Comparative Effectiveness Review
Number 244

Safety of Vaccines Used for Routine Immunization in the United States: An Update

Evidence Summary

Main Points

- Since the prior 2014 Agency for Healthcare Research and Quality (AHRQ) report on vaccine safety, we found no new evidence of increased risk for key adverse events following administration of vaccines that are routinely recommended for adults, children, and pregnant women.
- Signals from the prior report remain unchanged for adverse events that include anaphylaxis in adults and children, and febrile seizures and idiopathic thrombocytopenic purpura in children. There continues to be no evidence of increased risk of adverse events for vaccines currently recommended in pregnant women.
- There remains insufficient evidence to draw conclusions about some rare potential adverse events.

Background and Purpose

Considered one of the greatest public health achievements, vaccines are effective in controlling the spread of and even eradicating a variety of infectious diseases. In 2014, AHRQ developed a report based on a systematic review of vaccine safety[1] building upon the 2011 Institute of Medicine (IOM) consensus report *Adverse Effects of Vaccines: Evidence and Causality*.[2] Since the 2014 AHRQ report,[1] the routine immunization schedule has continued to evolve, with the inclusion of newly approved vaccines and modified indications and schedules for several existing vaccines.

Agency for Healthcare Research and Quality

This update of the 2014 AHRQ report was commissioned by the Office of the Assistant Secretary for Health's Office of Infectious Disease and HIV/AIDS Policy (OASH/OIDP). The scope of this systematic review of the evidence was to assess the safety of vaccines in the immunization schedule recommended for children and adolescents (hereafter, we refer to children and adolescents simply as "children"), adults, and pregnant women. The list of vaccines is based on the Centers for Disease Control and Prevention's (CDC) recommended immunization schedules[3, 4] and includes only those currently licensed for use in the United States by the Food and Drug Administration (FDA).[5]

Methods

The methods for this report followed AHRQ's Methods Guide for Effectiveness and Comparative Effectiveness Reviews for the Evidence-based Practice Center Program.[6] The report addressed three Key Questions (KQs). Studies evaluating vaccines included in the CDC's routine immunization schedules recommended for adults (KQ1), children (KQ2), and pregnant women (KQ3) were eligible for inclusion if they compared the vaccine to either no vaccine or the prior standard of care. The evidence review team was supported by a Technical Expert Panel (TEP) that comprised a diverse set of relevant stakeholders, including vaccine experts with clinical expertise in key populations, vaccine safety methodologists, and consumers.

We searched MEDLINE® (including TOXLINE), Embase®, CINAHL®, Cochrane CENTRAL (including International Clinical Trials Registry Platform registry), Web of Science, and Scopus through November 9, 2020, building on the prior 2014 report. In addition, we reference-mined existing reviews; searched the trial registry Clinicaltrials.gov; reviewed supplemental material submitted to AHRQ following a Federal Register Notice posted regarding the availability of a portal for submission of unpublished studies; and consulted with content experts.

With the assistance of the TEP, additional content expert input, and based on published literature, we determined a list of key adverse events *a priori* to allow synthesis across studies (Appendix A). Two reviewers independently screened citations; data were extracted by an experienced subject matter expert. We included experimental and observational studies with a comparator that reported the presence or absence of adverse events. We documented the observed rates of adverse events and assessed the relative risks between vaccinated and comparator groups. All studies that reported rates of adverse events that could be computed, whether from the prior 2014 report or the current search update, were combined in meta-analyses. When studies could not be combined statistically, we narratively synthesized the findings to inform the strength of evidence (SoE) assessment and to ensure that the available evidence was considered and integrated.

The SoE was assessed based on the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach and the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[6] We used four criteria to grade the SoE (study limitations, consistency, precision, and reporting bias). We differentiated *high*, *moderate*, *low*, and *insufficient* evidence to communicate the confidence in the findings across studies, as follows.

- *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: Evidence either is unavailable due to a lack of studies reporting on the outcomes, or the evidence does not permit a conclusion (e.g., due to conflicting results across studies or methodologic flaws).

The review protocol is posted on the Effective Health Care website at https://effectivehealthcare.ahrq.gov/products/safety-vaccines/protocol. The project was registered in PROSPERO (CRD42020180089).[7]

Results

We identified 189 studies in this update, adding to research studies reviewed in the original 2014 AHRQ report on the topic (which built on findings of a detailed IOM report on vaccine safety published in 2011).[1, 2] In total, 338 studies reported in 518 publications were reviewed across both reports.

Key Question 1: Safety of Vaccines in Adults

Table A synthesizes the findings across the prior 2014 report and the update for key adverse events following administration of vaccines routinely recommended for adults. Any findings originally from the prior report are noted as such, along with any changes to these findings. If no prior report findings are noted, this indicates that there were no findings for these key adverse events in the prior report. Additional key adverse events for which there was insufficient evidence (including for which there were no studies) can be found in the main report.

Table A. Strength of evidence for specific safety concerns in vaccines recommended for adults

Key:

Green box indicates no evidence of increased risk of specific adverse events

Red circle indicates evidence of risk of specific adverse events

White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Hepatitis A (HepA; Havrix®, Vaqta®)	☐ Insufficient evidence (no change from prior 2014 report; no new studies in update)
Hepatitis B (HepB; Engerix-B®, Recombivax HB®, HEPLISAV-B®)	🟩 Moderate: No evidence of increased risk of multiple sclerosis onset or exacerbation (no change from prior 2014 report; insufficient evidence in update) 🟩 Moderate: No evidence of increased risk of diabetes (no change from prior 2014 report; update also identified no evidence of increased risk) 🔴 Moderate: Anaphylaxis in patients allergic to yeast (causal relationship based on mechanistic evidence remains unchanged from prior 2014 report; no new studies in update) 🟩 Low: No evidence of increased risk of asthma, autoimmune disease, cardiovascular events, death, herpes zoster, reproductive system events, stroke
Hepatitis A and hepatitis B (HepA-HepB; Twinrix®)	☐ Insufficient evidence (no findings in prior 2014 report; insufficient evidence in update)
9-valent human papillomavirus (HPV9; Gardasil 9®)	☐ Insufficient evidence (not in use at time of prior 2014 report; no new studies in update); see Table B for studies that combined children and adults
Influenza, inactivated (IIV; Afluria Quadrivalent®, Flucelvax Quadrivalent®, Fluarix Quadrivalent®, Flulaval Quadrivalent®, Fluzone High Dose Quadrivalent®, Fluzone Quadrivalent®)	🟩 Low: No evidence of increased risk of asthma, cardiovascular events, death, myocardial infarction, reproductive system events, seizures, stroke
Influenza, inactivated, adjuvanted (aIIV; Fluad®, Fluad Quadrivalent®)	🟩 Moderate: No evidence of increased risk of cardiovascular events, stroke 🟩 Low: No evidence of increased risk of asthma, autoimmune disease, death, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, myocardial infarction, seizures
Influenza, recombinant (RIV; Flublok Quadrivalent®)	🟩 Low: No evidence of increased risk of cardiovascular events, death, encephalitis/encephalopathy, myocardial infarction, reproductive system events, stroke
Influenza, live attenuated (LAIV; FluMist Quadrivalent®)	☐ Insufficient evidence (no findings in prior 2014 report; insufficient evidence in update)
Measles, mumps, and rubella (MMR; M-M-R II®)	🟩 Moderate: No evidence of increased risk of type 1 diabetes mellitus (no change from prior 2014 report; no new studies in update)
Meningococcal A, C, W, and Y (MenACWY; MenACWY-D [Menactra®], MenACWY-CRM [Menveo®], MenACWY-TT [MenQuadfi®])	🟩 Moderate: No evidence of increased risk of death 🟩 Low: No evidence of increased risk of cardiovascular events, myocardial infarction, stroke
Meningococcal B (MenB; MenB-4C [Bexsero®], MenB-FHbp [Trumenba®])	☐ Insufficient evidence (not in use at time of prior 2014 report); see Table B for studies that combined children and adults

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
13-valent pneumococcal conjugate (PCV13; Prevnar 13®)	Moderate: No evidence of increased risk of cardiovascular events, herpes zoster, myocardial infarction, reproductive system events, stroke Low: No evidence of increased risk of acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, death, encephalitis/encephalopathy, herpes zoster, idiopathic thrombocytopenic purpura, meningitis, seizures
23-valent pneumococcal polysaccharide (PPSV23; Pneumovax®)	High: No evidence of increased risk of cardiovascular or cerebrovascular events in adults aged 65 years and older (no change from prior 2014 report; update also identified no evidence of increased risk or insufficient evidence) Moderate: No evidence of increased risk of death
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel®, Boostrix®) and tetanus and diphtheria (Td; TDVAX, Tenivac®)	High: Anaphylaxis to tetanus toxoid (causal relationship based on mechanistic evidence remains unchanged from prior 2014 report; no new studies in update)
Varicella (VAR; Varivax®)	Insufficient evidence (no findings in prior 2014 report; no new studies in update)
Zoster recombinant (RZV; Shingrix®)	High: No evidence of increased risk of herpes zoster Moderate: No evidence of increased risk of amyotrophic lateral sclerosis, anaphylaxis or systemic allergic reaction, asthma, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, meningitis, myocardial infarction, reproductive system events, seizures, stroke Low: No evidence of increased risk of acute disseminated encephalomyelitis, angioedema, ataxia, autoimmune disease, autoimmune thyroiditis (Hashimoto's disease)

Note: No evidence of increased risk indicates that the outcome was studied and that the findings of the studies did not constitute evidence of increased risk of the adverse event following administration of that vaccine (either because the risk was not statistically significantly increased or was reduced)

Key Question 2: Safety of Vaccines in Children

Table B synthesizes the findings across the prior 2014 report and the update for key adverse events following administration of vaccines routinely recommended for children. Any findings originally from the prior report are noted as such, along with any changes to these findings. If no prior report findings are noted, this indicates that there were no findings for these key adverse events in the prior report. Additional key adverse events for which there was insufficient evidence (including for which there were no studies) and evidence for combination vaccines can be found in the main report.

Table B. Strength of evidence for specific safety concerns in vaccines recommended for children

Key:

Green box indicates no evidence of increased risk of specific adverse events

Red circle indicates evidence of risk of specific adverse events

White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Diphtheria, tetanus, and acellular pertussis (DTaP; Daptacel®, Infanrix®)	Moderate: No evidence of increased risk of type 1 diabetes mellitus for vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens (no change from prior 2014 report; no new studies in update) Low: No evidence of increased risk of asthma or death
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	Moderate: No evidence of increased risk of type 1 diabetes mellitus for vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens (no change from prior 2014 report; no new studies in update) Low: No evidence of increased risk of cardiovascular events or death for Tdap
Haemophilus influenzae type b (Hib; PedvaxHIB®, ActHIB®, Hiberix®)	Insufficient evidence (no findings related to key adverse events in prior 2014 report; insufficient evidence in update)
Hepatitis A (HepA; Havrix, Vaqta)	Moderate: Idiopathic thrombocytopenic purpura in children aged 7 to 17 years (no change from prior 2014 report; no new studies in update)
Hepatitis B (HepB; Engerix-B, Recombivax HB)	Moderate: No evidence of increased risk of multiple sclerosis (no change from prior 2014 report; no new studies in update)
9-valent human papillomavirus (HPV9; Gardasil 9)	Low: No evidence of increased risk of autoimmune disease, birth defects, death, reproductive system events, seizures, spontaneous abortion
Inactivated poliovirus (IPV; IPOL®)	Insufficient evidence (no findings related to key adverse events in prior 2014 report; insufficient evidence in update)
Influenza, inactivated (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent)	Moderate: No evidence of increased risk of death Low: No evidence of increased risk of anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, cardiovascular events, febrile seizures, seizures for quadrivalent IIV
Influenza, live attenuated (LAIV; FluMist Quadrivalent)	Low: No evidence of increased risk of death or seizures

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Measles, mumps, and rubella (MMR; M-M-R II)	High: No evidence of increased risk of autism spectrum disorders (no change from prior 2014 report; update also identified no evidence of increased risk) High: Anaphylaxis in children with allergies (causal relationship based on mechanistic evidence remains unchanged from prior 2014 report; no new studies in update) High: Febrile seizures (no change from prior 2014 report; insufficient evidence in update) Moderate: Idiopathic thrombocytopenic purpura (no change from prior 2014 report; no new studies in update) Low: No evidence of increased risk for asthma
Meningococcal, A, C, W, and Y (MenACWY; MenACWY-D [Menactra], MenACWY-CRM [Menveo], MenACWY-TT [MenQuadfi])	Moderate: Anaphylaxis in children with allergies (causal relationship based on mechanistic evidence remains unchanged from prior 2014 report; update shows no evidence of increased risk among all children) Moderate: No evidence of increased risk of cardiovascular events, diabetes, febrile seizures, intussusception, idiopathic thrombocytopenic purpura, Kawasaki disease, seizures Low: No evidence of increased risk of acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction (among all children), asthma, autoimmune disease, death, encephalitis/encephalopathy, meningitis, multiple sclerosis, reproductive system events, transverse myelitis
Meningococcal B (MenB; MenB-4C [Bexsero], MenB-FHbp [Trumenba])	Moderate: No evidence of increased risk of anaphylaxis or systemic allergic reaction, reproductive system events Low: No evidence of increased risk of asthma, death, seizures
13-valent pneumococcal conjugate (PCV13; Prevnar 13)	Moderate: No evidence of increased risk of death Low: No evidence of increased risk of asthma, cardiovascular events, intussusception, meningitis, reproductive system events, seizures Low: Febrile seizures (downgraded from moderate increased risk in prior 2014 report for inconsistency, as update identified some studies reporting no increased risk)
23-valent pneumococcal polysaccharide (PPSV23; Pneumovax)	Insufficient evidence (no findings in prior 2014 report; insufficient evidence in update)

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Rotavirus (RV; Rotarix®, RotaTeq®)	High: No evidence of increased risk of diabetes Moderate: No evidence of increased risk of intussusception (downgraded from moderate increased risk in prior 2014 report, which was not confirmed when combining all available studies; some observational studies showed increased risk) Moderate: No evidence of increased risk of asthma, autoimmune disease, death, encephalitis/encephalopathy, febrile seizures, idiopathic thrombocytopenic purpura, seizures, stroke Low: No evidence of increased risk of anaphylaxis or systemic allergic reaction, autoimmune thyroiditis (Hashimoto's disease), Kawasaki disease, meningitis, reproductive system events
Varicella (VAR; Varivax)	High: Anaphylaxis (causal relationship based on mechanistic evidence remains unchanged from the prior 2014 report; no new studies in update) and herpes zoster, meningitis, or encephalitis as a result of vaccine strain viral reactivation (causal relationship based on mechanistic evidence remains unchanged from prior 2014 report; no new studies in update) Moderate: Idiopathic thrombocytopenic purpura in children aged 11 to 17 years (no change from prior 2014 report; no new studies in update)

Note: No evidence of increased risk indicates that the outcome was studied and that the findings of the studies did not constitute evidence of increased risk of the adverse event following administration of that vaccine (either because the risk was not statistically significantly increased or was reduced).

Key Question 3: Safety of Vaccines in Pregnant Women

Table C synthesizes the findings across the prior 2014 report and the update for key adverse events following administration of vaccines routinely recommended for pregnant women. Any findings originally from the prior report are noted as such, along with any changes to these findings. If no prior report findings are noted, this indicates that there were no findings for these key adverse events in the prior report. Additional key adverse events for which there was insufficient evidence (including for which there were no studies) can be found in the main report.

Table C. Strength of evidence for specific safety concerns in vaccines recommended for pregnant women

Key:

Green box indicates no evidence of increased risk of specific adverse events

Red circle indicates evidence of risk of specific adverse events

White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Hepatitis B (HepB; Engerix-B, Recombivax HB)	☐ Insufficient evidence (no findings in prior 2014 report; no new studies in update)
Influenza, inactivated (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent), Influenza, recombinant (RIV; Flublok Quadrivalent)	☐ Insufficient evidence (quadrivalent IIV and RIV not in use at time of prior 2014 report; no new studies in update)
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	■ Moderate: No evidence of increased risk of maternal cardiovascular events, maternal death, maternal diabetes, eclampsia/pre-eclampsia, preterm labor, maternal reproductive system events, stillbirth, cardiovascular events in infants, death in infants, encephalitis/encephalopathy in infants, seizures in infants ■ Low: No evidence of increased risk of maternal encephalitis/encephalopathy, autism in infants, birth defects in infants, febrile seizures in infants

Note: No evidence of increased risk indicates that the outcome was studied and that the findings of the studies did not constitute evidence of increased risk of the adverse event following administration of that vaccine (either because the risk was not statistically significantly increased or was significantly reduced).

Strengths and Limitations

Our review of the literature was extensive and designed to capture available evidence on the presence and absence of adverse events associated with vaccines currently in use in the United States for routine immunization. We used a broad search strategy and transparent protocol to minimize the risk of missing relevant studies. We reviewed the rates of key adverse events reported in vaccine studies that used a comparator, regardless of whether they could be definitively attributed to the intervention. Many new studies were randomized clinical trials or based on extensive administrative data sets.

While our literature search procedures were extensive, our report also had limitations. Many studies were not designed to assess safety of vaccines and reporting of adverse events varied. Identifying safety data is very challenging, since many publications focus on the clinical effectiveness of an intervention with either no, sparse, incomplete, or non-systematic assessment and/or reporting of safety aspects. Despite pooling data across studies, confidence intervals around risk estimates were often wide due to the rare nature of many of the events of interest. We considered all available data regardless of whether they could be combined statistically in the grading the SoE.

Discussion

This report evaluated adverse events in research studies of vaccines administered to adults, children, and pregnant women. The report reviews the evidence and provides the strength of evidence, communicating our confidence in the findings. The scope does not include the efficacy or effectiveness of vaccines, nor practice or policy recommendations regarding the administration of the vaccines. This report reviews currently recommended vaccines for routine use, and does not include new vaccines in development or under emergency use authorization, such as vaccines for the 2019 coronavirus disease (COVID-19) pandemic.

Regarding vaccines recommended for adults (KQ1), in this update we found either no new evidence of increased risk for key adverse events with varied SoE or insufficient evidence, including for newer vaccines such as recombinant influenza vaccine, adjuvanted inactivated influenza vaccine, and recombinant adjuvanted zoster vaccine. The prior 2014 report noted a signal for anaphylaxis for hepatitis B vaccines in adults with yeast allergy and for tetanus, diphtheria, and acellular pertussis vaccines. Regarding vaccines recommended for children and adolescents (KQ2), we found either no new evidence of increased risk for key adverse events with varied SoE or insufficient evidence, including for newer vaccines such as 9-valent human papillomavirus vaccine and meningococcal B vaccine. The prior 2014 report noted signals for rare adverse events – such as anaphylaxis, idiopathic thrombocytopenic purpura, and febrile seizures – with some childhood vaccines. Regarding vaccines recommended for pregnant women (KQ3), we found no evidence of increased risk for key adverse events with varied SoE among either pregnant women or their infants following administration of tetanus, diphtheria, and acellular pertussis vaccine during pregnancy.

Despite the large literature, there remains insufficient evidence for rare potential adverse events for which very large samples would be needed to estimate the risk or to definitively exclude a risk of such adverse events. Careful consideration should be given to research gaps; however, important factors must be taken into account when determining whether studies are warranted, including the severity and frequency of the adverse event being studied and the challenges of conducting sufficiently powered studies when investigating rare events. Potential risks of rare adverse events should be weighed against the protective benefits that vaccines provide.

Conclusion

Across this large body of research, we found no new evidence of increased risk since the prior 2014 report for key adverse events following administration of vaccines that are routinely recommended. Signals from the prior report remain unchanged for rare adverse events that include anaphylaxis in adults and children, and febrile seizures and idiopathic thrombocytopenic purpura in children. There is no evidence of increased risk of adverse events for vaccines currently recommended in pregnant women. There remains insufficient evidence to draw conclusions about some rare potential adverse events.

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Full Report

Gidengil C, Goetz MB, Maglione M, Newberry SJ, Chen P, O'Hollaren K, Qureshi N, Scholl K, Ruelaz Maher A, Akinniranye O, Kim TM, Jimoh O, Xenakis L, Kong W, Xu Z, Hall O, Larkin J, Motala A, Hempel S. Safety of Vaccines Used for Routine Immunization in the United States: An Update. Comparative Effectiveness Review No. 244. (Prepared by the Southern California Evidence-based Practice Center under Contract No. 290-2015-00010-I.) AHRQ Publication No. 21-EHC024. Rockville, MD: Agency for Healthcare Research and Quality; May 2021. DOI: https://doi.org/10.23970/AHRQEPCCER244.

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