	Meningococcal conjugate vaccine (MCV4); meningococcal polysaccharide vaccine (MPSV4), tetanus–diphtheria–acellular–pertussis vaccine (Tdap), tetanus and diphtheria vaccine (Td), tetanus, hepatitis B (HepB), human papillomavirus (HPV), and influenza vaccination	None	Incidence and attributable risk of GBS , per millions vaccinations MCV4 Cumulative incidence; one sided upper CI: 0; 2.09 Attributable risk: 0; 1.46 MPSV4 Cumulative incidence; one sided upper CI: 7.79; 37.00 Attributable risk: 7.16; 36.37 Tdap Cumulative incidence; one sided upper CI: 0; 2.49 Attributable risk: 0; 1.86 Td Cumulative incidence; one sided upper CI: 0; 8.02 Attributable risk: 0; 7.39 Tetanus Cumulative incidence; one sided upper CI: 0; 106.20 Attributable risk: 0; 105.57 Influenza Cumulative incidence; one sided upper CI: 3.49; 11.00 Attributable risk: 2.86; 10.37 HepB	None

Table 29. Postmarketing studies of multiple vaccines in children and adolescents (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
				Cumulative incidence; one sided upper CI: 8.04; 38.10 Attributable risk: 7.40; 37.47 HPV Cumulative incidence; one sided upper CI: 3.42; 10.80 Attributable risk: 2.79; 10.17	

BCG = Bacillus Calmette–Guérin; CI = confidence interval; CDT = combined diphtheria and tetanus; DTP = diphtheria, tetanus and pertussis; DTP-IPV = diphtheria-tetanus-pertussis-(inactivated) poliomyelitis vaccination; GHC = Group Health Cooperative; HBV = hepatitis B vaccine; HDM = house dust mite; Hep A = hepatitis A; Hib = *Haemophilus influenzae* Type b; HMO = health maintenance organization; HPV = human papillomavirus; IPV = polio vaccine; IRR = incidence rate ratio; ITP = immune thrombocytopenic purpura; MACS = Melbourne Atopy Cohort Study; MCV = measles-containing vaccine; MMR = measles, mumps, rubella; NCK = Northern California Kaiser; NWK = Northwest Kaiser Permanente; OR = odds ratio; SCCS = self-controlled case series; SCK = Southern California Kaiser; TBE = tick-born encephalitis; VAR = varicella; VSD = vaccine safety datalink

Note: Additional study details presented in Appendix C evidence tables.

Key Question 3: What is the evidence that vaccines recommended for **pregnant women**[25] are safe both for the woman and for her fetus/infant?

a. What AEs are collected in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?

b. What AEs are reported in clinical studies (phases I–IV) and in observational studies containing a control/comparison group?

Table 30 lists AEs collected or reported in studies of vaccines in pregnant women, abstracted verbatim. We interpreted "collected" to mean those specified a priori by investigators, while "reported" were any AEs reported by participants. The list does not imply an association with vaccination, as it contains AEs regardless of whether they were reported in vaccinated or unvaccinated study participants. Later we describe the studies further and assess association.

Table 30. Adverse events collected or reported in studies of pregnant women

Vaccine	Adverse Event
Influenza (inactive)	• Chest tightness or difficulty breathing • Cough • Death • Fever • Infant: Dermatitis contact • Infant: Hyperbilirubinemia neonatal • Infant: Respiratory distress • Infant: Seborrheic dermatitis • Infant: Upper respiratory tract infection • Malaise • Maternal: At least one adverse event • Maternal: Fever, cough, runny nose, nasal congestion, and skin itching • Maternal: Severe adverse event • Myalgia/Arthralgia • Small for gestational age • Sore throat, hoarseness, or pain swallowing • Stillbirth • Swelling of the face
Influenza - monovalent H1N1	• 5min APGAR score <7 • Allergy • Auricle defect • Chest infection • Chest pain • Cleft palate • Clubfoot • Congenital anomalies • Coryza • Cough • Death • Diarrhea • Downs Syndrome • Dyspnea • Ebstein's anomaly

Table 30. Adverse events collected or reported in studies of pregnant women (continued)

Vaccine	Adverse Event
	• Fetal death • Flu-like symptoms • Gestational diabetes • Headache • Hip dysplasia • Hydrocephalus • Hypertension • Hypospadias • Imperforate lacrimal duct • Infections • Inferior vena cava (IVC) syndrome • Intrauterine Growth Restriction (IUGR) • Laryngomalacia • Limb pain • Malaise • Mild pulmonary artery stenosis • Miscarriage • Myalgia • Nausea, Influenza, Pain, viral infection • Neonatal death (1st, 2nd and 3rd Tri) • Neonatal pathologies • Pelvic kidney • Persistent arterial duct • Pharyngitis • Premature rupture of membranes (PROM) • Prematurity • Preterm birth • Preterm labor • Pulmonary valve stenosis • Pyelitic dilatation • Pyrexia • Rash • Right pyelitic hypotension • Sinusitis • Skin tag on finger • Small for gestational age • Spontaneous abortion (1st, 2nd and 3rd Tri) • Stillbirth (01st, 2nd and 3rd Tri) • Talipes calcaneus • Trisomy 21# • Umbilical hernia • Unilateral cryptorchidism • Varus equinus • Ventriculomegaly Very preterm (<32w)

IUGR = intrauterine growth restriction; IVC = inferior vena cava; PROM = premature rupture of membranes

Key Question 3 – Pregnant Women (Continued):

c. What AEs are associated with these vaccines in women?

    1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?

    2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]

    3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether the vaccine is administered individually or in a combination vaccine product, the schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

d. What AEs are associated with these vaccines in the fetus/infant?

    1. For each AE associated with a particular vaccine, what is the average severity (grade 1/mild; grade 2/moderate; grades 3 and 4/severe)?

    2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?[a]

    3. For each AE associated with a particular vaccine, what are risk factors for the AE (including age, gender, race/ethnicity, genotype, underlying medical condition, whether vaccine administered individually or in a combination vaccine product, vaccine schedule of administration, adjuvants, medications administered)?

Influenza Vaccines

We identified four studies comparing vaccinated and unvaccinated pregnant women; the results are displayed in Table 31. A cohort study by Lin et al in Taiwan[230] compared 396 pregnant women who received AdimFlu-S influenza A (monovalent H1N1) between October 2009 and February 2010 with unvaccinated pregnant women; no difference in SAEs was

[a] Level of certainty was operationalized as the 95-percent confidence interval surrounding the risk or odds estimate—i.e., the statistical significance.

reported. A comparison of the medical records of the age-matched groups showed that significantly fewer women in the vaccinated group experienced at least one adverse event during the study period compared to unvaccinated women (OR 0.37, 95% CI 0.22, 0.68). One statistically significant adverse event difference in the infants was observed: hyperbilirubinemia was much less common in the vaccinated group (OR 0.08, 95% CI 0.03, 0.2).

A Canadian cohort study[231] by Fell and colleagues included 55,570 pregnant women who delivered a single baby during the 2009/2010 influenza season. Women vaccinated during pregnancy with monovalent H1N1 influenza vaccines were statistically less likely to experience a fetal death (OR 0.60, 95% CI 0.44-0.81), preterm birth defined as below 37 weeks gestational age (OR 0.92, 95% CI 0.85, 0.98), infants small for their gestational age (OR 0.74, 95% CI 0.66, 0.83), or delivering infants before gestation week 32 (OR 0.72, 95% CI 0.58, 0.88). Richards[232] also studied receipt of monovalent H1N1 by pregnant women. Receipt of vaccination was associated with lower risk of low birth weight and premature infants.

Nordin[233] used the VSD to assess the safety of TIV in pregnant women. No cases of GBS, transverse myelitis, optic neuritis, or Bell's Palsy were reported in the 42 days post-vaccination in this cohort of over 200,000 women. No association between the vaccine and serious adverse events was found. Infant outcomes were not studied.

Table 31. Cohort comparison studies of influenza vaccines in pregnant women

Author-Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Fell D. B. et al.,2012[231] Canada	Cohort	4	Sample size : 55,570, Mean age: NR, Age range: <18 - 40+	Influenza - monovalent H1N1, NR, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: 0 Days	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)**
Lin T. H. et al.,2012[230] Taiwan	Cohort	7	Sample size : 396, Mean age: 32.4,	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 influenza vaccines. The vaccine is a monovalent, unadjuvanted, inactivated, split-virus vaccine. One shot (0.5ml) of AdimFlu-Influenza (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	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)**
Dodds, L. et al. 2012[234] Canada	Cohort	NC	Sample size: 9,647, Age range: <20 - >=35,	Influenza (inactived), NR, Not reported, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: 0 Days	Composite outcome: OR 0.823 (0.636-1.067) Low birth weight: OR 0.702 (0.547-0.901)** Preterm birth: OR 0.842 (0.689-1.028) Small for gestational age <10th percentile: OR 0.749 (0.614-0.914)** Term low birth weight: OR 0.751 (0.488-1.154)

Table 31. Cohort comparison studies of influenza vaccines in pregnant women (continued)

Author-Year-Country	Study Design	McHarm Score	Population	Vaccine	Timing	OR, 95% CI, Versus Unvaccinated Group
Nordin, J.D. et al. 2013[233] USA	Cohort	NC	Sample size: 223,898, Mean age: 30.8, Age range: 14 –– 49	Influenza (inactived) , NR, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: 0 days	Altered mental status (3 day f/u): OR 1.329 (0.69-2.563) Autonomic disorders (42d f/u): OR 0.487 (0.054-4.361) Meningoencephalitis (42 d): OR 5.849 (0.608-56.235) Peripheral neuropathy or neuritis (42 d): OR 1.95 (0.876-4.34) cellulitis (3 day f/u): OR 0.928 (0.437-1.972)
Richards, J.L. et al. 2013[232] U.S.	Cohort	2	Sample size : 3,327, Mean age: 31.2, Age range: NR	Influenza (inactived), Influenza - monovalent H1N1, NR, Adjuvant: Not Reported, Preservative: Not reported, Delivery: Not reported	Dose1: 0 days	Low Birth weight (<2500g): OR 0.706 (0.522-0.956)** Pre-term birth (27-36 wk): OR 0.602 (0.461-0.787)** Preterm Birth (27-33 wk): OR 0.505 (0.297-0.859)** Preterm Birth (34-36 wk): OR 0.657 (0.486-0.889)** Small for gestational age: OR 1.144 (0.868-1.508)

CI = confidence interval; NR = not reported; OR = odds ratio

**Statistically significant.

Note: Additional study details presented in Appendix C evidence tables.

Post-licensure studies are displayed in Table 32. One study (Omer, 2011)[235] on TIV included 4,168 pregnant women and their newborns followed during the 2004/05 and 2005/06 flu seasons in the United States. Vaccination status and health outcomes were ascertained using self-reported data. The analysis adjusted for potential confounders including various types of influenza activity periods, maternal health, and demographic variables. Results showed that infants born during the influenza 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, 0.94). This relationship increased (adjusted OR 0.44, 95% CI 0.26, 0.73) during periods of local influenza activity, and was at its greatest during periods of widespread influenza activity. Results also indicate that during widespread influenza activity periods, newborns of vaccinated mothers had 69% lower odds of being small for gestational age (adjusted OR 0.31, 95% CI 0.13, 0.75) compared with newborns of unvaccinated mothers. Irving[236] used VSD to conduct a case-control study of miscarriage; no association with TIV was found.

Regarding monovalent H1N1, (Xu, 2012)[237] studied data obtained from 198 pregnant women who enrolled before 20 weeks of gestation in the U.S. Vaccine and Medication in Pregnancy Surveillance System study. The aim of this study was not to assess the effect of H1N1 on childbirth outcomes, but to illustrate the use of survival analysis methods. Data were analyzed using time-independent (naive) and time-dependent covariate Cox models to account for left-truncation (due to possible enrollment later than conception). The model was adjusted for time of vaccine exposure (1^{st}, 2^{nd} trimester), previous spontaneous abortion events, maternal smoking habits, age, and the presence of asthma. Vaccination was not statistically associated with spontaneous abortions during any trimester.

Summary

We found moderate strength evidence that neither monovalent H1N1 vaccine nor trivalent inactivated vaccine (TIV) is associated with serious adverse events in pregnant women or their offspring. Several studies report that these vaccines decrease the risk of adverse pregnancy outcomes.

Table 32. Postmarketing studies of influenza vaccines in pregnant women

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Omer et al. 2011[235] Retrospective cohort	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.	TIV	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 multivariate models by testing which potential confounders moved the relationship between immunization and birth outcome closer to 1.	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 mothers had 69% lower odds of being SGA (adjusted OR 0.31, 0.13 to 0.75).	Not reported
Irving, et al. 2013,[23][6] Case-control	N=486 (243 cases, 243 controls); Location=U.S.; Age=18-44 years; Setting=six health care organizations in the Vaccine Safety Datalink	Influenza TIV	Maternal age, health care utilization, maternal diabetes, parity	Odds of Influenza Vaccination in Cases of Early Pregnancy Loss in Varying Exposure Windows as Compared With Control Group Participants Adjusted ORs, 95% CI, p-value Primary analysis Exposed 1-28 d before reference date: 1.23 (0.53-2.89), 0.63 Exposed more than 28 d before reference date: 1.24 (0.54-2.86), 0.61 Secondary analysis Exposed while pregnant 0.80 (0.36-1.78), 0.58 Exposed before pregnant 2.34 (0.86-6.33), 0.10	None

Table 32. Postmarketing studies of influenza vaccines in pregnant women (continued)

Author / Year / Study Design	Population	Vaccines	Adjusted for These Confounders	Results Regarding Vaccine	Results Regarding Risk Factors
Xu et al. 2012[237] Retrospective cohort	198 pregnant women who enrolled before 20 weeks gestation; U.S./Vaccine and Medication in Pregnancy Surveillance System study	H1N1	Vaccine exposure (1st or 2nd trimester) Previous spontaneous abortion (SAB) events (0, 1, 2, >=3) smoking maternal age asthma Dependent variable: Spontaneous abortion (SAB)	Spontaneous abortion (SAB) RR (time-independent): 1.13(0.13, 10.24) RR (time-dependent): 1.13(0.13, 10.24) Vaccination during 1st trimester (n=119) SAB 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 loss>20weeks is still-birth, not SAB)(n=34) No. SAB: 0 Vaccination during 1st or 2nd trimester (n=153) SAB RR (time-independent): 0.58(0.10, 3.24) RR (time-dependent): 0.97(0.24, 3.94)	Not reported

CI = confidence interval; OR = odds ratio; PRAMS = Pregnancy Risk Assessment Monitoring System; RR = risk ratio; SAB = spontaneous abortion; SGA = small for gestational age

Note: Additional study details presented in Appendix C evidence tables.

Summary and Discussion

At the request of AHRQ and the Office of the Assistant Secretary for Health (OASH) we conducted an assessment of the evidence for the safety of vaccines recommended for routine use in the United States among adults, children, and pregnant women, according to ACIP guidelines. We conducted an extensive literature search for clinical trials and observational studies meeting our inclusion criteria: cohort studies comparing vaccinated and unvaccinated groups, case-control studies, self-controlled case series, and multivariate risk factor analyses. In this chapter, we describe the limitations of our review and present our conclusions. We also include a section on Research Gaps.

Limitations

Our literature search procedures were extensive; however, some unpublished trial results may not have been identified. An independent Scientific Resource Center (SRC) under contract with AHRQ requested Scientific Information Packets (SIPs) from the manufacturers of all vaccines routinely recommended in the United States. (The research team was prohibited from contacting manufacturers directly.) Only two companies responded; both manufacture vaccines against seasonal influenza.

We excluded non-English language studies. Although we were considering only vaccines approved for use in the United States, it is possible relevant epidemiological studies have been published in non-English journals.

An important limitation common to systematic reviews is the quality of the original studies included. We used a quality-rating instrument[32] developed by another Evidence-based Practice Center specifically to evaluate studies reporting harms. The scores are presented in the results tables and taken into consideration when rating the strength of the evidence. Studies that reported timing and severity, and defined AEs using standard, precise definitions were rated higher than those that did not. Epidemiological studies that used medical records to ascertain vaccination and health outcomes were also rated higher than those that relied on patient or parent report. Strengths and weaknesses of studies vary according to their design. Cohort studies of vaccines may use multivariate analyses to control for confounding factors, but they cannot capture potential differences between those who get vaccinated and those who do no. Self-controlled case series control for patient characteristics that do not change over time (gender, race-ethnicity, genetics) but cannot capture factors that are time-related. This is especially important when studying vaccinations of infants and toddlers.

Studies using passive surveillance such as the U.S. Vaccine Adverse Event Reporting System (VAERS),[16] are crucial in identifying signals regarding adverse events post-licensure. However, because by definition they do not consider the rate of such events in non-vaccinated populations, they are not designed to assess a statistical association between a vaccine and an adverse event, so they were excluded from this project. Thus, there may be important adverse event signals not identified in this report that warrant future research.

We included controlled trials that used formulations currently approved in the United States. We tried to exclude Phase II studies that used dosages that were never licensed and/ or formulations available only in other countries. Some studies reported the potency of the vaccines under study in a different manner or unit than that reported in other studies or the product materials. We assessed these findings to the best of our capabilities. We point out discrepancies in our results text.

Except where explicitly stated in the text, controlled trials of vaccines are conducted in healthy patients. Thus, persons who may be more susceptible to AEs may be excluded from trials, yet eligible to receive a vaccine after it is licensed. In addition, trials are generally underpowered to detect very rare events. For example, a trial of 1,000 patients may not detect an AE with an expected incidence of one in 5,000. Trials may also be underpowered to assess risk factors for the AEs they do detect.

Post-licensure epidemiological studies are conducted to investigate possible associations between vaccines and AEs reported in passive surveillance or multiple case reports. Such studies often do not limit their investigation to a particular brand or formulation. They may lump vaccines against a specific disease together. For example, a study might investigate the effect of "seasonal influenza vaccines" in general. Formulations of seasonal influenza vaccines change each season, the vaccine comes in inactivated or live form, and a particular batch may or may not contain a strain of H1N1. It is difficult to assess the applicability of studies that do not report specific details about vaccines.

In many studies, the severity of AEs was not reported. Our researchers coded the severity according to CATAE classification when possible. Severity is listed in our tables where available.

Most studies did not investigate potential risk factors for AEs that were found to be associated with vaccination.

Some post-licensure surveys use patient or parent recall for ascertainment of vaccination or health outcomes, rather than medical records. Subjects may not have copies of their vaccination or medical records, introducing recall bias. Advanced health information technology (HIT) systems that contain vaccination and medical records can make surveys unnecessary, leading to higher quality studies. In the United States, the CDC's Vaccine Safety Datalink (VSD) uses data obtained through such systems at nine large health care organizations, enabling very high quality studies. Nations with single payer healthcare often have electronic registries, which allow epidemiological studies of entire populations.

Conclusions

Table 33 summarizes our conclusions, given the caveats described in the Limitations section. The second column displays the strength of evidence (SOE) regarding statistical association of each vaccine type with key AEs.

Table 33. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Adults			
Diphtheria Toxoid, Tetanus Toxoid, and Acellular Pertussis Vaccines (Td, Tdap)	**High -** anaphylaxis	Evidence **"convincingly supports"** a causal relationship between the tetanus toxoid vaccine and anaphylaxis.	We identified two additional trial in adults. No AEs were associated with vaccine.
Hepatitis A Vaccine	**Insufficient-** acute disseminated encephalomyelitis, transverse myelitis, MS, Guillain-Barré Syndrome, chronic inflammatory disseminated polyneuropathy, Bells' Palsy, anaphylaxis, and autoimmune hepatitis	Evidence is **"inadequate to accept or reject"** any causal relationships with AEs the committee was tasked with investigating: acute disseminated encephalomyelitis, transverse myelitis, MS, Guillain-Barré Syndrome, chronic inflammatory demyelinating polyneuropathy, Bells' Palsy, anaphylaxis, and autoimmune hepatitis.	We identified one additional post-licensure study; there was no association of the vaccine with any adverse events or onset of medical conditions.

Table 33. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Hepatitis B Vaccine	**Insufficient -** optic neuritis, first demyelinating event, Guillain-Barré Syndrome, SLE, onset or exacerbation of vasculitis, polyarteritis nodosa, and onset or exacerbation of rheumatoid arthritis **Moderate** – No association with MS onset or exacerbation **Moderate** – anaphylaxis in patients allergic to yeast	Although no epidemiological studies were identified on anaphylaxis, mechanistic evidence **"favors acceptance"** of a causal relationship between the vaccine and anaphylaxis in yeast-sensitive individuals. Epidemiological studies of the following AEs in adults had evidence **"inadequate to accept or reject"** a causal relationship: optic neuritis, first demyelinating event, Guillain-Barré Syndrome, SLE, onset or exacerbation of vasculitis, polyarteritis nodosa, and onset or exacerbation of rheumatoid arthritis. A 2002 IOM review on Hep B vaccine and demyelinating neurological disorders concluded that the evidence "**favors rejection**" of a causal relationship with incident MS or MS relapse. No epidemiological studies of the following AEs in adults were found, evidence is also **"inadequate to accept or reject"** a causal relationship: encephalitis, encephalopathy, acute disseminated encephalomyelitis ADEM, transverse myelitis, neuromyelitis optica, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, erythema nodosum, onset or exacerbation of psoriatic arthritis, onset or exacerbation of reactive arthritis, and fibromyalgia.	No additional studies met our inclusion criteria.

Table 33. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Influenza Vaccines	**High –** arthralgia, myalgia, malaise, fever, pain at injection site, anaphylaxis **High –** 2009 Monovalent H1N1 vaccine with Guillain-Barré Syndrome (GBS) **High** – No association with cardiovascular events in the elderly **Insufficient** - Multiple Sclerosis (MS) onset & exacerbation	Studied two forms of influenza vaccine: live attenuated form, administered intranasally (LAIV), and inactivated form (TIV), administered intramuscularly. Evidence **"convincingly supports"** a causal relationship between influenza vaccines and anaphylaxis in persons allergic to egg or gelatin. However, in recent years, manufacturers have reduced the egg protein content.	Many clinical trials reported that influenza vaccines are associated with arthralgia, myalgia, malaise, fever, and pain in the short-term in adults. These adverse events (AEs) were not considered serious; severity was graded mild to moderate. Odds of experiencing these events were 1.5 to 2 times higher in vaccinated patients than in unvaccinated. Risk factors were not discussed in the trials. A high quality meta-analysis found an association between 2009 monovalent H1N1 vaccine and Guillain-Barré Syndrome (GBS) in the 42 days post vaccination; results translate to about 1.6 excess cases per million vaccinated. Post-licensure studies have found inconsistent evidence associating influenza vaccines with onset or exacerbation of MS in adults. Post-licensure studies have found influenza vaccines are NOT associated with increased risk of cardiovascular or cerebrovascular events in the elderly. Post-licensure studies have shown that influenza vaccines are NOT associated with increased risk of serious AEs (SAEs) in renal patients.
MMR Vaccine	**Moderate** – No association with Type 1 diabetes **Moderate -** transient arthralgia in women **Insufficient** - MS onset, Guillain-Barré Syndrome, chronic arthralgia in women, and chronic arthritis and arthropathy in men.	**Evidence "favors acceptance"** of a causal relationship with transient arthralgia in women. Evidence is **"inadequate to accept or reject"** a causal relationship with MS onset, Guillain-Barré Syndrome, chronic arthralgia in women, and chronic arthritis and arthropathy in men.	MMR was NOT associated with onset of type 1 diabetes in adults in one large high quality epidemiological study. RR=0.71 (95% CI 0.61, 0.83)

Table 33. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Pneumococcal Polysaccharide Vaccine	**High –** No association cardiovascular or cerebrovascular events in the elderly	Not covered	We found no placebo-controlled trials of the current formulation that reported adverse events data. (We did find trials of the current formulation that reported pneumonia or mortality; these were considered efficacy outcomes). Post-licensure studies of pneumococcal polysaccharide vaccine found vaccination was not associated with increased risk of cardiovascular events in older adults.
Zoster Vaccine	**Moderate** – injection site reactions, allergic reactions cellulitis possibly related to allergy	Recommended for U.S. adults over age 60; AEs specific to this age group were not covered.	In some reports of clinical trials, adverse events were reported only in categories such as "injection–related adverse events," "systematic adverse events," or "serious adverse events". Vaccination was associated with injection site reactions. In post-licensure studies, vaccination was associated with cellulitis possibly related to allergy and allergic reactions, such as redness and swelling 1 to 7 days post vaccination. These mild AEs occurred in less than 1% of patients, and were more likely in the younger (aged 50-59) vaccinees.[85,86]
Children and Adolescents			
Diphtheria Toxoid, Tetanus Toxoid, and Acellular Pertussis-Containing Vaccines (DTap, Td, Tdap)	**Moderate -** No association with type 1 diabetes **Insufficient -** infantile spasms, seizures, cerebellar ataxia, autism, ADEM, transverse myelitis, MS relapse, serum sickness, immune thrombocytopenic purpura, and SIDS.	Evidence **"favors rejection"** of a causal relationship between vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens and type 1 diabetes. Evidence is **"inadequate to accept or reject"** causal relationships between vaccination and the following: infantile spasms, seizures, cerebellar ataxia, autism, ADEM, transverse myelitis, MS relapse in children, serum sickness, immune thrombocytopenic purpura, and SIDS.	We found no additional studies that met our inclusion criteria.

Table 33. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Hepatitis B Vaccine	I**nsufficien**t – food allergy **Moderate** – No association with MS	Although no epidemiological studies were identified by the IOM, mechanistic evidence "**favored acceptance"** of a causal relationship between the vaccine and anaphylaxis in yeast-sensitive individuals. The IOM found evidence **"inadequate to accept or reject"** a causal relationship with any other AEs. A 2002 IOM report **"favors rejection"** of a causal relationship with MS onset or exacerbation.	Hepatitis B vaccine in the first 6 months of life was associated with elevated total IgE in a post-licensure study of children with a family history of food allergy, but not with clinical allergy[215215216216]
Hib	**Moderate –** No association with Serious Adverse Events in short term	Not covered	No serious adverse events were associated in three high quality clinical trials.
HPV Vaccine	**Moderate –** No association with juvenile rheumatoid arthritis, Type 1 diabetes, appendicitis, Guillain Barré Syndrome, seizures, stroke, syncope, venous thromboembolism **Moderate** – anaphylaxis in persons with allergies, fever, headache, mild GI AEs, skin infection **High** – Pain at injection site **Insufficient** - ADEM, transverse myelitis, neuromyelitis optica, MS, onset of Hashimoto's disease, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, amyotrophic lateral sclerosis, transient	Evidence **"favors acceptance"** of a causal relationship between the HPV vaccine and anaphylaxis. Evidence is **"inadequate to accept or reject"** causal relationships between HPV vaccines and the following: ADEM, transverse myelitis, neuromyelitis optica, MS, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, amyotrophic lateral sclerosis, transient arthralgia, pancreatitis, thromboembolic events, and hypercoagulable states.	A large post-licensure study found HPV vaccine was not associated with onset of juvenile rheumatoid arthritis or Type 1 diabetes. This study reported an IRR of 1.29 (95% CI 1.08, 1.56) of onset of Hashimoto's disease. However, investigation of a temporal relationship and biological plausibility revealed no consistent evidence of a safety signal. A large post-licensure study found HPV vaccine was NOT associated with Guillain Barré Syndrome, seizures, stroke, syncope, or venous thromboembolism. Several clinical trials found HPV vaccination associated with short-term severe pain at injection site. Trials also found vaccine associated with fever, headache, nausea and stomach ache. A secondary analysis including only black women who became pregnant within 3 to 4 years of receiving HPV vaccine in two trials reported a higher rate of spontaneous abortion in vaccinated subjects.

Table 33. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
	arthralgia, pancreatitis, thromboembolic events, spontaneous abortion, and hypercoagulable states		
Inactivated polio vaccine	**Insufficient –** food allergy	Not covered	One post-licensure study reported association between polio vaccine in newborns and sensitivity to food allergens.
Influenza Vaccines	**Moderate -** mild gastrointestinal disorders, febrile seizures **Low –** No association with other Serious Adverse Events in the short term in children with cancer or who have received organ transplants **Low** - influenza-like symptoms **Insufficient** – asthma exacerbation (with live vaccine), ADEM, transverse myelitis	The IOM committee studied seasonal influenza vaccines. The influenza vaccine is administered in two forms: a live attenuated form, administered intranasally, and an inactivated form, administered intramuscularly. Evidence was **"inadequate to accept or reject"** a causal relationship in the pediatric population between seasonal influenza vaccines and the following: seizures, (ADEM), and transverse myelitis. Evidence was **"inadequate to accept or reject"** a causal relationship between live attenuated influenza vaccine (LAIV) and asthma exacerbation or reactive airway disease (RAD) episodes.	Seasonal influenza vaccines were NOT associated with any serious adverse events in the short term in children with malignancy, IBD, urea cycle disorders or children who had received organ transplant in post-licensure studies. Both seasonal influenza vaccines and monovalent H1N1 vaccine were associated with mild gastrointestinal disorders, such as vomiting and diarrhea in children in the short-term in several large post-licensure studies. One large study[114114114115] found that younger vaccinated children (aged 5 to 8 years) were more likely to experience these symptoms than older vaccinated children (aged 9 to 17 years). (Children under 5 years of age were not included in that study). Both live and inactivated seasonal influenza vaccines were associated with influenza-like symptoms in children in the short term in multiple studies, while not associated in others. A large U.S. post-licensure study of children under age 5 years found TIV associated with febrile seizures. Risk was increased if PCV13 was administered concomitantly

Table 33. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Measles-Mumps-Rubella	**High –** No association with Autism Spectrum Disorders **High -** anaphylaxis in children with allergies, febrile seizures **Moderate** – Transient arthralgia **Moderate -** thrombocytopenic purpura **Insufficient** - encephalitis, encephalopathy, afebrile seizures, meningitis, cerebellar ataxia, acute disseminated encephalomyelitis, transverse myelitis, optic neuritis, neuromyelitis optica, MS onset, and chronic arthropathy	Evidence **"convincingly supports"** causal relationships with febrile seizures and, anaphylaxis. Evidence **"convincingly supports"** a causal relationship with measles inclusion body encephalitis in immunocompromised patients. Evidence **"favors acceptance"** of a causal relationship between MMR and transient arthralgia Evidence **"favors rejection"** of a causal relationship between MMR and autism. Evidence is **"inadequate to accept or reject"** a causal relationship with encephalitis, encephalopathy, afebrile seizures, cerebellar ataxia, acute disseminated encephalomyelitis, transverse myelitis, optic neuritis, neuromyelitis optica, MS onset, and chronic arthropathy.	Four additional postmarketing studies were identified. Vaccination was associated with thrombocytopenic purpura in the short term. MMR vaccination was associated with increased emergency department visits within two weeks; this is indirect support of the IOM's findings that MMR vaccine is associated with febrile seizures.
Meningococcal Vaccines (MCV4. MPSV)	**Moderate –** anaphylaxis in children with allergies **Insufficient -** encephalitis, encephalopathy, ADEM, transverse myelitis, MS, Guillain-Barré syndrome, CIDP, chronic headache.	Evidence **"convincingly supports"** a causal relationship with anaphylaxis in children who may be allergic to ingredients. Evidence is **"inadequate to accept or reject"** causal relationships between meningococcal vaccine (unspecified) and the following: encephalitis, encephalopathy, ADEM, transverse myelitis, MS, Guillain-Barré syndrome, CIDP, and chronic headache.	Two new trials of quadrivalent meningococcal conjugate vaccines found no association with any AEs assessed.

Table 33. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Miscellaneous & Combination Vaccines	**Moderate** - DTaP-IPV-Hib vaccination with febrile seizures **High** – no association of childhood leukemia with MMR, DTaP, Td, Hib, Hep B, and polio vaccines **Moderate** – Hepatitis A, MMR, and varicella vaccine with purpura	Not covered	Association of DTaP-IPV-Hib vaccination with febrile seizures in children was found in a very large, high quality post-licensure study. Rate for first dose was estimated as 5.5 cases per 100,000 person/days. Rate for second dose was estimated as 5.7 cases per 100,000 person/days. Multiple large epidemiological studies have assessed MMR, DTaP, Td, Hib, Hep B, and polio vaccine and have found no association with childhood leukemia. In a large post-licensure study of over 1.8 million vaccines recipients, purpura was associated with vaccination against Hepatitis A in children aged 7 to 17 years, vaccination against varicella in children aged 11 to 17, and MMR in children from 12 to 19 months of age. These results were based on one or two cases per vaccine type/age group. According to the authors most cases were mild and acute.
Pneumococcal Conjugate (PCV13)	**Moderate** – Febrile seizures	Not covered.	A recent study using the U.S. Vaccine Safety Datalink (VSD) found an association with febrile seizures. Estimated rate for 16-month old patients is 13.7 cases per 100,000 doses for PCV13 without concomitant TIV, and 44.9 per 100,000 doses for concomitant TIV and PCV13.

Table 33. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
Rotavirus Vaccines: RotaTeq and Rotarix	**Moderate** – intussusception	Not covered.	In clinical trials, there was no association between either of the two currently available vaccines (RotaTeq and Rotarix) and any serious adverse events, including intussusception, in the long or short-term. A high quality epidemiological study in Australia found RotaTeq was associated with intussusception 1 to 21 days following the first of three required doses in infants 1 to 3 months of age. Two case-control studies conducted in Latin America found an association of Rotarix with intussusception in children following the first of two required doses. Although one U.S. epidemiological study found no association, a recent analysis of the U.S. Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program found both RotaTeq and Rotarix associated with intussusception in the short term. Estimated rate was 1.1 to 1.5 cases per 100,000 doses of RotaTeq and 5.1 cases per 100,000 doses of Rotarix.
Varicella Vaccine	**High –** anaphylaxis, disseminated Oka VZV without other organ involvement, disseminated Oka VZV with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies, vaccine strain viral reactivation without other organ involvement, vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis	Evidence **"convincingly supports"** causal relationships between varicella virus vaccine and the following: disseminated Oka VZV without other organ involvement disseminated Oka VZV with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies, vaccine strain viral reactivation without other organ involvement, vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis, and anaphylaxis. The evidence is **"inadequate to accept or reject"** a causal relationship between the vaccine and seizures, ADEM, transverse myelitis, Guillain-Barré syndrome, small fiber neuropathy, onset or exacerbation of arthropathy, and thrombocytopenia.	We identifying one small trial in children with lupus (SLE); the trial reported no association with AEs.

Table 33. Summary: safety of vaccines used for routine immunization of adults (including pregnant women) and children (continued)

Vaccine	EPC Conclusions and Strength of Evidence	IOM Findings	Additional Findings From EPC
	Insufficient – seizures, ADEM, transverse myelitis, Guillain-Barré syndrome, small fiber neuropathy, onset or exacerbation of arthropathy, thrombocytopenia.		
Pregnant Women			
Influenza Vaccines	**Moderate** – No association with serious adverse events	Results not specific to pregnant women	Both monovalent H1N1 vaccine and seasonal influenza vaccine (inactivated) containing H1N1 strains were not associated with serious adverse events in pregnant women or their offspring in multiple trials and post-licensure studies. Studies report an association with lower risk of adverse pregnancy outcomes.

ADEM = acute disseminated encephalomyelitis; AEs = adverse events; CIDP = chronic inflammatory demyelinating polyneuropathy; DTaP = diphtheria, tetanus, and pertussis vaccine; EPC = Evidence-based Practice Center; GBS = Guillain-Barré Syndrome; Hep B = hepatitis B; Hib = Haemophilus influenzae type B; HPV = human papillomavirus; IOM = Institute of Medicine; LAIV = live attenuated influenza vaccine; MMR = measles, mumps, rubella vaccine; MS = multiple sclerosis; RAD = reactive airway disease; SIDS = sudden infant death syndrome; SLE = systemic lupus erythematosus; Td = tetanus-diphtheria; TIV = trivalent influenza vaccine; VZV = varicella-zoster virus

Research Gaps

Adults

There was insufficient evidence to determine whether influenza vaccines are associated with onset or exacerbation of MS.

A recent meta-analysis on 2009 monovalent H1N1 vaccine provided high strength evidence of association with Guillain Barré Syndrome in adults. As the vaccine is associated with only 1.6 excess cases per million vaccinated, it will be very difficult to assess risk factors.

The unknown association regarding MS and GBS and vaccines against hepatitis A, hepatitis B, and MMR presents a research gap; the IOM found evidence inadequate to accept or reject a causal relationship.

Some published vaccine trials were not specific in reporting AEs. Broad categories such as "injection–related adverse events," "systemic adverse events," "one or more adverse events" or "serious adverse events" were reported rather than specific AE. In addition, many studies reported on a list of pre-defined adverse events but did not rate the severity or provide enough information for our investigators to determine severity. Future trials of vaccines should report results with more granularity.

Children and Adolescents

There is insufficient evidence to determine any potential association between trivalent inactivated vaccine and asthma exacerbation, acute disseminated encephalomyelitis (ADEM), and transverse myelitis.

Febrile seizures were associated with MMR, influenza, and pneumococcal conjugate vaccines. Younger age was associated with increased risk in several studies. Large scale epidemiological studies could determine other patient risk factors.

A large post-licensure study found associations between both Rotarix and RotaTeq and intussusception in the short term following vaccination in U.S. children; patient risk factors were not reported.

Strong evidence for a lack of association of HPV vaccines with several serious medical conditions (juvenile rheumatoid arthritis, type 1 diabetes, GBS) has been found in large post-licensure studies. However, there is insufficient evidence regarding other serious conditions such as MS, chronic inflammatory demyelinating polyneuropathy, amyotrophic lateral sclerosis, and pancreatitis. Importantly, a recent analysis of long term follow-up data from two trials of Gardasil showed a possible increased risk of miscarriage of pregnancies within four years of vaccination among Black women. Large datasets from U.S. Managed Care Organizations (MCOs) include both immunizations and pregnancy records needed to investigate the potential relationship.

There is insufficient evidence to determine the possible association, if any, between vaccines such as DTaP, meningococcal vaccine, and varicella vaccine and the onset of nervous system conditions such as ADEM, transverse myelitis, MS, and GBS. Large scale epidemiological studies could provide additional data; however, as these medical conditions are extremely rare, it may be difficult to reach a level of evidence beyond "insufficient".

Pregnant Women

There is moderate strength of evidence that inactivated influenza vaccine is not associated with serious adverse events in pregnant women or their offspring. Given the 2013 recommendation to administer the Tdap vaccine during every pregnancy, passive surveillance systems should be monitored regularly for AEs in this population. This is a particular concern for women with multiple pregnancies over a period of a few years.

A reliable system of tracking when in pregnancy the vaccine was given is extremely important. In addition, in any study of vaccines and pregnancy, follow-up of newborns should be sufficiently long, as not all adverse effects may be apparent immediately after birth. The need for large numbers of pregnant exposures is particularly important given the relative low frequency of some birth defects and defining which are causal to vaccine. In addition, little is known about the patient factors which may influence the effect of the vaccine. Another unknown is how vaccination in pregnancy may affect the newborn's immune system/reaction to newborn vaccinations. The Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) has components to monitor safety of maternally-administered vaccines and their effect on recipients and their offspring. VAMPSS is a collaboration of the American Academy of Asthma Allergy and Immunology, the Organization of Teratology Information Specialists (OTIS) Research Center at the University of California San Diego and the Slone Epidemiology Center (SEC) at Boston University. The U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority contracted VAMPSS to perform safety monitoring of pandemic H1N1 influenza vaccine administered during the 2009 pandemic. As this report was being finalized, a VAMPSS study on the safety of H1N1 was released;[238,239] the authors found no meaningful evidence of increase risk of major birth defects, miscarriage, or low birth weight for gestational age. Further, existing federal systems such as the VSD and/or PRISM could be potentially be used, as well.

General Methodological Observations

Advanced health information technology (HIT) systems that contain both vaccination and health outcome records can be used to conduct high quality epidemiological studies. In the United States, the VSD contains data obtained through such systems at nine very large MCOs. The FDA's Mini-Sentinel program also conducts active surveillance using electronic healthcare databases from MCOs. Nations with single payer healthcare systems often have electronic registries which allow very large epidemiological studies of entire populations. Studies using these databases have greater validity than studies that rely on surveys that use patient / parent recall for ascertainment of vaccination or health outcome. Not only are such surveys subject to recall bias, but there may be no way of determining the formulation or brand of vaccination.

Observational studies should be powered adequately to determine risk factors such as demographic and health characteristics of patients. Analysis should be stratified by formulation and brand of vaccine, if possible. This is especially true for influenza vaccine, which differs from season to season.

Independent abstraction and systematic reassessment of the studies included in the Institute of Medicine consensus report "Adverse Effects of Vaccines: Evidence and Causality" may be a useful future endeavor. Odds ratios could be calculated for each event reported in each trial and post-licensure study, and, where appropriate, meta-analysis conducted to calculate overall odds ratios for each AE and each vaccine type. If these studies were abstracted, the totality of data

could be statistically analyzed to explore additional hypotheses and issues beyond the scope of the current report.

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Abbreviations/Acronyms

ACIP	Advisory Committee on Immunization Practices
ADEM	Acute disseminated encephalomyelitis
AEs	Adverse Events
AHRQ	Agency for Healthcare Research and Quality
ALL	Acute lymphoblastic leukemia
CAP	Community-acquired pneumonia
CCTs	Controlled Clinical Trials
CDC	Centers for Disease Control and Prevention
CER	Comparative Effectiveness Review
CI	Confidence Interval
CIDP	Chronic inflammatory demyelinating polyneuropathy
COPD	Chronic obstructive pulmonary disease
CTCAE	Common Terminology Criteria for Adverse Events
CVD	Cardiovascular Disease
DPT	Diphtheria–Pertussis–Tetanus vaccine
EPC	Evidence-based Practice Center
FDA	Food and Drug Administration
GBS	Guillain–Barré Syndrome
GERD	Gastroesophageal reflux disease
GI	Gastrointestinal
GPRD	General Practice Research Database (UK)
Hib	*Haemophilus influenzae* type b
HMO	Health Maintenance Organization
HPV	Human papillomavirus
HR	Hazard ratio
HZ	Herpes Zoster
ICD	International Classification of Diseases
IHD	Ischemic heart disease
ILI	Influenza-Like Illness
IOM	Institute of Medicine
IPD	Invasive pneumococcal disease
IPV	Inactivated polio vaccine
IRR	Incidence rate ratio
ITP	Idiopathic thrombocytic purpura
KQs	Key Questions
LAIV	Live attenuated influenza vaccine
MaxSPRT	Maximized sequential probability ratio test
MCO	Managed Care Organization

MCV	Meningococcal conjugate vaccine
MI	Myocardial infarction
MIV	Monovalent inactivated pandemic H1N1 vaccine
MMR	Measles, mumps, and rubella
MPSV	Meningococcal polysaccharide vaccine
MS	Multiple Sclerosis
NIH	National Institute of Health
OASH	Office of the Assistant Secretary for Health
OHSU	Oregon Health Sciences University
OR	Odds ratio
PAEDS	Pediatric Active Enhanced Disease Surveillance
PCV	Pneumococcal conjugate vaccine
PPV	Pneumococcal polysaccharide vaccination
PRAMS	Pregnancy Risk Assessment Monitoring System
PV	Pneumococcal vaccine
RAD	Reactive airway disease
RCTs	Randomized Controlled Trials
RR	Relative risk
SAE	Serious adverse events
SAS	Statistical Analysis System
SCCS	Self-controlled case series
SD	Standard deviation
SIDS	Sudden Infant Death Syndrome
SIPs	Scientific Information Packets
SLE	Systemic lupus erythematosus
SRC	Scientific Resource Center
Td	Tetanus, diphtheria
Tdap	Tetanus, diphtheria, and acellular pertussis vaccine
TEP	Technical Expert Panel
TIV	Trivalent influenza vaccine
TOO	Task Order Officer
TP	Thrombocytopenic purpura
USD	Urea cycle disorders
VAERS	Vaccine Adverse Event Reporting System
VICP	Vaccine Injury Compensation Program
VSD	Vaccine Safety Datalink
VZV	Varicella-Zoster Virus

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 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. Our search went through August 2013. 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

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

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

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

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

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

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

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

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

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

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

Appendix B. Data Abstraction Tools

Title and Abstract Screening Form

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

☐ Exclude-not found

Vaccine Safety Full-Text Inclusion Screening

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

Special interest studies where all groups were vaccinated (if one group got only "routine vaccines" go to next bold item)

We were going to research these issues of special interest to the TEP, but were unable due to resource constraints

- ☐ Pregnant women vs non-pregnant group
- ☐ High dose influenza vs other dose, in elderly
- ☐ Interdermal vs intramuscular administration of influenza vaccine
- ☐ Pneumococcal conjugate vaccine 13 (PCV13) vs Pneumococcal conjugate vaccine 7 (PCV7)
- ☐ Inactivated polio vaccine (IPV) vs Oral polio vaccine (OPV)
- ☐ Live attenuated influenza vaccine (LAIV) vs Trivalent influenza vaccine (TIV)
- ☐ Tetanus, diphtheria, acellular pertussis (TdaP) vs Tetanus, diphtheria (Td)
- ☐ Meningococcal conjugate vaccine (MCV4) vs meningococcal polysaccharide vaccine five (MPSV)

☐ **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

Case Control, Self-Controlled Case Series, or Multivariate Risk Factor Analyses

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*	

Data Abstraction Form-Controlled Trials and Head-to-Head Cohort Comparisons

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

McMaster Quality Assessment Scale for Harms (McHarm)	RATING
3. Were SEVERE events precisely defined?	● Yes ● 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

McMaster Quality Assessment Scale for Harms (McHarm)	RATING
	Response
9. Did the study specify the TIMING and FREQUENCY of collection of the harms?	● Yes ● No ● 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

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

Clear Response

15. Did the author(s) specify the type of analyses undertaken for harms data?

- ● Yes
- ● No
- ● 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

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

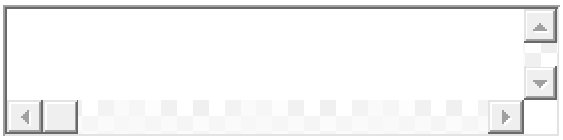
☐

- ☐ 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. Evidence Tables

Evidence Table 1. Postmarketing studies: Adults

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
Baxter, 2012, Retrospective cohort[73]	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.	NA	These were participants 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	

Evidence Table 1. Postmarketing studies: Adults

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
Baxter, et al. 2012,[86] Observational post-licensure (Phase IV) study; retrospective cohort	N=29,000; Location=California; Age=60+ years; Setting=Kaiser Permanente Northern California (KPNC), a US managed care organization	ZostavaxTM, a live, attenuated varicella-zoster virus vaccine	Entire population	Not really discussed. Study notes: From July 2006 through November 2007, 29,486 people 60 years of age or older were vaccinated with zoster vaccine at KPNC. Of them, 29,010 people had continuous KPNC membership for at least 180 days after vaccination, and were included in the study population.	Not discussed	Medical records. Detailed vaccination data are tracked and captured by the Kaiser Immunization Tracking System (KITS), one of the largest electronic tracking systems for immunization in the U.S. The KITS system collects, among other information, the patient's medical record number, date of vaccination, type of vaccine, route of administration, facility in which the vaccine was administered, manufacturer and vaccine lot number, and can be linked to other data sources to get additional information	Medical records. Subjects were followed for all postvaccination hospitalization and ED visits identified by International Classification of Diseases andRelatedHealthProblems-9(ICD9) codes in the electronic medical records.	Exact conditional method with mid-probability adjustment	Self-controlled	2006-2007	This study was sponsored by Merck Sharp & Dohme, Corp. Trung Nam Tran and Patricia Saddier were full time employees of Merck Sharp & Dohme, Corp. at the time of the study.	Table 2. Health outcomes with elevated RR and statistically significant unadjusted p-value ($p<0.05$)(N=29,010). Coronary atherosclerosis and other heart disease 1.86 (1.09–3.15); p=0.02 Coronary atherosclerosis (ATS) 1.97 (1.11–3.49); p=0.02 Percutaneous transluminal coronary angioplasty (PTCA) 2.26 (1.19–4.27); p=0.01 Systemic lupus, erythematosus and connective tissue disorders 8.57 (1.08–212.11); p=0.04	None	Table 3 shows RR for subsets of individuals: diabetics, people with CHD, and people 80+ years.

Evidence Table 1. Postmarketing studies: Adults

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
Duderstadt et al. 2012, Retrospective cohort[92]	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 systematically from those included, bias would be introduced into the study	Not applicable	Not discussed	Defense Medical Surveillance System	Defense Medical Surveillance 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 reported	
Eder et al. 2011, Case-control[91]	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 Arthritis (PsA) cohort, clinic-based. Controls from Toronto Psoriasis Cohort	Hepatitis A and B, influenza, pneumococcus	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 psoriasis patients. Study notes, "In order to minimize selection bias, psoriasis patients were recruited from several sources: dermatology clinics at Toronto Western Hospital and Women's College Hospital,	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 language skills. Overall, 159 PsA patients (83.6%) were included in the study. 196 patients with psoriasis (controls) were approached for enrollment, of whom 159 (81.1%)	Study did not note whether participants differed from nonparticipants.	Self-report through questionnaire	Clinical data were available from the cohorts' computerized databases	Logistic regression	Age, sex, duration and severity of psoriasis, and level of education.	Not reported	Krembil Foundation, Arthritis Society Spondyloarthritis Research Consortium of Canada National Research Initiative. Dr. Eder's work was supported by a fellowship grant from the Canadian Arthritis Network and by an Abbott Psoriatic Arthritis Fellowship. Ms.	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 reported	Recall bias was a concern; those with arthritis may show higher recall of triggers. By approaching patients with a recent onset of arthritis, the study population had a short interval from the onset of PsA of approximately 3 years. Authors avoided linking environmental exposures and arthritis in the questionnaire, and requested

Evidence Table 1. Postmarketing studies: Adults

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
			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	completed the questionnaire.							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.			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 computerized database that stores medical records from 6 medical centers and outpatient clinics. The aim was to assess whether there has been underreporting 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

Evidence Table 1. Postmarketing studies: Adults

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
														reported an infection. Therefore, 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."
Eurich et al. 2012, Prospective cohort[75]	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 requires 2-4 weeks to initiate a reasonable	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	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),	None	

Evidence Table 1. Postmarketing studies: Adults

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
			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								patient health management. TJM received Grants-in-aid from Capital Health; and unrestricted grants from Abbott Canada, Pfizer Canada and Janssen-Ortho Canada.	p=0.53 Hospitalization due to ACS: 0.36 (0.21 to 0.61), p=<0.001		
Farez et al. 2012, Self-controlled case series[62]	N=137 Multiple Sclerosis patients; Location=Argentina; Age=37 +/- 8 years (mean)	Influenza (monovalent 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 reported	

Evidence Table 1. Postmarketing studies: Adults

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
Garbe et al. 2012, Case-control[68]	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 reported.)	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 misclassification was a minor concern because drug exposures were assessed 1 week before the index date	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 information. An advisory board assessed ambiguous cases.	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 reported	
Glanz et al. 2011, Self-controlled case series[115]	N=66,283 who received trivalent inactivated influenza vaccine (TIV); Location=US; Age=24-59 months; Setting=Seven US managed care organizations (Vaccine	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	None given	

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	Safety Datalink)											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 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)		

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Greene et al. 2012, Self-controlled risk interval and case-centered analysis[56]	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 reported	Not reported	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, 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 illness onset inside of the 42-day risk period versus outside of that period was 2.0 (95% CI: 0.5, 8.1).	None	
Grimaldi-Bensouda et al. 2011, Prospective case-control[58]	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	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,	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	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:	Not reported	

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	centers treating neurologic disease in children; Controls from registry of general practice patients across France								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 months.	the end of the vaccination campaign on March 31, 2010		1.08 (0.09-13.15)		
Gwini et al. 2011, Self-controlled case series[67]	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 generalizability	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) 121-180 days: 1.02 (0.95–1.10)		
Hambidge et al. 2011, Self-controlled case series[69]	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	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	

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			likely to be vaccinated)										>=65 yrs: 0.94 (0.10, 8.55), p=1.0	
Hedlund et al. 2003, Prospective cohort[66]	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 during 3 consecutive years, 1998–2000	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 supported for 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 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	None	

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												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/100 000 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		
Hurst et al. 2011, Retrospective cohort[71]	N=51,730 adult Medicare patients with renal transplant; Location=US; Age=>=65 years; 9,678 had claims for	Influenza	Entire population	Not reported	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 mellitus,	2000-2006	Not specified	Vaccination in the first year after transplant was associated with lower risk of subsequent allograft loss and death Adjusted hazard ratio Allograft loss: 0.77 (0.69-0.85), p=0.001 Death: 0.82 (0.76-	Not reported	

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	influenza vaccine in the first year post transplant								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			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		
Johnstone et al. 2012, Prospective cohort[65]	N=31,546; Location=40 countries; Setting=Participants in the ONTARGE	Influenza, pneumococcal	Difficult to determine without more details on the original studies through which population	In total, 99.8% of participants were followed up until the primary outcome occurred or the	Not discussed	Self-report	All study outcomes were prospectively adjudicated by a central committee blinded to study	Logistic regression	Adjusted by propensity score for influenza vaccination (body mass index, age, sex,	2004 to 2007	This study was supported by a grant from Boehringer Ingelheim.	Association Between Influenza Vaccination and Risk of Major Adverse Vascular Events During the Influenza Season	Not reported	There was no association between pneumococcal vaccination and the primary

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	T /TRANSCEND trials: at least 55 years old and a history of vascular disease or diabetes with document end-organ damage		drawn from	end of study			medication allocation and influenza vaccination status with the use of standardized criteria		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		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	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 (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		outcome during any of the influenza seasons

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												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 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		
Siriwardena et al. 2010, Matched case-control[64]	N=78,706 (16,012 cases of myocardial infarction (MI), 62,964 controls); Location=UK; Age=40 to >=65; Setting=United Kingdom General Practice Research Database (GPRD), an extensively validated	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 controlled for in multivariate analyses	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 practitioner, and all health care attendances are recorded in the database. The database contains anonymized patient data that includes demographic	Data were extracted from the GPRD (assume by researchers). Cases were at least 40 years at the time of first acute myocardial 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 standardized (Read and	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 disease, chronic renal failure, immunosuppression and HIV, hyperlipidemia, family history	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 Kingdom	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 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/co	None given, but subgroup results shows for the following categories: Influenza 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–	

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	computerized database, representative of and comprising 5% of the population of England and Wales.					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., 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	Oxford Medical Information Systems [OXMIS]) codes.		of acute myocardial infarction, peripheral vascular disease, hypertension, smoking status, treatment with acetylsalicylic acid, treatment with statins, treatment with antihypertensives, 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			ntent/full/cmaj.091891/DC1)	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: 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-	

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						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)				season vaccination Yes: Model 1: 0.80 (0.76–0.84) 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) Model 2: 0.77 (0.70–0.85) Dec. to Mar.: Model 1: 0.86 (0.79–0.93) Model 2: 0.88	

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													(0.82–0.95) Apr. to Aug.: Model 1: 0.80 (0.73–0.86) Model 2: 0.84 (0.77–0.90) Pneumococcal < 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 (0.91–1.03)	
Tanner et al. 2012, Case-control[63]	N=286; Location=Utah; Age=20.4 to 92.5; Setting=The University of Utah Voice Disorders Center	Swine flu (Also assessed measles, mumps, and rubella separately - unsure if any of these are MMR)	Selected segment - University of Utah Voice Disorders Center	No details about dropping out over the course of the study, but 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	Not reported	Self-report through questionnaire. Trained examiners administered the questionnaire to each participant and were periodically audited to ensure accuracy.	Voice disorder diagnosis was confirmed by a 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	Logistic regression	Age, sex, race/ethnicity	Not reported	The work was supported in part by a University of Utah College of Health Research and Creative Grant	Vacc v. Nonvacc: 2.1 (0.9-5.0) Don't Know v. Nonvacc: 2.3 (1.3-4.1)	Not reported	

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				patients approached and invited to participate, 136 VC individuals completed the study (controls)			evaluation, and videolaryngostroboscopy, employing diagnostic criteria previously established and reported.							
Ting et al. 2011, Retrospective matched cohort (each pair included 1 vaccinated and 1 non-vaccinated COPD patient)[72]	586 patients with moderate to severe COPD identified in COPD Registers of 6 general practices in North Derbyshire UK. Age range 37-89 (median 68)	influenza	entire population of COPD patients in these 6-practices	n/a	n/a	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 0.52 [95% CI 0.29, 1.14])		Study did NOT look at exacerbations by COPD stage or other risk factors.
Tseng et al. 2010, Prospective cohort[74]	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	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	

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									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, 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				smokers: 1.11 (0.83-1.47), p=0.48 Diabetes: 1.04 (0.87-1.24), p=0.51 Hypertension: 1.10 (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	

Evidence Table 1. Postmarketing studies: Adults

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
Tseng et al. 2012, Case-centered and Self-controlled case series[85]	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 (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	Not reported	

Evidence Table 1. Postmarketing studies: Adults

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
												(0.40–2.05) 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: 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–		

Evidence Table 1. Postmarketing studies: Adults

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
												1.44) Allergic Reaction: 2.13 (1.87–2.40) SCCS Day 1-14 Cerebrovascular diseases: 0.94 (0.70–1.28) 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)		

Evidence Table 1. Postmarketing studies: Adults

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
												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: 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)		

Evidence Table 1. Postmarketing studies: Adults

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
Uno et al. 2012, Case-control[145]	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 Scale for Children-Third Edition. After the interview and testing, the diagnosis was made by the team according to the DSM-IV criteria.	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	
Vila-Corcoles et al. 2012, Prospective cohort[76]	N=27,204 (8,981 vaccinated, 18,223 unvaccinated); Location=Spain; Age=71.7 (mean at	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	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	Cohort members were followed from the start of the study (December 1, 2008) until the	This work was supported by a grant from the "Fondo de Investigación Sanitaria" of the	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),	Not reported	

Evidence Table 1. Postmarketing studies: Adults

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
	study start); Setting=nine primary care centers in the Health Region of Tarragona (a mixed residential-industrial urban area in the Mediterranean coast of Catalonia, Spain)						medical record review		before study start, influenza vaccination in prior autumn, history of coronary artery disease, history of stroke, history of chronic heart 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	occurrence of any event, change in pneumococcal vaccination status, disenrollment from the primary care center, death, or until the end of first 12-month follow-up (November 30, 2009).	Instituto de Salud Carlos III [FIS 09/00043] of the Spanish Health Ministry	p=0.12		

Evidence Table 1. Postmarketing studies: Adults

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
									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 in prior year, influenza vaccination in prior year, history of coronary artery disease, chronic heart disease, diabetes mellitus, hypercholesterolemia, 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					

Evidence Table 1. Postmarketing studies: Adults

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
									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, diabetes mellitus, cancer, chronic nephropathy, dementia, hypertension, hypercholesterolemia, obesity, smoking, and nursing home-resident					
Yu et al. 2007, Case-control[93]	N=1,875 (355 Graves' disease cases, 418 Hashimoto's thyroiditis cases, 1,102 controls); Location=Vaccine	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	None	Not discussed	Vaccine information was collected from administrative 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	Logistic regression	Controls were frequency-matched to cases by birth year, sex, and study site (HMO) All models adjusted for frequency-	January 1, 1999 through June 30, 2002	ID Biomedical, Chiron Therapeutics and Vaccines, and Sanofi Pasteur; Study supported by the	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)	Not reported	

Evidence Table 1. Postmarketing studies: Adults

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
	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; Setting=Three health maintenance organizations (HMOs)		exposure misclassification. Authors noted that case groups may have included some subjects with thyroid conditions other than Graves' disease or Hashimoto's thyroiditis.				Revision (ICD-9) codes for thyroid disease, associated with inpatient and outpatient medical encounters that were recorded in HMO administrative data systems.		matching variables (age groups, sex, site, and index year), personal and family history of autoimmune disease, smoking status, race, and education		Vaccine Safety Datalink contract with America's Health Insurance Plans, funded by the CDC	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) Polio: 1.17 (0.73–1.86)		
Zhang et al. 2012, Retrospective cohort[84]	N=463,541(4,026 with ankylosing spondylitis, 66,751 with inflammatory bowel disease, 11,030 with psoriatic arthritis, 89,565 with psoriasis, and 292,169 with RA); Location=US; Age=74 years (mean	Zoster Herpes	Could not control for differences between those who received vaccinations and those who did not (e.g., those receiving vaccines may be a healthier population). Misclassification of medication exposure	Actual vaccine administration dates were unknown for 59% of patients, which resulted in the exclusion of these patients from safety analyses potentially introducing bias	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 (hospitalization and physician visits)	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) 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)	Sex Men [Reference] Women Def 1: 1.22 (1.17-1.28) Def 2: 1.21 (1.17-1.26) Race White [Reference] Black Def 1: 0.67 (0.62-0.73) Def 2: 0.69 (0.64-0.74) Other Def 1: 0.89	

Evidence Table 1. Postmarketing studies: Adults

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
	at study start); Setting=US Medicare beneficiaries												(0.81-0.97) Def 2: 0.89 (0.83-0.95) Immune-mediated disease Rheumatoid arthritis [Reference] Ankylosing spondylitis Def 1: 0.98 (0.77-1.25) Def 2: 0.94 (0.77-1.13) Inflammatory bowel diseases 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 [Reference] Yes Def 1: 1.00	

Evidence Table 1. Postmarketing studies: Adults

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
													(0.95-1.05) Def 2: 1.25 (1.20-1.29) No. of physician 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 [Reference] 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: 0.84 (0.80-0.88) Def 2: 0.86 (0.82-0.89) Oral glucocorticoid use No [Reference] Yes	

Evidence Table 1. Postmarketing studies: Adults

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
													Def 1: 1.79 (1.71-1.86) Def 2: 1.69 (1.64-1.75)	

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Barrett P. N. et al, 2011 US[47]	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)**
Bhatla N. et al.,2010 India[89]	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)

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Frey S. et al,2010 US, Finland, Poland[48]	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)
Iorio V et al.,2010 Italy[49]	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)

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Jackson L. A. et al.,2010 US[50]	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)
Johnstone, J. et al. 2012[240] 40 countries	Cohort	2	Sample size : 31546, Mean age: 66 (approx), Age range: 55 - NR, Percent female: 29.9%	Influenza (inactived) , NR , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Not reported	Dose1: NR	Event: Any major cardiovascular event (during flu season) : 1.1% , Syscat: 2 , Sev: 3-4 Event: Any major cardiovascular event (non flu season) : 0.94% , Syscat: 2 , Sev: 3-4 Event: Non cardiovascular deaths : 0.01% , Syscat: 2 , Sev: 4 Event: Cancer deaths : 0% , Sev: 4 Event: Deaths from other causes : 0.05% , Sev: 4	Any major cardiovascular event (during flu season): OR 1.082 (0.834-1.404) Any major cardiovascular event (during flu season): OR 1.082 (0.834-1.404) Any major cardiovascular event (non flu season): OR 0.887 (0.674-1.168) Any major cardiovascular event (non flu season): OR 0.887 (0.674-1.168) Deaths from other causes: OR 0.228 (0.028-1.856) Deaths from other causes: OR 0.228 (0.028-1.856) Non cardiovascular deaths: OR 0.133 (0.017-1.024) Non cardiovascular deaths: OR 0.133 (0.017-1.024)

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Langley J. M., et al,2011 Canada[46]	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	
Lee S. et al,2011 Korea[90]	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)
Macaladad N. et al.,2007 Brazil, Costa Rica, Colombia, Mexico, Peru and Venezuela and the Philippines[78]	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%	

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Madhi S. A. e t al.,2011 South Africa[53]	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)
Mills R. et a.,2010 US[81]	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)**

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Murray A. V. et al.,2011 US, Canada, Spain, Germany, UK[83]	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)

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Ngan H. Y. S. et al., 2010 Hong Kong[88]	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)
Schmader K. E. et al.,2012 North America and Europe[79]	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)**

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Simberkoff M. S. et al.,2010 US[82]	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)

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Talaat K. R. et al.,2010 United States[52]	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)
Treanor J. J. et al.,2011 USA[51]	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)

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Vermeulen J. N. et al.,2012 US and Netherlands[80]	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)**
Wang, I.K. et al. 2013[54] Taiwan	Cohort	5	Sample size : 4018, Mean age: 70/59 (vaccinated/nonvaccinate, Age range: 18 - 65+, Percent female: 51%, Conditions: ESRD	Influenza (inactived) , Not specified , NR , Not reported , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Not reported	Dose1: Not reported	Event: Total hospitalization : 55% Event: Pneumonia/influenza-hospitalization : 17% , Syscat: 22 Event: Septicemia, bacteremia, and viremia-hospitalization : 12% , Syscat: 11 Event: Heart disease-hospitalization : 41% , Syscat: 2 Event: Respiratory Failure-hospitalization : 8% , Syscat: 22 Event: Intensive care unit admission-hospitalization : 2% Event: Mortality-hospitalization : 15%	Heart disease-hospitalization: OR 1.253 (1.072-1.465)** Intensive care unit admission-hospitalization: OR 0.341 (0.206-0.564)** Pneumonia/influenza-hospitalization: OR 1.238 (1.005-1.524)** Respiratory Failure-hospitalization: OR 0.963 (0.727-1.276) Septicemia, bacteremia, and viremia-hospitalization: OR 1.158 (0.916-1.464) Total hospitalization: OR 1.096 (0.94-1.277)

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Weinberg A. et al.,2010 US (No direct mentions)[87]	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)

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Barrett P. N. et al.,2011 US[47]				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
Bhatla N. et al.,2010 India[89]				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
Frey S. et al.,2010 US, Finland, Poland[48]	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

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Iorio A. et al.,2010 Italy[49]				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
Jackson L. A. et al.,2010 US[50]				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%
Johnstone, J. et al. 2012[240] 40 countries	Influenza (inactived) , Adjuvant: Not Reported , Preservative: Not reported , Delivery:	Dose1: NR	Event: Any major cardiovascular event (during flu season) : 155% , Syscat: 2 , Sev: 3-4 Event: Any major cardiovascular event (non flu season) : 0.97% , Syscat: 2 , Sev: 3-4 Event: Non cardiovascular deaths : 0.23% , Sev: 4 Event: Cancer deaths : 0.1% , Sev: 4 Event: Deaths from other causes : 0.13% , Sev: 4 AE: 0.01% AE: 0% AE: 0%	Nothing	Event: Any major cardiovascular event (during flu season) : 1.0% , Syscat: 2 , Sev: 3-4 Event: Any major cardiovascular event (non flu season) : 1.05% , Syscat: 2 , Sev: 3-4 Event: Non cardiovascular deaths : 0.08% , Sev: 4 Event: Cancer deaths : 0.03% , Sev: 4 Event: Deaths from other causes : 0.01% , Sev: 4

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Langley J. M. et al.,2011 Canada[46]	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:	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
Lee S. et al.,2011 Korea[90]				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
Macaladad N. et al.,2007 Brazil, Costa Rica, Colombia, Mexico, Peru and Venezuela and the Philippines[78]				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%

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Madhi S. A. et al.,2011 South Africa[53]				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%
Mills R. et al.,2010 US[81]				Nothing	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

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Murray A. V. et al.,2011 US, Canada, Spain, Germany, UK[83]				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%
Ngan H. Y. S. et al.,2010 Hong Kong[88]				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
Schmader K. E. et al.,2012 North America and Europe[79]				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%

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Simberkoff M. S. et al.,2010 US[82]				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

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Talaat K. R. et al.,2010 United States[52]	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
Treanor J. J. et al.,2011 USA[51]				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

Evidence Table 2. Vaccinated versus unvaccinated: Adults

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Vermeulen J. N. et al.,2012 US and Netherlands[80]				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%
Wang, I.K. et al. 2013[54] Taiwan				Nothing	Event: Total hospitalization : 53% Event: Pneumonia/influenza-hospitalization : 14% , Syscat: 22 Event: Septicemia, bacteremia, and viremia : 11% , Syscat: 11 Event: Heart disease : 36% , Syscat: 2 Event: Respiratory Failure : 8% , Syscat: 22 Event: Intensive care unit admission : 6% Event: Mortality : 18% AE: .56%
Weinberg A. et al.,2010 US (No direct mentions)[87]				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

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
Andrews et al. 2012, Prospective cohort, also analyzed as self-controlled case series[141]	N=343 cases of thrombocytopenic purpura (TP); Location=England, 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 (1.34–2.99) 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–	None	

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
												3.22) 0–42: 1.85 (1.23–2.78)		
Baxter, 2012, Retrospective cohort[114]	43,702 LAIV recipients, 53,366 matched unvaccinated controls, 43,702 TIV recipients Age: 5 to 17 years, Setting: Kaiser Permanente health system	LAIV, TIV, unvaccinated comparison group	Included all LAIV vaccine recipients in database	NA	NA	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. Hazard ratios (HR) were also calculated adjusting for matching factors and seasonal changes in background rates.	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 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.	
Benchimol, et al. 2013,[116]Self-controlled case series	N=26602; Location=Ontario, Canada; Age=< 19 years; Setting=Ontario Crohn's and	Influenza	IBD cases	Not discussed or none	Not discussed	Immunization codes were obtained from the Ontario Health Insurance Plan (OHIP) database,	Review of health administrative data.	SCCS: relative incidence estimation	Self-controlled and also matched controls. Each IBD case was matched to 5 (or 4 where a fifth could not be	1999-2010	Dr Benchimol is supported by a Career Development Award from the Canadian Child Health Clinician	TABLE 2 SCCS Analysis to Assess Risk of Increased Health Services Utilization in the Postvaccine Period in Children With IBD and Non-IBD Matched Controls	None	RI=relative incidence RIR=ratio RI of cases to controls

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
	Colitis Cohort (OCCC), a population-based registry of pediatric IBD patients derived from provincial health administrative data								found) controls according to gender, provincial administrative health region in which the subject resided, and date of birth.		Scientist Program. Dr Kwong is supported by a Clinician Scientist Award from the Department of Family and Community Medicine, University of Toronto. Dr Wilson holds the Canada Research Chair in Public Health Policy. The Institute for Clinical Evaluative Sciences receives funding from the Ontario Ministry of Health and Long-Term Care	Overall all-cause health services utilization (hospitalizations + ED visits + outpatient visits) RI in IBD Patients, (95CI) p-value Days 3–14: 1.19 (0.88–1.59) .26 Days 15–30: 0.83 (0.61–1.13) .23 Days 31–45: 0.96 (0.71–1.29) .78 Days 46–60: 0.81 (0.58–1.12) .20 Days 61–75: 0.94 (0.69–1.26) .66 Days 76–90: 0.79 (0.57–1.09) .15 Days 91–180: 0.99 (0.85–1.16) .89 Pooled day 3–180: 0.95 (0.84–1.07) .38 Pooled day 15–180: 0.92 (0.82–1.04) .19 RI in Controls, (95CI) p-value Days 3–14: 0.64 (0.47–0.89) .007 Days 15–30: 0.95 (0.75–1.20) .65 Days 31–45: 0.68 (0.52–0.91) .008 Days 46–60: 0.93 (0.73–1.19) .56 Days 61–75: 0.87 (0.68–1.11) .26 Days 76–90: 0.91 (0.71–1.16) .44 Days 91–180: 0.96 (0.85–1.09) .56		

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
												Pooled day 3–180: 0.90 (0.82–0.98) .018 Pooled day 15–180: 0.91 (0.83–1.00) .055 RIR of Cases Versus Controls, (95CI) p-value Days 3–14: 1.60 (1.05–2.44) .03 Days 15–30: 0.74 (0.51–1.08) .12 Days 31–45: 1.18 (0.79–1.76) .42 Days 46–60: 0.73 (0.49–1.08) .12 Days 61–75: 0.91 (0.63–1.33) .64 Days 76–90: 0.74 (0.50–1.09) .13 Days 91–180: 0.85 (0.71–1.02) .09 Pooled day 3–180: 0.89 (0.78–1.02) .09 Pooled day 15–180: 0.85 (0.74–0.97) .02 Hospitalizations (all causes) RI in IBD Patients, (95CI) p-value Days 3–14: 0.79 (0.18–3.37) .75 Days 15–30: 1.14 (0.39–3.31) .82 Days 31–45: 0.60 (0.14–2.55) .49 Days 46–60: 0.59 (0.14–2.49) .47 Days 61–75: 2.01 (0.86–4.69) .11 Days 76–90: 0.57		

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
												(0.13–2.43) .40 Days 91–180: 0.69 (0.35–1.36) .43 No data other categories ED visits (all causes) RI in IBD Patients, (95CI) p-value Days 3–14: 0.73 (0.27–2.03) .55 Days 15–30: 0.89 (0.41–1.95) .77 Days 31–45: 0.72 (0.29–1.80) .48 Days 46–60: 1.57 (0.81–3.07) .18 Days 61–75: 0.98 (0.42–2.26) .96 Days 76–90: 0.99 (0.43–2.31) .99 Days 91–180: 1.12 (0.73–1.72) .60 RI in Controls, (95CI) p-value Days 3–14: 0.58 (0.21–1.58) .28 Days 15–30: 1.12 (0.58–2.16) .74 Days 31–45: 0.94 (0.45–1.94) .86 Days 46–60: 1.35 (0.73–2.47) .33 Days 61–75: 0.98 (0.50–1.96) .97 Days 76–90: 0.76 (0.35–1.64) .49 Days 91–180: 1.02 (0.72–1.45) .91 RIR of Cases Versus Controls, (95CI) p-		

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
												value Days 3–14: 1.21 (0.30–4.94) .79 Days 15–30: 0.83 (0.31–2.24) .72 Days 31–45: 0.80 (0.26–2.50) .70 Days 46–60: 1.09 (0.46–2.59) .85 Days 61–75: 0.88 (0.31–2.52) .81 Days 76–90: 1.17 (0.38–3.55) .78 Days 91–180: 0.94 (0.57–1.56) .81 TABLE 3 SCCS Analysis of IBD-Related Health Services Utilization (Hospitalizations + ED Visits + Outpatient Visits) RI, 95CI, p-value Days 3–14: 1.05 (0.68–1.63) .82 Days 15–30: 0.45 (0.26–0.80) .006 Days 31–45: 0.68 (0.42–1.11) .12 Days 46–60: 0.89 (0.58–1.36) .58 Days 61–75: 0.68 (0.43–1.10) .11 Days 76–90: 0.81 (0.52–1.26) .35 Days 91–180: 0.87 (0.70–1.09) .24 Pooled days 3–180: 0.81 (0.68–0.96) .014 Pooled days 15–180: 0.78 (0.66–0.94)		

Evidence Table 3. Postmarketing studies: Children-adolsecents

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												.007		
Bernsen et al. 2006,[214] Study says observational cross-sectional study - they are collecting information on exposures and outcomes at the same 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	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 not. Study assessed the possibility of selection bias due to low response rates of schools and children and determined that the chances were small	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 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	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 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	Autumn 2003–Spring 2004	Not reported	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 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)	Not reported	

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
									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; 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					

Evidence Table 3. Postmarketing studies: Children-adolsecents

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									(yes/no); Frequent (at least 1 day/week) consumption of fish; Frequent exercise (school gym 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					

Evidence Table 3. Postmarketing studies: Children-adolsecents

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Bertuola et al. 2010, Case-control[142]	N=2,311 (387 cases, 1924 controls); Location=Italy; 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 Hospital, Naples	MMR	Both cases and controls chosen from a population of hospitalized children lessening the chance of selection bias	None	NA	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 reported	
Buttery et al. 2011, Observed/expected analysis[181]	Children under 24 months old receiving RotaTeq (N=296,023) or, Rotarix (302,455)in Australia; Active surveillance	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	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	Active surveillance through the Australian Pediatric Surveillance Unit (APSU) and Pediatric Active Enhanced Disease Surveillance (PAEDS) study. Surveillance of	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;	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,	None	

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	mechanisms		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 observed excess cases." Differences in surveillance methods between the two mechanisms may have led to biases in estimation of exposure and outcome (underestimates)			national vaccination registry (ACIR) in PAEDS cases	registered pediatricians and surgeons across Australia (APSU) and surveillance of four major tertiary pediatric hospitals across Australia.				the Sydney Medical School, University of Sydney; CSL Limited (CSL) and GlaxoSmithKline. The PAEDS pilot study is funded by the Department of Health and Ageing, Commonwealth Government of Australia.	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) Dose 2: 0.88 (0.29, 2.05) Total: 1.37 (0.73, 2.34)		

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			. There may have been overestimation of incidence rate.											
Chao et al. 2012, Prospective cohort[201]	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	None	cluster of disease onset in relation to vaccination timing, dose sequence or age was found for any autoimmune condition. None of the estimated IRR was significantly elevated except Hashimoto's disease [IRR=1.29, 95% confidence interval: 1.08-1.56]. Further investigation of temporal relationship and biological plausibility revealed no consistent evidence for a safety signal for autoimmune thyroid

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												Multiple sclerosis: 1.37 (0.74–3.20) Other demyelinating diseases of central nervous system: 0.71 (0.38–2.13) Optic neuritis: 1.45 (1.00–2.91) Uveitis: 1.28 (0.53–6.39)		conditions. The SRC and the investigators identified no autoimmune safety concerns in this study
Chen et al. 1997, Prospective cohort[220]	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 Cooperative (GHC) of Puget Sound in Washington, Northwest Kaiser Permanente (NWK) in Oregon,	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 reported (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 (0.50-1.00) 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-	Not reported	Article discusses the VSD generally and then gives a couple examples of the analytic capabilities which are abstracted here

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	Northern California Kaiser (NCK), and Southern California Kaiser (SCK) Permanente											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 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		

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												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		
Gallagher and Goodman 2010, Cross-sectional[186]	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	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	

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			missing data may introduce bias in the analysis											
Gee et al. 2011, Prospective cohort[202]	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	
Gilbertson et al. 2011, Prospective cohort[70]	N=118,533 Medicare patients who initiated hemodialysis before August 1, 2003 and were alive through October 31, 2005; Location= US	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.	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.	

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	Age=>=18 years;								Also controlled for influenza vaccination.					
Gold et al. 2010, Self-Controlled Case Series[221]	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 events."	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	
Groves et al. 1999, Case-control[224]	N=878; Location=nine Midwestern and Mid-Atlantic states; Age=0-14 years;	Oral or injected poliovirus vaccine, trivalent diphtheria–tetanus–pertussis vaccine,	Author notes, controls selected using random-digit dialing were more likely to be offspring of parents with higher	Mothers of 96% of eligible cases and 75% of eligible controls from the nine states completed an initial telephone	Not discussed	Data collection forms were completed by the mothers using vaccination records from physicians or by the	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	Patient diagnosis between 1989 and 1993. Unsure when data was collected.	Not reported	Effect of vaccination (ever vs never) on subsequent risk of childhood acute lymphoblastic leukemia (439 matched pairs) Measles–mumps–	Not reported	Kleinerman et al, 1997. Kleinerman RA, Linet MS, Hatch EE, Wacholder S, Tarone RE,

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	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 diagnosis were eligible for the vaccination component of the study.	bivalent diphtheria–tetanus vaccine, bivalent tetanus–diphtheria vaccine, monovalent tetanus vaccine, trivalent measles–mumps–rubella vaccine, Haemophilus influenza group b (Hib) vaccines, hepatitis B virus vaccine and other vaccines	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 income and parental education, and no such inverse association was observed for any other vaccine.	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 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.		physicians themselves.			and/or preschool	After 1993, before 1999 when study was published.		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) conjugate vaccine: 0.57 (0.36–0.89)		Severson RK, Kaune WT, Friedman DR, Haines CM, Muirhead CR, Boice JD and Robison LL (1997) Magnetic field exposure assessment in a case-control study of childhood leukemia. Epidemiology 8: 575–583. Details case ascertainment
Gruber et al. 2008, Retrospective cohort[215]	N=2173 (cases with atopic dermatitis and family history of allergy); Location=12 countries, Australia,	Diphtheria, tetanus, pertussis, polio, Haemophilus influenza Type B, hepatitis B, mumps, measles,	Participants recruited into a randomized clinical trial but no real details given. Results for this paper taken from screening population	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	Logistic regression	Total assessed: country, age, gender, birth weight, maternal age, family history of atopy, presence of siblings, breastfeeding,	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	Not reported	ORs are also presented in figure 2

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
	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	rubella, varicella, BCG, meningococci and pneumococci	before randomization occurred.				measurements were performed in three central laboratories with the Pharmacia ImmunoCAP fluorescence enzyme immunoassay technology		parental smoking, day care, exposure to pet animals and SCORAD total index			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 (0.14–0.56), p = 0.0003 varicella immunization since birth: 0.37 (0.21–0.65), p = 0.0005		

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												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		

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Hambidge et al. 2011, Matched case-control (and self-controlled case series)[241]	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 reported	
Hummel et al. 2000, Prospective cohort[228]	N=823; Location=Germany; Age=0-2 years; Setting=German BABYDIAB Study	Bacille Calmette-Guérin [BCG]); haemophilus influenza (HIB); diphtheria,	Study design described in another paper (See comment box)	From 1989 until the time of analysis (1999), 1,002 of 1,553 offspring recruited at birth had reached the	Not discussed	Structured questionnaires	Direct measurement	Odds ratios were calculated as the ratio of the proportion of offspring with islet antibodies in	None mentioned	1989-1999	Work was supported by grants from the Bundesministerium für Forschung, Bildung und	Figure 2. Risk (odds ratio) for developing islet antibodies with respect to environmental factors. (Estimates from figure)	None given	Ziegler AG, Hummel M, Schenker M, Bonifacio E: Antibody appearance and risk for the

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		tetanus, and pertussis (DTP); poliomyelitis; tick-born encephalitis (TBE); and measles, mumps, and rubella (MMR)		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				those with breast-feeding times greater and less than 3 months and in those with and without a vaccination event.			Technologie	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)		development of childhood diabetes in offspring of parents with type 1 diabetes: the German BABYDIAB Study. Diabetes 48:460–468, 1999
Italian Multicenter Study Group for Drug and Vaccine Safety in Children, 2011, Case-control[113]	N=683 children aged 1 month to 18 years, hospitalized through the emergency departments of eight pediatric hospitals/wards in Italy	A-H1N1 Seasonal influenza	Potentially some selective recruitment of vaccinated children that should have been attenuated by enrolling cases on a specified day of the week	Aside from initial exclusions, no attrition discussed	Not discussed	Parental report	Active surveillance. Both clinically defined and laboratory confirmed hospitalizations for Influenza Like Illness (ILI) were considered. Adverse events ascertained through parental report	Logistic regression	Age and chronic diseases; the ORs of A-H1N1 and seasonal vaccine were each adjusted for the other influenza vaccine	November 2009 to August 2010	Italian Medicines Agency	OR of influenza-like illness Any flu vaccine 2.7 (1.6 to 4.7) A-H1N1 1.3 (0.6 to 3.1) Seasonal vaccine 2.1 (1.1 to 4.1)	Not reported	

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Kelly et al. 2012, Retrospective cohort[242]	N=104,076 children presenting to Perth hospitals with febrile convulsion	Influenza	Entire population was assessed though unknown if hospital cases differed systematically in the 9 hospitals assessed from other area hospitals	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 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	None given	
Klein et al. 2008, Prospective cohort[243]	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.	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 vaccine-related adverse event	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 anomalies (n 1)	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 (0.6–1.8),p=0.96	None	

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		Infants born earlier in the study period might have received the combination DTP/Hib or DTaP/Hib vaccines, whereas those born later might have received DTaP/IPV/ HBV vaccine"	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									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		
Klein et al. 2011, Case-control[244]	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 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	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 recommended dose of polio, hepatitis B, and MMR by age two. Risk of hospitalization during post vaccination days 0 to	None	

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				subjects and 1,540 matched control subjects.								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.		
Ma et al. 2005, Case-control[225]	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)	Not reported	

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												ALL: 1.01 (0.78, 1.31)		
MacArthur et al. 2008, Case-control[226]	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 exposure misclassification, since information was not always corroborated with the index child's vaccination or medical records."	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 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	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 asked to recall their child's immunization history	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, gender, and age.	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 provided by a research unit infrastructure grant from the Michael Smith Foundation for Health Research	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) Hepatitis 1.09 (0.34-3.52) Other vaccine 0.81 (0.58-1.13)	None given	

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Mommers et al. 2004, Case-control[216]	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 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	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 age 5–6 years.	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) 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)	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)	

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				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.								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) Measles: 1.59 (0.61–4.17) Rubella: 0.80 (0.54–1.19) Hib: 0.94 (0.67–1.32)	1 older sibling 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	

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													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)	
Morgan et al. 2011, Self-controlled case series[117]	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 hyperammonemia in first 30 days of life, or hospital	Clinical records	Clinical records	Conditional 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 reported	

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					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.									
Mullooly et al. 2007, Case-control[217]	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	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,	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	Not reported	

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				a positive skin test for at least one 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.					calendar period of skin test (1978–93, 1994–99, 2000–01)			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 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)		
Mullooly et al. 2011, Self-controlled case series[245]	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	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 positive predictive value	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)	None	

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
				there was no evidence of increased wheezing lower respiratory diseases (WLRD) risk in either population			(PPV) of diagnosis codes and the accuracy of medical-care encounter sequences as proxies for WLRD onsets					8–14 days HBV: 0.84 (0.72–0.98) DTaP: 0.97 (0.85–1.11) 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–		

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
												1.05) 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 (0.43–0.79) 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)		

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
												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)		
O'Leary et al. 2012, Retrospective cohort[143]	N=1.8 million from 5 managed care organizations; Location=Colorado, Hawaii, Georgia, Northern CA,	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	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	None reported	Authors: ITP is unlikely after early childhood vaccines other than MMR. Because of the small number of exposed

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
	Massachusetts; Age=6 weeks to 17 years;		practices across the five sites									MMR: 5.48 (1.61, 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		cases and potential confounding, the possible association of ITP with hepatitis A, varicella, and tetanus-diphtheria-acellular pertussis vaccines in older children requires further investigation.

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
Pagaoa et al. 2011, Case-control[227]	N=14,000(2800 cancer cases, 11,200 controls); Location=Texas; Age=2 to 17 years; Setting=Texas Cancer Registry combined with birth certificate data to identify eligible participants	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 Hib), 4-3-1-3-3, 4-3-1-3-3-1	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 sex, child's birth year, child's ethnicity, child's birth weight, mother's age at child's birth	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 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	None reported	

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
												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: 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		

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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
												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 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		

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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
												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		
Pahud et al. 2012, Case-centered method[229]	N=110 encephalitis cases; Location=CA; Age= 6 months to 18 years	Many analyzed, measles virus-containing vaccines and pertussis antigen containing vaccines reported	Of 1,434 cases, immunization records were requested for over 800 and received for only 246. 136 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	Not discussed	Not discussed	Immunization records request	Medical record review	Logistic regression	None reported	Between July 1998 and December 2008	America's Health Insurance Plans (AHIP) Vaccine Safety Fellowship program under contract from the Centers for Disease Control and Prevention (CDC)	Association with pre-defined risk windows Measles virus-containing vaccines 5–15 days: OR=1.31 (0.30–5.77) Pertussis antigen-containing vaccines 0–3 days: OR=1.37 (0.33–5.78)	None reported	
Patel et al. 2011, Case-control (also did self-controlled case-series)[183]	N=2665 (615 cases of intussusception, 2050 controls);	RV1, Rotarix	Neighborhood controls - possible differences in risk factors or exposure	A total of 615 infants with intussusception (285 in Mexico and 330 in Brazil)	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	OR (95% CI) for intussusception (Case-control) Rotavirus vaccination	Not reported	

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	Location=Mexico, Brazil; Age=45-245 days; Setting=53 hospitals in 7 states in Brazil and at 16 hospitals in 10 states in Mexico		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)	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.							Program for Appropriate Technology in Health (PATH) and in part by the U.S. Department of Health and Human Services	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 (0.1–2.2) 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		

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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
												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) 15–21 days: 0.9 (0.4–2.0)		

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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
Rowhani-Rahbar et al. 2012, Case-centered[222]	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	
Stowe et al. 2011, Self-controlled case series[111]	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	Not reported	

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												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) 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)		

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												4–7 Days post vaccine: 0 0–7 Days post vaccine: 1.96 (0.62–6.14)		
Sun et al. 2012, Prospective cohort study and self-controlled case series[219]	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	Differences between boys and girls not significant.	

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												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 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)		
Thomson et al. 2010, Prospective cohort[218]	N=488; Location=Australia; Age=2-6 years (outcomes ascertained at 6 years); Setting=Melbourne Atopy Cohort Study (MACS), an ongoing prospective cohort study initiated in	Triple antigen [diphtheria, tetanus and pertussis (DTP)], combined diphtheria and tetanus (CDT), measles mumps rubella (MMR)	Study notes, "Loss to follow-up is a potential issue for prospective studies as selective loss to 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	By 6 yr of age, 488 (79%) of the original birth cohort of 620 remained, representing a cumulative 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	Not assessed	Parental report	Parental report of consistent symptoms and/or physician/doctor diagnosis	Linear regression	Parental socio-demographics, allergic disease, parental smoking history; parental education; gender of child and older siblings, pet ownership of at least one dog and/or cat	The MACS recruited 620 infants born between February 1990 and November 1994	MACS was initially supported by Nestle´ Australia, while the Asthma Foundation of Victoria supported the 10-yr follow-up.	RR (95% CI) for Asthma Triple antigen (DTP) 1st year: 4.75 (0.88, 25.58) 2nd year: 0.74 (0.56, 0.96) 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,	RR (95% CI) for Asthma Socio-demographics child Gender (male) 1.61 (1.21, 2.14) Older siblings (at least 1) 1.27 (1.17, 1.38) Characteristics mother Education (tertiary) 0.94 (0.67,	

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
	1989		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."	another 89 were loss to follow up at the two year old data collection. Reason for loss to follow up were not provided.								1.00)	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,	

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
													1.81) 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)	
Tse et al. 2012, Self-controlled risk interval, current vs. historical vaccine design[112]	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	
Velázquez et al. 2012, Self-controlled case-series[182]	N=698 infants < 1 year old in Mexico with intussusception Active surveillance across hospitals in	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-	Review of records, confirmed by review of Expanded Program on Immunization cards. If direct review of Expanded Program on Immunization	Review of hospital admission and discharge logs, and emergency department, pediatric ward, surgery and radiology files. Episodes of intussusception were classified as	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:	Not reported	

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
	Mexico from the Mexican Institute of Social Security				participants	cards was not possible, vaccination history was confirmed from available clinical files (medical charts or the IMSS database). If this was not possible, vaccination history was confirmed through parent/guardian recall.	definite according to the case definition developed by the Brighton Collaboration Working Group for Intussusception, and were confirmed by radiography, surgery or postmortem examination					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		
Wilson et al. 2011, Self-controlled case series[144]	N=413,957; Location=Ontario, Canada; Age=12 and 18 months;	Live MMR	Newborn Screening Ontario dataset captures over 99% of births	Not applicable	Not applicable	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 Database	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	None given	

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
							was used to ascertain cases of death.					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 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		

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
												(Combined risk interval): 1.25 (1.17-1.33), p=0.0001		
Yih, et al. 2013,[185] Self-controlled risk interval (SCRI) and a cohort design	N=124 total cases, 613,000 infant-years; Location=U.S.; Age=5-36.9 weeks; Setting=Post-Licensure Rapid Immunization Safety Monitoring program (PRISM), participants were members of Mini-Sentinel Data Partners Aetna, HealthCore, or Humana	RotaTeq, Rotarix	Self-controlled, however physicians may have screened cases more heavily knowing about their vaccination status. Sensitivity analysis revealed this to be not a major contributor to any increased risk	343 potential cases of intussusception were identified in the electronic data. Of these, 267 (78%) had medical record review, and 124 were considered Level 1 on Brighton levels of diagnostic certainty. Charts for the non-reviewed 76 potential cases (22%) were unobtainable due to inability to locate the provider, provider refusal to participate, or there being no record of the patient at the provider	Risk estimates generally decreased with the addition of Brighton Level 2 cases and with the addition of cases for which charts were not obtained; but estimates that were statistically significant in the primary analysis generally retained their significance, and in fact some of the Rotarix estimates became statistically significant with the addition of these cases lacking charts. The attenuation	Claims data and medical record review	Claims data with adjudication	SCRI: logistic regression Cohort: Poisson regression	SCRI: age Cohort: age, sex, Data Partner, and exposure status	January 2004 to September 2011	FDA	Table 2. Case counts and risk estimates (RR, 95% CI) for Brighton Level 1 confirmed intussusception after RotaTeq, risk estimates incorporate a correction factor for cases lacking charts (which make up 22% of the total by dose, study design, and age adjustment. Attributable potential cases ascertained). Pre-specified: Tate age-adjustment Post-hoc: PRISM age-adjustment SCRI, Risk Window 1-7 days Dose 1 Pre-specified: 9.1, 2.2-39 Post-hoc: 7.0, 1.7-29 Dose 2 Pre-specified: 1.8, 0.4-7.2 Post-hoc: 1.8, 0.4-7.2 Dose 3 Pre-specified: 2.2, 0.5-9.7 Post-hoc: 2.3, 0.5-10	None	

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
					of observed risk is not surprising, as we would expect greater misclassification of the outcome to be introduced by the addition of these unconfirmed potential cases, tending to cause bias toward the null. Furthermore, it is not clear that the validity of our risk estimate increases through the addition of Level 2 cases where there is less diagnostic certainty.							All Pre-specified: 3.3, 1.5-7.4 Post-hoc: 3.0, 1.4-6.8 SCRI, Risk Window 1-21 days Dose 1 Pre-specified: 4.2, 1.1-16 Post-hoc: 3.4, 0.9-13 Dose 2 Pre-specified: 1.0, 0.3-3.1 Post-hoc: 1.0, 0.3-3.1 Dose 3 Pre-specified: 1.0, 0.2-3.9 Post-hoc: 1.0, 0.2-4.0 All Pre-specified: 1.6, 0.8-3.3 Post-hoc: 1.5, 0.7-3.1 Cohort Dose 1 Pre-specified: 2.6, 1.2-5.8 Post-hoc: 2.9, 1.4-6.0 Dose 2 Pre-specified: 0.9, 0.4-2.2 Post-hoc: 0.8, 0.3-		

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
												2.0 Dose 3 Pre-specified: 0.9, 0.4-2.2 Post-hoc: 0.9, 0.4-2.2 All Pre-specified: 1.3, 0.8-2.1 Post-hoc: 1.3, 0.8-2.1 Table 3. Case counts and risk estimates for Brighton Level 1 confirmed intussusception after Rotarix, by dose, study design, and age adjustment. Pre-specified: Tate age-adjustment Post-hoc: PRISM age-adjustment SCRI, Risk Window 1-7 days Dose 1 Pre-specified: infinity Post-hoc: none Dose 2 Pre-specified: 3.5, 0.5-25 Post-hoc: 3.6, 0.5-25 Dose 3 Pre-specified: 5.7, 0.9-34		

Evidence Table 3. Postmarketing studies: Children-adolsecents

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
												Post-hoc: 5.5, 0.9-33 SCRI, Risk Window 1-21 days Dose 1 Pre-specified: infinity Post-hoc: none Dose 2 Pre-specified: 1.7, 0.3-10 Post-hoc: 1.7, 0.3-10 Dose 3 Pre-specified: 2.3, 0.4-13 Post-hoc: 2.3, 0.4-13 Cohort Dose 1 Pre-specified: 2.9, 0.4-22 Post-hoc: 3.2, 0.4-23 Dose 2 Pre-specified: 5.1, 1.6-16 Post-hoc: 4.6, 1.5-15 Dose 3 Pre-specified: 3.8, 1.4-10 Post-hoc: 3.7, 1.4-10		

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Andrews N. et al.,2010 UK[246]	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	
Armah G. E. et al.,2010 Ghana, Kenya, Mali[146]	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)
Barbosa, C.M..et al. 2012[206] Brazil	Controlled Clinical Trial	4	Sample size : 134, Mean age: 15, Age range: 5 - 18, Percent female: 78%	Varicella , Biken , Aventis Pasteur , >=1000 plaque forming units of virus/0.5 mL , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Days	Any adverse event : 42.9% , Syscat: 8, 7 , Sev: 1 Event: Herpes zoster (45 day f/u) : 0% , Syscat: 23	

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Block S. L. et al.,2007 United States, Finland[147]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Block S. L. et al.,2010 Asia, Europe, Latin America, North America[188]	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)
Capeding M. R. Z. et al.,1996 Philippines[120]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Chang C.-C. et al.,2009 Taiwan[148]	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)
Christie C. D. C. et al.,2010 Jamaica[149]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Clark, L.R. et al. 2013[200] Europe, Latin America, North America	Controlled Clinical Trial	3	Sample size : 700, Mean age: 20, Age range: 16 - 24, Percent female: 100%, Percent pregant: Percent Pregnant: 25%	Human papillomavirus (HPV) , Not reported. Quadrivalent vaccine targeting HPV-6/11 , Gardasil, Merck Sharp & Dohme, Corp. , Quadrivalent vaccine targeting HPV-6/11/16/18 , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Intramuscular	Dose1: Day 1 Days Dose2: Month 2 Month Dose3: Month 6 Month	Any SAE : 1.7% Event: One or more injection-site AE : 49% , Syscat: 8 Event: One or more systemic AE : 35.8% Event: Vaccine-related systemic AE : 23.8% Event: Serious vaccine-related AE : 0% Event: Abnormal live birth : 3% , Syscat: 18 Event: Congenital or other anomaly - live birth : 1% , Syscat: 18 Event: Other medical condition - live birth : 2% , Syscat: 18 Event: Number of fetal losses : 24.2% , Syscat: 18 Event: Spontaneous abortion : 20% , Syscat: 18 Event: Late fetal death : 0% , Syscat: 18 Event: Elective abortion : 17.4% , Syscat: 18	Abnormal live birth: OR 0.766 (0.182-3.23) Congenital or other anomaly - live birth: OR 1.281 (0.08-20.564) Number of fetal losses: OR 7.876 (2.694-23.025)** One or more injection-site AE: OR 1.384 (1.024-1.871)** One or more systemic AE: OR 1.362 (0.988-1.876) Spontaneous abortion: OR 0.798 (0.44-1.447) Vaccine-related systemic AE: OR 1.414 (0.977-2.046)
De Carvalho N. et al.,2010 Brazil[194]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Dennehy P. H. et al.,2005 United States, Canada[150]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Englund J. A. et al.2010 US[105]	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)
Giuliano A. R. et al.,2011 18 countries[193]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Gotoh K. et al.,2011 Japan[110]	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)
Goveia M. G. et al.,2007 11 countries[151]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Grant L. R et al.,2012 United States[152]	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)
Greenhawt, M.J. et al. 2012[109] US	Controlled Clinical Trial	1	Sample size : 143, Mean age: NR, Age range: 14 - 17, Percent female: 36.7%, Conditions: Egg allergy	Influenza (inactived) , Fluzone , Sanofi , Formulation had ovo-albumin content of 0.1 microgram per 0.5 ml dose , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Not reported	Dose1: 0 Days Dose2: 30 mins NR	Syscat: Not clear Event: Localized urticaria : 35.7% , Syscat: 23 Event: Systemic urticaria : 35.7% , Syscat: 23 Event: Oro-facial angioedema : 42.8% , Syscat: 23 Event: Throat itching : 21.4% , Syscat: 7 Event: Throat swelling : 14.3% , Syscat: 7 Event: Stridor : 7.1% , Syscat: 22 Event: Cough : 21.4% , Syscat: 22 Event: Dyspnea : 14.3% , Syscat: 22 Event: Wheezing : 14.3% , Syscat: 22 Event: Hypotension : 7.1% , Syscat: 26 Event: Vomiting : 64.3% , Syscat: 7 Event: Abdominal pain : 21.4% , Syscat: 7	Dyspnea: OR 0.117 (0.02-0.693)** Hypotension: OR 0.577 (0.047-7.119) Localized urticaria: OR 1.019 (0.232-4.466) Oro-facial angioedema: OR 1.8 (0.407-7.957) Stridor: OR 0.577 (0.047-7.119) Systemic urticaria: OR 0.494 (0.116-2.105) Throat itching: OR 1.273 (0.214-7.582) Throat swelling: OR 2.667 (0.216-32.961) Wheezing: OR 2.667 (0.216-32.961)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Halasa N. et al.,2011 US[106]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Huu, T.N. et al. 2013[118] Vietnam	Controlled Clinical Trial	7	Sample size : 300, Mean age: 8.7, Age range: 6 - 12, Percent female: 43.3%	Haemoph. Influen. type b (Hib) protein conjugate, Routine Vaccines , Experimental: SynflorixRoutine: Infarix hexa , GlaxoSmithKline , PHiD-CV (Synflorix™, GlaxoSmithKline, Rixensart,Belgium) contained 1µg of each capsular polysaccharideof pneumococcal serotypes 1, 5, 6B, 7F, 9V, 14, and 23Fand 3µg of serotype 4 capsular polysaccharide conju-gated individually to NTHi protein D; 3µg of serotype18C capsular polysaccharide conjugated to tetanus tox-oid; and 3µg of serotype 19F capsular polysaccharideconjugated to diphtheria toxoid. Routine: DTPa-HBV-IPV/Hib vaccine (Infanrix hexa™,GlaxoSmithKline, Rixensart, Belgium) contained=30 IUof diphtheria toxoid,=40 IU of tetanus toxoid, 25µgofpertussis t , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Days Dose2: 28-42 Days Dose3: 28-42 Days	Event: SAEs (total) : 4.5% , Syscat: See below , Sev: 2-3 Event: SAE- convulsion : 1.0% , Syscat: 17 , Sev: 2-3 Event: SAE- diarrhea : 1.0% , Syscat: 7 , Sev: 2-3 Event: SAE-bronchiolitis : 1.0% , Syscat: 22 , Sev: 2-3 Event: SAE- autoimmune thrombocytopenia : 0.5% , Syscat: 1 , Sev: 2-3 Event: SAE- upper respiratory tract infection : 0.5% , Syscat: 22 , Sev: 2-3 Event: SAE- gastro-oesophageal reflux disease : 0.5% , Syscat: 7 , Sev: 2-3 Event: SAE - hydronephrosis : 0.5% , Syscat: 20 , Sev: 2-3 Event: SAE- fungal infection : 0.5% , Syscat: 11 , Sev: 2-3 Event: SAE - Kawasaki ’ s disease : 0.5% , Syscat: 1 , Sev: 2-3 Event: SAE - coagulopathy : 0.5% , Syscat: 1 , Sev: 2-3	SAE- convulsion: OR 0.332 (0.055-2.017) SAE- diarrhea: OR 0.503 (0.07-3.621) SAE- fungal infection: OR 0.25 (0.022-2.791) SAE- gastro-oesophageal reflux disease: OR 0.505 (0.031-8.159) SAEs (total): OR 0.75 (0.259-2.169)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Kang, S. et al. 2008[199] Korea	Controlled Clinical Trial	4	Sample size : 176, Mean age: 16.6, Age range: 9 - 23, Percent female: 100%	Human papillomavirus (HPV) , Gardasil , Merck , Mixture of four recombinant HPV type-specific VLPsconsisting of the L1 major capsid proteins of HPV 6,11, 16, and 18 synthesized inSaccharomyces cerevisiae.The four VLP types were purified and adsorbedonto amorphous aluminum hydroxyphosphate sulfateadjuvant. , Adjuvant: Aluminum , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Days Dose2: 1 Month Dose3: 6 Month	Any adverse event : 77.8% , Syscat: 8, 23 , Sev: 1 Any SAE : 2.5% , Syscat: 8 , Sev: 3 Event: Vaccine related AE : 72.6% , Syscat: 8, 23 , Sev: 1 Event: SAE - death : 0.8% , Sev: 4 Event: Vaccine related SAE : 0% Event: Discontinued due to AE : 8.23% , Syscat: 12 , Sev: 4 Event: Discontinued due to vaccine related AE : 0% Event: Discontinued due to SAE : 0% Event: Discontinued due to vaccine related SAE : 0%	Vaccine related AE: OR 154.063 (20.474-1159.27)**
Kawamura N. et al.,2011 Japan[153]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Kerdpanich A. et al.,2010 Thailand[154]	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)
Khalil, M. et al. 2012[212] Saudi Arabia	Controlled Clinical Trial	4	Sample size : 238, Mean age: 6.3, Age range: 5 - 8, Percent female: 55.0%	Meningococcal conjugate , Menactra, PA , Sanofi , Quadrivalent (A, C, Y, and W-135) meningococcal diph-theria toxoid-conjugate vaccine , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Days	Event: Grade 2-3 Fever : 5.2% , Syscat: 8 , Sev: 2-3 Event: Grade 2-3 Headache : 1.3% , Syscat: 8 , Sev: 2-3 Event: Grade 2-3 Malaise : 4.5% , Syscat: 8 , Sev: 2-3 Event: Grade 2-3 Myalgia : 2.6% , Syscat: 8 , Sev: 2-3 Event: SAE - Upper respiratory infection (unsolicited AE) : 0.6% , Syscat: 22 , Sev: 3 Event: SAE - Headache (unsolicitied AE) : 0.6% , Syscat: 8 , Sev: 3	Grade 2-3 Fever: OR 1.508 (0.389-5.842) Grade 2-3 Headache: OR 1.113 (0.099-12.453) Grade 2-3 Malaise: OR 4.027 (0.487-33.3) Grade 2-3 Myalgia: OR 2.255 (0.248-20.507) SAE - Headache (unsolicitied AE): OR 0.553 (0.034-8.949)
Khatun, S. et al. 2012[198] Bangladesh	Controlled Clinical Trial	4	Sample size : 67, Mean age: NR, Age range: 9 - 13, Percent female: 100%	Human papillomavirus (HPV) , Cervarix , GlaxoSmithKline , In this preparation, the L1protein of each HPV type is expressed via a recombinantbaculo virus vector. The VLPs of each HPV type are pro-duced separately and consist of purified L1 VLPs ofHPV-16/18 at 20/20-g per dose formulated on AS04 adju-vant comprising 500 gm of aluminum hydroxide and 50 gmof 3-deacylated monopods phage lipid A. , Adjuvant: ASO 4 , Preservative: Not reported , Delivery: Not reported	Dose1: 0 Days Dose2: 1 Dose3: 6	Any SAE : 0% Event: Any AE after 1st dose : 80% , Syscat: 8, 7 Event: Any AE after 2nd dose : 88% , Syscat: 8, 7 Event: Any AE after 3rd dose : 90% , Syscat: 8, 7 Event: SAE : 0%	Any AE after 1st dose: OR 16 (4.043-63.326)** Any AE after 2nd dose: OR 53.778 (9.89-292.432)** Any AE after 3rd dose: OR 81 (12.938-507.104)**

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Kim D. S. et al.,2008 Korea[155]	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)
Kim J. S. et al.,2012 South Korea[156]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Kim, S. C. et al.,2011 Korea[191]	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)**

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Klein, N.P. et al. 2012[213] U.S., Colombia, Argentina	Controlled Clinical Trial	2	Sample size : 1508, Mean age: 65.5, Age range: 55 - 89, Percent female: 47.8%	Meningococcal conjugate, Routine Vaccines , NR (likely Novartis, the trial sponsor) , Lyphilized Men A component with liquid MenCWY component, Each dose contained 10micrograms of MenA oligosacchirides and 5microgram each of MenC, MenW-135, and MenY conjugated to CRM197 (~50microgram) , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Month Dose2: 2 Month Dose3: 2 Month	Event: Urticaria (6m) : 1% , Syscat: 23 , Sev: 2-3 Event: Urticaria (12m) : <1% , Syscat: 23 , Sev: 2-3 Event: Severe change in eating habits (6m) : <1% , Syscat: 8 , Sev: 2-3 Event: Severe change in eating habits (12m) : 1% , Syscat: 8 , Sev: 2-3 Event: Severe sleepiness (6m) : 1% , Syscat: 8 , Sev: 2-3 Event: Severe sleepiness (12m) : <1% , Syscat: 8 , Sev: 2-3 Event: Severe persistent crying (6m) : <1% , Syscat: 8 , Sev: 2-3 Event: Severe persistent crying (12m) : 1% , Syscat: 8 , Sev: 2-3 Event: Severe irritability (6m) : 1% , Syscat: 8 , Sev: 2-3 Event: Severe irritability (12m) : 1% , Syscat: 8 , Sev: 2-3 Event: Severe vomiting (6m) : 0% , Syscat: 7 , Sev: 2-3 Event: Severe vomiting (12m) : <1% , Syscat: 7 , Sev: 2-3 Event: Severe diarrhea (6m) : <1% , Syscat: 7 , Sev: 2-3 Event: Severe diarrhea (12m) : 1% , Syscat: 7 , Sev: 2-3 Event: SAE- Death : 0% , Syscat: 0 , Sev: 2-3 Event: SAE- Kawasaki disease (after 3rd dose of MenC) : <1% , Syscat: 1 , Sev: 2-3 Event: SAE- partial complex seizures (after 2nd dose of Men C) : <1% , Syscat: 17 , Sev: 2-3 Event: SAE - Febrile convulsions (after 3rd dose of MenC) : <1% , Syscat: 17 , Sev: 2-3	Severe change in eating habits (12m): OR 3.574 (0.439-29.129) Severe change in eating habits (6m): OR 0.507 (0.102-2.519) Severe irritability (12m): OR 0.675 (0.233-1.955) Severe irritability (6m): OR 3.06 (0.367-25.49) Severe persistent crying (12m): OR 0.761 (0.214-2.707) Severe sleepiness (12m): OR 0.507 (0.102-2.519) Severe sleepiness (6m): OR 3.06 (0.367-25.49) Urticaria (12m): OR 0.507 (0.102-2.519) Urticaria (6m): OR 0.888 (0.259-3.048)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Laserson K. F. et al.,2012 Kenya[157]	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)**
Lau, Y.L. et al. 2013[179] China	Controlled Clinical Trial	1	Sample size : 3025, Mean age: 11.6, Age range: 6 - 12, Percent female: Not reported%	Rotavirus , RotarixTM , GlaxoSmithKline , Each dose of the lyophilized formulation of RIX4414 (RotarixTM, GlaxoSmithKline, Belgium) vaccine contained at least 106.0 median cell culture infectious dose (CCID50) of live, attenuated human G1P rotavirus. The RIX4414 vaccine was reconstituted in a calcium carbonate buffer before oral administration. , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Oral	Dose1: 2 Month Dose2: 4 Month	Any SAE : 29% Event: Intussusception : 0.3% , Syscat: 7 Event: Gastroenteritis-related symptoms requiring <=1 hospitalization : 8% , Syscat: 7	Gastroenteritis-related symptoms requiring <=1 hospitalization: OR 0.793 (0.616-1.021) Intussusception: OR 2.001 (0.366-10.943)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Levin M. J. et al.,2010 US (not stated explicitly)[190]	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[189]	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)
Madhi S. A. et al.,2010 South Africa and Malawi[158]	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)
Madhi, S.A. et al. 2013[108] South Africa	Controlled Clinical Trial	4	Sample size : 410, Mean age: 23.8, Age range: 6 - 59, Percent female: 59%	Influenza (inactived) , VAXIGRIP , Sano?-Aventis , Adjuvant: Adjuvant Free , Preservative: Not reported , Delivery: Intramuscular	Dose1: Not reported Dose2: 1 month later Month	Any SAE : 0% Event: Pain at site of injection : 2.3% , Syscat: 8 Event: Fever at least 37.5o C : 4.2% , Syscat: 8 Event: Induration at injection site : 2.3% , Syscat: 8 Event: Weakness : 4.5% , Syscat: 8	Uncalcuable

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Moreira Jr E. D. et al.,2011 18 countries including Brazil, Germany, Mexico, US, South Africa, Australia, Canada[187]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Narang A. et al.,2009 India[159]	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)**
Omenaca F. et al.,2012 France, Portugal, Poland and Spain[160]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Phua K. B. et al.,2005 Singapore[161]	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)
Phua K. B. et al.,2009 Hong Kong, Singapore, Thailand[162]	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)
Phua K. B. et al.,2012 Singapore, Hong Kong, Taiwan[163]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Rodriguez Z. M. et al.,2007 United States[164]	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)
Roteli-Martins C. M. et al.,2012 Brazil[195]	#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)
Ruiz-Palacios G. M. et al.,2006 Finland, Argentina, Brazil, Chile, Colombia, the Dominican Republic, Honduras, Mexico, Nicaragua, Panama, Peru, Venezuela[165]	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)**

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Santosham M. et al.,1991 United States[119]	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)**
Schwarz, T.F. et al. 2012[196] Taiwan, Germany, Honduras, Panama, and Colombia	Controlled Clinical Trial	NC	Sample size : 588, Mean age: 12, Percent female: 100%, Percent pregant: Percent Pregnant: 5%	Human papillomavirus (HPV) , HPV-16/18 AS04-adjuvanted vaccine , GlaxoSmithKline , Each dose of the HPV-16/18 vaccine consisted of 20 ®g each of HPV-16 andHPV-18 L1 proteins, self-assembled as virus-like particles, adjuvanted with the Adjuvant System AS04 (comprising 500 ®g of aluminum hydroxide and 50®g of MPL). , Adjuvant: ASO 4 , Preservative: Not reported , Delivery: Not reported	Dose1: 0 Month Dose2: 1 Month Dose3: 6 Month	Any SAE : 8% Event: New onset chronic disease : 9% , Syscat: NG Event: Medically significant condition : 51% , Syscat: NG	New onset chronic disease: OR 2.822 (1.818-4.38)**

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Shui I. M. et al.,2012 US[184]	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)
Sow S. O. et al.,2012 Vietnam, Bangledash, Ghana, Kenya, Mali[166]	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)
Sow, P. S. et al. 2013[197] Senegal, Tanzania	Controlled Clinical Trial	5	Sample size : 676, Mean age: 16.9, Age range: 10 - 25, Percent female: 100%	Human papillomavirus (HPV) , Cervarix , GlaxoSmithKline , Each dose of HPV-16/18 AS04-adjuvanted vaccine Cervarix ® (GlaxoSmithKline Vaccines) contained 20 µg each of HPV-16 and HPV-18 L1 viruslike particles, 50 µ g of 3-O-desacyl-4 ' -monophosphoryl lipid A, and 500 µ g of Al(OH)3. , Adjuvant: Aluminum , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Days Dose2: 1 Month Dose3: 5 Month	Event: Death : 0% Event: SAE : 3.8% Event: AE leading to premature discontinuation : 0% Event: Medically significant condition : 69.3% Event: New onset chronic disease : 2.4% Event: New onset autoimmune disease : .4% , Syscat: 10	Medically significant condition: OR 0.745 (0.518-1.07) New onset autoimmune disease: OR 0.5 (0.07-3.573) New onset chronic disease: OR 0.49 (0.209-1.148) SAE: OR 0.595 (0.288-1.229)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Steele A. D. et al.,2010 South Africa[167]	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)
Tregnaghi M. W. et al.,2011 Argentina, Brazil, Colombia, Dominican Republic, Honduras, and Panama[169]	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)
Vesikari T. et al.,2004 Finland[170]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Vesikari T. et al.,2006 Finland[171]	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)
Vesikari T. et al.,2006 11 countries[172]	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	
Vesikari T. et al.,2011 Finland[173]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Zaman K. et al.,2009 Bangladesh[175]	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%, Syscat: 8, Sev: 3 Event: fever: rectal temperature >39.5 ?C: 3%, Syscat : 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)
Zaman K. et al.,2010 Bangladesh and Vietnam[176]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Zaman K. et al.,2012 Bangladesh[177]	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)

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Andrews N. et al.,2010 UK[246]	Haemoph. influenza. type b (Hib) protein conjugate, Polio (inactivated only), Tdap, Pediacel, Sanofi, Adjuvant: Not Reported, Preservative: Not reported, Delivery:	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%		
Armah G. E. et al.,2010 Ghana, Kenya, Mali[146]				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%
Barbosa, C.M..et al. 2012[206] Brazil	Varicella , Biken , Aventis-Pasteur , >=1000 plaque forming units of virus/0.5 mL , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Intramuscular	Dose1: 0 Days	Any adverse event : 46.4% , Syscat: 7, 8 , Sev: 1 Event: Herpes Zoster : 0% , Syscat: 23	Nothing	Any adverse event : 23.1% , Syscat: 7,8 , Sev: 1 Event: Herpes zoster : 3.8% , Syscat: 23
Block S. L. et al.,2007 United States, Finland[147]				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

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
					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%
Block S. L. et al.,2010 Asia, Europe, Latin America, North America[188]				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:

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
					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%
Capeding M. R. Z. et ak.,1996 Philippines[120]	:			Routine Vaccines	Event: Serious adverse reactions: 0% Event: Irritability: 22%, Syscat: 8 Event: Fever: 22%, Syscat: 8
Chang C.-C. et al.,2009 Taiwan[148]				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
Christie C. D. C. et al.,2010 Jamaica[149]				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
Clark, L.R. et al. 2013[200] Europe, Latin America, North				Placebo Unsure of adjuvants, preservatives and formulations	Any SAE : 1.6% Event: One or more injection-site AE : 41% , Syscat: 8 Event: One or more systemic AE : 29.1%

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
America					Event: Vaccine-related systemic AE : 18.2% Event: Serious vaccine-related AE : 0% Event: Abnormal live birth : 4.5% , Syscat: 18 Event: Congenital or other anomaly - live birth : 1% , Syscat: 18 Event: Other medical condition - live birth : 30% , Syscat: 18 Event: Number of fetal losses : 27% , Syscat: 18 Event: Spontaneous abortion : 6% , Syscat: 18 Event: Late fetal death : 3% , Syscat: 18 Event: Elective abortion : 18% , Syscat: 18
De Carvalho N. et al.,2010 Brazil[194]				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%
Dennehy P. H. et al.,2005 United States, Canada[150]	Rotavirus, Routine Vaccines, RIX4414, GlaxoSmithKline, Adjuvant: Not Reported, Preservative: Not reported, Delivery:	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	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

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
			Event: Mesenteric adenitis: 1%, Syscat: 7, Sev: Serious AE: 0% AE: 0% AE: 0%		
Englund J. A. et al., 2010 US[105]				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
Giuliano A. R. et al.,2011 18 countries[193]				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%
Gotoh K. et al.,2011 Japan[110]				Nothing	Any SAE: 0% Event: Acute allograft rejection: 2.8%, Syscat: 10 Event: Acute febrile illness: 31.0%, Syscat: 8

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
					Event: Influenza virus infection: 5.6%, Syscat: 10
Goveia M. G. et al.,2007 11 countries[151]				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
Grant L. R. et al.,2012 United States[152]				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
Greenhawt, M.J. et al. 2012[109] US				Placebo Unsure of adjuvants, preservatives and formulations	Event: Localized urticaria : 35.2% , Syscat: 23 Event: Systemic urticaria : 52.9% , Syscat: 23 Event: Orofacial angioedema : 29.4% , Syscat: 23 Event: Throat itching : 17.6% , Syscat: 7 Event: Throat swelling : 5.9% , Syscat: 7 Event: Stridor : 11.7% , Syscat: 22 Event: Cough : 1% , Syscat: 22 Event: Dyspnea : 5.9% , Syscat: 22 Event: Wheezing : 11.7% , Syscat: 22 Event: Hypotension : 5.9% , Syscat: 26 Event: Vomiting : 58.8% , Syscat: 7 Event: Abdominal pain : 11.7% , Syscat: 7
Halasa N. et al.,2011 US[106]				Placebo Unsure of adjuvants, preservatives and	Any adverse event: 90% Any SAE: 0% Event: Fever >100C: 40%, Syscat: 8, Sev: 1-3

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
				formulations	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
Huu, T.N. et al. 2013[118] Vietnam				Routine Vaccines	Event: SAE (total) : 6.0% , Syscat: See below , Sev: 2-3 Event: SAE-bronchiolitis : 3.0% , Syscat: 22 , Sev: 2-3 Event: SAE-diarrhea : 2.0% , Syscat: 7 , Sev: 2-3 Event: SAE-fungal infection : 2.0% , Syscat: 11 , Sev: 2-3 Event: SAE- urinary tract infection : 1.0% , Syscat: 11, 20 , Sev: 2-3 Event: SAE- gastro- oesophageal reflux diseas : 1.0% , Syscat: 7 , Sev: 2-3 Event: SAE - oral candidiasis : 1% , Syscat: 11 , Sev: 2-3 Event: SAE - viral infection : 1.0% , Syscat: 11 , Sev: 2-3
Kang, S. et al. 2008[199] Korea				Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event : 71.2% , Syscat: 8, 23 , Sev: 1 Any SAE : 0% Event: SAE- Pharyngitis : 1.7% , Syscat: 22 , Sev: 3 Event: Vaccine related SAE : 0% Event: Discontinued due to AE : 0% Event: Discontinued due to vaccine related AE : 0% Event: Discontinued due to SAE : 0% Event: Discontinued due to vaccine related SAE : 0%
Kawamura N . et al.,2011 Japan[153]				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

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
					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
Kerdpanich A. et al.,2010 Thailand[154]	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:	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
Khalil, M. et al. 2012[212] Saudi Arabia				Routine Vaccines , They had no prior MPSV4, they got the MCV only	Event: Grade 2/3- Fever : 3.5% , Syscat: 8 , Sev: 2-3 Event: Grade 2/3- Headache : 1.2% , Syscat: 8 , Sev: 2-3 Event: Grade 2/3- Malaise : 1.2% , Syscat: 8 , Sev: 2-3 Event: Grade 2/3- Myalgia : 1.2% , Syscat: 8 , Sev: 2-3 Event: SAE - Upper respiratory tract infection (unsolicited) : 1.2% , Syscat: 22 , Sev: 3 Event: SAE- Pharyngitis (unsolicited) : 1.2% , Syscat: 22 , Sev: 3
Khatun, S. et al. 2012[198] Bangladesh				Nothing	Any SAE : 0% Event: Any AE after 1st dose : 20% , Syscat: 8, 7 Event: Any AE after 2nd dose : 12% , Syscat: 8, 7 Event: Any AE after 3rd dose : 10% , Syscat: 8, 7 Event: SAE : 0%
Kim D. S. et	:			Placebo	Event: One or more serious adverse event: 11.1%

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
al.,2008 Korea[155]				Unsure of adjuvants, preservatives and formulations	Event: Intussusception: 0%, Syscat: 7
Kim J. S. et al.,2012 South Korea[156]				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%
Kim S. C. et al.,2011 Korea[191]				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

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Klein, N.P. et al. 2012[213] U.S., Colombia, Argentina				Routine Vaccines	Event: Uriticaria (6m) : 1% , Syscat: 23 , Sev: 2-3 Event: Uriticaria (12m) : 1% , Syscat: 23 , Sev: 2-3 Event: Severe change in eating habits (6m) : 1% , Syscat: 8 , Sev: 2-3 Event: Severe change in eating habits (12m) : <1% , Syscat: 8 , Sev: 2-3 Event: Severe sleepiness (6m) : <1% , Syscat: 8 , Sev: 2-3 Event: Severe sleepiness (12m) : 1% , Syscat: 8 , Sev: 2-3 Event: Severe persistent crying (6m) : 1% , Syscat: 8 , Sev: 2-3 Event: Severe persistent crying (12m) : <1% , Syscat: 8 , Sev: 2-3 Event: Severe irritability (6m) : 1% , Syscat: 8 , Sev: 2-3 Event: Severe irritability (12m) : <1% , Syscat: 8 , Sev: 2-3 Event: Severe diarrhea (6m) : <1% , Syscat: 7 , Sev: 2-3 Event: Severe diarrhea (12m) : <1% , Syscat: 7 , Sev: 2-3 Event: SAE-Death : 0% , Sev: 2-3 Event: SAE- Kawasaki disease : 0% , Syscat: 1 , Sev: 2-3 Event: SAE- partial complex seizures : 0% , Syscat: 17 , Sev: 2-3 Event: SAE- convulsions : 0% , Syscat: 17 , Sev: 2-3
Laserson K. F. et al.,2012 Kenya[157]				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

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
					Event: Nervous system disorders: 2.7%, Syscat: 17, Sev: Serious Event: Reproductive system and breast disorders: 0%, Syscat: 22, Sev: Serious
Lau, Y.L. et al. 2013[179] China				Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any SAE : 32% Event: Intussusception : 0.1% , Syscat: 7 Event: Gastroenteritis-related symptoms requiring <=1 hospitalization : 10% , Syscat: 7
Levin M. J. et al.,2010 US (not stated explicitly)[190]				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[189]				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%
Madhi S. A. et al.,2010 South Africa and Malawi[158]				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%
Madhi, S.A. et al. 2013[108] South Africa				Placebo Unsure of adjuvants, preservatives and formulations	Any SAE : 0%
Moreira Jr E. D. et al.,2011 18 countries including Brazil,	:			Placebo Placebo includes same adjuvants, preservatives, formulations as the active	Any adverse event: 64.2% Any SAE: 0.6% Event: Death (entire study): 0.5%, Sev: 5 Event: discontinued due to an adverse experience

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Germany, Mexico, US, South Africa, Australia, Canada[187]				group	(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
Narang A. et al.,2009 India[159]				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

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
					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
Omenaca F. et al.,2012 France, Portugal, Poland and Spain[160]	:			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
Phua K. B. et al.,2005 Singapore[161]	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:	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
Phua K. B. et al.,2009 Hong Kong, Singapore, Thailand[162]	:			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%
Phua K. B. et al.,2012				Placebo, Routine Vaccines Placebo includes same	Any adverse event: 0.26% Event: Intussusception: 0.02%

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year-Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Singapore, Hong Kong, Taiwan[163]				adjuvants, preservatives, formulations as the active group	Event: gastroenteritis: 0.05%
Rodriguez Z.M. et al., 2007[164] United States				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
Roteli-Martins C. M et al.,2012 Brazil[195]				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%
Ruiz-Palacios G. M. et al.,2006 Finland, Argentina, Brazil, Chile, Colombia, the Dominican Republic, Honduras, Mexico, Nicaragua, Panama, Peru, Venezuela[165]				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%
Santosham M. et al.1991 United States[119]				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
Schwarz, T.F. et				Routine Vaccines	Any SAE : 3%

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
al. 2012[196] Taiwan, Germany, Honduras, Panama, and Colombia					Event: New onset chronic disease : 3% , Syscat: NG Event: Medically signi?cant condition : 26% , Syscat: NG

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents					
Shui I. M. et al.,2012 US[184]				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
Sow S. O. et al.,2012 Vietnam, Bangledash, Ghana, Kenya, Mali[166]				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
Sow, P. S. et al. 2013[197] Senegal, Tanzania				Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Event: Death : 0% Event: SAE : 6.2% Event: AEs leading to premature discontinuation : 0% Event: Medically significant condition : 75.2% Event: New onset chronic disease : 4.9% Event: New onset autoimmune disease : 0.9% , Syscat: 10
Steele A. D. et al.,2010 South Africa[167]	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	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%

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents					
Tregnaghi M. W. et al.,2011 Argentina, Brazil, Colombia, Dominican Republic, Honduras, and Panama[169]				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
Vesikari T. et al.,2004 Finland[170]				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
Vesikari T. et al.,2006 Finland[171]	:			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
Vesikari T. et al.,2006 11 countries[172]				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
Vesikari T. et al.,2011 Finland[173]	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 rep	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

Evidence Table 4. Vaccinated versus unvaccinated: Children-adolescents					
Zaman K. et al.,2010 Bangladesh and Vietnam[176]				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%
Zaman K. et al.,2012 Bangladesh[177]				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
Zaman K., et al.,2009 Bangladesh[175]				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

Evidence Table 5. Postmarketing 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
Baxter, et al. 2013,[55] Case-centered and cohort	N=415 cases; Location=California; Age=48.5 years (mean), 5-87 years (range); Setting=Kaiser Permanente Northern California (KPNC)	Influenza (TIV), 23-valent pneumococcal polysaccharide, IPV, Tdap, I-typhoid, Hepatitis A, Hepatitis B, Td	Medical reviewer aware of study hypothesis, may have influenced case selection	Of the 892 potential cases for which medical records were available, 114 were rejected by the MRAs, and 242 were rejected by the reviewing neurologist, either as incompatible with GBS or because of not enough information or no weakness found in chart review. Of the 550 confirmed cases, 415 were incident within the study period, and patients were KPNC members at the time of GBS onset, so were eligible for inclusion in the analysis	Not discussed	Medical record review	Medical record review	Case-centered: Logistic regression model with a case-centered specification Cohort: Poisson regression	Case-centered: Age and sex matching for expected odds Cohort: age	1995-2006	This work was supported by a subcontract with America's Health Insurance Plans under contract 200-2002-00732 from the CDC, as a part of the Vaccine Safety Datalink.	Table 2. Odds Ratio of Vaccination in a 6- or 10-Week Risk Interval Before Onset of Guillain-Barre Syndrome, Using a Case-Centered Analysis Design OR, 95% CI, p=value 6-week Risk Interval IPV: 7.19 (0.18-281.03), 0.245 Tdap: None (0.16 to NE), 0.249 PPV-23: 0.72 (0.11-2.87), 0.722 Hep A: 2.22 (0.30-10.63), 0.36 Hep B: 0.43 (0.02-2.56), 0.455 Td: 1.43 (0.33-4.56), 0.558 TIV: 1.11 (0.39-3.08), 0.83 10-week Risk Interval IPV: 4.15 (0.11-163.38), 0.39 Tdap: None (.09 to NE), 0.377 PPV-23: 0.44 (0.07-1.72), 0.281 Hep A: 2.00 (0.39-8.74), 0.366 Hep B: 0.24 (0.01-1.46), 0.15	None	

Evidence Table 5. Postmarketing 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**
												Td: 1.14 (0.32-3.29), 0.783 TIV: 0.99 (0.33-2.70), 0.991 Table 3. Number of Guillain-Barre Syndrome Cases and Crude Rates per 100 000 Person-Years (Cohort analysis) Relative rate, 95% CI, p=value 1.3, (0.75-2.26), 0.35		
Crawford, et al., 2012[59], Self-controlled case series	N=44 Location=Victoria, Australia Age=48 (median); 7-95 years (range) Setting=An active surveillance system for GBS was established in 10 hospitals in Victoria	Monovalent H1N1 vaccine (Panvax, CSL Limited) TIV (Fluvax, CSL Limited; Vaxigrip, Sanofi Pasteur; Influvac, Abbott)	GBS cases only	Sixty-six cases of probable GBS were identified in the 12-month study period. Three cases were excluded, leaving 63 GBS episodes in 62 individuals. Of these, nine were excluded, as on review they did not meet diagnostic criteria for GBS. Four further confirmed cases were excluded, as the date of	Not discussed	Research assistants obtained informed consent once "possible" GBS cases were identified. A detailed immunisation history was then obtained from study participants and their primary health care physician (following patient consent)		Standard and pseudolikelihood methods	None, self-controlled design	September 30, 2009 to September 30, 2010	This study was funded by CSL Ltd as part of postmarketing surveillance, with financial support for study nurses at each site.	Table 3: Pandemic (H1N1) 2009 influenza A immunisation and Guillain-Barré syndrome: relative incidence (RI) estimates from the self-controlled case series with a 42-day postvaccination risk window Base: 3.41 (0.78–14.97) No seasonal trivalent influenza vaccine: 3.39 (0.77–14.91) No period adjustment: 2.92 (0.75–11.31) Three 2-week	None	

Evidence Table 5. Postmarketing 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**
				onset of symptoms predated the availability of the monovalent H1N1 vaccine. In six cases, data were only available from the hospital medical record (ie, neither the patient nor primary care physician were available). These cases with incomplete immunisation histories were excluded from the primary analysis, leaving 44 cases.								periods 0–13 days: 3.74 (0.41–34.05) 14–27 days: 3.35 (0.38–29.64) 28–41 days: 3.19 (0.35–28.67) Only Brighton level 1–2 cases: 3.99 (0.82–19.55) Include unconfirmed cases: 2.71 (0.62–11.85) Include incomplete vaccine history: 3.25 (0.75–14.21) Include incomplete vaccine history and second episode: 3.34 (0.76–14.59) Include all: 2.25 (0.54–9.37)		
Irving, et al. 2013,[236] Case-control	N=486 (243 cases, 243 controls); Location=US; Age=18-44 years; Setting=six health care organizations in the Vaccine Safety Datalink	Influenza (TIV)	No data on possible case ascertainment or vaccine administration differences across health plans	Three hundred eighty-six potential cases of spontaneous abortion were identified electronically; 255 cases were confirmed by medical record review and matched to control group participants. After excluding six	Not discussed	Medical record review	Medical record review	Conditional logistic regression	Maternal age, health care utilization, maternal diabetes, parity	Autumn of 2005 or 2006	Funded through a subcontract with America's Health Insurance Plans (AHIP) under contract 200-2002-00732, from the Centers for Disease Control and Prevention	Table 3. Odds of Influenza Vaccination in Cases of Early Pregnancy Loss in Varying Exposure Windows as Compared With Control Group Participants Adjusted ORs, 95% CI, p-value Primary analysis Exposed 1-28 d before reference	None	

Evidence Table 5. Postmarketing 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**
				pairs with unknown vaccination status, one pair with an invalid LMP, and five pairs with fetal demise at less than 5 weeks of gestation, 243 pairs were included in the final analysis.							(CDC).	date: 1.23 (0.53-2.89), 0.63 Exposed more than 28 d before reference date: 1.24 (0.54-2.86), 0.61 Secondary analysis Exposed while pregnant 0.80 (0.36-1.78), 0.58 Exposed before pregnant 2.34 (0.86-6.33), 0.10		
Isai et al., 2012[61], cross-sectional in that both exposure and outcome are ascertained at the same time, but outcomes are ascertained following vaccination in EudraVigilance database	N=50,221 adverse events; Location=European Union; Age=Unknown; Setting=EudraVigilance database	Flu vaccines: Cantgrip, Celtura, Celvapan, Fluval, Focetria, Pandemrix, Panenza	Unsure if EudraViligance contains AEs from all authorized medicines	Not discussed	Not discussed	Database review	Database review	No statistical comparisons	None	October 1, 2009 to 31 December 31, 2010	Not reported	Analysis 1 included all cases as reported. Analysis 2 used cases assessed as certain, probable or possible according to WHO Causality assessment and available Brighton Collaboration definitions Using analysis 1, the reporting ratio calculated as the percentage of autoimmune ADRs amongst all reported ADRs shows comparable results for nonadjuvanted (0.94% [0.64–1.24]) and adjuvanted (0.60% [0.53–0.67]) vaccines.	None	

Evidence Table 5. Postmarketing 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**
												The calculation using analysis 2 (restricted analysis) included 15 cases of autoimmune disorders for nonadjuvanted vaccines and121 cases for adjuvanted ones. The reporting ratio was 0.37% (0.18–0.56) and 0.26% (0.22–0.31), respectively. For the calculation of reporting rates using the estimated number of vaccinees as the denominator, analysis 1 resulted in a reporting rate of 9.98 (6.81–13.16) per million for nonadjuvanted vaccines and of 6.87 (6.06–7.68) per million for adjuvanted vaccines. Using analysis 2, the reporting rates were respectively 3.94 (1.95–5.94) and 3.01 (2.47–3.55) per million.		
Klein, et al. 2012,[203],Retrospective cohort	N=189,629; Location=California; Age=9-26 years; Setting=Kai	Quadrivalent human papillomavirus vaccine (HPV4)	Entire population	Not discussed	Not discussed	Electronic medical record review	Electronic medical record review	Conditional logistic regression	None	2006-2008	This study was funded by Merck & Co.	Table 2. Summary of HCUP Categories With Elevated ORs Following HPV4 Vaccination in the Combined	None	

Evidence Table 5. Postmarketing 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**
	ser Permanente in California											ED/Hospital Setting, All Doses Combined Viral infection Days 1-60 Risk Interval: 1.1 (0.9-1.3) Days 1-14 Risk Interval: 1.5 (1.2-2.0) Attention-deficit, conduct, and disruptive behavior disorders Days 1-60 Risk Interval: 1.5 (1.2-2.0) Days 1-14 Risk Interval: 1.5 (1.0-2.3) Disease of nervous system and sense organs Days 1-60 Risk Interval: 1.0 (0.9-1.1) Days 1-14 Risk Interval: 1.2 (1.0-1.3) Ear conditions Days 1-60 Risk Interval: 1.2 (1.0-1.5) Days 1-14 Risk Interval: 1.5 (1.1-1.9) Disorders of peripheral nervous system		

Evidence Table 5. Postmarketing 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**
												Days 1-60 Risk Interval: 2.1 (1.0-4.2) Days 1-14 Risk Interval: 2.1 (0.8-5.7) Diseases of circulatory system Days 1-60 Risk Interval: 1.1 (1-1.3) Days 1-14 Risk Interval: 1.2 (1.0-1.5) Diseases of heart Days 1-60 Risk Interval: 1.1 (0.1-1.3) Days 1-14 Risk Interval: 1.3 (1.0-1.6) COPD and bronchiectasis Days 1-60 Risk Interval: 1.5 (1-2.2) Days 1-14 Risk Interval: 1.8 (1.1-3.2) Asthma Days 1-60 Risk Interval: 1.2 (1.1-1.4) Days 1-14 Risk Interval: 1.21 (1-1.47) Disease of skin and subcutaneous tissue Days 1-60 Risk Interval: 1.0 (0.8-		

Evidence Table 5. Postmarketing 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**
												1.1) Days 1-14 Risk Interval: 1.5 (1.2-1.9) Skin and subcutaneous tissue infections Days 1-60 Risk Interval: 1.1 (0.9-1.4) Days 1-14 Risk Interval: 1.8 (1.3-2.4) Cellulitis and abscess Days 1-60 Risk Interval: 1.1 (0.8-1.4) Days 1-14 Risk Interval: 1.6 (1.2-2.3) Diseases of musculoskeletal system and connective tissue Days 1-60 Risk Interval: 1.1 (1-1.2) Days 1-14 Risk Interval: 1.2 (1.0-1.4) Spondylosis, disc intervertebral disorders, back problems Days 1-60 Risk Interval: 1.1 (0.9-1.3) Days 1-14 Risk		

Evidence Table 5. Postmarketing 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**
												Interval: 1.4 (1.0-1.8) Congenital anomalies Days 1-60 Risk Interval: 1.6 (1.1-2.3) Days 1-14 Risk Interval: 2.5 (1.6-4.0) Other congenital anomalies Days 1-60 Risk Interval: 1.8 (1.1-3.0) Days 1-14 Risk Interval: 3.6 (2.0-6.3) Fever of unknown origin Days 1-60 Risk Interval: 1.1 (0.9-1.4) Days 1-14 Risk Interval: 1.5 (1.0-2.1) Lymphadenitis Days 1-60 Risk Interval: 1.0 (0.6-1.8) Days 1-14 Risk Interval: 2.3 (1.2-4.4) Diabetes mellitus Days 1-60 Risk Interval: 2.2 (1.1-4.4) Days 1-14 Risk		

Evidence Table 5. Postmarketing 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**
												Interval: 2.5 (1.0-6.4) Attention-deficit disorder Days 1-60 Risk Interval: 1.7 (1.1-2.8) Days 1-14 Risk Interval: 2.1 (1.1-4.1) Personality disorders Days 1-60 Risk Interval: 1.8 (0.9-3.4) Days 1-14 Risk Interval: 2.8 (1.3-6.4) Disorders of teeth and jaw Days 1-60 Risk Interval: 1.1 (0.6-2.1) Days 1-14 Risk Interval: 2.6 (1.2-5.6) Congenital anomalies Days 1-60 Risk Interval: 1.7 (1.0-2.8) Days 1-14 Risk Interval: 2.7 (1.4-5.3) Other congenital anomalies Days 1-60 Risk Interval: 2.3 (1.1-5.0)		

Evidence Table 5. Postmarketing 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**
												Days 1-14 Risk Interval: 5.1 (2.2-11.9)		
Lee et al. 2011, Self-controlled design or a current versus historical comparison[60]	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 seasonal trivalent inactivated (TIV) and live, attenuated (LAIV) influenza vaccines	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 Poisson-based MaxSPRT or the Poisson-based conditional MaxSPRT (CMaxSPRT) was used logistic regression	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 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).	None	
Matheson et al. 2010, Prospective cohort[247]	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)	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	Multivariate: Sex, birthplace and history of bacterial infection, parental smoking, and parental asthma, history of viral infection, birth	2004	National Health and Medical Research Council of Australia, Clifford Craig Foundation of Tasmania and Victorian & Tasmanian	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)	None	Giles GG, Lickiss N, Gibson HB. Respiratory symptoms in Tasmanian adolescents: a follow up of the 1961 birth cohort.

Evidence Table 5. Postmarketing 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**
				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.				was used to estimate the association between childhood immunizations and asthma developing after the age of 7 yrs	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 asthma onset after the age of 21 yrs as the outcome was also adjusted for adult smoking, and socio-economic status in adult life		Asthma Foundations	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 (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		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.

Evidence Table 5. Postmarketing 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**
												(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)		
Nakajima et al. 2007, Prospective cohort[248]	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	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:	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	Not reported	

Evidence Table 5. Postmarketing 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**
			vaccination. Such a detection bias is more likely with eczema, given that eczema is more likely to develop in early 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						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			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 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		

Evidence Table 5. Postmarketing 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**
												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 (0.57-1.83), 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		
Ray et al. 2011, Prospective cohort and case-control[249]	N=1,660 (415 Rheumatoid arthritis cases, 1245 controls) Location=CA; Age=15-59 years; Setting=Kaiser Permanente Northern CA	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	Not reported	

Evidence Table 5. Postmarketing 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**
	members											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 (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		
Siberry et al. 2010,[250] 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 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	324 original participants, 305 final	Subjects included in the immunogenicity analysis (n = 305) were similar to those not included except that	Vaccines were administered by authors	Observation and self-report	Multivariable logistic regression	Not reported	Between July and October of 2007	National Institute of Allergy and Infectious Diseases cooperative agreement #5 U01 AI41110 with the Pediatric AIDS Clinical	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.	

Evidence Table 5. Postmarketing 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**
			family history of Guillain–Barré Syndrome (GBS); and (4) no meningococcal polysaccharide vaccine within last 2 years and no MCV4 at any time		those not included were less likely to be receiving HAART						Trials Group (PACTG) and #1 U01 AI068616 with the IMPAACT Group			
Tokars et al. 2012, Self-controlled analyses[251]	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 reported	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 reported	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) Unknown: 1.4 (0.2, 9.0) Seasonal vaccine	

Evidence Table 5. Postmarketing 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**
													within 42 days before H1N1 vaccine No: 2.4 (1.3, 4.5) Yes: 1.6 (0.6, 4.0)	
Velentgas et al. 2012,[223] Retrospective cohort study	N=12.6 million; Location=U.S.; Age=11- to 21-year-olds; Setting:Five US health plans	Meningococcal conjugate vaccine (MCV4); meningococcal polysaccharide vaccine (MPSV4), tetanus–diphtheria–acellular–pertussis vaccine (Tdap), tetanus and diphtheria vaccine (Td), tetanus, hepatitis B (HepB), human papillomavirus (HPV), and influenza vaccination	Entire population	Not discussed	Not discussed	Automated claims and enrollment data were used to identify vaccinations. Authors identified MCV4 (ACYW-135-D, Menactra W), meningococcal polysaccharide vaccine (MPSV4), tetanus–diphtheria–acellular–pertussis vaccine (Tdap), tetanus and diphtheria vaccine (Td), tetanus, hepatitis B (HepB), human papillomavirus (HPV), and influenza vaccinations and their associated dates of	Inpatient and outpatient medical claims were searched to identify instances of the ICD-9 code 357.0 (i.e. GBS). Medical charts for potential GBS cases were requested by the health plans from the hospital of treatment or other provider, such as a neurologist, rehabilitation hospital, or primary care provider. Photocopies of relevant sections of the medical record were obtained for adjudication review. GBS case adjudication was performed by a panel of three neurologists under the oversight of one	Incidence rate estimation	None	2005-2008	This study was funded by a contract from Sanofi-Pasteur to Harvard Pilgrim Health Care.	. Risk and attributable risk of GBS after vaccination, according to vaccine type MCV4 Cumulative incidence; one sided upper CI: 0; 2.09 Attributable risk: 0; 1.46 MPSV4 Cumulative incidence; one sided upper CI: 7.79; 37.00 Attributable risk: 7.16; 36.37 Tdap Cumulative incidence; one sided upper CI: 0; 2.49 Attributable risk: 0; 1.86 Td Cumulative incidence; one sided upper CI: 0; 8.02 Attributable risk: 0; 7.39	None	

Evidence Table 5. Postmarketing 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**
						administration using Current Procedural Terminology, Healthcare Common Procedure Coding System, or ICD-9 procedure codes as present in the medical claims data.	of the authors (A.A.A.).					Tetanus Cumulative incidence; one sided upper CI: 0; 106.20 Attributable risk: 0; 105.57 Influenza Cumulative incidence; one sided upper CI: 3.49; 11.00 Attributable risk: 2.86; 10.37 HepB Cumulative incidence; one sided upper CI: 8.04; 38.10 Attributable risk: 7.40; 37.47 HPV Cumulative incidence; one sided upper CI: 3.42; 10.80 Attributable risk: 2.79; 10.17		
Wise et al. 2012, Retrospective cohort[252]	N=408 Guillain–Barré syndrome (GBS) cases; Location=US; Age=0-65+ (no average measures given); Setting=10 sites of the Emerging	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	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	Active, population-based surveillance for GBS cases. Trained surveillance officers reviewed medical records to gather standardized information on patient characteristics, clinical presentation, and	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 reported	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)	Not reported	

Evidence Table 5. Postmarketing 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**
	Infections Program (EIP): California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee			411 GBS cases 408 vaccinated		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	medical history for every suspected GBS case.					25+: 1.36 (0.84-1.91) Total: 1.43 (0.94-1.89)		
Yih et al. 2012,[253] 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. For selected rare outcomes, current vs.-historical comparison methods were used	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 members and 9 state/city immunization registries contributed records	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 control periods.	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 (0.86-1.20), 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	None	

Evidence Table 5. Postmarketing 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**
												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: 0.95 (0.54-1.68), 0.82 Encephalitis/myelitis/encephalomyelitis >=6 months: 0.85 (0.28-2.54), 0.69 Other cranial nerve		

Evidence Table 5. Postmarketing 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**
												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 >=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:		

Evidence Table 5. Postmarketing 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**
												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 Anaphylaxis >=6 months: 0.67 (0.22-2.00), 0.47 2009 H1N1 Vaccines With		

Evidence Table 5. Postmarketing 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**
												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: 2.00 (0.09-46.9), 0.57 >=25 years: 1.05 (0.49-2.25), 0.88 Seizures 6 months–24 years:		

Evidence Table 5. Postmarketing 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**
												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		

Evidence Table 6. Vaccinated versus unvaccinated: Mixed population

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Mallory R. M et al,2010 US[107]	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[174]	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%	

Evidence Table 6. Vaccinated versus unvaccinated: Mixed population

Author- Year- Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Mallory R. M. et akl.,2010 US[107]			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
Phonrat, B. et al. 2013[254] Thailand				Placebo Placebo includes same adjuvants, preservatives, formulations as the active group	Any adverse event : 69.5% Any SAE : 0% Event: SAE : 0% Event: Arthalgia (1st immunization) : 2.07(ofcases)% , Syscat: 15 Event: Arthalgia (2nd immunization) : 2.41(ofcases)% , Syscat: 15
Vesikari T. et al.,2004 Belgium, Germany[174]	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:	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%

Evidence Table 7. Postmarketing 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[235]	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 multivariate models by testing which potential confounders moved the relationship between	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 mothers had 69% lower odds of being SGA (adjusted OR	NA	Maternal immunization is associated with reduced likelihood of prematurity and SGA except during the pre-influenza activity period.

Evidence Table 7. Postmarketing 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
									immunization and birth outcome closer to 1.			0.31, 0.13 to 0.75).		
Whitehouse et al. 2011, Prospective cohort[255]	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 inclined to seek health services rather than children in actual need of assistance"	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 Foundation	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	
Xu et al. 2012, retrospective cohort[237]	n=198 pregnant women who enrolled before 20 weeks gestation; US/Vaccine and Medication	H1N1	Self-selected population (women who contacted the system)	n/a	Participants were all pregnant women	n/r	n/r	time-independent (naive) and time-dependent covariate Cox models to account for left-truncation	vaccine exposure (1st or 2nd trimester) Previous spontaneous abortion (SAB) events (0, 1, 2, >=3) smoking	n/r	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%	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

Evidence Table 7. Postmarketing 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
	in Pregnancy Surveillance System study							(due to possible enrollment later than conception) and vaccine exposure timing	maternal age asthma Dependent variable: SAB			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 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)		analysis methods to study effects of vaccines on SAB

Evidence Table 7. Postmarketing studies: Pregnant women

Author- Year- Country	Study Design	McHarm Score	Population	Vaccine1	Timing1	Adverse Event1	OR, 95% CI, versus unvaccinated group
Dodds, L. et al. 2012[234] Canada	Cohort	NC	Sample size : 9647, Age range: <20 - >=35, Percent female: 100%	Influenza (inactived) , NR , Not reported , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Not reported	Dose1: NG	Event: Small for gestational age <10th percentile : 6.6% , Syscat: 18 Event: Low birth weight : 4% , Syscat: 18 Event: Term low birth weight : 1.4% , Syscat: 18 Event: Preterm birth : 6.5% , Syscat: 18 Event: Composite outcome : 3.7% , Syscat: 18	Composite outcome: OR 0.823 (0.636-1.067) Low birth weight: OR 0.702 (0.547-0.901)** Preterm birth: OR 0.842 (0.689-1.028) Small for gestational age <10th percentile: OR 0.749 (0.614-0.914)** Term low birth weight: OR 0.751 (0.488-1.154)
Fell D. B. et al.,2012 Canada[231]	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)**
Lin T. H. et al.,2012 Taiwan[230]	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	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)**

				(0.5ml) of AdimFlu-S®influenza A (H1N1) vacci ne 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			
Nordin, J.D. et al. 2013[233] USA	Cohort	1	Sample size : 223898, Mean age: 30.8, Age range: 14 - 49, Percent female: 100%, Percent pregant: Percent Pregnant: 100%	Influenza (inactived) , NR , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Not reported	Dose1: NR NR	Any adverse event : 0.077% , Sev: (3 d f,u, full cohort) Event: cellulitis (3 day f/u) : 1.3% , Syscat: 23 Event: seizures (3 day f/u) : 0.1% , Syscat: 17 Event: Altererd mental status (3 day f/u) : 2% , Syscat: 19 Event: Autonomic disorders (42d f/u) : 0.1% , Syscat: 17 Event: Cranial nerve disorders (42 d) : 0% , Syscat: 17 Event: Degeneration of CNS (42 d) : 0.1% , Syscat: 17 Event: Demyelinating disease (42 d) : 0.1% , Syscat: 17 Event: Peripheral neuropathy or neuritis (42 d) : 1.6% , Syscat: 17 Event: Guillan Barre syndrome (42 d) : 0% , Syscat: 17 Event: Meningoencephalitides (42 d) : 0.4% , Syscat: 17 Event: Movement disorders (42 d) : 0% , Syscat: 17 Event: Myoneural disorders (42 d) : 0.1% , Syscat: 17 Event: Paralytic syndromes (42 d) : 0.1% , Syscat: 17 Event: Psychoses (42 d) : 0.7% , Syscat: 19 Event: Spinocerebellar disease (42 d) : 0% , Syscat: 17 Event: Myocarditis/pericarditis (42 d) : 0.1% , Syscat: 2 Event: Thrombocytopenia (42 d, full cohort)) : 10.4% , Syscat: 1 Event: Any neurologic event (42 d, first trimester exposures) : 4.1% , Syscat: 17, 19 Event: Any neurologic event (42d, full cohort) : 22% , Syscat: 17, 19 Event: Thrombocytopenia (42d, first trimester exposure) : 6% , Syscat: 1 Event: Any event (3d, first trimester exposure) :16%	Altererd mental status (3 day f/u): OR 1.329 (0.69-2.563) Autonomic disorders (42d f/u): OR 0.487 (0.054-4.361) Meningoencephalitides (42 d): OR 5.849 (0.608-56.235) Peripheral neuropathy or neuritis (42 d): OR 1.95 (0.876-4.34) cellulitis (3 day f/u): OR 0.928 (0.437-1.972)

Evidence Table 7. Postmarketing studies: Pregnant women

Richards, J.L. et al. 2013[232] US	Cohort	2	Sample size : 3327, Mean age: 31.2, Age range: NR, Percent female: 100%	Influenza (inactived), Influenza - monovalent H1N1 , NR , Adjuvant: Not Reported , Preservative: Not reported , Delivery: Not reported	Dose1: NR NR	Event: Pre-term birth (27-36 wk) : 7.6% , Syscat: 18 , Sev: 1,2 Event: Preterm Birth (27-33 wk) : 1.7% , Syscat: 18 , Sev: 1,2 Event: Preterm Birth (34-36 wk) : 6.0% , Syscat: 18 , Sev: 1,2 Event: Low Birth weight (<2500g) : 6.4% , Syscat: 18 , Sev: 1, 2 Event: Small for gestational age : 9.3% , Syscat: 18 , Sev: 1, 2	Low Birth weight (<2500g): OR 0.706 (0.522-0.956)** Pre-term birth (27-36 wk): OR 0.602 (0.461-0.787)** Preterm Birth (27-33 wk): OR 0.505 (0.297-0.859)** Preterm Birth (34-36 wk): OR 0.657 (0.486-0.889)** Small for gestational age: OR 1.144 (0.868-1.508)

Evidence Table 7. Postmarketing studies: Pregnant women

Author- Year-Country	Vaccine2	Timing2	Adverse Event2	Control group	Adverse Events Control
Dodds, L. et al. 2012[234] Canada				Nothing	Event: Small for gestational age <10th percentile : 8.6% , Syscat: 18 Event: Low birth weight : 5.6% , Syscat: 18 Event: Term low birth weight : 1.9% , Syscat: 18 Event: Preterm birth : 7.7% , Syscat: 18 Event: Composite outcome : 4.5% , Syscat: 18
Fell D. B. et al.2012 Canada[231]				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
Lin T. H. et al.,2012 Taiwan[230]	:			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%
Nordin, J.D. et al. 2013[233] USA				Nothing	Any adverse event : 6.8% , Sev: (3 d f,u, full cohort) Event: cellulitis (3 day f/u) : 1.4% , Syscat: 23 Event: seizures (3 day f/u) : 0% , Syscat: 17 Event: Altererd mental status (3 day f/u) : 1.5% , Syscat: 19 Event: Autonomic disorders (42d f/u) : .3% , Syscat: 17 Event: Cranial nerve disorders (42 d) : 0% , Syscat: 17 Event: Degeneration of CNS (42 d) : 0% , Syscat: 17 Event: Demyelinating disease (42 d) : 22% , Syscat: 17 Event: Peripheral neuropathy or neuritis (42 d) : 1.5% , Syscat: 17

					Event: Guillan Barre syndrome (42 d) : .1% , Syscat: 17 Event: Meningoencephalitides (42 d) : .2% , Syscat: 17 Event: Movement disorders (42 d) : 0% , Syscat: 17 Event: Myoneural disorders (42 d) : .1% , Syscat: 17 Event: Paralytic syndromes (42 d) : .1% , Syscat: 17 Event: Psychoses (42 d) : .4% , Syscat: 19 Event: Spinocerebellar disease (42 d) : .1% , Syscat: 17 Event: Myocarditis/pericarditis (42 d) : 0% , Syscat: 2 Event: Thrombocytopenia (42 d, full cohort)) : 11.5% Event: Any neurologic event (42 d, first trimester exposures) : 3.8% , Syscat: 17 Event: Any neurologic event (42d, full cohort) : 0.03% , Syscat: 17 Event: Thrombocytopenia (42d, first trimester exposure) : 20% , Syscat: 1 Event: Any event (3 d, first trimester exposure) : 31% AE: 0.02% AE: 0% AE: 0% AE: 0% AE: 0% AE: 0% AE: 0% AE: 0%
Richards, J.L. et al. 2013[232] US				Nothing	Event: Preterm birth (27-36wk) : 12.1% , Syscat: 18 , Sev: 1, 2 Event: Preterm (27-33 wk) : 3.3% , Syscat: 18 , Sev: 1, 2 Event: Preterm (34-36wk) : 8.8% , Syscat: 18 , Sev: 1, 2 Event: Low birth weight (<2500g) : 8.8% , Syscat: 18 , Sev: 1, 2 Event: Small for gestational age : 8.2% , Syscat: 18 , Sev: 1, 2

Appendix D. Excluded Studies and Background Papers

Articles Could Not Be Obtained – 5

1. Blatter M. Open trial to evaluate the safety and immunogenicity of a fifth (booster) dose of diphtheria, tetanus, acellullar pertussis vaccine in healthy children. Unpublished; Report No.: Internal clinical trial report (014). June 1996.

2. Fox S. Study confirms rotavirus vaccine-intussusception link. Infections in Medicine. 2001 Apr;18(4):182-. PMID: WOS:000168263900004.

3. Gustafsson L., Hallander H.O., Gothefors L. An immunogenicity and safety study of combined adsorbed tetanus, low dose diptheria and acellullar pertussis vaccine (TdaP5v and TdaP1v) given as a school-leaving booster to 14–15-year old adolescents primed with a five-component acellullar pertussis vaccine at 3, 5 and 12 months of age and a booster dose at 5 1/2 years of age. Unpublished. September 2011.

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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.

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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, et al. 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).

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2010;2(25):25ra4. PMID: 2010309645 MEDLINE (http://www.ncbi.nlm.nih.gov/pubmed/20424013).

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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).

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