Vaccine Safety Publications

CDC's Immunization Safety Office monitors the safety of licensed and authorized vaccines and conducts high-quality vaccine safety research. This research is peer-reviewed and published in reputable scientific outlets.

The vaccine safety articles and studies listed on this page include a full citation, a short summary, and a link to the free PMC article, when available.

CDC Publications by Vaccine Safety System

- Vaccine Adverse Event Reporting System (VAERS)
- Vaccine Safety Datalink (VSD)
- Clinical Immunization Safety Assessment (CISA) Project

Publications About Specific Vaccine Safety Topics

- Human Papillomavirus (HPV) Vaccine Safety [PDF – 2 pages]
- Vaccines and Autism [PDF – 2 pages]
- Thimerosal Publications and References

COVID-19 Vaccine Safety Articles and Studies by Topic

An asterisk (*) denotes a newly published article added

Allergic Reactions

Shimabukuro T, Nair N. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine *JAMA* 2021 Feb 23;325(8):780-781 doi: 10.1001/jama.2021.0600.

Pfizer-BioNTech COVID-19 vaccine was authorized by the Food and Drug Administration (FDA) for emergency use in December 2020. CDC and FDA immediately began safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). One health outcome in particular that CDC and FDA monitored for was severe allergic reaction, or anaphylaxis. From December 14–23, 2020, 1.89 million first doses of Pfizer-BioNTech COVID-19 vaccine were administered. The most commonly reported non-anaphylaxis allergic reactions included: rash, itchy skin, itchy and scratchy sensations in the throat, and mild respiratory symptoms. Safety monitoring identified 21 anaphylaxis reports, corresponding to an estimated rate of 11.1 cases per million doses administered; 17 (81%) had a history of allergies or allergic reactions. No deaths from anaphylaxis were reported. CDC has guidance on the use of mRNA COVID-19 vaccines and management of anaphylaxis.

Shimabukuro T, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021. *JAMA* 2021 Feb 12; doi:10.1001/jama.2021.1967. Epub ahead of print.

In December 2020, FDA issued Emergency Use Authorizations for two mRNA-based vaccines for prevention of COVID-19 disease: Pfizer-BioNTech COVID-19 vaccine (December 11) and Moderna COVID-19 vaccine (December 18). After implementation of the vaccines, cases of anaphylaxis following both vaccines were reported. Anaphylaxis is a severe, life-threatening allergic reaction that

can occur after vaccination. During December 14, 2020 through January 18, 2021, over 9.9 million doses of Pfizer-BioNTech vaccine and over 7.5 million doses of Moderna vaccine were administered. In this same time, CDC identified 66 anaphylaxis cases reported to VAERS: 47 following Pfizer-BioNTech vaccine (rate of 4.7 cases per million doses) and 19 following Moderna vaccine (rate of 2.5 cases per million doses). There were no deaths from anaphylaxis reported after either vaccine. Continued safety monitoring of mRNA COVID-19 vaccines has confirmed anaphylaxis following vaccination is a rare event.

CDC COVID-19 Response Team Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine— United States, December 21, 2020-January 10, 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Jan 22:70(4);125-129.

On December 18, 2020, FDA issued an Emergency Use Authorization for Moderna COVID-19 vaccine to prevent COVID-19. As of January 10, 2021, over 4 million first doses of the vaccine had been administered. Many people did not have any side effects after COVID-19 vaccination. However, some serious adverse reactions were reported, such as the life-threatening allergic reaction, anaphylaxis. From December 21, 20201 through January 10, 2021, VAERS received 108 reports following Moderna vaccine identified as possible allergic reaction, including anaphylaxis. Through case review of medical reports, 10 cases were determined to be anaphylaxis (a rate of 2.5 cases of anaphylaxis per million doses). Of the 10 cases, 9 had a history of allergies or allergic reaction, including 5 who had a history of anaphylaxis. Anaphylaxis following Moderna vaccine appears to be a rare event. CDC and FDA will continue to monitor for anaphylaxis following COVID-19 vaccines.

CDC COVID-19 Response Team Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14-23, 2020 *MMWR Morb Mortal Wkly Rep.* 2021 Jan 15:70(2);46-51.

On December 11, 2020, FDA issued an Emergency Use Authorization for Pfizer-BioNTech COVID-19 vaccine to prevent COVID-19. As of December 23, 2020, over 1.8 million first doses of the vaccine had been administered. During this time, CDC and FDA were notified through multiple channels of suspected cases of anaphylaxis following vaccination. Anaphylaxis is a severe, life-threatening allergic reaction that occurs rarely after vaccination. From December 14-23, 2020, VAERS received 175 reports identified as possible allergic reaction, including anaphylaxis. Through case review of medical reports, 21 cases were determined to be anaphylaxis (a rate of 11.1 cases of anaphylaxis per million doses). Most anaphylaxis cases (81%) occurred in persons with a history of allergies or allergic reactions. Anaphylaxis following Pfizer-BioNTech vaccine appears to be a rare event. CDC and FDA will continue to monitor for anaphylaxis following COVID-19 vaccines.

General Safety*

Rosenblum HG, Gee JM, Liu R, Marquez PL, Zhang B, Strid P, Abara WE, McNeil MM, Myers TR, Hause AM, Su JR, Baer B, Menschik D, Markowitz LE, Shimabukuro TT, Shay DK. Safety monitoring of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to Vaccine Adverse Events Reporting System and v-safe *Lancet Infect Dis*.2022 Mar 7;S1473-3099(22)0054-8. Online ahead of print.

In December 2020, two mRNA COVID-19 vaccines were authorized for emergency use in the United States. Clinical trials showed these vaccines to be safe, and post-authorization monitoring is necessary to evaluate their safety in larger and diverse populations. VAERS and v-safe are two national systems CDC uses to monitor COVID-19 vaccine safety. During the first six months of the COVID-19 vaccination program (December 14, 2020 through June 14, 2021) over 298 million doses of mRNA vaccines were administered in the

U.S. In that period, over 7.9 million people enrolled in v-safe. Local (pain, redness, swelling at injection site) and systemic (fever, fatigue, and headache) reactions were reported more frequently following dose 2 compared to dose 1. The majority of symptoms were reported as mild, peaked on day 1 following vaccination, and were short-lived. Of the 340,000 adverse event reports to VAERS, the majority (92%) were classified as non-serious (similar to the local and systemic reactions reported to v-safe); 6.6% serious, non-death; 1.3% deaths. An in-depth review of reports of death found rates of death reported to VAERS were lower than expected background rates by age group. This analysis reinforces the safety of COVID-19 vaccines.

Hause AM, Bags J, Myers TR, Su JR, Blanc PG, Girwa Baumblatt JA, Woo EJ, Gee J, Shimabukuro TT, Shay DK. Safety Monitoring of COVID-19 Vaccine Booster Doses Among Adults — United States, September 22, 2021-February 6, 2022 *MMWR Morb Mortal Wkly Rep* 2022 Feb 11;71. Early Release.

The Food and Drug Administration authorized booster doses for COVID-19 vaccines: at least 5 months after dose 2 of Pfizer-BioNTech COVID-19 vaccine for people ages 12 years and older; at least 5 months after dose 2 of Moderna COVID-19 vaccine for people ages 18 years and older; and at least 2 months after a single-dose primary series for people 18 years and older. CDC reviewed adverse events and health impact surveys following a booster dose reported to the v-safe after vaccination health checker and adverse events reported to the Vaccine Adverse Event Reporting System (VAERS). The review included people who received both a different and the same booster dose as their primary series (doses 1 and 2, and in some cases dose 3). From September 22, 2021–February 6, 2022, about 82.6 million U.S. residents ages 18 years and older received a COVID-19 vaccine booster dose. People who received the same mRNA COVID-19 vaccine booster as they did for the primary series reported local and systemic reactions (such as pain, fatigue, and headache) less frequently than after dose 2. Myocarditis was rarely reported following mRNA COVID-19 vaccine boosters. No unexpected patterns of adverse events were identified, and COVID-19 vaccine boosters are recommended for everyone ages 12 years and older

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Oliver SE, Wallace M, See I, Mbaeyi S, Godfrey M, Hadler SC, Jatlaoui TC, Twentyman E, Hughes MM, Rao AK, Fiore A, Su JR, Broder KR, Shimabukuro T, Lale A, Shay DK, Markowitz LE, Wharton M, Bell BP, Brooks O, McNally V, Lee GM, Talbot HK, Daley MF. Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices – United States, December 2021. *Morb Mortal Wkly Rep.* 2022 Jan 20;71(3):90-95.

Lipkind HS, Vazquez-Benitez G, DeSilva M, Vesco KK, Ackerman-Banks C, Zhu J, Boyce TG, Daley MF, Fuller CC, Getahun D, Irving SA, Jackson LA, Williams JTB, Zerbo O, McNeil MM, Olson CK, Weintraub E, Kharbanda KO. Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Orgnizations, United States, December 15, 2020-July 22, 2021. *MMWR Morb Mort Wkly Rep.* 2022 Jan 4:71 Early release.

Hause Am, Baggs J, Marquez P, Myers TR, Gee J, Su JR, Zhang B, Thompson D, Shimabukuro TT, Shay DK. COVID-19 Vaccine Safety in Children Ages 5-11 years — United States, November 3-December 19, 2021. *MMWR Morb Mort Wkly Rep.* 2021 Dec 31:70(5152);1755-1760.

Moro PL, McNeil MM. Successes of the CDC monitoring systems in evaluating post-authorization safety of COVID-19 vaccines [Editorial] . *Expert Rev Vaccines*. 2021 Dec 27. Online ahead of print.

Abara WE, Gee J, Mu Y, Deloray M, Ye T, Shay DK, Shimabukuro T. Expected Rates of Select Adverse Events following Immunization for COVID-19 Vaccine Safety Monitoring *J Infect Dis.* 2021 Dec 27;jiab628. Online ahead of print.

Chapin-Bardales J, Myers T, Gee J, Shay DK, Marquez P, Baggs J, Zhang B, Licata C, Shimabukuro TT. Reactogenicity within 2 weeks after mRNA COVID-19 vaccines: Findings from the CDC v-safe surveillance system. *Vaccine* 2021 Oct 16; ISSN 0264-410X.

Hause AM, Baggs J, Gee J, Marquez P, Myers TR, Shimabukuro TT, Shay DK. Safety Monitoring of an Additional Dose of COVID-19 Vaccine — United States, August 12-September 19, 2021 *MMWR Morb Mortal Wkly Rep.* epub 2021 Sep 28.

On August 12, 2021, the Food and Drug Administration (FDA) expanded the Emergency Use Authorizations for Pfizer-BioNTech and Moderna (mRNA) COVID-19 vaccines to include an additional dose following the 2-dose vaccination series to those with compromised immune systems. From August 12 through September 19, over 22,000 v-safe enrollees reported an additional COVID-19 dose after completing the primary 2-dose mRNA vaccination series, most with the same vaccine. Among those who completed surveys for all 3 doses, local reactions (like pain or swelling where the shot was given) were reported slightly more after dose 3 compared with after dose 2 (79% vs. 78%), while reported systemic reactions (tiredness, headache) were slightly less common after dose 3 (74% vs. 77%). These side effects were mostly mild to moderate and short-lived. These findings did not show unexpected patterns of adverse events following an additional dose of COVID-19 vaccines. CDC will continue to monitor the safety of additional doses of COVID-19 vaccines and provide data to guide recommendations and protect the public's health.

Klein NP, Lewis N, Goddard K, Fireman B, Zerbo Q, Hanson KE, Donahue JG, Kharbanda EO, Naleway A, Clark Nelson J, Xu S, Yih WK, Glanz JM, Williams JTB, Hambridge SJ, Lewin BJ, Shimabukuro TT, DeStefano F, Weintraub ES. Surveillance for Adverse Events After COVID-19 mRNA Vaccination *JAMA* 2021 Sept 3. Doi:10.1001/jama.2021.15072.

The Vaccine Safety Datalink (VSD) has conducted weekly near real-time monitoring, or Rapid Cycle Analysis (RCA), of Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines since those vaccines received emergency use authorization from the Food and Drug Administration in December 2020. Between December 14, 2020 through June 25, 2021, over 11.8 million doses of mRNA were administered to 6.2 million people in the VSD network; 57% received Pfizer-BioNTech and 43% received Moderna. During that time period, VSD monitored 23 pre-specified health outcomes, including myocarditis/pericarditis and anaphylaxis. Researchers identified 34 cases of myocarditis/pericarditis in people ages 12 to 39 years; a majority (85%) were males. Among this age group, there is an increased risk of 6.3 additional myocarditis cases per million mRNA vaccinations administered in the first week following vaccination. The rate of anaphylaxis following vaccination was 4.8 cases per million doses of Pfizer-BioNTech and 5.1 per million doses of Moderna vaccination. VSD monitoring did not detect safety signals for any other pre-specified outcomes. Additional research is ongoing. Getting vaccinated remains the best way to protect against COVID-19 infection.

Rosenblum HG, Hadler SC, Moulia D, Shimabukuro TT, Su JR, Tepper NK, Ess KC, Woo EJ, Mba-Jonas A, Alimchandani M, Nair N, Klein NP, Hanson KE, Markowitz LE, Wharton M, McNally VV, Romero JR, Talbot K, Lee GM, Daley MF, Mbaeyi SA, Oliver SE. Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices — United States, July 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Aug 10.

On July 22, 2021, CDC's Advisory Committee on Immunization Practices (ACIP) reviewed a benefit-risk analysis of Guillain-Barré syndrome (GBS) following Johnson & Johnson's Janssen (J&J/Janssen) vaccine, as well as the latest information on thrombosis with thrombocytopenia syndrome (TTS) following J&J/Janssen vaccination and myocarditis following mRNA vaccination (Pfizer-BioNTech and Moderna vaccines). As of June 30, 2021, about 12.6 million doses of Janssen vaccine had been administered and 141 million 2nd

mRNA vaccine doses had been administered. Overall, there were 7.8 cases of GBS per million J&J/Janssen doses; 3 cases of TTS per million J&J/Janssen doses and 3.5 cases of myocarditis per million 2nd mRNA vaccine doses. After assessing the data, ACIP concluded that the benefits of COVID-19 vaccination in preventing COVID-19 illness, associated hospitalizations, ICU admissions, and death outweigh serious but rare risks of GBS, TTS, and myocarditis.

Pingali C, Meghani M, Razzaghi H, , Lamias MJ, Weintraub E, Kenigsberg TA, Klein NP, Lewis N, Fireman B, Zerbo O, Bartlett J, Goddard K, Donahue J, Hanson K, Naleway A, Kharbanda EO, Yih K, Clark Nelson J, Lewin BJ, Williams JTB, Glanz JM, Singletom JA, Patel SA. COVID-19 Vaccination Coverage Among Insured Persons Aged ≥ 16 years, by Race/Ethnicity and Other Selected Characteristics — Eight Integrated Health Care Organizations, United States, December 14, 2020-May 15, 2021. *MMWR Morb Mortal Wkly* Rep. 2021 Jul 16;70(28):985-990.

Gubernot D, Jazwa A, Niu M, Baumblatt J, Gee J, Moro P, Duffy J, Harrington T, McNeil MM, Broder K, Su J, Kamidani S, Olson CK, Panagiotakopoulos L, Shimabukuro T, Forshee R, Anderson S, Bennet S. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines *Vaccine* 2021 Jun 23;39(28):3666-3677. Epub 2021 May 14.

Hause AM, Gee J, Johnson T, Jazwa A, Marquez P, Miller E, Su J, Shimabukuro TT, Shay DK. Anxiety-Related Adverse Event Cluster After Janssen COVID-19 Vaccination — Five U.S. Mass Vaccination Sites, April 2021 *MMWR Morb Mortal Wkly Rep.* 2021 April 20. Epub ahead of print.

From April 7-9, 2021, 5 weeks after the J&J/Janssen COVID-19 vaccine was authorized by FDA for emergency use, clusters of anxiety-related events after Janssen vaccination were reported to CDC. The reports came from 5 mass vaccination sites in different states; 4 closed temporarily to investigate the cases. Of the 8,624 Janssen vaccine recipients, there were 64 reports of anxiety-related events, including 17 reports of fainting. Commonly reported symptoms were light-headedness/dizziness (56%), excessive sweating (31%), fainting (27%), nausea or vomiting (25%) and low blood pressure (16%). Additionally, CDC reviewed all reports to VAERS of fainting after Janssen vaccine between March 2 through April 11, 2021 and identified 653 reports out of 8 million doses administered. Review of reports found that fainting occurs in 8 per 100,000 doses administered. Vaccine providers should observe individuals for 15 minutes after COVID-19 vaccination for signs of immediate anxiety-related reactions or fainting.

Shay DK, Gee J, Su JR, Myers TR, Marquez P, Liu R, Zhang B, Licata C, Clark TA, Shimabukuro TT. Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine — United States, March-April 2021. *MMWR Morb Mortal Wkly Rep.* 2021 April 30. Epub ahead of print.

Johnson & Johnson's Janssen COVID-19 vaccine was authorized by FDA for emergency use on February 27, 2021. By April 21, nearly 8 million doses of the Janssen COVID-19 vaccine had been administered. CDC researchers reviewed safety monitoring data from VAERS and the v-safe after-vaccination health checker, and found 97% of reported reactions after vaccination, such as headache, fever, chills, injection site pain, and fatigue, were nonserious and consistent with clinical trials data. CDC and FDA issued a pause of the Janssen vaccine April 12–23, 2021, after 6 cases of cerebral venous sinus thrombosis (CVST), a serious condition that involves blood clots in the brain, were identified in VAERS. By April 25, a total of 17 thrombotic (blood clots) events with thrombocytopenia (low platelet counts) were reported to VAERS, including 3 thrombotic events not occurring in the brain. CDC and FDA continue to monitor the safety of COVID-19 vaccines, analyzing the risks and benefits of continued use.

Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, Marquez PL, Olson CK, Liu T, Chang KT, Ellington SR, Burke VK, Smoots AN, Green CJ, Licata C, Zhang BC, Alimchandani M, Mba-Jonas A, Martin SW, Gee JM, Meaney-Delman DM. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons *N Engl J Med* 2021 April 21. DOI: 10.1056/NEJMoa2104983 Epub ahead of print.

Pregnant people were not included in the messenger RNA (mRNA) COVID-19 vaccine clinical trials. Because of the increased risk of severe illness from COVID-19, CDC has provided guidance to pregnant people who may want to get a COVID-19 vaccine. The safety of mRNA vaccines in pregnant people is monitored through 3 systems: v-safe after vaccination health checker, the v-safe pregnancy registry and VAERS. From December 14, 2020 through February 28, 2021, 35,691 v-safe participants ages 16 to 54 identified as pregnant. Injection site pain was commonly reported. Of those, 3,958 enrolled in the v-safe pregnancy registry: 827 completed pregnancy; 712 (86.1%) had live births, with most vaccinations completed in the 3rd trimester. In the VAERS reports following mRNA vaccinations, 155 (70.1%) were nonpregnancy specific; 66 (29.9%) were pregnancy and neonatal specific events. The analysis of v-safe and VAERS data did not show any safety concerns among pregnant persons who received mRNA COVID-19 vaccines.

Chapin-Bardales J, Gee J, Myers T. Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines *JAMA Insights* 2021 April 5. doi:10.1001/jama.2021.5374 Epub ahead of print.

CDC created v-safe, a smartphone-based tool, to monitor in near-real time the safety of COVID-19 vaccines authorized by FDA for emergency use. V-safe uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination. Researchers reviewed data collected from v-safe from December 14, 2020 to February 28, 2021, including side effects and reactions to the mRNA COVID-19 vaccines. Over 3.6 million v-safe participants completed at least one health check-in after the first dose and over 1.9 million after the second dose. Injection site pain was commonly reported after first (70%) and second doses (75%) of either mRNA vaccine. Systemic reactions, such as fatigue, headache, muscle pain, chills, fever, and joint pain were the top symptoms reported by participants after the first mRNA vaccine dose. These reports increased substantially after the second dose among both mRNA vaccines. People aged 65 years and older reported fewer reactions than younger people. While v-safe is voluntary and includes less than 10% of people vaccinated, reported reactions to the mRNA vaccines were consistent with results observed in clinical trials.

Gee J, Marquez P, Su J, Calvert GM, Liu R, Myers T, Nair N, Martin S, Clark T, Markowitz L, Lindsey N, Zhang B, Licata C, Jazwa A, Sotir M, Shimabukuro T. First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020-January 13, 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Feb 26;70;283-288.

The U.S. FDA authorized two COVID-19 vaccines for emergency use in December 2020: Pfizer-BioNTech and Moderna. During clinical trials, there were reports of local reactions where the shot was given, and systemic reactions affecting other parts of the body. Safety monitoring for these vaccines has been the most intense and comprehensive in U.S. history. From December 14, 2020 through January 13, 2021, almost 14 million vaccine doses were distributed. During that time, over 1.6 million vaccine recipients enrolled in v-safe, and VAERS received 6,994 reports of adverse events following vaccination. About 91% of VAERS reports were non-serious; commonly reported symptoms included headache (22.4%), fatigue (16.5%) and dizziness (16.5%). V-safe enrollees reported similar local and systemic reactions. While deaths were reported to VAERS, available documentation did not suggest a causal link between the vaccine and death. Overall, no unusual or unexpected reporting patterns were detected.

Mortality

Xu S, Huang R, Sy LS, Glenn SC, Ryan DS, Morrissette K, Shay DS, Vazquez-Benitez G, Glanz JM, Klein NP, McClure D, Liles EG, Weintraub ES, Tseng HF, Qian L. COVID-19 Vaccination and Non-COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020-July 31, 2021 *MMWR Morb Mortal Wkly Rep.* epub 2021 Oct 22.

Since COVID-19 vaccinations have become available in December 2020, an estimated 182 million people in the United States were fully vaccinated against COVID-19 by September 21, 2021. However, since April 2021, the number of people starting to get COVID-19 vaccines has decreased. People have cited vaccine safety concerns as deterrents to getting a COVID-19 vaccine, concerns that include deaths following COVID-19 vaccination. Although deaths after COVID-19 vaccination have been reported to VAERS, there have been few studies done to evaluate the mortality not associated with COVID-19 among vaccinated and unvaccinated groups. To analyze this, researchers conducted a study using the Vaccine Safety Datalink, comparing those who received COVID-19 vaccines and those who did not between December 2020 through July 2021. This study included data from 11 million people; 6.4 million received either Pfizer-BioNTech, Moderna or Janssen COVID-19 vaccine and 4.6 were unvaccinated. The analysis showed that those who received COVID-19 vaccinations had lower rates of mortality for non-COVID-19 causes than those unvaccinated. These findings provide evidence that COVID-19 vaccines are safe and support current vaccination recommendations.

Multisystem Inflammatory Syndrome (MIS)

Yousaf AR, Cortese MM, Taylor AW, Broder KR, Oster ME, Wong JM, Guh AY, McCormick DW, Kamidani S, Schlaudecker EP, Edwards K, Creech B, Staat MA, Belay ED, Marquez P, Su JR, Salzman MB, Thompson D, Campbell AP, MIS-C Investigation Authorship Group. Reported Cases of Multisystem Inflammatory Syndrome in Children in Children (MIS-C) Aged 12-20 Years in the United States Who Received COVID-19 Vaccine, December 2020 through August 2021 . *Lancet Child Adolesc Health*. 2022 Feb 22;S2352-4642(22)00028-1. Online ahead of print.

Belay ED, Godfred Cato S, Rao AK, Abrams J, Wilson WW, Lim S, Newton-Cheh C, Melgar M, DeCuir J, Webb B, Marquez P, Su JR, Meng L, Grome HN, Schlaudecker E, Talaat K, Edwards K, Barnett E, Campbell AP, Broder KR, Bamrah Morris S. Multisystem Inflammatory Syndrome in Adults after SARS-CoV-2 infection and COVID-19 vaccination . *Clin Infect Dis.* 2021 Nov 28;cia963. Online ahead of print.

Myocarditis

Oster ME, Shay DK, Su JR, Gee J, Creech B, Broder KR, Edwards K, Soslow JH, Dendy JM, Schlaudecker E, Lang SM, Barnett ED, Ruberg FL, Smith MJ, Campbell MJ, Lopes RD, Sperling LS, Baumblatt JA, Thompson DL, Marquez PL, Strid P, Woo J, Puglsey R, Reagan-Steiner S, DeStefano F, Shimabukuro TT. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US from December 2020 to August 2021 *JAMA.* 2022 Jan 18;327(4):331-340. Online ahead of print.

Since mRNA-based COVID-19 vaccines were authorized for emergency use in December 2020, there have been reports of myocarditis, or inflammation of the heart muscle, following vaccination. To see if there was an association between mRNA COVID-19 vaccination and myocarditis, researchers reviewed reports submitted to the Vaccine Adverse Event Reporting Systems (VAERS) from December 2020 through August 31, 2021. In that time, more than 192 million people ages 12 years and older have received at least one dose of mRNA COVID-19 vaccines. From this population, VAERS received 1,626 myocarditis reports that met case definition. The review found the rates myocarditis were highest following the second dose of mRNA vaccine among adolescent and young adult males. Myocarditis is a rare but serious adverse event that can occur following mRNA COVID-19 vaccination. The benefits of COVID-19 vaccination continue to outweigh any potential risks, including myocarditis.

Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, Broder KR, Gee J, Weintraub E, Shimabukuro T, Scobie HM, Moulia D, Markowitz LE, Wharton M, McNally VV, Romero JR, Keipp Talbot H, Lee GM, Daley MF, Oliver SE. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Jul 9;70:977-982.

Two mRNA COVID-19 vaccines were given emergency use authorization (EUA) by the Food and Drug Administration (FDA) in December 2020: Pfizer-BioNTech and Moderna COVID-19 vaccines. Pfizer-BioNTech was authorized for individuals 16 years and older, and Moderna for adults 18 years and older. In May 2021, FDA expanded Pfizer-BioNTech vaccine's authorization to include adolescents aged 12 to 15 years. After reported myocarditis/pericarditis among mRNA vaccine recipients, mostly in younger males after the 2nd dose, the Advisory Committee on Immunization Practices (ACIP) held a meeting to review these reports and conduct a risk-benefit assessment of mRNA COVID-19 vaccination in the U.S. Evidence presented showed that the highest rates of myocarditis were reported in males aged 12-17 and 18-24 (62.8 and 50.5 reported cases of myocarditis per million 2nd mRNA doses administered, respectively). On June 23, after reviewing all the available information, ACIP determined that the benefits of mRNA COVID-19 vaccination under EUA outweighed the risks of myocarditis in all populations. CDC and FDA will continue to monitor cases of myocarditis among mRNA COVID-19 vaccine recipients.

Shay DK, Shimabukuro, TT, DeStefano F. Myocarditis After Immunization with mRNA-Based COVID-19 Vaccines: Editorial . *JAMA Cardiol.* Published online June 29, 2021. doi:10.1001/jamacardio.2021.2821.

CDC researchers reviewed several case reports of acute myocarditis occurring in people following mRNA-based COVID-19 vaccinations (Pfizer BioNTech or Moderna). The first report included 4 cases of myocarditis developed 1 to 5 days after getting dose 2 of mRNA-based COVID-19 vaccine. Second report included 23 cases of acute myocarditis within 4 days of vaccination, mostly after dose 2. The last report included 7 cases in adolescents, ages 14-19. All presented with myocarditis or myopericarditis (heart muscle and lining inflammation) within 4 days of dose 2. The review of these cases showed clinical similarities and there were no other known causes for their acute myocarditis, suggesting a likely association with vaccination. Myocarditis following COVID-19 vaccination is rare. Researchers will continue to look into myocarditis following COVID-19 vaccination.

Pediatrics (under 18 years old)

Yousaf AR, Cortese MM, Taylor AW, Broder KR, Oster ME, Wong JM, Guh AY, McCormick DW, Kamidani S, Schlaudecker EP, Edwards K, Creech B, Staat MA, Belay ED, Marquez P, Su JR, Salzman MB, Thompson D, Campbell AP, MIS-C Investigation Authorship Group. Reported Cases of Multisystem Inflammatory Syndrome in Children in Children (MIS-C) Aged 12-20 Years in the United States Who Received COVID-19 Vaccine, December 2020 through August 2021 . *medRxiv – the preprint server for health sciences.* 2022 Jan 6. Doi.org/10.1101/2022.01.03.22268681.

DeSilva MB, Haapal J, Vazquez-Benitez G, Daley MF, Nordin JD, Klein NP, Henninger ML, Williams JTB, Hambidge SJ, Jackson ML, Donahue JG, Qian L, Lindley MC, Gee J, Weintraub ES, Kharbanda EO. Association of the COVID-19 Pandemic with Routine Childhood Vaccination Rates and Proportion Up to Date with Vaccinations Across 8 US Health Systems in the Vaccine Safety Datalink . *JAMA Pediatr.* 2022 Jan 1;176(1):68-77. Doi: 10.1001/jamapediatrics.2021.4251.

Hause AM, Gee J, Baggs J, Abara WE, Marquez P, Thompson D, Su JR, Licata C, Rosenblum HG, Myers TR, Shimabukuro TT, Shay DK. COVID-19 Vaccine Safety in Adolescents—United States, December 14, 2020—July 16, 2021. *MMWR Morb Mortal Wkly Rep.* 2021 Jul 30.

As of July 2021, Pfizer-BioNTech COVID-19 Vaccine (Pfizer-BioNTech) is the only COVID-19 vaccine authorized for use in adolescents (people aged 12–17 years). To evaluate the safety of Pfizer-BioNTech in adolescents, researchers reviewed data collected from VAERS and v-safe between December 14, 2020 through July 16, 2021. Over 8.9 million Pfizer-BioNTech doses were administered to adolescents ages 12-17. VAERS received 9,246 reports of adverse events in adolescents; over 90% of reports were non-serious. Myocarditis was reported in 4.3% (397) of all VAERS reports. Of the 129,000 adolescents who enrolled in v-safe, the most frequently reported side effects included injection site pain, fatigue, headache, and weakness. With the exception of myocarditis, the safety findings were similar to what was observed during preauthorization trials. CDC and FDA are actively monitoring the safety of COVID-19 vaccines. Serious adverse events after COVID-19 vaccination are rare, and CDC continues to recommend everyone 12 years and older get vaccinated as soon as possible to help protect against COVID-19.

Pregnancy

Moro PL, Panagiotakopoulos L, Oduyebo T, Olson CK, Myers T. Monitoring the safety of COVID-19 vaccines in pregnancy in the US. *Human Vaccines & Immunotherapies.* 2021 Nov 10. doi.org/10.1080/21645515.2021.1984132.

Zauche LH, Wallace B, Smoots AN, Olson CK, Oduyebo T, Kim SY, Petersen EE, Ju J, Beauregard J, Wilcox AJ, Rose CE, Meaney-Delman DM, Ellington SR, CDC v-safe COVID-19 Pregnancy Registry Team. Receipt of mRNA COVID-19 Vaccines and Risk of Spontaneous Abortion *N Engl J Med.* 2021 Sept 8. Dpo: 10.1056/NEJMc2113891.

Although pregnant people are at increased risk for severe illness from COVID-19, the COVID-19 vaccination rate among pregnant people has been much lower than that of the general U.S. population. Data about vaccination during pregnancy was initially limited because pregnant participants were excluded from COVID-19 vaccine clinical trials. To evaluate the safety of mRNA vaccines in pregnant people, researchers analyzed data on miscarriage, or a pregnancy loss that occurs before 20 weeks of pregnancy, collected from v-safe COVID-19 Vaccine Pregnancy Registry participants. Over 2,400 registry participants received at least one dose of an mRNA COVID-19 vaccine just before pregnancy or within the first 20 weeks of pregnancy. The cumulative risk of miscarriage among those who received an mRNA COVID-19 vaccine was similar (14.1%) to previously published background rates (11 to 16%) . Therefore, this study demonstrated no increased risk of miscarriage following receipt of COVID-19 mRNA vaccine in early pregnancy. Research will continue on the safety of COVID-19 vaccines in pregnant people.

Kharbanda EO, Haapala J, DeSilva M, Vazquez-Benitez G, Vesco KK, Naleway AL, Lipkind HS. Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy *JAMA* 2021 Sep 8. Doi:10.1001/jama.2021.15494

Although pregnant people are at increased risk for severe illness from COVID-19, the COVID-19 vaccination rate among pregnant people has been much lower than that of the general U.S. population. Data about vaccination during pregnancy was initially limited because pregnant participants were excluded from vaccine clinical trials. Researchers within the Vaccine Safety Datalink, a collaboration between CDC and 9 health systems, representing approximately 3% of the U.S. population, analyzed data from 8 health systems from December 15, 2020 through June 28, 2021 to evaluate whether there's an association between COVID-19 vaccine and miscarriage (pregnancy loss that occurs before 20 weeks of pregnancy). This analysis included over 105,000 pregnancies. About 14% received one or more doses of one of the 3 available COVID-19 vaccines during pregnancy before 20 weeks' gestational age. The analysis found that people who were currently pregnant at the time of COVID-19 vaccination and those who became pregnant after vaccination did not have an increased risk of miscarriage. Research will continue on the safety of COVID-19 vaccines in pregnant

people.

Razzaghi H, Meghani M, Pingali C, Crane B, Naleway A, Weintraub E, Kenigsberg TA, Lamias MJ, Irving SA, Kauffman TL, Vesco KK, Daley MF, DeSilva M, Donahue J, Getahun D, Glee S, Hambidge SJ, Jackson LJ, Lipkind HS, Nelson J, Zerbo O, Oduyebo T, Singleton JA, Patel SA. COVID-19 Vaccination Coverage Among Pregnant Women During Pregnancy — Eight Integrated Health Care Organizations, United States, December 14, 2020-May 8, 2021. *MMWR Morb Mortal Wkly Rep*. 2021 Jun 18;70(24):895-899.

Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, Marquez PL, Olson CK, Liu R, Chang KT, Ellington SR, Burkel VK, Smoots AN, Green CJ, Licata C, Zhang BC, Alimchandani M, Mba-Jonas A, Martin SW, Gee JM, Meaney-Delman DM, CDC v-safe COVID-19 Pregnancy Registry Team. Prelimiary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons . *N Engl J Med*. 2021 Jun 17;384(24):2273-2282. Epub 2021 Apr 21.

Pregnant people were not included in the messenger RNA (mRNA) COVID-19 vaccine clinical trials. Because of the increased risk of severe illness from COVID-19, CDC has provided guidance to pregnant people who may want to get a COVID-19 vaccine. The safety of mRNA vaccines in pregnant people is monitored through 3 systems: v-safe after vaccination health checker, the v-safe pregnancy registry and VAERS. From December 14, 2020 through February 28, 2021, 35,691 v-safe participants ages 16 to 54 identified as pregnant. Injection site pain was commonly reported. Of those, 3,958 enrolled in the v-safe pregnancy registry: 827 completed pregnancy; 712 (86.1%) had live births, with most vaccinations completed in the 3rd trimester. In the VAERS reports following mRNA vaccinations, 155 (70.1%) were nonpregnancy specific; 66 (29.9%) were pregnancy and neonatal specific events. The analysis of v-safe and VAERS data did not show any safety concerns among pregnant persons who received mRNA COVID-19 vaccines.

Thrombosis with Thrombocytopenia Syndrome (TTS)

See I, Lale A, Marquez P, Streiff MB, Wheeler AP, Tepper NK, Woo EJ, Broder KR, Edwards KM, Gallego R, Geller AI, Jackson KA, Sharma S, Talaat KR, Walter EB, Akpan IJ, Ortel TL, Urrutia VC, Walker S, Yui JC, Shimabukuro TT, Mba-Jonas A, Su JR, Shay DK. Case Series of Thrombosis with Thrombocytopenia Syndrome after COVID-19 vaccination—United States, December 2020 to August 2021 . *Ann Intern Med.* 2022 Jan 18. Doi: 10.7326/M21-4502 Online ahead of print.

Thrombosis with thrombocytopenia syndrome (TTS) is a rare, potentially life-threatening condition that involves blood clots with low platelet counts and has been seen following COVID-19 vaccination. Clinicians from the Clinical Immunization Safety Assessment (CISA) Project reviewed reports to the Vaccine Adverse Event Reporting System (VAERS) to investigate TTS following COVID-19 vaccination. From December 14, 2020 through August 31, 2021, over 14.1 million doses of Johnson & Johnson's Janssen and 351 million doses of mRNA vaccines were given. CISA confirmed 57 reports of TTS: 54 following Janssen COVID-19 vaccine and 3 following mRNA COVID-19 vaccines. Most cases of TTS following Janssen vaccination occurred in females and in people younger than 50 years. All cases of TTS following Janssen involved hospitalization, including 36 admitted to intensive care units. Of the 54 cases, 37 were discharged home, 9 were discharged to post-acute care, and 8 died. The reporting rate of TTS cases per million doses administered was 3.83 following Janssen vaccination, whereas the rate following mRNA vaccination (.0085) was consistent with the background rate of TTS. This analysis of data concluded that TTS is a rare, but serious adverse event associated with Janssen COVID-19 vaccination.

MacNeil JR, Su JR, Broder KR, Guh AY, Gargano JW, Wallace M, Hadler SC, Scobie HM, Blain AE, Moulia D, Daley MF, McNally VV, Romero JR, Keipp Talbot H, Lee GM, Bell BP, Oliver SE. Updated Recommendations from the Advisory Committee on Immunization Practices for Use of Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of

Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021. *MMWR Morb Mortal Wkly Rep.* 2021 Apr 30;70:651-656.

The Johnson & Johnson/Janssen (Janssen) COVID-19 vaccine was authorized for emergency use on February 27, 2021. On April 13, CDC and the Food and Drug Administration (FDA) recommended pausing the use of Janssen vaccine after thrombosis with thrombocytopenia syndrome (TTS) was reported among vaccine recipients. TTS is a rare syndrome that involves blood clots in large blood vessels with low platelets. The Advisory Committee on Immunization Practices (ACIP) held two emergency meetings to review reports of TTS following Janssen vaccine and conducted a risk-benefit assessment. The estimated reporting rate of TTS was 7 cases of TTS per million Janssen doses administered to women aged 18-49 years. After their review, on April 23, ACIP concluded that the benefits of resuming Janssen COVID-19 vaccination among persons aged 18 years and older outweighed the risks and reaffirmed its interim recommendation under FDA's Emergency Use Authorization (EUA), which includes a new warning for rare clotting events, primarily in women aged 18-49 years. CDC and FDA will continue to closely monitor reports of TTS following Janssen vaccination.

See I, Su JR, Lale A, Woo EJ, Guh AY, Shimabukuro TT, Streiff MB, Rao AK, Wheeler AP, Beavers SF, Durbin AP, Edwards K, Miller E, Harrington TA, Mba-Jonas A, Nair N, Nguyen DT, Talaat KR, Urrutia VC, Walker SC, Creech B, Clark TA, DeStefano F, Broder KR. US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021 *JAMA* 2021 April 30. Doi:10.1001/jama.2021.7517 Epub ahead of print.

Around 7 million doses of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine were given between March 2–April 12, 2021. During this time, VAERS received reports following J&J/Janssen vaccination of cerebral venous sinus thrombosis (CVST) with thrombocytopenia, which involves blood clots in the brain with low platelet counts. By April 21, there were 12 reports of CVST and thrombocytopenia. This serious condition was reported in women between 18 and under 60 years. All were hospitalized; 10 were admitted to intensive care units (ICU). As of April 21, 4 patients were sent home, 2 were moved to hospital units outside of ICU, 3 continued ICU care, and 3 died. The review shows that U.S. cases of CVST and thrombocytopenia after J&J/Janssen vaccination were clinically similar to CVST cases in Europe after Oxford/AstraZeneca COVID-19 vaccination. Investigation of the potential relationship between J&J/Janssen vaccine and CVST with thrombocytopenia is ongoing.

Pre-print Manuscripts

These articles listed were posted on a pre-print server and are in the process of being submitted to a scientific or medical journal. Articles posted on a pre-print server **contain preliminary data and are not peer reviewed** (reviewed and evaluated by others in the same field but not involved in the study).

The purpose of posting studies on pre-print is to provide the most current data available to the public. When a manuscript is submitted to a peer review journal, additional data may become available and may alter the analysis of the data posted in the pre-print article.

Hanson KE, Goddard K, Lewis N, Fireman B, Myers TR, Bakshi N, Weintraub E, Donahue JG, Nelson JC, Xu S, Glanz JM, Williams JTB, Alpern JD, Klein NP. Guillain-Barré Syndrome after COVID-19 Vaccination in the Vaccine Safety Datalink . *medRxiv – the preprint server for health sciences* 2021 Dec 5 http://doi.org/10.1101.2021.12.03.21266419.

Clinical Research Studies

Observational Maternal COVID-19 Vaccination Study

Principal Investigators: Geeta K Swamy, Karen R Broder, Elizabeth Schlaudecker, Stephen I Pelton

Locations: Centers for Disease Control and Prevention, Boston Medical Center, Duke University, Cincinnati Children's Hospital Medical Center

First Posted: April 1, 2021 Summary

Recruitment Status: Recruiting

Safety of Simultaneous COVID-19 and IIV4 Vaccination

Principal Investigators: Emmanuel B Walter, Kawsar Talaat, Elizabeth Schlaudecker, Karen R Broder

Locations: Centers for Disease Control and Prevention, Duke University, Cincinnati Children's Hospital Medical Center and Johns Hopkins University

First Posted: August 31, 2021 Summary

Recruitment Status: Recruiting

CDC Vaccine Safety Publications by Year

How to search articles by keyword

To search articles on this page by keyword, first click the "open all" tab to list all publications. Then use the "find on this page" function available in most browsers. On desktop, press CTL+F (PC) or CMD+F (Mac) on your keyboard. A "find" text box will open at the top or bottom of your browser. Type the word or phrase you want to search for.

2022

Rosenblum HG, Gee JM, Liu R, Marquez PL, Zhang B, Strid P, Abara WE, McNeil MM, Myers TR, Hause AM, Su JR, Baer B, Menschik D, Markowitz LE, Shimabukuro TT, Shay DK. Safety monitoring of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to Vaccine Adverse Events Reporting System and v-safe *Lancet Infect Dis*.2022 Mar 7;S1473-3099(22)0054-8. Online ahead of print.

In December 2020, two mRNA COVID-19 vaccines were authorized for emergency use in the United States. Clinical trials showed these vaccines to be safe, and post-authorization monitoring is necessary to evaluate their safety in larger and diverse populations. VAERS and v-safe are two national systems CDC uses to monitor COVID-19 vaccine safety. During the first six months of the COVID-19 vaccination program (December 14, 2020 through June 14, 2021) over 298 million doses of mRNA vaccines were administered in the U.S. In that period, over 7.9 million people enrolled in v-safe. Local (pain, redness, swelling at injection site) and systemic (fever, fatigue, and headache) reactions were reported more frequently following dose 2 compared to dose 1. The majority of symptoms were reported as mild, peaked on day 1 following vaccination, and were short-lived. Of the 340,000 adverse event reports to VAERS, the majority (92%) were classified as non-serious (similar to the local and systemic reactions reported to v-safe); 6.6% serious, non-death; 1.3% deaths. An in-depth review of reports of death found rates of death reported to VAERS were lower than expected background rates by age group. This analysis reinforces the safety of COVID-19 vaccines.

Yousaf AR, Cortese MM, Taylor AW, Broder KR, Oster ME, Wong JM, Guh AY, McCormick DW, Kamidani S, Schlaudecker EP, Edwards K, Creech B, Staat MA, Belay ED, Marquez P, Su JR, Salzman MB, Thompson D, Campbell AR, MIS-C Investigation Authorship Group. Reported Cases of Multisystem Inflammatory Syndrome in Children in

AP, MIS-C Investigation Authorship Group. Reported Cases of Multisystem Inflammatory Syndrome in Children in Children (MIS-C) Aged 12-20 Years in the United States Who Received COVID-19 Vaccine, December 2020 through August 2021 . *Lancet Child Adolesc Health*. 2022 Feb 22;S2352-4642(22)00028-1. Online ahead of print.

Hause AM, Bags J, Myers TR, Su JR, Blanc PG, Girwa Baumblatt JA, Woo EJ, Gee J, Shimabukuro TT, Shay DK. Safety Monitoring of COVID-19 Vaccine Booster Doses Among Adults — United States, September 22, 2021-February 6, 2022 *MMWR Morb Mortal Wkly Rep* 2022 Feb 11;71. Early Release.

The Food and Drug Administration authorized booster doses for COVID-19 vaccines: at least 5 months after dose 2 of Pfizer-BioNTech COVID-19 vaccine for people ages 12 years and older; at least 5 months after dose 2 of Moderna COVID-19 vaccine for people ages 18 years and older; and at least 2 months after a single-dose primary series for people 18 years and older. CDC reviewed adverse events and health impact surveys following a booster dose reported to the v-safe after vaccination health checker and adverse events reported to the Vaccine Adverse Event Reporting System (VAERS). The review included people who received both a different and the same booster dose as their primary series (doses 1 and 2, and in some cases dose 3). From September 22, 2021–February 6, 2022, about 82.6 million U.S. residents ages 18 years and older received a COVID-19 vaccine booster dose. People who received the same mRNA COVID-19 vaccine booster as they did for the primary series reported local and systemic reactions (such as pain, fatigue, and headache) less frequently than after dose 2. Myocarditis was rarely reported following mRNA COVID-19 vaccine boosters. No unexpected patterns of adverse events were identified, and COVID-19 vaccine boosters are recommended for everyone ages 12 years and older.

Irving SA, Groom HC, Dandamudi P, Daley MF, Donahue JG, Gee J, Hechter R, Jackson LA, Klein NP, Lile E, Myers TR, Stokley S. A decade of data: Adolescent vaccination in the Vaccine Safety Datalink, 2007 through 2016 *Vaccine*. 2022 Feb 23;40(9):1246-1252 Epub 2022 Feb 4.

Oliver SE, Wallace M, See I, Mbaeyi S, Godfrey M, Hadler SC, Jatlaoui TC, Twentyman E, Hughes MM, Rao AK, Fiore A, Su JR, Broder KR, Shimabukuro T, Lale A, Shay DK, Markowitz LE, Wharton M, Bell BP, Brooks O, McNally V, Lee GM, Talbot HK, Daley MF. Use of Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated interim recommendations from the Advisory Committee on Immunization Practices—United States, December 2021. *MMWR Morb Mortal Wkly Rep*. 2022 Jan 21;71(3):90-95.

Oster ME, Shay DK, Su JR, Gee J, Creech B, Broder KR, Edwards K, Soslow JH, Dendy JM, Schlaudecker E, Lang SM, Barnett ED, Ruberg FL, Smith MJ, Campbell MJ, Lopes RD, Sperling LS, Baumblatt JA, Thompson DL, Marquez PL, Strid P, Woo J, Puglsey R, Reagan-Steiner S, DeStefano F, Shimabukuro TT. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US from December 2020 to August 2021 *JAMA*. 2022 Jan 18;327(4):331-340. Online ahead of print.

Since mRNA-based COVID-19 vaccines were authorized for emergency use in December 2020, there have been reports of myocarditis, or inflammation of the heart muscle, following vaccination. To see if there was an association between mRNA COVID-19 vaccination and myocarditis, researchers reviewed reports submitted to the Vaccine Adverse Event Reporting Systems (VAERS) from December 2020 through August 31, 2021. In that time, more than 192 million people ages 12 years and older have received at least one dose of mRNA COVID-19 vaccines. From this population, VAERS received 1,626 myocarditis reports that met case definition. The review found the rates myocarditis were highest following the second dose of mRNA vaccine among adolescent and young adult males. Myocarditis is a rare but serious adverse event that can occur following mRNA COVID-19 vaccination. The benefits of COVID-19 vaccination continue to outweigh any potential risks, including myocarditis.

See I, Lale A, Marquez P, Streiff MB, Wheeler AP, Tepper NK, Woo EJ, Broder KR, Edwards KM, Gallego R, Geller AI, Jackson KA, Sharma S, Talaat KR, Walter EB, Akpan IJ, Ortel TL, Urrutia VC, Walker S, Yui JC, Shimabukuro TT, Mba-Jonas A, Su JR, Shay DK. Case Series of Thrombosis with Thrombocytopenia Syndrome after COVID-19 vaccination—United States, December 2020 to August 2021 . *Ann Intern Med.* 2022 Jan 18. Doi: 10.7326/M21-4502 Online ahead of print.

Thrombosis with thrombocytopenia syndrome (TTS) is a rare, potentially life-threatening condition that involves blood clots with low platelet counts and has been seen following COVID-19 vaccination. Clinicians from the Clinical Immunization Safety Assessment (CISA) Project reviewed reports to the Vaccine Adverse Event Reporting System (VAERS) to investigate TTS following COVID-19 vaccination. From December 14, 2020 through August 31, 2021, over 14.1 million doses of Johnson & Johnson's Janssen and 351 million doses of mRNA vaccines were given. CISA confirmed 57 reports of TTS: 54 following Janssen COVID-19 vaccine and 3 following mRNA COVID-19 vaccines. Most cases of TTS following Janssen vaccination occurred in females and in people younger than 50 years. All cases of TTS following Janssen involved hospitalization, including 36 admitted to intensive care units. Of the 54 cases, 37 were discharged home, 9 were discharged to post-acute care, and 8 died. The reporting rate of TTS cases per million doses administered was 3.83 following Janssen vaccination, whereas the rate following mRNA vaccination (.0085) was consistent with the background rate of TTS. This analysis of data concluded that TTS is a rare, but serious adverse event associated with Janssen COVID-19 vaccination.

Navarro RA, Lin CC, Colli B, Qian L, Liu ILA, Sy LS, Jacobsen SJ, Tartof SY. Safety of Influenza Vaccination During Orthopedic Surgery Hospitalizations *J Am Acad Orthop Surg*. 2022 Jan 15;30(2):e155-e163. Doi: 10.5435/JAAOS-D-21-00101.

Woo EJ, Moro PL. Postmarketing safety surveillance of high-dose quadrivalent influenza vaccine: Reports to the Vaccine Adverse Event Reporting System . *Vaccine.* 2022 Jan 12. ISSN: 0264-410X. Online ahead of print.

The recombinant hemagglutinin quadrivalent influenza vaccine (Flublok Quadrivalent; RIV4) was approved by FDA in October 2016 for persons 18 years and older to reduce the risk from flu and flu-related complications. To analyze the safety profile of RIV4 since its approval, researchers reviewed adverse events reported to VAERS. From July 1, 2017 through June 30, 2020, VAERS received 849 reports after RIV4 vaccination. A majority of reports (810; 95%) were non-serious; injection site reactions were reported most often. There were 131 reports of allergic reactions. A majority of allergic reactions (127) were reported as non-serious, but required immediate medical care. Reports of allergic reactions do not necessarily suggest that RIV4 is particularly allergenic; some individuals may have a hypersensitivity to drug or vaccine exposure. Among serious adverse event reports, there were 10 cases of Guillain-Barré syndrome. Overall, the analysis did not identify any new safety concerns of RIV4.

Lipkind HS, Vazquez-Benitez G, DeSilva M, Vesco KK, Ackerman-Banks C, Zhu J, Boyce TG, Daley MF, Fuller CC, Getahun D, Irving SA, Jackson LA, Williams JTB, Zerbo O, McNeil MM, Olson CK, Weintraub E, Kharbanda KO. Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Orgnizations, United States, December 15, 2020-July 22, 2021 *MMWR Morb Mort Wkly Rep.* 2022 Jan 4:71 Early release.

DeSilva MB, Haapal J, Vazquez-Benitez G, Daley MF, Nordin JD, Klein NP, Henninger ML, Williams JTB, Hambidge SJ, Jackson ML, Donahue JG, Qian L, Lindley MC, Gee J, Weintraub ES, Kharbanda EO. Association of the COVID-19 Pandemic with Routine Childhood Vaccination Rates and Proportion Up to Date with Vaccinations Across 8 US Health Systems in the Vaccine Safety Datalink *JAMA Pediatr.* 2022 Jan 1;176(1):68-77. Doi: 10.1001/jamapediatrics.2021.4251.

2021

Groom HC, Crane B, Naleway AL, Weintraub E, Daley MF, Wain K, Kurilo MB, Burganowski R, DeSilva MB, Donahue JG, Glenn SC, Goddard K, Jackson ML, Kharbanda EO, Lewis N, Lou Y, Lugg M, Scott E, Sy LS, Williams JTB, Irving SA. Monitoring vaccine safety using the Vaccine Safety Datalink: Assessing capacity to integrate data from Immunization Information Systems *Vaccine*. 2022 Jan 31;40(5):752-756. Epub 2021 Dec 31.

Hause Am, Baggs J, Marquez P, Myers TR, Gee J, Su JR, Zhang B, Thompson D, Shimabukuro TT, Shay DK. COVID-19 Vaccine Safety in Children Ages 5-11 years — United States, November 3-December 19, 2021. *MMWR Morb Mort Wkly Rep.* 2021 Dec 31:70(5152);1755-1760.

Abara WE, Gee J, Mu Y, Deloray M, Ye T, Shay DK, Shimabukuro T. Expected Rates of Select Adverse Events following Immunization for COVID-19 Vaccine Safety Monitoring *J Infect Dis*. 2021 Dec 27;jiab628. Online ahead of print.

Moro PL, McNeil MM. Successes of the CDC monitoring systems in evaluating post-authorization safety of COVID-19 vaccines [Editorial] . *Expert Rev Vaccines.* 2021 Dec 27. Online ahead of print.

Perez-Vilar S, Dores G, Marquez PL, Ng CS, Cano MV, Rastogi A, Lee L, Su JR, Duffy J. Safety surveillance of meningococcal group B vaccine (Bexsero®), Vaccine Adverse Event Reporting System, 2015-2018 . *Vaccine*. 2022 Jan 21;40(2):247-254. Epub 2021 Dec 7.

Hanson KE, Goddard K, Lewis N, Fireman B, Myers TR, Bakshi N, Weintraub E, Donahue JG, Nelson JC, Xu S, Glanz JM, Williams JTB, Alpern JD, Klein NP. Guillain-Barré Syndrome after COVID-19 Vaccination in the Vaccine Safety Datalink . *medRxiv – the preprint server for health sciences.* 2021 Dec 5 http://doi.org/10.1101.2021.12.03.21266419.

Glanz JM, Clarke CL, Daley MF, Shoup JA, Hambidge SJ, Williams JTB, Groom HC, Kharbanda EO, Klein NP, Jackson LA, Lewin BJ, McClure DL, Xu S, DeStefano F. The Childhood Vaccination Schedule and the Lack of Association with Type 1 Diabetes . *Pediatrics.* 2021 Dec 1;148(6):e2021051910. Doi: 10.1542/peds.2021-051910 Online ahead of print.

Goud R, Lufkin B, Duffy J, Whitaker B, Wong HL, Liao J, Lo AC, Weintraub E, Kelman JA, Forshee RA. Risk of Guillain-Barré Syndrome Following Recombinant Zoster Vaccine in Medicare Beneficiaries . *JAMA Intern Med.* 2021 Dec 1;181(12):1623-1630. Doi: 10.1001/jamainternmed.2021.6227. Online ahead of print.

Belay ED, Godfred Cato S, Rao AK, Abrams J, Wilson WW, Lim S, Newton-Cheh C, Melgar M, DeCuir J, Webb B, Marquez P, Su JR, Meng L, Grome HN, Schlaudecker E, Talaat K, Edwards K, Barnett E, Campbell AP, Broder KR, Bamrah Morris S. Multisystem Inflammatory Syndrome in Adults after SARS-CoV-2 infection and COVID-19 vaccination . *Clin Infect Dis.* 2021 Nov 28;cia963. Online ahead of print.

Moro PL, Panagiotakopoulos L, Oduyebo T, Olson CK, Myers T. Monitoring the safety of COVID-19 vaccines in pregnancy in the US . *Human Vaccines & Immunotherapies.* 2021 Nov 10. doi.org/10.1080/21645515.2021.1984132.

Xu S, Huang R, Sy LS, Glenn SC, Ryan DS, Morrissette K, Shay DS, Vazquez-Benitez G, Glanz JM, Klein NP, McClure D, Liles EG, Weintraub ES, Tseng HF, Qian L. COVID-19 Vaccination and Non-COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020-July 31, 2021 *MMWR Morb Mortal Wkly Rep.* epub 2021 Oct 22.

Since COVID-19 vaccinations have become available in December 2020, an estimated 182 million people in the United States were fully vaccinated against COVID-19 by September 21, 2021. However, since April 2021, the number of people starting to get COVID-19 vaccines has decreased. People have cited vaccine safety concerns as deterrents to getting a COVID-19 vaccine, concerns that include deaths following COVID-19 vaccination. Although deaths after COVID-19 vaccination have been reported to VAERS, there have been few studies done to evaluate the mortality not associated with COVID-19 among vaccinated and unvaccinated groups. To analyze this, researchers conducted a study using the Vaccine Safety Datalink, comparing those who received COVID-19 vaccines and those who did not between December 2020 through July 2021. This study included data from 11 million people; 6.4 million received either Pfizer-BioNTech, Moderna or Janssen COVID-19 vaccine and 4.6 were unvaccinated. The analysis showed that those who received COVID-19 vaccinations had lower rates of mortality for non-COVID-19 causes than those unvaccinated. These findings provide evidence that COVID-19 vaccines are safe and support current vaccination recommendations.

Chapin-Bardales J, Myers T, Gee J, Shay DK, Marquez P, Baggs J, Zhang B, Licata C, Shimabukuro TT. Reactogenicity within 2 weeks after mRNA COVID-19 vaccines: Findings from the CDC v-safe surveillance system. *Vaccine* 2021 Oct 16; ISSN 0264-410X.

Hause AM, Baggs J, Gee J, Marquez P, Myers TR, Shimabukuro TT, Shay DK. Safety Monitoring of an Additional Dose of COVID-19 Vaccine — United States, August 12-September 19, 2021 *MMWR Morb Mortal Wkly Rep.* epub 2021 Sep 28.

On August 12, 2021, the Food and Drug Administration (FDA) expanded the Emergency Use Authorizations for Pfizer-BioNTech and Moderna (mRNA) COVID-19 vaccines to include an additional dose following the 2-dose vaccination series to those with compromised immune systems. From August 12 through September 19, over 22,000 v-safe enrollees reported an additional COVID-19 dose after completing the primary 2-dose mRNA vaccination series, most with the same vaccine. Among those who completed surveys for all 3 doses, local reactions (like pain or swelling where the shot was given) were reported slightly more after dose 3 compared with after dose 2 (79% vs. 78%), while reported systemic reactions (tiredness, headache) were slightly less common after dose 3 (74% vs. 77%). These side effects were mostly mild to moderate and short-lived. These findings did not show unexpected patterns of adverse events following an additional dose of COVID-19 vaccines. CDC will continue to monitor the safety of additional doses of COVID-19 vaccines and provide data to guide recommendations and protect the public's health.

Zauche LH, Wallace B, Smoots AN, Olson CK, Oduyebo T, Kim SY, Petersen EE, Ju J, Beauregard J, Wilcox AJ, Rose CE, Meaney-Delman DM, Ellington SR, CDC v-safe COVID-19 Pregnancy Registry Team. Receipt of mRNA COVID-19 Vaccines and Risk of Spontaneous Abortion *N Engl J Med.* 2021 Sept 8. Dpo: 10.1056/NEJMc2113891.

Although pregnant people are at increased risk for severe illness from COVID-19, the COVID-19 vaccination rate among pregnant people has been much lower than that of the general U.S. population. Data about vaccination during pregnancy was initially limited because pregnant participants were excluded from COVID-19 vaccine clinical trials. To evaluate the safety of mRNA vaccines in pregnant people, researchers analyzed data on miscarriage, or a pregnancy loss that occurs before 20 weeks of pregnancy, collected from v-safe COVID-19 Vaccine Pregnancy Registry participants. Over 2,400 registry participants received at least one dose of an mRNA COVID-19 vaccine just before pregnancy or within the first 20 weeks of pregnancy. The cumulative risk of miscarriage among those who received an mRNA COVID-19 vaccine was similar (14.1%) to previously published background rates (11 to 16%) . Therefore, this study demonstrated no increased risk of miscarriage following receipt of COVID-19 mRNA vaccine in early pregnancy. Research will continue on the safety of COVID-19 vaccines in pregnant people.

Kharbanda EO, Haapala J, DeSilva M, Vazquez-Benitez G, Vesco KK, Naleway AL, Lipkind HS. Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy *JAMA* 2021 Sep 8. Doi:10.1001/jama.2021.15494

Although pregnant people are at increased risk for severe illness from COVID-19, the COVID-19 vaccination rate among pregnant people has been much lower than that of the general U.S. population. Data about vaccination during pregnancy was initially limited because pregnant participants were excluded from vaccine clinical trials. Researchers within the Vaccine Safety Datalink, a collaboration between CDC and 9 health systems, representing approximately 3% of the U.S. population, analyzed data from 8 health systems from December 15, 2020 through June 28, 2021 to evaluate whether there's an association between COVID-19 vaccine and miscarriage (pregnancy loss that occurs before 20 weeks of pregnancy). This analysis included over 105,000 pregnancies. About 14% received one or more doses of one of the 3 available COVID-19 vaccines during pregnancy before 20 weeks' gestational age. The analysis found that people who were currently pregnant at the time of COVID-19 vaccination and those who became pregnant after vaccination did not have an increased risk of miscarriage. Research will continue on the safety of COVID-19 vaccines in pregnant people.

Klein NP, Lewis N, Goddard K, Fireman B, Zerbo Q, Hanson KE, Donahue JG, Kharbanda EO, Naleway A, Clark Nelson J, Xu S, Yih WK, Glanz JM, Williams JTB, Hambridge SJ, Lewin BJ, Shimabukuro TT, DeStefano F, Weintraub ES. Surveillance for Adverse Events After COVID-19 mRNA Vaccination *JAMA* 2021 Sept 3. Doi:10.1001/jama.2021.15072.

The Vaccine Safety Datalink (VSD) has conducted weekly near real-time monitoring, or Rapid Cycle Analysis (RCA), of Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines since those vaccines received emergency use authorization from the Food and Drug Administration in December 2020. Between December 14, 2020 through June 25, 2021, over 11.8 million doses of mRNA were administered to 6.2 million people in the VSD network; 57% received Pfizer-BioNTech and 43% received Moderna. During that time period, VSD monitored 23 pre-specified health outcomes, including myocarditis/pericarditis and anaphylaxis. Researchers identified 34 cases of myocarditis/pericarditis in people ages 12 to 39 years; a majority (85%) were males. Among this age group, there is an increased risk of 6.3 additional myocarditis cases per million mRNA vaccinations administered in the first week following vaccination. The rate of anaphylaxis following vaccination was 4.8 cases per million doses of Pfizer-BioNTech and 5.1 per million doses of Moderna vaccination. VSD monitoring did not detect safety signals for any other pre-specified outcomes. Additional research is ongoing. Getting vaccinated remains the best way to protect against COVID-19 infection.

Rosenblum HG, Hadler SC, Moulia D, Shimabukuro TT, Su JR, Tepper NK, Ess KC, Woo EJ, Mba-Jonas A, Alimchandani M, Nair N, Klein NP, Hanson KE, Markowitz LE, Wharton M, McNally VV, Romero JR, Talbot K, Lee GM, Daley MF, Mbaeyi SA, Oliver SE. Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices — United States, July 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Aug 10.

On July 22, 2021, CDC's Advisory Committee on Immunization Practices (ACIP) reviewed a benefit-risk analysis of Guillain-Barré syndrome (GBS) following Johnson & Johnson's Janssen (J&J/Janssen) vaccine, as well as the latest information on thrombosis with thrombocytopenia syndrome (TTS) following J&J/Janssen vaccination and myocarditis following mRNA vaccination (Pfizer-BioNTech and Moderna vaccines). As of June 30, 2021, about 12.6 million doses of Janssen vaccine had been administered and 141 million 2nd mRNA vaccine doses had been administered. Overall, there were 7.8 cases of GBS per million J&J/Janssen doses; 3 cases of TTS per million J&J/Janssen doses and 3.5 cases of myocarditis per million 2nd mRNA vaccine doses. After assessing the data, ACIP concluded that the benefits of COVID-19 vaccination in preventing COVID-19 illness, associated hospitalizations, ICU admissions, and death outweigh serious but rare risks of GBS, TTS, and myocarditis.

Hause AM, Gee J, Baggs J, Abara WE, Marquez P, Thompson D, Su JR, Licata C, Rosenblum HG, Myers TR, Shimabukuro TT, Shay DK. COVID-19 Vaccine Safety in Adolescents—United States, December 14, 2020—July 16, 2021. *MMWR Morb Mortal Wkly Rep.* 2021 Jul 30.

As of July 2021, Pfizer-BioNTech COVID-19 Vaccine (Pfizer-BioNTech) is the only COVID-19 vaccine authorized for use in adolescents (people aged 12–17 years). To evaluate the safety of Pfizer-BioNTech in adolescents, researchers reviewed data collected from VAERS and v-safe between December 14, 2020 through July 16, 2021. Over 8.9 million Pfizer-BioNTech doses were administered to adolescents ages 12-17. VAERS received 9,246 reports of adverse events in adolescents; over 90% of reports were non-serious. Myocarditis was reported in 4.3% (397) of all VAERS reports. Of the 129,000 adolescents who enrolled in v-safe, the most frequently reported side effects included injection site pain, fatigue, headache, and weakness. With the exception of myocarditis, the safety findings were similar to what was observed during preauthorization trials. CDC and FDA are actively monitoring the safety of COVID-19 vaccines. Serious adverse events after COVID-19 vaccination are rare, and CDC continues to recommend everyone 12 years and older get vaccinated as soon as possible to help protect against COVID-19.

Pingali C, Meghani M, Razzaghi H, , Lamias MJ, Weintraub E, Kenigsberg TA, Klein NP, Lewis N, Fireman B, Zerbo O, Bartlett J, Goddard K, Donahue J, Hanson K, Naleway A, Kharbanda EO, Yih K, Clark Nelson J, Lewin BJ, Williams JTB, Glanz JM, Singletom JA, Patel SA. COVID-19 Vaccination Coverage Among Insured Persons Aged ≥ 16 years, by Race/Ethnicity and Other Selected Characteristics — Eight Integrated Health Care Organizations, United States, December 14, 2020-May 15, 2021. *MMWR Morb Mortal Wkly Rep*. 2021 Jul 16;70(28):985-990.

Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, Broder KR, Gee J, Weintraub E, Shimabukuro T, Scobie HM, Moulia D, Markowitz LE, Wharton M, McNally VV, Romero JR, Keipp Talbot H, Lee GM, Daley MF, Oliver SE. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Jul 9;70:977-982.

Two mRNA COVID-19 vaccines were given emergency use authorization (EUA) by the Food and Drug Administration (FDA) in December 2020: Pfizer-BioNTech and Moderna COVID-19 vaccines. Pfizer-BioNTech was authorized for individuals 16 years and older, and Moderna for adults 18 years and older. In May 2021, FDA expanded Pfizer-BioNTech vaccine's authorization to include adolescents aged 12 to 15 years. After reported myocarditis/pericarditis among mRNA vaccine recipients, mostly in younger males after the 2nd dose, the Advisory Committee on Immunization Practices (ACIP) held a meeting to review these reports and conduct a risk-benefit assessment of mRNA COVID-19 vaccination in the U.S. Evidence presented showed that the highest rates of myocarditis were reported in males aged 12-17 and 18-24 (62.8 and 50.5 reported cases of myocarditis per million 2nd mRNA doses administered, respectively). On June 23, after reviewing all the available information, ACIP determined that the benefits of mRNA COVID-19 vaccination under EUA outweighed the risks of myocarditis in all populations. CDC and FDA will continue to monitor cases of myocarditis among mRNA COVID-19 vaccine recipients.

Shay DK, Shimabukuro, TT, DeStefano F. Myocarditis After Immunization with mRNA-Based COVID-19 Vaccines: Editorial . *JAMA Cardiol.* Published online June 29, 2021. doi:10.1001/jamacardio.2021.2821.

CDC researchers reviewed several case reports of acute myocarditis occurring in people following mRNA-based COVID-19 vaccinations (Pfizer BioNTech or Moderna). The first report included 4 cases of myocarditis developed 1 to 5 days after getting dose 2 of mRNA-based COVID-19 vaccine. Second report included 23 cases of acute myocarditis within 4 days of vaccination, mostly after dose 2. The last report included 7 cases in adolescents, ages 14-19. All presented with myocarditis or myopericarditis (heart muscle and lining inflammation) within 4 days of dose 2. The review of these cases showed clinical similarities and there were no other known causes for their acute myocarditis, suggesting a likely association with vaccination. Myocarditis following COVID-19 vaccination is rare. Researchers will continue to look into myocarditis following COVID-19 vaccination.

Razzaghi H, Meghani M, Pingali C, Crane B, Naleway A, Weintraub E, Kenigsberg TA, Lamias MJ, Irving SA, Kauffman TL, Vesco KK, Daley MF, DeSilva M, Donahue J, Getahun D, Glee S, Hambidge SJ, Jackson LJ, Lipkind HS, Nelson J, Zerbo O, Oduyebo T, Singleton JA, Patel SA. COVID-19 Vaccination Coverage Among Pregnant Women During Pregnancy — Eight Integrated Health Care Organizations, United States, December 14, 2020-May 8, 2021. *MMWR Morb Mortal Wkly Re*p. 2021 Jun 18;70(24):895-899.

Naleway AL, Crane B, Irving SA, Bachman D, Vesco KK, Daley MF, Getahun D, Glenn SC, Hambidge SJ, Jackson LA, Klein NP, McCarthy NL, McClure DL, Panagiotakopoulos L, Panozzo CA, Vazquez-Benitez G, Weintraub E, Zerbo O, Kharbanda EO. Vaccine Safety Datalink infrastructure enhancements for evaluating the safety of maternal vaccination *Ther Adv Drug Saf.* 2021 Jun 14;12:20420986211021233. eCollection 2021.

Xu S, Clarke Cl, Newcomer SR, Daley MF, Glanz JM. Sensitivity analyses if unmeasured and partially-measure confounders using multiple imputation in a vaccine safety study . *Pharmacoepidemiol Drug Saf.* 2021 Sept;30(9):1200-1213. Epub 2021 May 31.

Liles E, Irving SA, Dandamudi P, Belongia EA, Daley MF, DeStefano F, Jackson LA, Jacobsen SJ, Kharbanda E, Klein NP, Weintraub E, Naleway AL. Incidence of pediatric inflammatory bowel disease within the Vaccine Safety Datalink network and evaluation of association with rotavirus vaccination *Vaccine*. 2021 Jun 16;39(27):3614-3620. Epub 2021 May 26.

Gubernot D, Jazwa A, Niu M, Baumblatt J, Gee J, Moro P, Duffy J, Harrington T, McNeil MM, Broder K, Su J, Kamidani S, Olson CK, Panagiotakopoulos L, Shimabukuro T, Forshee R, Anderson S, Bennet S. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines . *Vaccine.* 2021 Jun 23;39(28):3666-3677. Epub 2021 May 14.

MacNeil JR, Su JR, Broder KR, Guh AY, Gargano JW, Wallace M, Hadler SC, Scobie HM, Blain AE, Moulia D, Daley MF, McNally VV, Romero JR, Keipp Talbot H, Lee GM, Bell BP, Oliver SE. Updated Recommendations from the Advisory Committee on Immunization Practices for Use of Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021. *MMWR Morb Mortal Wkly Rep.* 2021 Apr 30;70:651-656.

The Johnson & Johnson/Janssen (Janssen) COVID-19 vaccine was authorized for emergency use on February 27, 2021. On April 13, CDC and the Food and Drug Administration (FDA) recommended pausing the use of Janssen vaccine after thrombosis with thrombocytopenia syndrome (TTS) was reported among vaccine recipients. TTS is a rare syndrome that involves blood clots in large

thrombocytopenia syndrome (TTS) was reported among vaccine recipients. TTS is a rare syndrome that involves blood clots in large blood vessels with low platelets. The Advisory Committee on Immunization Practices (ACIP) held two emergency meetings to review reports of TTS following Janssen vaccine and conducted a risk-benefit assessment. The estimated reporting rate of TTS was 7 cases of TTS per million Janssen doses administered to women aged 18-49 years. After their review, on April 23, ACIP concluded that the benefits of resuming Janssen COVID-19 vaccination among persons aged 18 years and older outweighed the risks and reaffirmed its interim recommendation under FDA's Emergency Use Authorization (EUA), which includes a new warning for rare clotting events, primarily in women aged 18-49 years. CDC and FDA will continue to closely monitor reports of TTS following Janssen vaccination.

Shay DK, Gee J, Su JR, Myers TR, Marquez P, Liu R, Zhang B, Licata C, Clark TA, Shimabukuro TT. Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine — United States, March-April 2021. *MMWR Morb Mortal Wkly Rep.* 2021 April 30. Epub ahead of print.

Johnson & Johnson's Janssen COVID-19 vaccine was authorized by FDA for emergency use on February 27, 2021. By April 21, nearly 8 million doses of the Janssen COVID-19 vaccine had been administered. CDC researchers reviewed safety monitoring data from VAERS and the v-safe after-vaccination health checker, and found 97% of reported reactions after vaccination, such as headache, fever, chills, injection site pain, and fatigue, were nonserious and consistent with clinical trials data. CDC and FDA issued a pause of the Janssen vaccine April 12–23, 2021, after 6 cases of cerebral venous sinus thrombosis (CVST), a serious condition that involves blood clots in the brain, were identified in VAERS. By April 25, a total of 17 thrombotic (blood clots) events with thrombocytopenia (low platelet counts) were reported to VAERS, including 3 thrombotic events not occurring in the brain. CDC and FDA continue to monitor the safety of COVID-19 vaccines, analyzing the risks and benefits of continued use.

Daley MF, Reifler LM, Shoup JA, Narwaney KJ, Kharbanda EO, Groom HC, Jackson ML, Jacobsen SJ, McLean HQ, Klein NP, Williams JTB, Weintraub ES, McNeil MM, Glanz JM. Temporal Trends in Undervaccination: a Population-Based Cohort Study *Am J Prev Med*. 2021 Jul;61(1):64-72. Epub 2021 Apr 30.

See I, Su JR, Lale A, Woo EJ, Guh AY, Shimabukuro TT, Streiff MB, Rao AK, Wheeler AP, Beavers SF, Durbin AP, Edwards K, Miller E, Harrington TA, Mba-Jonas A, Nair N, Nguyen DT, Talaat KR, Urrutia VC, Walker SC, Creech B, Clark TA, DeStefano F, Broder KR. US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021 *JAMA* 2021 April 30. Doi:10.1001/jama.2021.7517 Epub ahead of print.

Around 7 million doses of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine were given between March 2–April 12, 2021. During this time, VAERS received reports following J&J/Janssen vaccination of cerebral venous sinus thrombosis (CVST) with thrombocytopenia, which involves blood clots in the brain with low platelet counts. By April 21, there were 12 reports of CVST and thrombocytopenia. This serious condition was reported in women between 18 and under 60 years. All were hospitalized; 10 were admitted to intensive care units (ICU). As of April 21, 4 patients were sent home, 2 were moved to hospital units outside of ICU, 3 continued ICU care, and 3 died. The review shows that U.S. cases of CVST and thrombocytopenia after J&J/Janssen vaccination were clinically similar to CVST cases in Europe after Oxford/AstraZeneca COVID-19 vaccination. Investigation of the potential relationship between J&J/Janssen vaccine and CVST with thrombocytopenia is ongoing.

Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, Marquez PL, Olson CK, Liu T, Chang KT, Ellington SR, Burke VK, Smoots AN, Green CJ, Licata C, Zhang BC, Alimchandani M, Mba-Jonas A, Martin SW, Gee JM, Meaney-Delman DM. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons *N Engl J Med* 2021 April 21. DOI: 10.1056/NEJMoa2104983 Epub ahead of print.

Pregnant people were not included in the messenger RNA (mRNA) COVID-19 vaccine clinical trials. Because of the increased risk of severe illness from COVID-19, CDC has provided guidance to pregnant people who may want to get a COVID-19 vaccine. The safety of mRNA vaccines in pregnant people is monitored through 3 systems: v-safe after vaccination health checker, the v-safe pregnancy registry and VAERS. From December 14, 2020 through February 28, 2021, 35,691 v-safe participants ages 16 to 54 identified as

pregnant. Injection site pain was commonly reported. Of those, 3,958 enrolled in the v-safe pregnancy registry: 827 completed pregnancy; 712 (86.1%) had live births, with most vaccinations completed in the 3rd trimester. In the VAERS reports following mRNA vaccinations, 155 (70.1%) were nonpregnancy specific; 66 (29.9%) were pregnancy and neonatal specific events. The analysis of v-safe and VAERS data did not show any safety concerns among pregnant persons who received mRNA COVID-19 vaccines.

Hause AM, Gee J, Johnson T, Jazwa A, Marquez P, Miller E, Su J, Shimabukuro TT, Shay DK. Anxiety-Related Adverse Event Cluster After Janssen COVID-19 Vaccination — Five U.S. Mass Vaccination Sites, April 2021 *MMWR Morb Mortal Wkly Rep.* 2021 April 20. Epub ahead of print.

From April 7-9, 2021, 5 weeks after the J&J/Janssen COVID-19 vaccine was authorized by FDA for emergency use, clusters of anxiety-related events after Janssen vaccination were reported to CDC. The reports came from 5 mass vaccination sites in different states; 4 closed temporarily to investigate the cases. Of the 8,624 Janssen vaccine recipients, there were 64 reports of anxiety-related events, including 17 reports of fainting. Commonly reported symptoms were light-headedness/dizziness (56%), excessive sweating (31%), fainting (27%), nausea or vomiting (25%) and low blood pressure (16%). Additionally, CDC reviewed all reports to VAERS of fainting after Janssen vaccine between March 2 through April 11, 2021 and identified 653 reports out of 8 million doses administered. Review of reports found that fainting occurs in 8 per 100,000 doses administered. Vaccine providers should observe individuals for 15 minutes after COVID-19 vaccination for signs of immediate anxiety-related reactions or fainting.

Chapin-Bardales J, Gee J, Myers T. Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines *JAMA Insights* 2021 April 5. doi:10.1001/jama.2021.5374 Epub ahead of print.

CDC created v-safe, a smartphone-based tool, to monitor in near-real time the safety of COVID-19 vaccines authorized by FDA for emergency use. V-safe uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination. Researchers reviewed data collected from v-safe from December 14, 2020 to February 28, 2021, including side effects and reactions to the mRNA COVID-19 vaccines. Over 3.6 million v-safe participants completed at least one health check-in after the first dose and over 1.9 million after the second dose. Injection site pain was commonly reported after first (70%) and second doses (75%) of either mRNA vaccine. Systemic reactions, such as fatigue, headache, muscle pain, chills, fever, and joint pain were the top symptoms reported by participants after the first mRNA vaccine dose. These reports increased substantially after the second dose among both mRNA vaccines. People aged 65 years and older reported fewer reactions than younger people. While v-safe is voluntary and includes less than 10% of people vaccinated, reported reactions to the mRNA vaccines were consistent with results observed in clinical trials.

Kharbanda EO, Vazquez-Benitez G, DeSilva MB, Naleway AL, Klein NP, Hechter RC, Glanz JM, Donahue JG, Jackson LA, Sheth SS, Greenberg V, Panagiotakopoulos L, Mba-Jonas A, Lipkind HS. Association of Inadvertent 9-Valent Human Papillomavirus Vaccine in Pregnancy with Spontaneous Abortion and Adverse Birth Outcomes *JAMA Netw Open*.2021 Apr 1;4(4):e214340.

Woo EK, Moro PL. Postmarketing safety surveillance of quadrivalent recombinant influenza vaccine: Reports to the vaccine adverse event reporting system. *Vaccine.* 2021 Mar 4;S0264-410X(21)00232-2. Epub ahead of print.

The recombinant hemagglutinin quadrivalent influenza vaccine (Flublok Quadrivalent; RIV4) was approved by FDA in October 2016 for persons 18 years and older to reduce the risk from flu and flu-related complications. To analyze the safety profile of RIV4 since its approval, researchers reviewed adverse events reported to VAERS. From July 1, 2017 through June 30, 2020, VAERS received 849 reports after RIV4 vaccination. A majority of reports (810; 95%) were non-serious; injection site reactions were reported most often. There were 131 reports of allergic reactions. A majority of allergic reactions (127) were reported as non-serious, but required

immediate medical care. Reports of allergic reactions do not necessarily suggest that RIV4 is particularly allergenic; some individuals may have a hypersensitivity to drug or vaccine exposure. Among serious adverse event reports, there were 10 cases of Guillain-Barré syndrome. Overall, the analysis did not identify any new safety concerns of RIV4.

Shimabukuro T, Nair N. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine *JAMA* 2021 Feb 23;325(8):780-781 doi: 10.1001/jama.2021.0600.

Pfizer-BioNTech COVID-19 vaccine was authorized by the Food and Drug Administration (FDA) for emergency use in December 2020. CDC and FDA immediately began safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). One health outcome in particular that CDC and FDA monitored for was severe allergic reaction, or anaphylaxis. From December 14–23, 2020, 1.89 million first doses of Pfizer-BioNTech COVID-19 vaccine were administered. The most commonly reported non-anaphylaxis allergic reactions included: rash, itchy skin, itchy and scratchy sensations in the throat, and mild respiratory symptoms. Safety monitoring identified 21 anaphylaxis reports, corresponding to an estimated rate of 11.1 cases per million doses administered; 17 (81%) had a history of allergies or allergic reactions. No deaths from anaphylaxis were reported. CDC has guidance on the use of mRNA COVID-19 vaccines and management of anaphylaxis.

Gee J, Marquez P, Su J, Calvert GM, Liu R, Myers T, Nair N, Martin S, Clark T, Markowitz L, Lindsey N, Zhang B, Licata C, Jazwa A, Sotir M, Shimabukuro T. First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020-January 13, 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Feb 26;70;283-288.

The U.S. FDA authorized two COVID-19 vaccines for emergency use in December 2020: Pfizer-BioNTech and Moderna. During clinical trials, there were reports of local reactions where the shot was given, and systemic reactions affecting other parts of the body. Safety monitoring for these vaccines has been the most intense and comprehensive in U.S. history. From December 14, 2020 through January 13, 2021, almost 14 million vaccine doses were distributed. During that time, over 1.6 million vaccine recipients enrolled in v-safe, and VAERS received 6,994 reports of adverse events following vaccination. About 91% of VAERS reports were non-serious; commonly reported symptoms included headache (22.4%), fatigue (16.5%) and dizziness (16.5%). V-safe enrollees reported similar local and systemic reactions. While deaths were reported to VAERS, available documentation did not suggest a causal link between the vaccine and death. Overall, no unusual or unexpected reporting patterns were detected.

Perez-Vilar S, Hu M, Weintraub, Arya D, Lufkin B, Myers T, Woo EJ, Lo AC, Cho S, Swarr M, Liao J, Wernecke M, MaCurdy T, Kelman J, Anderson S, Duffy J, Forshee RA. Guillain-Barré Syndrome After High-Dose Influenza Vaccine Administration in the United States, 2018-2019 Flu Season *J Infect Dis*. 2021 Feb 13;223(3):416-425. Doi: 10.1093/infdis/jiaa543.

Shimabukuro T, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021. *JAMA* 2021 Feb 12; doi:10.1001/jama.2021.1967. Epub ahead of print.

In December 2020, FDA issued Emergency Use Authorizations for two mRNA-based vaccines for prevention of COVID-19 disease: Pfizer-BioNTech COVID-19 vaccine (December 11) and Moderna COVID-19 vaccine (December 18). After implementation of the vaccines, cases of anaphylaxis following both vaccines were reported. Anaphylaxis is a severe, life-threatening allergic reaction that can occur after vaccination. During December 14, 2020 through January 18, 2021, over 9.9 million doses of Pfizer-BioNTech vaccine and over 7.5 million doses of Moderna vaccine were administered. In this same time, CDC identified 66 anaphylaxis cases reported to VAERS: 47 following Pfizer-BioNTech vaccine (rate of 4.7 cases per million doses) and 19 following Moderna vaccine (rate of 2.5 cases per million doses). There were no deaths from anaphylaxis reported after either vaccine. Continued safety monitoring of mRNA COVID-19 vaccines has confirmed anaphylaxis following vaccination is a rare event.

CDC COVID-19 Response Team Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine— United States, December 21, 2020-January 10, 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Jan 22:70(4);125-129.

On December 18, 2020, FDA issued an Emergency Use Authorization for Moderna COVID-19 vaccine to prevent COVID-19. As of January 10, 2021, over 4 million first doses of the vaccine had been administered. Many people did not have any side effects after COVID-19 vaccination. However, some serious adverse reactions were reported, such as the life-threatening allergic reaction, anaphylaxis. From December 21, 20201 through January 10, 2021, VAERS received 108 reports following Moderna vaccine identified as possible allergic reaction, including anaphylaxis. Through case review of medical reports, 10 cases were determined to be anaphylaxis (a rate of 2.5 cases of anaphylaxis per million doses). Of the 10 cases, 9 had a history of allergies or allergic reaction, including 5 who had a history of anaphylaxis. Anaphylaxis following Moderna vaccine appears to be a rare event. CDC and FDA will continue to monitor for anaphylaxis following COVID-19 vaccines.

CDC COVID-19 Response Team Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14-23, 2020 *MMWR Morb Mortal Wkly Rep.* 2021 Jan 15:70(2);46-51.

On December 11, 2020, FDA issued an Emergency Use Authorization for Pfizer-BioNTech COVID-19 vaccine to prevent COVID-19. As of December 23, 2020, over 1.8 million first doses of the vaccine had been administered. During this time, CDC and FDA were notified through multiple channels of suspected cases of anaphylaxis following vaccination. Anaphylaxis is a severe, life-threatening allergic reaction that occurs rarely after vaccination. From December 14-23, 2020, VAERS received 175 reports identified as possible allergic reaction, including anaphylaxis. Through case review of medical reports, 21 cases were determined to be anaphylaxis (a rate of 11.1 cases of anaphylaxis per million doses). Most anaphylaxis cases (81%) occurred in persons with a history of allergies or allergic reactions. Anaphylaxis following Pfizer-BioNTech vaccine appears to be a rare event. CDC and FDA will continue to monitor for anaphylaxis following COVID-19 vaccines.

Su JR, McNeil MM, Welsh KJ, Marquez PL, Ng C, Yan M, Cano MV Myopericarditis after vaccination, Vaccine Adverse Event Reporting System (VAERS), 1990-2018 . *Vaccine*. 2021 Jan 29; 39(5):839-845. Epub 2021 Jan 6.

Myopericarditis, an inflammation of the heart muscle and tissue around the heart, has many causes including viral infections. While not confirmed as a cause, myopericarditis after vaccination has been periodically reported. Researchers identified reports of myopericarditis following vaccination submitted to the Vaccine Adverse Event Reporting System (VAERS) from 1990–2018. During 1990–2018, VAERS received a total 620,195 reports: 708 (0.1%) met the case definition or were physician-diagnosed as myopericarditis. Most (79%) reports described males, 69% were serious, and 72% had symptom onset within 2 weeks of vaccination. Overall, smallpox (59%) and anthrax (23%) vaccines were most commonly reported, with higher reporting rates only after smallpox vaccine. Myopericarditis remains rarely reported after vaccines licensed for use in the United States. In this analysis, myopericarditis was most commonly reported after smallpox vaccine, and less commonly after other vaccines.

2020

Moro PL, Marquez P. Reports of cell-based influenza vaccine administered during pregnancy in the Vaccine Adverse Event Reporting System (VAERS), 2013-2020. *Vaccine.* 2021 Jan 22;39(4):678-681. Epub 2020 Dec 25

Flucelvax (ccIIV3 or ccIIV4; ccIIV) was approved by FDA for use in persons aged 18 years and older. There are limited data on the safety of ccIIV in pregnant women or their infants. To assess the safety of ccIIV given during pregnancy, researchers searched VAERS for reports of adverse events (AEs) from July 1, 2013 through May 31, 2020. During that time, VAERS received 4,852 reports following ccIIV, and 391 reports included pregnant women (8%). Of those, 24 (6.1%) were classified as serious. Two neonatal deaths were reported; no maternal deaths occurred. Among the 340 reports with trimester information, ccIIV was administered during the second trimester in 170 (50%). The most frequently reported pregnancy-specific AE was premature delivery (85; 21.7%). There were 62 reports (15.9%) of low birth weight of infants and 15 report of birth defects. While these results are different than previous pregnancy reviews after inactivated influenza vaccines (IIV), no safety concerns were identified.

Kharbanda EO, Vazquez-Benitez G, DeSilva MB, Spaulding AB, Daley MF, Naleway AL, Irving SA, Klein NP, Tseng HF, Jackson LA, Hambridge SJ, Olaiya O, Panozzo CA, Myers TR, Romitti PA. Developing Algorithms for Identifying Major Structural Birth Defects Using Automated Electronic Health Data. *Pharmacoepidemiol Drug Saf.* 2021 Feb;30(2):266-274. Epub 2020 Dec 3.

Vaccine Safety Datalink (VSD) researchers often rely on electronic health records when conducting observational studies. To improve case identification, researchers use algorithms to accurately identify diagnoses for particular conditions or diseases. Algorithms used in previous studies for selected birth defects were based on *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) codes. In October 2015, the United States transitioned to the 10th edition (ICD-10-CM). In this study, researchers updated, validated, and refined algorithms for use with ICD-10-CM codes. Final algorithms were applied to a group of live births delivered between October 2015 through September 2017 at 8 VSD sites and were compared to the original ICD-9-CM algorithms applied to a group of live births in 2004-2013. Results demonstrated that the new ICD-10-CM algorithms can be used for future studies of maternal vaccine safety.

Panagiotakopoulos L, McCarthy NL, Tepper NK, Kharbanda NK, Lipkind HS, Vazquez-Benitez G, McClure DL, Greenberg V, Getahun D, Glanz JM, Naleway AL, Klein NP, Nelson JC, Weintraub ES. Evaluating the Association of Stillbirths After Maternal Vaccination in the Vaccine Safety Datalink. *Obstet Gynecol.* 2020 Dec;136(6):1086-1094.

The Advisory Committee on Immunization Practices recommends women receive vaccinations against flu and tetanus, diphtheria, and acellular pertussis (Tdap) during each pregnancy. Despite reassuring safety data, pregnant women often have concerns about the safety of vaccines for them and their babies. Researchers used the VSD to evaluate whether vaccinations given during pregnancy were associated with stillbirth (fetal death occurring on or after 20 weeks gestation). The study compared 795 stillbirths (confirmed with medical record review) and 3,180 live birth controls between September 30, 2015 and January 1, 2020. Researchers found 51.7% of stillbirth cases and 52.9% live birth controls were exposed to vaccines during pregnancy, including flu and Tdap vaccines. The findings show that vaccination during pregnancy did not increase the risk of stillbirth, including recommended, non-recommended, and contraindicated vaccines. Overall, the study results support the safety of ACIP recommendations during pregnancy.

Haber P, Tate J, Marquez PL, Moro PL, Parashar U. Safety Profile of rotavirus vaccines among individuals aged ≥8 months of age, United States, vaccine adverse event reporting system (VAERS), 2006-2019. *Vaccine.* 2020 Nov 29;S0264-410X(20)31466-3. Online ahead of print.

Two live oral rotavirus vaccines, RotaTeq (RV5) and Rotarix (RV1), were introduced into the routine vaccination program in 2006 and 2008, respectively. RV1 is administered at ages 2 and 4 months and RV5 is administered at ages 2, 4, and 6 months. The series is recommended prior to 8 months of age to decrease the risk of intussusception (IS), an intestinal obstruction common in younger children. However, there is limited safety data on the vaccines when given to children older than 8 months. Researchers in the Vaccine Adverse Event Reporting System (VAERS) analyzed reports of adverse events (AEs) following rotavirus vaccination submitted January 2006 through December 2019. A total 344 reports were submitted: 309 reports included children 8 months to 5 years of age, and 35 reports included children 6 years and older. While known AEs were identified – diarrhea, fever and vomiting – no new or unexpected safety concerns were identified for those vaccinated beyond the recommended age.

Perez-Vilar S, Hu M, Weintraub E, Arya D, Lufkin B, Myers T, Woo EJ, Lo A, Chu S, Swarr M, Liao J, Wernecke M, MaCurdy T, Kelman J, Anderson S, Duffy J, Forshee RA. Guillain-Barré Syndrome After High-Dose Influenza Vaccine Administration in the United States, 2018–2019 Season *J Infect Dis.* 2020 Nov 2; jiaa543. Online ahead of print.

While an association between influenza vaccination and Guillain-Barré syndrome (GBS) was first noticed in 1976, studies in subsequent flu seasons have assessed the risk and found either no or small risk of GBS following influenza vaccination. Early during the 2018-2019 flu season, the Vaccine Safety Datalink (VSD) identified a statistical signal for an increased risk of GBS in days 1–42 following high-dose influenza vaccine (IIV3-HD) administration. The signal was rapidly evaluated using Medicare data by conducting early- and end-of-season analyses. The Medicare analyses, which included more than 7 million IIV3-HD vaccinations, did not detect a statistically significant increased GBS risk. The VSD end-of-season analysis also did not find an increased GBS risk among more than 600,000 IIV3-HD vaccinations. These analyses determined that if a GBS risk existed, it was similar to that from prior seasons.

Duffy J, Marquez P, Dores GM, Ng C, Su J, Cano J, Perez-Vilar S. Safety Surveillance of bivalent meningococcal group B vaccine, Vaccine Adverse Event Reporting System, 2014-2018. *Open Forum Infec Dis.*2020 Oct 27. Online ahead of print.

Licensed in October 2014, MenB-FHbp was the first meningococcal group B vaccine approved for use in the United States. The Advisory Committee on Immunization Practices recommends the 3-dose series for individuals aged 10-25 years who are at an increased risk of meningococcal B disease. Researchers reviewed reports of adverse events (AEs) following MenB-FHbp submitted to the Vaccine Adverse Event Reporting System (VAERS) from October 2014 through December 2018. During this time period, VAERS received 2,106 reports involving MenB-FHbp, representing 698 reports per million doses distributed (over 3 million doses were distributed in this analysis period). The most common AEs reported were fever (27%), headache (25%), and pain (16%). Overall, the review did not identify any new safety issues. The most commonly reported AEs following MenB-FHbp were consistent with those identified in clinical trials as described in the package insert.

Miller ER, McNeil MM, Moro PL, Duffy J, Su JR. The reporting sensitivity of the Vaccine Adverse Event Reporting System (VAERS) for anaphylaxis and for Guillain-Barré syndrome. *Vaccine.* 2020 Nov 3;38(47)7458-7463. Epub 2020 Oct 7.

Underreporting is an important limitation that is common to passive surveillance systems. The number of adverse events (AEs) that occur after vaccination and the percentage of those that get reported to the Vaccine Adverse Event Reporting System (VAERS) is unknown. To determine the sensitivity of VAERS in capturing AE reports, researchers analyzed pre-specified outcomes – anaphylaxis and Guillain-Barré syndrome (GBS) – reported to VAERS and determined if they are similar to previous estimates for other severe AEs. These estimates used were obtained from published studies of the Vaccine Safety Datalink of anaphylaxis and GBS following vaccination. VAERS sensitivity for capturing anaphylaxis after seven different vaccines ranged from 13-76%; sensitivity for capturing GBS after three different vaccines ranged from 12-64%. For anaphylaxis and GBS, VAERS sensitivity is comparable to previous estimates for detecting important AEs following vaccination.

Panagiotakopoulos L, Myers TR, Gee J, Lipkind HS, Kharbanda EO, Ryan DO, Williams, JTB, Naleway AL, Klein NP, Hambridge SJ, Jacobsen SJ, Glanz JM, Jackson LA, Shimabukuro TT, Weintraub ES. SARS-CoV-2 Infection Among Hospitalized Pregnant Women: Reasons for Admission and Pregnancy Characteristics – Eight U.S. Health Care Centers, March 1-May 30, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1355-1359. 2020 Sept 25.

As part of CDC surveillance of COVID-19 hospitalizations, Vaccine Safety Datalink researchers identified 105 pregnant women with SARS-CoV-2 infection from March 1 through May 30, 2020. Of those, 43 (41%) were admitted for COVID-19 illness (e.g., worsening respiratory status) and 62 (59%) were admitted for pregnancy-related treatment or procedures (e.g, delivery) and identified with SARS-CoV-2 infection. More pregnant women with prepregnancy obesity and gestational diabetes were hospitalized for the treatment of COVID-19 illness than pregnant women admitted for pregnancy-related reasons. Intensive care was required in 30%

(13/43) of pregnant women admitted for COVID-19 illness, and one pregnant woman died from COVID-19. Adverse birth outcomes, such as preterm delivery and stillbirth, were more common among pregnant women with SARS-CoV-2 infection, regardless of symptoms. Pregnant women should take preventive measures to protect themselves against SARS-CoV-2 infection.

Mbaeyi SA, Bozio CH, Duffy J, Rubin LG, Hariri S, Stephens DS, MacNeil JR. Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR Recomm Rep.* 2020 Sept;69(No. RR-9):1-41.

This report compiles and summarizes all recommendations from CDC's Advisory Committee on Immunization Practices (ACIP) for use of meningococcal vaccines in the United States; it is intended for use by clinicians and public health providers. A systematic literature search was completed to review all available evidence on the immunogenicity, effectiveness, and safety of U.S. licensed quadrivalent meningococcal conjugate (MenACWY) and serogroup B meningococcal (MenB) vaccines among age groups for which the vaccines were approved. To further assess vaccine safety, data were evaluated from the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD), two post-licensure surveillance systems for adverse events.

Myers TR, McNeil MM, NG CS, Li R, Marquez PL, Moro PL, Omer SB, Cano MV. Adverse Events Following Quadrivalent Meningococcal Diphtheria Toxoid Conjugate Vaccine (Menactra ®) Reported to the Vaccine Adverse Event Reporting System (VAERS), 2005-2016. *Vaccine.* 2020 Sep 11;38(40):6291-6298 Epub 2020 Jul 31.

Licensed in January 2005, Menactra was the first quadrivalent meningococcal conjugate vaccine approved to provide protection against invasive meningococcal disease. It is licensed for use in individuals aged 9 months through 55 years. Researchers reviewed reports of adverse events (AEs) after Menactra to the Vaccine Adverse Event Reporting System (VAERS) from 2005-2016, including serious reports, selected pre-specified outcomes, and use during pregnancy. From January 2005 thought June 2019, VAERS received 13,075 reports of AEs following Menactra vaccination. Most reports (94%) were classified as non-serious; commonly reported AEs included injection site redness and swelling, fever, headache, and dizziness. There were 36 reports of death following Menactra; researchers did not find any evidence to suggest the vaccine caused the deaths. This review did not reveal any new safety concerns and provides further reassurance regarding the safety of Menactra.

Moro PL, Woo EL, Marquez P, Cano M. Monitoring the safety of high-dose, trivalent inactivated influenza vaccine in the vaccine adverse event reporting system (VAERS), 2011-2019. *Vaccine.* 2020 Aug 18;38(37):5923-5926. Epub 2020 Jul 21.

Older adults are at higher risk of developing serious complications from flu. In December 2009, the high-dose trivalent influenza vaccine (IIV3-HD) was licensed for adults 65 years and older. Using the Vaccine Adverse Event Reporting System, researchers analyzed the 12,320 reports submitted after IIV3-HD vaccination from 2011-2019. Of the total, there were 61 reports of GBS and 13 of anaphylaxis. Nearly 6% of all reports were classified as serious (723). The most commonly reported serious events were fever (30.2%), weakness (28.9%), and shortness of breath (24.9%). There were 55 reports of death following IIV3-HD, and cause of deaths reported were typical for those in this age group with no evidence to suggest the vaccine caused the deaths. There were reports of 13 pregnant women and 59 children who inadvertently received IIV3-HD. Overall, this review of IIV3-HD did not reveal any new safety concerns among individual adults 65 years and older.

Wang SV, Stefanini K, Lewis E, Newcomer SR, Fireman B, Daley MF, Glanz JM, Duffy J, Weintraub E, Kulldorf M. Determining Which of Several Simultaneously Administered Vaccines Increase Risk of an Adverse Event *Drug Saf.* 2020 Oct;43(10):1057-1065. Epub 2020 Jul 1.

The CDC childhood immunization schedule recommends all children get vaccinated. Children may get multiple vaccinations on the same day. If a child has an adverse event after getting multiple vaccinations, it would be difficult to determine which vaccine, if any, caused the event. Using observed data from two Vaccine Safety Datalink sites, researchers developed a systematic process to determine which of the simultaneously administered vaccine(s) are most likely to have caused an observed increase in risk of an adverse event. From the five scenarios simulated, the process determined which of the vaccines contributed to the simulated excess risk. This process could be used again in the future to provide valuable information on the potential risk of adverse events following individual and simultaneous vaccinations.

Hesse EM, Navarro RA, Daley MF, Getahun D, Henninger ML, Jackson LA, Nordin J, Olson SC, Zerbo O, Zheng C, Duffy J. Risk for Subdeltoid Bursitis After Influenza Vaccination: A Population-Based Cohort Study *Ann Intern Med.* 2020 Aug 18;173(4):253-261. Epub 2020 Jun 23.

Subdeltoid bursitis, characterized by pain or loss of motion in the shoulder, has been reported as an adverse event following intramuscular vaccination in the upper arm, and most case reports involved the influenza vaccine. With over 160 million U.S. doses distributed annually and recommended to everyone over 6 months of age, researchers wanted to estimate the risk of subdeltoid bursitis following influenza vaccination. In this cohort study using data from 7 Vaccine Safety Datalink sites, researchers included people who received an inactivated influenza vaccine during the 2016–2017 flu season, totaling 2.9 million people. The analysis to calculate risk of bursitis compared cases that appeared 3 days following vaccination to a control period 30-60 days following vaccination. There were an estimated 7.78 (95% CI 2.19-13.38) additional cases of bursitis per one million people vaccinated. While an increased risk of bursitis following vaccination was present, the overall risk was small.

Hause AM, Panagiotakopoulos L, Weintraub E, Sy LS, Glenn SC, Tseng HF, McNeil MM. Adverse Outcomes in Pregnant Women Hospitalized with Respiratory Syncytial Virus Infection: A Case-Series *Clin Infect Dis.* 2020 Jun 2; ciaa668. Online ahead of print.

Respiratory syncytial virus (RSV) is a common respiratory virus that usually causes mild, cold-like symptoms and can be serious for infants and older adults. RSV infection in pregnant women has not been well described and can be clinically severe and result in hospitalization. CDC has emphasized the need to characterize RSV infection during pregnancy, including burden of the illness, risk factors for severe disease, and pregnancy and neonatal outcomes. In this study, researchers identified 25 pregnant women at Kaiser Permanente Southern California who tested positive for RSV. Ten of those women (40%) were hospitalized: five were diagnosed with pneumonia/atelectasis, two with respiratory failure (one requiring mechanical ventilation), and two with sepsis. Six women had a pregnancy complication during hospitalization, including one induced preterm birth. The information from this study may inform the benefits of maternal vaccination for an RSV vaccine intended to protect infants.

Suragh TA, Hibbs B, Marquez P, McNeil MM. Age inappropriate influenza vaccination in infants less than 6 months old, 2010-2018 *Vaccine.* 2020 May 6;38(21):3747-3751. Epub Apr 6.

Annual influenza (flu) vaccination is recommended for everyone 6 months or older, and vaccination in infants less than 6 months old is a vaccine error. There are few safety studies in this population. Researchers searched the Vaccine Adverse Event Reporting System (VAERS) for reports of adverse events (AEs) following flu vaccination in infants less than 6 months old from 2010-2018. A total of 114 reports were found; 21 reported a specific AE. Fever, irritability, crying and diarrhea were the most common symptoms. Researchers identified several risk factors: 1) individuals getting vaccinated together resulting in patient mix-ups, 2) healthcare provider not verifying the patient's information, and 3) provider confusion due to similarities in vaccines' packaging and names of vaccines that sound alike. This study adds valuable information about the general absence of serious AEs in infants vaccinated with flu vaccine; yet, providers should be vigilant to avoid these preventable errors.

Glanz JM, Clarke CL, Xu S, Daley MF, Shoup JA, Schroeder EB, Lewin BL, McClure DL, Kharbanda E, Klein NP, DeStefano F. Association between Rotavirus Vaccine and Type 1 Diabetes in Children. *JAMA Pediatr.* 2020 May 1;174(5):455-462. Epub 2020 Mar 9.

Type 1 diabetes mellitus (T1DM) is an autoimmune disease that tends to occur in genetically susceptible individuals and is primarily diagnosed during childhood. Previous research suggests that a live attenuated rotavirus vaccine could either increase or decrease the risk of T1DM in early childhood. Researchers conducted a study of children enrolled in 7 integrated healthcare organizations in the Vaccine Safety Datalink. There were 386,937 children enrolled born between 2006 and 2014. During their infancy, 360,169 children were exposed to the full series of rotavirus vaccination, 15,765 partially exposed and 11,003 unexposed. By the end of 2017, 464 children had developed T1DM. The incidence of T1DM was not significantly different across the vaccination groups, indicating that rotavirus vaccination is not associated with T1DM in children.

Hause AM, Hesse EM, Ng C, Marquez P, McNeil MM, Omer SB. Association Between Vaccine Exemption Policy Change in California and Adverse Event Reporting. *Pediatr Infec Dis J.,* May; 39(5):369-373. Epub 2020 Mar 5.

California Senate Bill 277 (SB277) eliminated non-medical immunization exemptions starting February 19, 2015. Since the bill's introduction, the rate of medical exemptions in the state has increased. There is a perception that filing a report to the Vaccine Adverse Event Reporting System (VAERS) may aid in applying for a medical exemption. Researchers wanted to describe trends of reporting to VAERS after SB277. From June 2011-July 2018, 6,703 VAERS reports were submitted from California. Parent-submitted reports increased after SB277, from 14% to 23%. The median reporting time by parents increased from 9 days post-vaccination in 2013-2014 to 31 days in 2016-2017. Overall, there was an increase in reports submitted more than 6 months post-vaccination and reports describing behavioral and developmental symptoms. These changes in reporting patterns after SB277's implementation may indicate more parents are using VAERS to assist in applying for a medical exemption for their child.

Newcomer SR, Daley MF, Marwaney KJ, Xu S, DeStefano F, Groom HC, Jackson ML, Lewin BJ, McLean HQ, Nordin JD, Zerbo O, Glanz JM. Order of Live and Inactivated Vaccines and Risk of Non-vaccine-targeted Infections in US Children 11-23 Months of Age. *Pediatr Infect Dis J.,* 2020 Mar:39(3);247-253.

Children in the United States receive up to 28 vaccine doses against 14 diseases before their 2nd birthday and 3 are live vaccines. Some observational studies suggest that receiving live vaccines may be associated with decreased non-vaccine targeted infection (NVTI) risk. Researchers conducted a retrospective study within the Vaccine Safety Datalink to estimate the risk of NVTIs based on most recent vaccine type received in children 11-23 months of age. Electronic health records and immunization data were reviewed from children born between 2003-2013. Among 428,608 children, 4.9% had more than 1 immunization visit with live vaccines only and 10.3% had a NVTI. Researchers observed modest associations between live vaccine receipt and a decreased risk of NVTIs, which may have been influenced by multiple factors, including healthcare-seeking behavior. In total, the results support the current sequence of live and inactivated vaccines in the U.S. vaccine schedule with respect to NVTI.

Walter EB, Klein NP, Wodi AP, Roundtree W, Todd CA, Wiesner A, Duffy J, Marquez PL, Broder K. Fever after Influenza, Diphtheria-Tetanus-Acellular Pertussis, and Pneumococcal Vaccinations. *Pediatrics*. 2020 Mar;145(3):e20191909.

A previous CDC study showed that children aged 6-23 months had an increased risk for febrile seizure after simultaneously receiving inactivated influenza vaccine (IIV), pneumococcal conjugate vaccine (PCV13) and diphtheria-tetanus-acellular pertussis vaccine (DTaP). Researchers wanted to see if administering the IIV at a separate visit reduced the risk of post-vaccination fever and potentially febrile seizure. In the 2017-2018 influenza season, 221 children aged 12-16 months were randomized at two CISA sites into 2 groups. Both groups had 2 visits, 2 weeks apart: group 1 (simultaneous) received the PCV13, DTaP, and quadrivalent IIV (IIV4) vaccines at visit 1; no vaccines at visit 2. Group 2 (sequential) received PCV13 and DTaP at visit 1 and IIV4 visit 2. Similar proportions of children in both groups had fever on days 1-2 after visits (simultaneous 8.1%; sequential 9.3%). Delaying IIV4 by 2 weeks in children receiving DTaP and PCV13 did not reduce fever occurrence after vaccination.

Havers FP, Moro PL, Hunter P, Hariri S, Bernstein H. Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines: Updated Recommendations of the Advisory Committee on Immunization Practices – United States, 2019. *MMWR Morb Mortal Wkly Rep.* 2020 Jan;69:77-83..

In 2005, the Advisory Committee on Immunization Practices recommended a single dose of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine for adolescents and adults. After the initial Tdap vaccine, booster doses of tetanus and diphtheria toxoids (Td) vaccine are recommended every 10 years or when indicated for wound management. During the October 2019 meeting, ACIP updated its recommendation to allow the use of Tdap or Td in situations where only Td was recommended. These situations include the tetanus booster recommended for adults every 10 years, tetanus prophylaxis when indicated for wound management in people who previously received Tdap, and for multiple doses in the catch-up immunization schedule for people 7 years of age and older with an unknown or incomplete vaccination history. This recommendation update allows providers to have flexibility at the point-of-care for patients.

2019

Haber P, Moro PL, Ng C, Dores GM, Perez-Vilar S, Marquez PL, Cano M. Safety review of tetanus toxoid, reduced diphtheria toxoid, acellular pertussis vaccines (Tdap) in adults aged ≥ 65 years, Vaccine Adverse Event Reporting System (VAERS), United States, September 2010 – December 2018. *Vaccine.*. 2020 Feb 5;38(6):1476-1480. Epub 2019 Dec 28.

The Advisory Committee on Immunization Practices recommends vaccination in adults 65 years of age and older with tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap). To date, few studies have assessed the safety of Tdap in this age group. Using the Vaccine Adverse Event Reporting System (VAERS), researchers analyzed reports of adverse events (AEs) following Tdap in adults 65 years and older. From September 2010 to December 2018, VAERS received 1,798 reports; 94% were classified as non-serious. The most common AEs were injection site redness (26%), pain (19%), and swelling (18%). Of 104 serious reports, 7 deaths were reported; none had evidence to suggest the vaccine caused the deaths. Serious non-death reports included nervous system disorders (35.1%; n=34) and infections (18.6%; n=18). Overall, the analysis did not identify any new safety concerns and is consistent with prior post-marketing observations and pre-licensure studies.

Li R, Stewart B, Rose C. A Bayesian approach to sequential analysis in post-licensure vaccine safety surveillance. *Pharm Stat.* 2020 May;19(3):291-302 Epub 2019 Dec 22.

Bayesian statistics is an approach for learning from evidence as it accumulates. While this analytic method is used in other areas of public health with acknowledged practical benefits, its potential application in vaccine safety monitoring analysis has not been fully realized. In this study, researchers compare the use of a traditional (frequentist) sequential method and a Bayesian method, with simulations and a real-world vaccine safety example. The performance was evaluated using 3 metrics: false positive rate, false negative rate, and average earliest detection time. The authors found that depending on the background rate of adverse events, the Bayesian sequential method could significantly improve performance in terms of the false negative rate and decrease the earliest time to producing a safety signal for further analysis. Overall, the Bayesian sequential approach was found to show promise as an alternative for vaccine safety monitoring.

Su JR, Haber P, Ng CS, Marquez PL, Dores GM, Perez-Vilar S, Cano MV. Erythema multiforme, Stevens Johnson syndrome, and toxic epidermal necrolysis reported after vaccination, 1999-2017. *Vaccine*. 2020 Feb 11;38(7): 1746-1752. Epub 2019 Dec 20.

While some dermatologic adverse events are common after vaccination (i.e. redness at the injection site), erythema multiforme (EM), Stevens Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and SJS/TEN are rare. Since the last review of VAERS data for these conditions, over 37 new vaccines were approved for use in the United States. Of the 466,027 reports to VAERS during 1999–2017, researchers identified and reviewed 984 reports of EM, 89 of SJS, 6 of SJS/TEN, and 7 of TEN. Most reports of EM (91%) were non-serious; 52% of SJS and all reports of SJS/TEN and TEN were serious. Most reports (58%) occurred within 7 days after vaccination. Childhood vaccines were reported most often; 48% of reports were of children younger than 4 years. Of 6 reported deaths, 5 were exposed or potentially exposed to medications known to cause these conditions, and 1 had severe dehydration. Overall, reporting of these conditions after vaccination remained rare, with no new safety concerns identified.

Yu W, Zheng C, Xie F, Chen W, Mercado C, Sy LS, Qian L, Glenn S, Tseng HF, Lee G, Duffy J, McNeil MM, Daley MF, Crane B, McLean HQ, Jackson LA, Jacobsen SJ. The use of natural language processing to identify vaccine-related anaphylaxis at five health care systems in the Vaccine Safety Datalink. *Pharmacoepidemiolo Drug Saf.* 2020 Feb;29(2): 182-188 Epub 2019 Dec 3.

Anaphylaxis is a rare but serious allergic reaction that can be caused by various triggers, including vaccine components. Natural language processing (NLP) uses computers to analyze large amounts of text. Vaccine Safety Datalink (VSD) researchers developed an NLP application to identify vaccine-related anaphylaxis cases from electronic medical record notes and implemented the method at 5 VSD sites. The NLP system was trained on a dataset of 311 potential anaphylaxis cases and validated on another 731 potential cases. NLP was then applied to the notes of 6.4 million vaccinated patients, and it captured 8 additional true cases confirmed by manual chart review. This study demonstrated the potential to apply NLP to clinical notes to identify anaphylaxis cases and its use to improve sensitivity and efficiency in future vaccine safety studies.

Hesse EM, Atanasoff S, Hibbs BF, Adegoke OJ, Ng C, Marquez P, Osborn M, Su JR, Moro PL, Shimabukuro T, Nair N. Shoulder Injury Related to Vaccine Administration (SIRVA): Petition Claims to the National Vaccine Injury Compensation Program, 2010-2016. *Vaccine.* 2020 Jan 29;38(5): 1076-1083. Epub 2019 Nov 28.

Petitioner claims for shoulder injury related to vaccine administration (SIRVA) to the National Vaccine Injury Compensation Program (VICP) increased substantially from 2010 to 2016. The Health Resources and Services Administration and the Centers for Disease Control and Prevention initiated a joint scientific review of clinical characteristics of SIRVA petitions to VICP. Researchers queried VICP's Injury Compensation System database for alleged SIRVA and SIRVA-like injuries and conducted a descriptive analysis of claims recommended by VICP for concession as SIRVA injuries; 476 claims were identified and 400 of them involved influenza vaccine. Of the 476 claims, 227 reported a suspected administration error; 172 reported 'injection too high' on the arm. Injection too high on the arm could be a factor due to the risk of injecting into underlying non-muscular tissues. Healthcare providers should be aware of proper injection technique and anatomical landmarks when administering vaccines.

Hibbs BF, Ng CS, Museru O, Moro PL, Marquez P, Woo EJ, Cano MV, Shimabukuro TT. Reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010-2017. *Vaccine.* 2020 Jan 29;38(5):1137-1143. Epub 2019 Nov 26.

Some case reports have suggested that if inactivated influenza vaccine (IIV) is improperly administered, shoulder dysfunction may occur. Researchers reviewed reports of adverse events (AEs) made to the Vaccine Adverse Event Reporting System (VAERS) following IIV from July 2010 to June 2017. During this time, approximately 996 million flu vaccine doses were distributed in the United States. Of the 59,230 reports submitted, 1,220 met analysis criteria of atypical shoulder pain and dysfunction starting within 48 hours following IIV and continuing for more than 1 week. The analysis suggests these reports were not common, averaging 2% of flu vaccine AEs reported each year; most were females (82.6%), median age was 52 years. While the cause of these cases is unknown, vaccines given improperly might be a factor. Proper vaccine administration education and training are preventive measures

improperly might be a factor. Proper vaccine administration education and training are preventive measures.

Donahue JG, Kieke BA, Lewis EM, Weintraub ES, Hanson KE, McClure DL, Vickers ER, Gee J, Daley MF, Destefano F, Hechter RC, Jackson LA, Klein NP, Naleway AL, Nelson JC, Belongia EA. Near Real-Time Surveillance to Assess the Safety of the 9-valent Human Papillomavirus Vaccine. *Pediatrics.* 2019 Dec; 144(6): e20191808. Epub 2019 Nov 18.

Gardasil 9 (human papillomavirus 9-valent vaccine, recombinant; 9vHPV) was approved in 2014 for females and males to protect against 9 types of human papillomavirus infections that can cause cancer. CDC's Vaccine Safety Datalink (VSD) conducted near real-time post-licensure safety monitoring following 9vHPV for 11 pre-specified adverse events (AEs), including anaphylaxis, allergic reaction, appendicitis, certain neurological disorders, pancreatitis, and stroke. From October 2015 to October 2017, 838,991 9vHPV doses were administered to people aged 9-26 years at 6 VSD sites. Statistical signals were detected for 2 expected AEs: injection site reactions and syncope. Signals were also detected for appendicitis, pancreatitis, and allergic reaction; however, evaluation and medical record reviews did not confirm these to be true associations. Overall, no new safety concerns were identified. The results are consistent with pre-licensure clinical trial data and support the favorable safety profile of 9vHPV.

Shimabukuro TT, Su JR, Marquez PL, Mba-Jonas A, Arana JE, Cano MV. Safety of the 9-Valent Human Papillomavirus Vaccine. *Pediatrics* 2019 Dec; 144(6). pii: e20191791. Epub 2019 Nov 18.

Gardasil 9 (human papillomavirus 9-valent vaccine, recombinant; 9vHPV) was approved in 2014 for females and males to protect against 9 types of human papillomavirus infections that can cause cancer. Researchers analyzed reports of adverse events (AEs) after 9vHPV to the Vaccine Adverse Event Reporting System (VAERS) from December 2014 to December 2017. During that time, approximately 28 million 9vHPV doses were distributed in the United States. Of the 7,244 reports received, 31% were female, nearly 22% were male, and 47% of reports did not identify gender. Over 97% of reports were classified as non-serious. There were 2 deaths reported; no information in the reports or medical records suggested the deaths were related to vaccination. Overall, the analysis revealed no new or unexpected safety concerns. The 9vHPV safety profile is consistent with pre-licensure clinical trial data, and with the post-marketing safety data of Gardasil, the earlier quadrivalent HPV vaccine.

Moro PL, McNeil MM. Challenges in evaluating post-licensure vaccine safety: observations from the Center for Disease Control and Prevention. *Expert Rev Vaccines.* 2019 Oct; 18(10): 1091-1101 Epub 2019 Oct 19.

There is overwhelming scientific evidence that supports the safety of vaccines and their proven ability to prevent illness and death caused by infectious diseases. Yet like any medicine, no vaccine can be considered completely safe and completely effective. Prior to licensure, vaccines undergo extensive safety and efficacy evaluations. After licensure, they require follow up studies and continuous monitoring to investigate any new or unexpected adverse events (AEs). This article presents challenges in monitoring U.S. vaccines for AEs after licensure and describes CDC's post-licensure safety surveillance infrastructure, including the Vaccine Adverse Event Reporting System, the Vaccine Safety Datalink, and the Clinical Immunization Safety Assessment project. The authors describe each system's unique strengths and limitations, and the harmonized approach they provide in meeting vaccine safety monitoring challenges.

Groom HC, Smith N, Irving SA, Koppolu P, Vazquez-Benitez G, Kharbanda EO, Daley MF, Donahue JG, Getahun D, Jackson LA, Klein NP, McCarthy NL, Nordin JD, Panagiotakopoulos L, Naleway AL. Uptake and safety of hepatitis A vaccination during pregnancy: A Vaccine Safety Datalink study. *Vaccine*. 2019 Oct 16;37(44):6648-6655. Epub 2019 Sep 20.

Although uncommon, infection with hepatitis A virus during pregnancy is associated with gestational complications and pre-term labor. CDC recommends that pregnant women who are at an increased risk of contracting hepatitis A get the Hepatitis A vaccine (HepA). Current safety data, however, are limited on maternal HepA vaccination. Researchers used the Vaccine Safety Datalink to compare pregnancies with HepA exposure to other vaccine exposures, and those with no exposure, from 2004-2015. Of nearly 667,000 pregnancies, 1,140 had HepA exposure. The rate of maternal HepA vaccination was low, and rarely due to documented risk

factors. The results did not show an increased risk of adverse events for HepA vaccination during pregnancy. There was an identified association of maternal HepA exposure and small-for-gestational age (SGA) infants, however, the difference in rates were small (4%), and likely due to other factors. Further research may be needed to further explore this association.

McNeil MM, Paradowska-Stankiewicz I, Miller ER, Marquez PL, Seshadri S, Collins LC Jr, Cano MV. Adverse events following adenovirus type 4 and type 7 vaccine, live, oral in the Vaccine Adverse Event Reporting System (VAERS), United States, October 2011-July 2018. *Vaccine*. 2019 Oct 16; 37(44): 6760-6767 Epub 2019 Sep 20.

Adenovirus vaccine (adenovirus type 4 and type 7, live, oral) was licensed by FDA in March 2011 for use in U.S. military personnel ages 17-50 years. The vaccine was first routinely given to recruits in October 2011. Researchers reviewed reports of adverse events (AEs) following the adenovirus vaccine from October 2011 to July 2018 using the Vaccine Adverse Event Reporting System (VAERS). VAERS received 100 adverse event reports; 39 were considered serious. While the reporting rate for serious AEs was higher than with other vaccines given in a comparison recruit population (39% versus 18%), no unexpected or concerning pattern of adenovirus vaccine AEs were identified. Reports showed multiple other vaccines (95%) and penicillin G (50%) were given at the same time, and these exposures may have contributed to the higher reporting rate for serious AEs observed with the adenovirus vaccine. Future studies without these exposures would be helpful in clarifying the vaccine's safety profile.

Donahue JG, Kieke BA, King JP, Mascola MA, Shimabukuro TT, DeStefano F, Hanson KE, McClure DL, Olaiya O, Glanz JM, Hechter RC, Irving SA, Jackson LA, Klein NP, Naleway AL, Weintraub ES, Belongia EA. Inactivated influenza vaccine and spontaneous abortion in the Vaccine Safety Datalink in 2012-13, 2013-14, and 2014-15. *Vaccine.* 2019 Oct 16;37(44):6673-6681. Epub 2019 Sep 17.

A prior study in the Vaccine Safety Datalink (VSD) covering the two influenza seasons from 2010-2012 reported an association between inactivated influenza vaccine (IIV) and spontaneous abortion (SAB), but only among women who had also been vaccinated in the previous influenza season. In follow-up, VSD researchers conducted a larger case-control study over three more recent influenza seasons (2012-2015). Women with SAB were matched with women who had live births according to VSD site, influenza vaccination status in the previous influenza season, and other factors. The main analysis included 1,236 women. During the three influenza seasons, researchers found no association between IIV and SAB, including among women vaccinated in the previous season. These findings lend support to current recommendations for influenza vaccination at any time during pregnancy, including the first trimester.

Kochhar S, Excler JL, Bok K, Gurwith M, McNeil MM, Seligman SJ, Khuri-Bulos N, Klug B, Laderoute M, Robertson JS, Singh V, Brighton Collaboration Viral Vector Vaccines Safety Working Group (V3SWG). Defining the Interval for Monitoring Potential Adverse Events Following Immunization (AEFIs) After Receipt of Live Viral Vectored Vaccines. *Vaccine.* 2019 Sep 10;37(38): 5796-5802.

New viral vector vaccines that use live viruses to create an immune response are being developed to fight serious infectious agents like HIV and Ebola. As some live recombinant vectored vaccines may replicate, a key challenge is defining the length of time for monitoring potential adverse events following immunization (AEFI). Potential options include: 1) adapting from the current relevant regulatory guidelines; 2) convening a panel of experts to review the evidence from a systematic literature search to narrow down a list of likely potential or known AEFI and establish the optimal risk window(s); and 3) conducting "near real-time" prospective monitoring for unknown clustering's of AEFI in validated large linked vaccine safety databases. Depending on the infrastructure, human resources, and databases available in different countries, the authors suggest appropriate options can be determined by regulatory agencies and investigators.

Christianson MS, Wodi P, Talaat K, Halsey N. Primary Ovarian Insufficiency and Human Papilloma Virus Vaccines: A Review of the Current Evidence. *Am J Obstet Gynecol*. 2020 Mar;222(3):239-244. Epub 2019 Aug 31.

Human papillomavirus (HPV) is the primary cause of cervical cancer, and vaccination is the primary means of preventing cancers caused by HPV infection. Despite HPV vaccine being available for over a decade, coverage rates are lower than other vaccines. Public concerns regarding the vaccine's safety, including that it may cause primary ovarian insufficiency (POI), have been identified as an important barrier to vaccination. POI-related concerns are driven in part by isolated reports of ovarian failure following the HPV vaccine. In this Clinical Immunization Safety Assessment Project review, researchers summarize published peer-reviewed literature on HPV vaccines and POI. In summary, the current evidence is insufficient to suggest or support a causal relationship between HPV vaccination and POI. Healthcare providers can help address concerns about POI and the HPV vaccine by sharing these findings during consultations with their patients.

DeStefano F, Monk Bodenstab H, Offit PA. Principal Controversies in Vaccine Safety in the United States. *Clin Infect Dis.* 2019 Aug 1;69(4):726-731.

Concerns about vaccine safety can lead to decreased acceptance of vaccines and resurgence of vaccine-preventable diseases. The authors summarize the key evidence on some of the main current vaccine safety controversies in the United States, including: 1) MMR vaccine and autism; 2) thimerosal, a mercury-based vaccine preservative, and the risk of neurodevelopmental disorders; 3) vaccine-induced Guillain-Barré Syndrome (GBS); 4) vaccine-induced autoimmune diseases; 5) safety of HPV vaccine; 6) aluminum adjuvant-induced autoimmune diseases and other disorders; and 7) too many vaccines given early in life predisposing children to health and developmental problems. A possible small increased risk of GBS following influenza vaccination has been identified, but the magnitude of the increase is less than the risk of GBS following influenza infection. Otherwise, the biological and epidemiologic evidence does not support any of the reviewed vaccine safety concerns.

McNeil MM. Vaccine-Associated Anaphylaxis. *Curr Treat Options Allergy.* 2019 Sep; 6(3): 297-308. Epub 2019 Jul 16.

Anaphylaxis is a rare, serious hypersensitivity reaction, which can happen within minutes and is characterized by multisystem involvement. Although anaphylaxis may occur after any vaccine, the risk following flu vaccines is important to understand due to the large number of persons vaccinated annually. This review looks at two recent CDC studies that confirm its rarity. In a 25-year review of data from the Vaccine Adverse Event Reporting System, reports in children most commonly followed childhood vaccinations, and in adults most often followed influenza vaccine. In a Vaccine Safety Datalink study, the estimated incidence of anaphylaxis was 1.3 per million vaccine doses administered for all vaccines and 1.6 per million doses for IIV3 (trivalent) influenza vaccine. Despite its rarity, the rapid onset and potentially lethal nature of anaphylaxis requires that all personnel and facilities providing vaccinations have procedures in place to treat it.

Edwards K, Hanquet G, Black S, Mignot E, Jankosky C, Shimabukuro T, Miller E, Nohynek H, Neels P. Meeting Report Narcolepsy and Pandemic Influenza Vaccination: What We Know and What We Need to Know Before the Next Pandemic? A Report From the 2nd IABS Meeting. *Biologicals.* 2019 Jul;60:1-7.

Scientific and public health experts and key stakeholders gathered to discuss the state of knowledge on the relationship between adjuvanted monovalent pH1N1 vaccines and narcolepsy. There was consensus that an increased risk of narcolepsy was consistently observed after Pandemrix (AS03-adjuvanted), but similar associations following Arepanrix (AS03) or Focetria (MF59) were not observed. It is not clear whether the differences are due to vaccine composition or other factors such as the timing of large-scale vaccination programs relative to pH1N1 wild-type virus circulation in different geographic regions. Limitations of retrospective observational methodologies could also be contributing to some of the differences across studies. Additional research is needed to further explain the association and possible mechanistic pathways, and to aid in planning and preparation for vaccination programs in advance of the next influenza pandemic.

Hesse EM, Hibbs BF, Cano MV. Notes from the Field: Administration of Expired Injectable Influenza Vaccines Reported to the Vaccine Adverse Event Reporting System — United States, July 2018–March 2019. *MMWR Morb Mortal Wkly Rep.* 2019; 68: 529–530. 2019 June 14.

During the 2018-2019 flu season, the Vaccine Adverse Event Reporting System received 125 reports (totaling 192 patients) of people receiving expired inactivated influenza vaccine (IIV). During that time, 169.1 million doses of seasonal flu vaccine were distributed. Of those who received the expired IIV, 70% were in high-risks group for influenza (under the age of 5, over the age of 50 and pregnant women). Researchers found the reported adverse events were consistent with adverse events following administration of non-expired seasonal IIV, suggesting no additional safety issues associated with receipt of expired IIV. To avoid inadvertent administration of expired IIV, CDC recommends facilities that administer vaccines follow the guidance in the Vaccine Storage and Handling Toolkit, and make plans for the safe disposal or return of any remaining IIV after the expiration date of June 30 each year.

Weinmann S, Naleway AL, Koppolu P, Baxter R, Belongia EA, Hambidge SJ, Irving SA, Jackson ML, Lewin B, Liles E, Marin M, Smith N, Weintraub E, Chun C. Incidence of Herpes Zoster Among Children: 2003-2014. *Pediatrics.* 2019 Jul; 144(1). Pii: e20182917. Epub 2019 Jun 10.

After the 1996 introduction of routine varicella (chickenpox) vaccination in the U.S., most studies evaluating the incidence of pediatric herpes zoster (HZ), also known as shingles, reported lower incidence over time, with varying degrees of decline. Researchers used data from 6 integrated health care organizations surveyed by the Vaccine Safety Datalink to examine HZ incidence rate in children from 2003-2014. Using electronic medical records from children aged 0 to 17 years, researchers identified HZ cases and calculated HZ incidence rates for all children and children who were vaccinated versus unvaccinated. Researchers then calculated rates for the 12-year period, examined temporal trends, and compared HZ rates by month and year of age at vaccination. This population-based study confirms the decline in pediatric HZ incidence and the significantly lower incidence among children who are vaccinated, and reinforces the benefit of routine varicella vaccination to prevent pediatric HZ.

Moro PL, Arana J, Marquez PL, Ng C, Barash F, Hibbs BF, Cano M. Is there any harm in administering extra-doses of vaccine to a person? Excess doses of vaccine reported to the Vaccine Adverse Event Reporting System (VAERS), 2007-2017. *Vaccine.* 2019 Jun 19; 37(28): 3730-3734. Epub 2019 May 30.

The administration of an extra dose of a vaccine may occur due to a vaccination error or when there is need to provide immunization in a person with uncertain vaccination histories (e.g., refugees). There is little data available on the safety of an extra dose of vaccine. Researchers searched for adverse events following the administration of excess doses of vaccines using the Vaccine Adverse Events Reporting System from January 2007 through the end of July 2017. Of 366,815 total reports received, over 5,000 (1.4%) reported an excess dose of vaccine was administered and less than 4,000 (76.9%) did not describe an AE. The top two vaccines reported were trivalent inactivated influenza (15.4%), and varicella (13.9%). The most common events were fever (12.8%), and injection site reaction (9.7%). Among reports where an AE was reported, researchers did not observe any unexpected conditions or clustering of AEs.

Hanson KE, McLean HQ, Belongia EA, Stokley S, McNeil MM, Gee J, VanWormer JJ.Sociodemograhic and clinical correlates of human papillomavirus vaccine attitudes and receipt among Wisconsin adolescents. *Papillomavirus Res.* 2019 Dec; 8: 100168; Epub 2019 May 25.

Few studies have assessed adolescent human papillomavirus (HPV) vaccine attitudes and whether they are associated with vaccination uptake. The Vaccine Safety Datalink conducted an HPV vaccine study in an integrated healthcare system to identify factors associated with adolescents' attitude changes and their link to vaccine receipt. Adolescents who had not completed the HPV vaccine series were surveyed using a modified version of the Carolina HPV Immunization Attitudes and Beliefs Scale before and during a campaign to improve HPV vaccination rates. Adolescents' attitudes to HPV slightly improved during the period of the campaign. However, attitude changes were not associated with receipt of HPV vaccines and adolescents identified as opposed to HPV vaccine before the campaign began were less likely to receive a HPV vaccine dose afterwards. More research is needed to learn how HPV vaccine attitudes form in parents and children, and how best to address concerns about vaccine harms.

Kochhar S, Edwards KM, Ropero Alvarez AM, Moro PL, Ortiz JR. Introduction of new vaccines for immunization in pregnancy – Programmatic, regulatory, safety and ethical considerations . *Vaccine*. 2019 May 31; 37(25): 3267-3277. Epub 2019 May 6.

Women are encouraged to get immunizations when they are pregnant; but in certain areas of the world, there are no programs to implement vaccine recommendations. Maternal immunization is a promising strategy to reduce infectious disease-related illness and death in pregnant women and their infants. Pre-requisites for introducing immunization during pregnancy include: (1) political commitment and adequate financial resources, (2) healthcare workers to deliver vaccines, (3) combining immunization programs with prenatal care and maternal/child health services, and (4) access to prenatal care for pregnant women in low and middle-income countries where births occur in healthcare facilities. A system to advance a vaccine program from product licensure to successful country-level implementation needs to include evidence of anticipated vaccine program impact, developing supportive policies, and translating policies into local action.

Hechter RC, Qian L, Tartof SY, Sy LS, Klein NP, Weintraub E, Mercado C, Naleway A, McLean HQ, Jacobsen SJ. Vaccine safety in HIV-infected adults within the Vaccine Safety Datalink Project . *Vaccine.* 2019 May 31; 37(25): 3296-3302. Epub 2019 May 4.

Despite the increased risk of vaccine-preventable infectious diseases in adults with HIV, vaccine coverage among this risk group remains low; safety concerns around side effects or impact on HIV disease may be a factor. Using data from 5 U.S. integrated healthcare sites in the Vaccine Safety Datalink, researchers evaluated the safety of recommended vaccinations among HIV-infected adults. They evaluated 20,417 HIV-infected adults from 2002-2013 and found an elevated risk of cellulitis and infection, particularly among patients with high viral load and those who received bacterial vaccines. These findings were consistent with prior reports in the literature. The analysis did not find an increased risk of other adverse events of interest. Patients with HIV with very high viral load might have elevated risk for stroke and cerebrovascular diseases; future research should examine further. Overall, this study reassures that vaccines currently recommended for HIV-infected adults are safe.

Cook AJ, Wellman RD, Marsh T, Shoaibi A, Tiwari R, Nguyen M, Boudreau D, Weintraub ES, Jackson L, Nelson JS. Applying sequential surveillance methods that use regression adjustment or weighting to control confounding in a multisite, rare-event, distributed setting: Part 2 in-depth example of a reanalysis of the measles-mumps-rubella-varicella combination vaccine and seizure risk. *J Clin Epidemiol.* 2019 Sep; 113: 114-122. Epub 2019 May 2.

Safety surveillance of newly marketed vaccines is a public health priority. National systems have linked vast amounts of electronic health record (EHR) data across multiple health care organizations and insurers. This allows monitoring of large patient groups for potential safety concerns. Group sequential methods (methods of evaluating data as it is entered) involve routine estimation and testing of vaccine-outcome associations over time. This method can lead to earlier identification of excess risk compared with one-time analysis. Researchers assessed the use of two different sequential methods for safety monitoring: analysis-based confounder adjustment (influential variables) and weighting (the number items or events). Both methods were applied to the FDA's Sentinel network, that already positively paired the outcome to the vaccine. The estimates from both methods were similar and comparable to prior studies of different designs and are viable alternatives for safety monitoring.

DeStefano F, Shimabukuro TT. The MMR Vaccine and Autism. *Annu Rev Virol.* 2019 Sep; 6. Epub 2019 Apr 15.

The most damaging vaccine safety controversy of recent years began as an exploration of the possible role of measles and measles vaccines in causing of inflammatory bowel disease (IBD). That work eventually evolved into a report published in 1998, but subsequently retracted by the journal, that suggested Measles-mumps-rubella (MMR) vaccine causes autism. Although numerous scientific studies have since refuted a connection between MMR vaccine and autism, some parents are still hesitant to accept MMR vaccination of their children because they are uncertain about the safety of the vaccine. In this review, the authors summarize the

genesis of the controversy and review the scientific evidence against a causal association. Also discussed is the effect of the controversy on MMR vaccine acceptance and the resurgence of measles outbreaks, as well as what can be done to bolster vaccine confidence, including the central role of scientists and healthcare providers.

Zheng C, Yu W, Xie F, Chen W, Mercado C, Sy LS, Qian L, Glenn S, Lee G, Tseng HF, Duffy J, Jackson LA, Daley MF, Crane B, McLean HQ, Jacobsen SJ. The use of natural language processing to identify Tdap-related local reactions at five health care systems in the Vaccine Safety Datalink , *International Journal of Medical Informatics*, 2019 Jul; 127(1386-5056): 27-34. Epub 2019 Apr 13.

The Vaccine Safety Datalink (VSD) plays a critical role in monitoring adverse events after vaccinations by using the electronic health records. Most studies performed in the VSD rely on diagnosis codes and manual chart review for outcome identification and confirmation. A natural language processing (NLP) system was developed, then deployed and executed at multiple institutions. The system achieved reasonable accuracy in identifying a specific vaccine-related adverse event. This study demonstrates the feasibility of using NLP to reduce the potential burden of conducting manual chart review in future vaccine safety studies. “False negatives” of diagnosis codes are not commonly investigated in vaccine safety studies. NLP can identify cases missed by diagnosis codes. NLP has many potential applications in future vaccine safety studies based on the considerations of the pros and cons of NLP and the specific requirements of the study.

Myers TR, McCarthy NL, Panagiotakopoulos L, Omer SB. Estimation of the Incidence of Guillain-Barré Syndrome During Pregnancy in the United States . *Open Forum Infectious Diseases*. 2019 Mar; 6(3): ofz071.

Guillain-Barré syndrome (GBS) is an adverse event of interest after vaccination, yet little is known about how frequently this rare neurologic disorder occurs during pregnancy. GBS may be an outcome of particular interest during Zika vaccine trials, because it has been associated with Zika virus infection. In this Vaccine Safety Datalink study, researchers identified potential GBS cases from January 1, 2004 through July 31, 2015 during pregnancy and the 42 days following birth. Of the 1.2 million pregnancies that met inclusion criteria, 35 potential cases of GBS were identified and 2 cases were confirmed as incident GBS during pregnancy. The resulting estimated incidence rate for GBS during pregnancy was 2.8 GBS cases per million person-years. These findings will help inform future safety assessments of Zika and other vaccines in pregnant populations.

Klein NP, Goddard K, Lewis E, Ross P, Gee J, DeStefano F, Baxter R. Long term risk of developing type 1 diabetes after HPV vaccination in males and females. *Vaccine*. 2019 Mar 28; 37(14):1938-1944. Epub 2019 Mar 1.

Despite scientific evidence, public concerns that the human papillomavirus (HPV) vaccine can cause autoimmune diseases persist. The Vaccine Safety Datalink evaluated whether HPV vaccine is associated with a long-term increased risk of type 1 diabetes at one participating site. This retrospective cohort study identified all potential type 1 diabetes cases from Kaiser Permanente Northern California members who were between 11 and 26 years old any time after June 2006 through December 2015 – over 900,000 individuals. Of the 2,613 cases of type 1 diabetes identified, 338 (123 vaccinated with HPV and 265 unvaccinated) remained in the analysis. Over the 10 years of the study period, comparing vaccinated with unvaccinated persons, researchers did not find an increased risk of type 1 diabetes associated with HPV vaccine receipt.

Haber P, Moro PL, Ng C, Dores GM, Lewis P, Cano M. Post-licensure surveillance of trivalent adjuvanted influenza vaccine (aIIV3; Fluad), Vaccine Adverse Event Reporting System (VAERS), United States, July 2016-June 2018. *Vaccine.* 2019 Mar 7;37(11):1516-1520. Epub 2019 Feb 7.

Trivalent adjuvanted influenza vaccine (aIIV3; Fluad®) was approved in the U.S. in 2015 for adults aged 65 years and older, and has been in use since the 2016-2017 influenza season. Using the Vaccine Adverse Event Reporting System, researchers analyzed U.S. reports for aIIV3 submitted from July 2016 to June 2018, totaling 630 reports. Of note, there were 79 reports of people under the age

of 65 who received the vaccine. The most commonly reported adverse events were consistent with pre-licensure studies, and included injection site pain and redness. Researchers did not identify any new safety concerns associated with aIIV3 among individuals indicated for the vaccine (65 years of age or older). Importantly, vaccine providers should be aware of and follow the prescribing information for the vaccine and administer it only to patients in the recommended age range.

Hesse EM, Shimabukuro TT, Su JR, et al. Postlicensure Safety Surveillance of Recombinant Zoster Vaccine (Shingrix) — United States, October 2017–June 2018. *MMWR Morb Mortal Wkly Rep.* 2019 Feb 1; 68(4):91–94.

This is the first report covering post-licensure safety monitoring of the recombinant zoster vaccine (RZV; Shingrix, GSK) in the Vaccine Adverse Event Reporting System (VAERS) during the initial 8 months of use in the United States. From October 2017 to June 2018, VAERS received 4,381 adverse event reports related to Shingrix; 4,251 (97%) were classified as non-serious. During that timeframe, about 3.2 million doses of Shingrix were distributed in the United States. The most common symptoms reported were fever, and injection site pain and redness. These findings are consistent with pre-licensure clinical trial data, and no unexpected patterns were detected. Clinicians should counsel patients to expect common reactions such as pain, swelling, and redness at the injection site, along with possible body aches, fever, and chills. These reactions usually resolve on their own in 2 to 3 days.

Landazabal CS, Moro PL, Lewis P, Omer SB. Safety of 9-valent human papillomavirus vaccine administration among pregnant women: Adverse event reports in the Vaccine Adverse Event Reporting System (VAERS), 2014-2017 . *Vaccine*. 2019 Feb 21; 37(9):1229-1234. Epub 2019 Jan 16.

9-valent human papillomavirus vaccine (9vHPV) was approved by FDA in December 2014. 9vHPV is not recommended during pregnancy but some women of childbearing age may be inadvertently exposed. This study assessed reports to Vaccine Adverse Event Reporting System (VAERS) of pregnant women vaccinated with 9vHPV in the United States between December 2014-December 2017. Disproportionate reporting of adverse events (AEs) was assessed using proportional reporting ratios. A total of 82 pregnancy reports were identified. Sixty reports (73.2%) did not describe an AE. The most frequently reported AEs were miscarriage and injection site reactions (both n=3; 3.7%). Of note, miscarriage may occur in up to one-third of pregnancies; the observed reports in this study were not unusual or unexpected. No disproportional reporting for any AE was found. Overall, no unexpected AEs were observed among these pregnancy reports.

Su JR, Moro PL, Ng CS, Lewis PW, Said MA, Cano MV. Anaphylaxis after vaccination reported to the Vaccine Adverse Event Reporting System, 1990-2016. *J Allergy Clin Immunol*. 2019 Apr; 143(4):1465-1473. Epub 2019 Jan 14.

Anaphylaxis is a rare, potentially life-threatening hypersensitivity reaction that can occur after vaccination. During 1990–2016, the Vaccine Adverse Event Reporting System (VAERS) received a total of 467,960 reports. Researchers identified 828 reports describing persons who were physician-diagnosed with or met the Brighton Collaboration case definition for anaphylaxis. Of reports in people aged 18 years or younger, 65% were male; childhood vaccines were most commonly reported. Of reports in people aged 19 years and older, 80% were female, and influenza vaccines were most commonly reported. Over 40% of the 828 reports described persons with no history of hypersensitivity. Of 8 reported deaths, 4 had no history of hypersensitivity. Anaphylaxis after vaccination is rare, but can occur, including among persons with no history of hypersensitivity. Providers who administer vaccines should be prepared to manage severe hypersensitivity reactions.

Tartof SY, Qian L, Liu IA, Tseng HF, Sy LS, Hechter RC, Lewin BJ, Jacobsen SJ. Safety of Influenza Vaccination Administered During Hospitalization . *Mayo Clin Proc*. 2019 Mar; 94(3):397-407. Epub 2019 Jan 8.

CDC recommends that hospitalized patients who are eligible to receive influenza vaccine be vaccinated before discharge; however, previous data suggest that rates of influenza immunization among hospitalized patients before discharge remain low. In a retrospective cohort study conducted at Kaiser Permanente Southern California, investigators analyzed whether influenza

vaccination during hospitalization was associated with an increased risk of outpatient and emergency department visits, readmissions, fever, and clinical laboratory evaluations for infection in the 7 days following discharge. Investigators found no increased risk for these outcomes among those vaccination during hospitalization compared with those who were never vaccinated or were vaccinated at other times. These findings provide reassurance about the safety of influenza vaccination during hospitalization.

2018

McClure DL, Jacobsen SJ, Klein NP, Naleway AL, Kharbanda EO, Glanz JM, Jackson LA, Weintraub ES, McLean HQ. Similar relative risks of seizures following measles containing vaccination in children born preterm compared to full-term without previous seizures or seizure-related disorders . *Vaccine*. 2019 Jan 3; 37(1):76-79. Epub 2018 Nov 23.

In the United States, measles-mumps-rubella (MMR) and measles-mumps-rubella-varicella (MMRV) vaccines are recommended to children at age 12 months and older. These vaccines are associated with a small increased risk of febrile seizures during the second week after vaccination. This Vaccine Safety Datalink study assessed the relative risk of febrile seizures after MMR/MMRV vaccination in children born preterm and children born full-term. Prior to this study, limited data were available on the safety of vaccinations given during the second year of life in preterm children. Researchers looked at 532,375 children (45,343 preterm and 487,032 full-term) who received their first dose of measles-containing vaccine at age 12 through 23 months. The data showed similar relative risk of seizure in both groups. The results support current Advisory Committee on Immunization Practices recommendations to administer the first dose of these vaccines at age 12 through 15 months for all children, including those born preterm.

McNeil MM, Duderstadt SK, Sabatier JF, Ma GG, Duffy J. Vaccination and Risk of Lone Atrial Fibrillation in the Active Component United States Military. *Hum Vaccin Immunother.* 2018 Nov 16;15(3): 669-676. Epub 2019 Jan 8.

In this retrospective population-based cohort study of nearly 3 million U.S. military personnel, researchers looked at whether receiving the anthrax vaccine absorbed (AVA) increased the risk of atrial fibrillation in those who did not have identifiable underlying risk factors or structural heart disease (lone atrial fibrillation). The authors used the Defense Medical Surveillance System to review military personnel on active duty from January 1, 1998 through December 31, 2006. Following over 11,000 person-years of service, the study found no elevated risk of diagnosed lone atrial fibrillation associated with AVA (adjusted risk ratio of 0.99), influenza, or smallpox vaccinations given during military service. These findings may be helpful in planning future vaccine safety research.

Moro PL, Lewis P, Cano M Adverse events following purified chick embryo cell rabies vaccine in the Vaccine Adverse Event Reporting System (VAERS) in the United States, 2006-2017 – Correspondence *Travel Medicine and Infectious Disease* 2019 May-Jun; 29(1477-8939): 80-81. Epub 2018 Oct 26.

Rabies is a viral disease of mammals most often transmitted through the bite of a rabid animal and is life threatening. For those exposed to the virus, the benefits of vaccination outweigh the risks. There are two cell cultures rabies vaccines available in the United States: human diploid cell vaccine (HDCV – licensed in 1980) and purified chick embryo cell vaccine (PCECV – licensed in 1997). A safety study on PCECV has not been done since 2005. Researchers re-assessed the safety of the vaccine in the Vaccine Adverse Event Reporting System (VAERS) from January 2006 through June 2017. Excluding non-U.S. reports and duplicate records, VAERS received 604 reports involving PCECV during the 10 year time frame. Of those, 42 were coded as serious reports. No deaths were reported. Data mining analysis did not reveal disproportional reporting for any adverse event. Adverse events reported were consistent with previous post-licensure study and no new or unexpected adverse events were observed.

Weibel D, Sturkenboom M, Black S, de Ridder M, Dodd C, Bonhoeffer J, Vanrolleghem A, van der Maas N, Lammers GJ, Overeem S, Cauch-Dudek K, Juhasz D, Campitelli M, Datta AN, Kallwei U, Huan WT, Hsu CY, Chen HC, Giner-Soriano M, Morros R, Gaig C, Tió E, Perez-Vilar S, Diez-Domingo J, Puertas FJ, Svenson LW, Mahmud SM, Carleton B,

Naus M, Arnheim-Dahlström L, Pedersen L, DeStefano F, Shimabukuro TT. Narcolepsy and Adjuvanted Pandemic Influenza A (H1N1) 2009 Vaccines – Multi-county Assessment. *Vaccine.* 2018 Oct 1;26(41):6202-6211.

In 2010, a safety signal was detected for narcolepsy in several European countries following vaccination with Pandemrix, a monovalent pandemic H1N1 (pH1N1) vaccine containing AS03 adjuvant. The reports followed large-scale pH1N1 vaccination campaigns during 2009-10. To investigate further, a study team including CDC scientists analyzed vaccine safety data on adjuvanted pH1N1 vaccines (Arenaprix-AS03, Focetria-MF59, and Pandemrix-AS03) from 10 global study sites. Researchers did not detect any new associations between the vaccines and narcolepsy.

Suragh TA, Lamprianou A, MacDonald NE, Loharikar AR, Balakrishnan MR, Benes O, Hyde TB, McNeil MM. Cluster Anxiety-Related Adverse Events Following Immunization (AEFI): An Assessment of Reports Detected in Social Media and Those Identified Using an Online Search Engine. *Vaccine.* 2018 Sep25;26(40):5949-5954.

Adverse events following immunization (AEFI) that arise from anxiety can occur in clusters and may result in unnecessary medical treatments and disrupted vaccination programs. News of these incidents can spread rapidly via the internet and social media. In this study, researchers used Google and Facebook to identify reports of cluster anxiety-related AEFIs not found in traditional peer-reviewed literature and found 39 reports referring to 18 unique cluster events. The most common vaccine mentioned was human papillomavirus (HPV) vaccine (48.7%). The majority of reports (97.4%) involved children; all occurred in a school setting or as part of vaccination campaigns. Five vaccination programs were reportedly halted despite investigations finding no link between the adverse events and the vaccines. These results demonstrate the potential for using information from the web to supplement traditional sources for identifying cluster anxiety-related AEFIs.

Suragh TA, Lewis P, Arana J, Mba-Jonas A, Li R, Stewart B, Shimabukuro TT, Cano M. Safety of bivalent human papillomavirus vaccine in the US vaccine adverse event reporting system (VAERS), 2009-2017. *Br J Clin Pharmacol*. 2018 Dec; 84(12):2928-2932. Epub 2018 Sep 21.

In 2009, bivalent human papillomavirus vaccine (2vHPV, Cervarix) was licensed for use in the United States. Due to low use in the marketplace, the manufacturer stopped supplying 2vHPV in the United States in 2016 and withdrew it from the U.S. market completely in late 2017. The vaccine is currently licensed and used in at least 134 other countries worldwide. In this review, reports submitted to the Vaccine Adverse Event Reporting Systems (VAERS) following 2vHPV vaccination during 2009-2017 were analyzed. During this period, over 720,000 2vHPV doses were distributed in the U.S.; VAERS received 241 adverse event reports. Researchers did not identify any new or unexpected safety concerns in their review.

Fortner KB, Swamy GK, Broder KR, Jimenez-Truque N, Zhu Y, Moro PL, Liang J, Walter EB, Heine RP, Moody MA, Yoder S, Edwards KM. Reactogenicity and immunogenicity of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) in pregnant and nonpregnant women . *Vaccine.* 2018 Oct 8; 36(42):6354-6360. Epub 2018 Sep 13.

CDC recommends that pregnant women receive Tdap vaccine to protect young infants from pertussis (whooping cough). The CISA Project study enrolled 374 pregnant and 225 nonpregnant women to evaluate safety and immune responses after Tdap; 53% of the pregnant women had received Tdap in the past. Pregnancy and infant health outcomes were also assessed and will be described in a future report. Injection-site and systemic reactions (e.g., fever) were assessed for 7 days after Tdap. Blood was collected from the women before and after Tdap to evaluate immune responses. Researchers found that Tdap was well-tolerated in pregnant and nonpregnant women. Pregnant women were more likely to report moderate or severe injection-site pain (18%) compared with nonpregnant women (11%) but this did not lead to medical visits. Prior Tdap receipt did not increase occurrence of moderate or severe reactions in pregnant women. Immune responses to all Tdap vaccine antigens were robust in both groups.

Groom HC, Irving SA, Koppolu P, Smith N, Vazquez-Benitez G, Kharbanda EO, Daley MF, Donahue JG, Getahun D, Jackson LA, Tse Kawai A, Klein NP, McCarthy NL, Nordin JD, Sukumaran L, Naleway AL. Uptake and safety of Hepatitis B vaccination during pregnancy: A Vaccine Safety Datalink study. *Vaccine*. 2018 Oct 1; 36(41):6111-6116. Epub 2018 Sep 5.

Hepatitis B virus (HBV) infection acquired during pregnancy can pose a risk to the infant at birth that can lead to significant and lifelong morbidity. Hepatitis B vaccine (HepB) is recommended for anyone at increased risk for contracting HBV infection, including pregnant women. Prior to this study, limited data were available on the safety of HepB administration during pregnancy. In this Vaccine Safety Datalink retrospective cohort study, researchers assessed potential association between maternal HepB vaccinations and pre-specified maternal and infant safety outcomes, looking at pregnancies resulting in live births from 2004-2015. Women were continuously enrolled from 6 months pre-pregnancy to 6 weeks postpartum. Most women who received maternal HepB did not have high-risk indications for vaccination. The study found there was no increased risk for the examined adverse events in women who received maternal HepB or in their offspring.

Grohskopf LA, Sokolow LZ, Broder KR, Walter EB, Fry AM, Jernigan DB. Prevention and Control of Seasonal Influenza with Vaccines: Recommendation of the Advisory Committee on Immunization Practices – United States, 2018-2019 Influenza Season. *MMWR Recomm Rep.* 2018 Aug 24;67(No. RR-3):1-20.

Routine annual influenza vaccination is recommended for all persons 6 months of age and older who do not have contraindications. A licensed, recommended, and age-appropriate vaccine should be used. Inactivated influenza vaccines (IIVs), recombinant influenza vaccine (RIV), and live attenuated influenza vaccine (LAIV) are expected to be available for the 2018–19 season. For adults 65 years and older, any age-appropriate IIV formulation or RIV4 are acceptable options. Given unknown but theoretical concerns of increased reactogenicity when administering two new adjuvant-containing vaccines, selection of a nonadjuvanted influenza vaccine may be considered in situations where influenza vaccine and another vaccine containing a new adjuvant are to be administered concomitantly; vaccination should not be delayed if a specific product is not available. Vaccines with newer adjuvants, like other vaccines, should be administered at separate sites from other vaccines that are given concomitantly.

Naleway AL, Mittendorf KF, Irving SA, Henninger ML, Crane B, Smith N, Daley MF, Gee J. Primary Ovarian Insufficiency and Adolescent Vaccination. *Pediatrics.* 2018 Sep; 14(3). Epub 2018 Aug 21.

Published case series have suggested a potential association between human papillomavirus (HPV) vaccination and primary ovarian insufficiency (POI). But, no population-based epidemiological studies have been reported. To the authors' knowledge, this new Vaccine Safety Datalink study – a population-based, retrospective cohort study of nearly 200,000 women – is a first, and overcomes some of the limitations of earlier post-licensure monitoring that relied on passive reporting. Researchers found there was no elevated risk of POI following HPV, Tdap, IIV, and MenACWY vaccination in women of reproductive age. These findings should lessen concern about potential impact on fertility from adolescent vaccination.

Haber P, Amin M, Ng C, Weintraub E, McNeil MM. Reports of lower respiratory tract infection following dose 1 of RotaTeq and Rotarix vaccines to the Vaccine Adverse Event Reporting System (VAERS), 2008-2016. *Hum Vaccin Immunother.* 2018 Jul 11:1-5. Epub 2018 Jul 26.

A recent GlaxoSmithKline post-marketing study found a possible association between the administration of the first dose of the rotavirus vaccine Rotarix and lower respiratory tract infections (LRTI) in infants 0-6 days after vaccination. Using Vaccine Adverse Event Reporting System data, this study examined reports of LRTIs in infants 6-15 weeks old who received one of two rotavirus vaccines, Rotarix or RotaTeq, in addition to either the 7-valent (PCV7) or 13-valent (PCV13) pneumococcal conjugate vaccine. Reports of LRTIs occurring in the 0-29 day window following the first dose of the rotavirus vaccination were analyzed between January 2008 and December 2016. Researchers found LRTI rates were not different in those infants from rates of LRTIs in infants receiving other recommended childhood vaccines.

Kharbanda EO, Vazquez-Benitez G, Lipkind HS, Sheth SS, Zhu J, Naleway AL, Klein NP, Hechter R, Daley MF, Donahue JG, Jackson ML, Kawai AT, Sukumaran L, Nordin JD. Risk of Spontaneous Abortion After Inadvertent Human Papillomavirus Vaccination in Pregnancy . *Obstet. Gynecol.* 2018 Jul; 132(1): 35-44.

Quadrivalent human papillomavirus vaccine (4vHPV) is not recommended during pregnancy but may be given inadvertently when pregnancy status is not known. While data on HPV vaccine exposures during or around the time of pregnancy have not raised concerns, additional safety studies are needed. Using the Vaccine Safety Datalink, researchers conducted a retrospective observational cohort study that evaluated the risk of spontaneous abortion following 4vHPV before and during pregnancy. Between January 2008 and November 2014, 2,800 pregnancies were identified with 4vHPV exposure. The authors found the risk of spontaneous abortion did not increase among women who received 4vHPV before or during pregnancy. These findings are consistent with pre-licensures clinical trials and post-licensure safety studies.

Su JR, Ng C, Lewis PW, Cano MV. Adverse events after vaccination among HIV-positive persons, 1990-2016. *PLoS One*. 2018 Jun 19; 13(6) e0199229.

Vaccines are especially critical for people with chronic health conditions such as HIV infection, and are recommended by Advisory Committee on Immunization Practices and CDC based on a person's immune status. Through this study, researchers looked at U.S. reports to Vaccine Adverse Event Reporting System during 1990-2016 to investigate if people living with HIV experienced unexpected adverse events (AEs) or unusual patterns of AEs after vaccination. The analysis found no unexpected or unusual patterns of AEs. These results support the safety of recommended vaccines in people with HIV. Of note, 2 people with HIV with severely compromised immune systems died from widespread infection after receiving live virus vaccines. Healthcare providers should be aware of a patient's immune status prior to administration of live virus vaccines. Following ACIP best practices can help prevent rare, but life-threatening, AEs.

Walker WL, Hills SL, Miller ER, Fischer M, Rabe IB. Adverse events following vaccination with an inactivated, Vero cell culture-derived Japanese encephalitis vaccine in the United States, 2012-2016 . *Vaccine*. 2018 Jul 5; 36(29):4369-4374. Epub 2018 Jun 8.

Inactivated Vero cell culture-derived vaccine (JE-VC; IXIARO) was licensed by Food and Drug Administration in 2009 and has a generally favorable safety profile. In this review of adverse events (AEs) following JE-VC reported to Vaccine Adverse Event Reporting System during May 1, 2012 through April 30, 2016, researchers found reporting rates of AEs were similar to those of the previous analysis (2009-2012). Although reporting rates of AEs in children could not be calculated, there were low numbers of reported events in this age group. Safety surveillance for this relatively new vaccine continues to be important to monitor AE reporting rates and identify possible rare serious events.

Moro PL, Perez-Vilar S, Lewis P, Bryant-Genevier M, Kamiya H, Cano M. Safety Surveillance of Diphtheria and Tetanus Toxoids and Acellular Pertussis (DTaP) Vaccines . *Pediatrics*. 2018 Jul; 142(1). Epub 2018 Jun 4.

Diphtheria, tetanus toxoids and acellular pertussis (DTaP) vaccines were first licensed by the Food and Drug Administration in 1991. To assess the post-licensure safety of DTaP vaccines, researchers reviewed reports of adverse events following vaccination submitted to the Vaccine Adverse Event Reporting System (VAERS). From January 1991 to December 2016, 50,157 reports were submitted to VAERS following DTaP vaccination. The most frequently reported adverse events were injection site redness (25.3%), fever (19.8%), and injection site swelling (15.0%). This assessment did not identify any new or unexpected safety issues and supports the favorable safety profile from pre-clinical trials. Reports of non-serious vaccination errors, such as incorrect vaccine administered or wrong site, call for better education of providers on the specific indications for each of the DTaP vaccines.

Jackson ML, Yu O, Nelson JC, Nordin JD, Tartof SY, Klein NP, Donahue JG, Irving SA, Glanz JM, McNeil MM, Jackson LA. Safety of repeated doses of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine in adults and adolescents . *Pharmacoepidemiol. Drug Saf.* 2018 Aug; 27(8): 921-925. Epub 2018 Jun 3.

Because protective pertussis immunity may wane within 5 years of Tdap (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis) vaccine receipt, maintaining protection may require repeated vaccination. A possible strategy would be to recommend Tdap in place of decennial Td (tetanus toxoid, reduced diphtheria) doses. This VSD study evaluated the safety of repeated doses of tetanus-containing vaccine at intervals <10 years between doses among a population of 68,915 non-pregnant adults and adolescents. Compared to 7,521 subjects who received a subsequent dose of Td vaccine, 61,394 subjects who received a subsequent dose of Tdap did not have significantly elevated risk of medical visits for seizure, cranial nerve disorders, limb swelling, pain in limb, cellulitis, paralytic syndromes, or encephalopathy/encephalitis/meningitis. These results suggest that repeated Tdap vaccination has acceptable safety relative to Tdap vaccination followed by subsequent Td vaccination.

Tseng HF, Sy LS, Qian L, Liu IA, Mercado C, Lewin B, Tartof SY, Nelson J, Jackson LA, Daley MF, Weintraub E, Klein NP, Belongia E, Liles EG, Jacobsen SJ. Pneumococcal Conjugate Vaccine Safety in Elderly Adults . *Open. Forum Infect. Dis.* 2018 May 2; 5(6): ofy100. Epub 2018 Jun.

The 13-valent pneumococcal conjugate vaccine (PCV13) and the 23-valent pneumococcal polysaccharide vaccine (PPSV23) are both licensed vaccines recommended for use in adults 65 years of age and older to protect against pneumococcal disease. PPSV23 protects against 23 types of the approximately 90 types of pneumococcal bacteria and was first licensed in 1983; the newer PCV13 vaccine protects against 13 types of pneumococcal bacteria and was licensed in 2010. In this large cohort study using data from 6 Vaccine Safety Datalink sites, researchers compared the risk in adults 65 years of age and older for serious adverse events (AEs) following vaccination with either PCV13 or PPSV23. The analysis did not find an increased risk of adverse events following PCV13 administration compared to PPSV23, and should provide reassurance regarding use of PCV13.

Shimabukuro TT, Miller ER, Strikas RA, Hibbs BF, Dooling K, Goud R, Cano MV Notes from the Field: Vaccine Administration Errors Involving Recombinant Zoster Vaccine — United States, 2017–2018. *MMWR Morb Mortal Wkly Rep.* 2018 May 25; 67: 585–586.

During the first four months of RZV (Shingrix®) monitoring (October 20, 2017-February 20, 2018), Vaccine Adverse Event Reporting System received a total of 155 reports, of which 13 (8%) documented an administration error, some with more than one type of error. Vaccine providers may be confusing administration procedures and storage requirements between the older ZVL (Zostavax®) vaccine and the newly licensed RZV. Prior experience indicates that reports of administration errors are highest shortly after licensure and recommendation, likely due to lack of familiarity with a new vaccine. To prevent RZV administration errors, vaccine providers should be aware of prescribing information, storage requirements, preparation guidelines, and Advisory Committee on Immunization Practices recommendations for herpes zoster vaccines.

Miller ER, Lewis P, Shimabukuro TT, Su J, Moro P, Woo EJ, Jankosky C, Cano M. Post-licensure safety surveillance of zoster vaccine live (Zostavax®) in the United States, Vaccine Adverse Event Reporting System (VAERS), 2006-2015 . *Hum Vaccin Immunother.* 2018 Mar 26; 14(8): 1963-1969 Epub 2018 May 18.

Herpes zoster (HZ), or shingles, is caused by reactivation of varicella-zoster virus—the same virus that causes chickenpox. Live-attenuated HZ vaccine (zoster vaccine live, ZVL, Zostavax) was licensed by the Food and Drug Administration in 2006 to prevent shingles and is recommended by CDC for people 60 years and older. Researchers reviewed reports of adverse events following ZVL to the Vaccine Adverse Event Reporting System (VAERS) from May 1, 2006 through January 31, 2015. During this time, close to 22 million ZVL doses were distributed. VAERS received 23,092 reports; 96% were classified as non-serious. The most common adverse events reported included injection site pain (27%), HZ (17%), injection site swelling (17%) and rash (14%). This review did not detect new or unexpected safety signals.

Carter RJ, Idriss A, Widdowson MA, Samai M, Schrag SJ, Legardy-Williams JK, Estivariz CF, Callis A, Carr W, Webber W, Fischer ME, Hadler S, Sahr, Thompson M, Gerby SM, Edem-Hotah J, M'baindu Momoh R, McDonald W, Gee JM, Flagbata Kallon A, Spencer-Walters D, Bresee JS, Cohn A, Hersey S, Gibson L, Schuchat A, Seward JF. Implementing a Multisite Clinical Trial in the Midst of an Ebola Outbreak: Lessons Learned from the Sierra Leone Trial to Introduce a Vaccine Against Ebola. *J Infect Dis.* 2018 Jen 15;217(suppl_1):S16-S23. Epub 2018 May 18.

Ebola is a highly contagious disease with a high mortality rate, with no licensed vaccine available as of 2018. Vaccine development includes rigorous testing and 3 phases of clinical trials. The Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE) was the second clinical trial phase to study the investigational Ebola virus vaccine rVSVΔ-ZEBOV-GP. It was conducted during an unprecedented Ebola epidemic. Even before the outbreak, Sierra Leone had limited infrastructure and staff to conduct the trials. The STRIVE team addressed these challenges by allocating time to renovate the sites; providing ongoing support to maintain the water, electricity, and internet services; and training nearly 350 local staff members without hindering the Ebola response efforts. By strengthening the infrastructure and increasing the number of properly trained staff, Sierra Leone is now better equipped to conduct future clinical trials and in a better position to manage Ebola cases and clusters.

Xu S, Clarke CL, Newcomer SR, Daley MF, Glanz JM. Analyzing self-controlled case series data when case confirmation rates are estimated from an internal validation sample . *Biom. J.* 2018 Jul; 60(4): 748-760. Epub 2018 May 16.

Vaccine safety studies are often observational studies using electronic health records (EHR), however, these studies face some challenges, including outside influences (confounding) and outcome misclassification. To handle the confounding effect, researchers use self-controlled case series (SCCS) study design and review of EHRs to validate cases. SCCS design is limited to those individuals who experienced the event during or outside of certain times. While SCCS can adjust for some factors, it cannot adjust for others. This review considered 4 approaches for analyzing SCCS data: observed cases, confirmed cases only, known confirmation rate, and multiple imputation. Researchers found through simulation that when misclassification of adverse events is present, multiple imputation analysis should be considered. When only a sample of presumptive cases can be validated, this approach can address the influence of false-positive cases in EHR data.

Zerbo O, Modaressi S, Goddard K, Lewis E, Fireman BH, Daley MF, Irving SA, Jackson LA, Donahue JG, Qian L, Getahun D, DeStefano F, McNeil MM, Klein NP. Vaccination Patterns in Children After Autism Spectrum Disorder Diagnosis and in Their Younger Siblings . *JAMA Pediatr.* 2018 May 1; 172(5): 469-475.

Recently, several outbreaks of vaccine-preventable diseases generated concerns about the impact of increasing rates of undervaccination. This study investigates whether rates of vaccination in children with autism spectrum disorder (ASD) and their younger siblings differ from rates of vaccination in the general pediatric population. Results show that both children with ASD and their younger siblings are significantly less likely to be fully vaccinated than children in families without a child with ASD. Although the reasons for undervaccination are not fully explored in this study, results suggest that parental refusal of vaccination may play an important role.

Liang JL, Tiwari T, Moro P, Messonnier NE, Reingold A, Sawyer M, Clark TA. Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2018 Apr 27 ;67(No. RR-2):1–44.

This report compiles and summarizes recommendations from CDC's Advisory Committee on Immunization Practices on the prevention and control of tetanus, diphtheria, and pertussis in the U.S. This report is a comprehensive summary of previously published recommendations replacing previously published reports and policy notes and does not contain any new recommendations. Infants and young children are recommended to receive a 5-dose series of diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccines, with a booster dose of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap)

vaccine. Adults who never received Tdap are recommended to receive a booster dose. Women are recommended to receive a dose of Tdap during each pregnancy, regardless of previous receipt. Adolescents and adults are recommended to receive a booster tetanus and diphtheria toxoids (Td) vaccine every 10 years to assure ongoing protection against tetanus and diphtheria.

Donahue, J. Response to three Letters to the Editor regarding: Donahue JG, et al. Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1pdm09 in 2010-11 and 2011-12 . *Vaccine*. 2018 Apr 19; 36(17): 2231-2232.

Summaries are not made for a response to a letter to the editor.

Daley MF, Shoup JA, Newcomer SR, Jackson ML, Groom HC, Jacobsen SJ, McLean HQ, Klein NP, Weintraub ES, McNeil MM, Glanz JM. Assessing Potential Confounding and Misclassification Bias When Studying the Safety of the Childhood Immunization Schedule . *Acad. Pediatr.* 2018 Sept – Oct; 18(7): 754-762. Epub 2018 Mar 28.

Some parents are concerned the childhood immunization schedule could increase risk for allergic disorders, including asthma. This, along with the overall safety of the schedule, has parents delaying their children's vaccinations. Researchers wanted to examine if there was a risk of vaccination status misclassification (between parent and health record) and if risk factors of asthma and other allergies varied by status. This survey was conducted among parents of children 19-35 months old at 8 Vaccine Safety Datalink sites. Among a sample of 2,043 parents, 1,209 (59.2%) responded. The observed agreement between parents and health record for no vaccines was 94% and 87.3 % for receiving all vaccines, no delay. Results showed that misclassification of vaccination status was uncommon, and parents' reports of asthma risk factors generally did not vary by vaccination status. The data from this study will assist future observational studies with measurement and controlling disease risk.

Glanz JM, Newcomer SR, Daley MF, DeStefano F, Groom HC, Jackson ML, Lewin BJ, McCarthy NL, McClure DL, Narwaney KJ, Nordin JD, Zerbo O. Association Between Estimated Cumulative Vaccine Antigen Exposure Through the First 23 Months of Life and Non-Vaccine-Targeted Infections From 24 Through 47 Months of Age . *JAMA*. 2018 Mar 6; 319(9): 906-913.

Up to 15% of parents delay their children's immunizations because of concerns that early childhood vaccines may overwhelm the immune system and cause children to be more susceptible to other infections. While a Danish study did not find evidence that multiple vaccine antigen exposure was associated with the risk for non-vaccine-targeted infectious diseases, this type of study has not been completed in the United States. In this case control study, data was collected from 6 Vaccine Safety Datalink sites to compare children with non-vaccine targeted infections to children without such infections. There were 944 children ages 24 through 47 months enrolled (193 cases, and 751 controls) and the results were not different between the two groups in their estimated cumulative vaccine antigen exposure during the first 23 months of life. In summary, exposure to multiple vaccines did not increase a child's risk of non-vaccine targeted infections.

Irving SA, Groom HC, Stokley S, McNeil MM, Gee J, Smith N, Naleway AL. Human Papillomavirus Vaccine Coverage and Prevalence of Missed Opportunities for Vaccination in an Integrated Healthcare System . *Acad. Pediatr.* 2018 Mar; 18(2S): S85-S92.

Human papillomavirus (HPV) vaccination has been recommended in the United States for female and male adolescents since 2006 and 2011, respectively. However, vaccination rates for HPV compared to other childhood vaccines are lower. Researchers designed an assessment and provider-feedback intervention to increase HPV vaccine rate and identify missed opportunities for vaccination. The assessment and intervention occurred at 9 Oregon-based Kaiser Permanente Northwest outpatient clinics between April 2015 and June 2016. An average 29,021 adolescents ages 11-17 were included. Researchers collected baseline data four years prior to the

intervention and found that vaccination rates were increasing; after intervention, there were no significant increases. Researchers did identify that missed opportunities decreased during the intervention for females 13-17 years old. Increasing HPV rates in large health systems is challenging, but other interventions are worth examining.

Kuntz J, Crane B, Weinmann S, Naleway AL. Myocarditis and pericarditis are rare following live viral vaccinations in adults . *Vaccine.* 2018 Mar 14; 36(12): 1524-1527. Epub 2018 Feb 15.

Cardiac complications including myocarditis, pericarditis, and arrhythmias following smallpox vaccination have been rarely reported in the United States. However, after 67 cases of myocarditis or pericarditis were reported after a vaccination campaign of military personnel, there was a need to assess these outcomes among adults after live-viral vaccinations. In this study using data from 4 Vaccine Safety Datalink sites from 1996-2007, researchers identified over 400,000 adults who received at least 1 live viral vaccine. Of those, there was only 1 probable case of pericarditis and no cases of myocarditis in 42 days following vaccination. Self-controlled risk interval analysis found there is no increased risk of myopericarditis in the 42 days following vaccination. The study findings suggest that the occurrence of myopericarditis following live viral vaccination is rare, not higher than the background rate, and much lower than rates following smallpox vaccination.

Markowitz LE, Gee J, Chesson H, Stokley S. Ten Years of Human Papillomavirus Vaccination in the United States. *Acad Pediatr*. 2018 Mar; 18(2S):S3-S10.

Since human papillomavirus (HPV) vaccine was first introduced for females in the United States in 2006, vaccination policy has evolved as additional HPV vaccines were licensed and new data became available. The United States was the first country to adopt a gender-neutral routine HPV immunization policy in 2011. Researchers summarized reviews of the first 10 years of the HPV vaccination program, including the evolution in vaccine policy, the vaccination program and coverage, and post-licensure vaccine safety studies. Reviews show coverage is increasing, although it remains lower than for other vaccines recommended for adolescents. There are various reasons for low coverage, and efforts are ongoing to increase vaccine uptake. The safety profile of HPV vaccine has been well established from 10 years of post-licensure monitoring. Despite low coverage, the early effects of the HPV vaccination program have exceeded expectations.

Arana JE, Harrington T, Cano M, Lewis P, Mba-Jonas A, Rongxia L, Stewart B, Markowitz LE, Shimabukuro TT. Post-licensure safety monitoring of quadrivalent human papillomavirus vaccine in the Vaccine Adverse Event Reporting System (VAERS), 2009-2015 . *Vaccine*. 2018 Mar 20; 36(13):1781-1788. Epub 2018 Feb 21.

This study reviewed adverse events reported to Vaccine Adverse Event Reporting Systems following Gardasil® (4vHPV) vaccination between January 2009 and December 2015. A previous review did not include males because they were not recommended for vaccination at the time; this study includes both males and females. The analysis found 94.2% of the 19,760 reported adverse events were non-serious, and included headache, nausea, and fatigue. More than 60 million 4vHPV doses were distributed in the United States at the time, making the crude adverse event reporting rate 327 reports per million 4vHPV doses distributed. No unexpected or new safety concerns or reporting patterns were found.

Sukumaran L, McCarthy NL, Kharbanda EO, Vazquez-Benitez G, Lipkind HS, Jackson L, Klein NP, Naleway AL, McClure DL, Hechter RC, Kawai AT, Glanz JM, Weintraub ES. Infant Hospitalizations and Mortality After Maternal Vaccination . *Pediatrics.* 2018 Mar; 14(3). Epub 2018 Feb 20.

Influenza and Tdap vaccines are recommended for pregnant women. However, there are limited data on long-term outcomes of infants born to mothers vaccinated during pregnancy. This case-control study found that influenza and Tdap vaccines in pregnancy are not associated with an increased risk of hospitalization or death in infants during the first six months of life. These findings contribute to the knowledge of the long-term safety of vaccination during pregnancy.

Li R, Weintraub E, McNeil MM, Kulldorff M, Lewis EM, Nelson J, Xu S, Qian L, Klein NP, DeStefano F. Meningococcal conjugate vaccine safety surveillance in the Vaccine Safety Datalink using a tree-temporal scan data mining method . *Pharmacoepidemiol. Drug Saf.* 2018 Apr; 27(4): 391-397. Epub 2018 Feb 15.

Traditional pharmacovigilance techniques used in vaccine safety are generally geared to detecting adverse events (AEs) based on pre-defined sets of conditions or diagnoses. Using a newly developed tree-temporal scan statistic data mining method, researchers performed a pilot study to evaluate the safety profile of the meningococcal conjugate vaccine Menactra®. The authors detected known AEs following the vaccine; no new safety concerns were raised. The study demonstrates that the tree-temporal scan statistic data mining method can be successfully applied to screen broadly for a wide range of vaccine-AE associations within a large health care data network.

Zhou H, Thompson WW, Belongia EA, Fowlkes A, Baxter R, Jacobsen SJ, Jackson ML, Glanz JM, Naleway AL, Ford DC, Weintraub E, Shay DK. Estimated rates of influenza-associated outpatient visits during 2001-2010 in six US integrated health care delivery organizations . *Influenza. Other Respir. Viruses.* 2018 Jan; 12(1): 122-131. Epub 2018 Feb 15.

Influenza (flu) related illnesses are responsible for many morbidity cases during each flu season, but these illnesses are difficult to count: symptoms are non-specific, diagnostic codes for flu-related symptoms are broad, and lab testing is not routine. This makes population-based estimates of flu-related outpatient visits during flu epidemics or pandemics uncommon. In this study using data from 6 Vaccine Safety Datalink sites from 2001-2010, researchers estimated flu-related outpatient visits. Researchers modeled the rates of outpatient visits with diagnostic codes of pneumonia or acute respiratory visits. Of the nearly 7.7 million people enrolled, children had higher estimated flu-related outpatient rates than adults during pre-pandemic and pandemic seasons. Rates estimated with pneumonia visits plus flu-coded visits were similar to previous studies using confirmed flu cases. These numbers are crucial for measuring the potential benefits of flu prevention and treatment.

McNeil MM, DeStefano F. Vaccine-associated hypersensitivity . *J. Allergy Clin. Immunol.* 2018 Feb; 141(2): 463-472.

Vaccines are considered one of the most effective public health interventions – resulting in major reductions of vaccine preventable diseases and death. Vaccine-associated hypersensitivity reactions are not infrequent; however, serious acute-onset anaphylaxis reactions are extremely rare. Risk of anaphylaxis after all vaccines is estimated to be 1.31 per million vaccine doses administered. This review focuses on serious hypersensitivity reactions following flu vaccines, given the large number of people vaccinated yearly and the formulation changes the vaccines go through each year to match circulating flu viruses. Recent advances in vaccine technology, along with new vaccines and the universal flu vaccination recommendation (people 6 months of age and older), make continued safety monitoring for hypersensitivity reactions following flu vaccination particularly important.

McNeil MM, Hibbs BF, Miller ER, Cano MV. Notes from the Field: Errors in Administration of an Excess Dosage of Yellow Fever Vaccine – United States, 2017. *MMWR Morb Mortal Wkly Rep.* 2018 Jan 26; 67:109-110.

Following a March 2017 report to Vaccine Adverse Event Reporting System (VAERS) of four persons receiving incorrect dosages of yellow fever vaccine, CDC conducted a VAERS search and literature review for similar reported administration errors. Reports were few (15 in VAERS; 67 in literature) and most did not involve an adverse event. However, the error was costly in terms of medical follow-up and vaccine wastage. More distinctive single/multi-dose packaging and in-service training might prevent future errors.

Hibbs BF, Miller E, Shi J, Smith K, Lewis P, Shimabukuro TT. Safety of Vaccines That Have Been Kept Outside of Recommended Temperatures: Reports to the Vaccine Adverse Event Reporting System (VAERS), 2008-2012. *Vaccine.* 2018 Jan 25;36(4):553-558.

This review does not indicate any substantial direct health risk from administration of vaccines kept outside of recommended temperatures. However, there are potential costs and risks, including vaccine wastage, possible decreased protection, and patient inconvenience related to revaccination. Maintaining high vigilance, proper staff training, regular equipment maintenance, and having adequate auxiliary power are important components of comprehensive vaccine cold chain management.

Haber P, Moro PL, Ng C, Lewis PW, Hibbs B, Schillie SF, Nelson NP, Li R, Stewart B, Cano MV. Safety of Currently Licensed Hepatitis B Surface Antigen Vaccines in the United States, Vaccine Adverse Event Reporting System (VAERS), 2005-2015. *Vaccine*. 2018 Jan 25;26(4):559-564.

This study is based on a national vaccine safety data and reassures the public on the safety of Hepatitis B vaccine(s). Although it reveals increased reports of vaccine storage errors, and incorrect dose or wrong vaccine given to infants or adults, no adverse events are noted. The findings highlight the need for education and training of health providers on prevention of vaccine administration errors.

Schillie S, Vellozzi C, Reingold A, Harris A, Haber P, Ward JW, Nelson NP. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. *MMWR Recomm Rep*. 2018 Jan 12; 67(No. RR-1):1-31.

Hepatitis B is a serious disease that affects the liver. The virus is highly infectious and can be transmitted in the absence of visible blood. As part of the recommended immunization schedule for infants and children, Hepatitis B vaccine should be given to children in three doses between birth and 18 months of age. In January 2018, the Advisory Committee on Immunization Practices (ACIP) published new recommendations for the vaccine. These include: 1) administration of the universal hepatitis B vaccination within 24 hours of birth of medically stable infants, 2) testing pregnant women for Hepatitis B, 3) post-vaccination serologic testing for infants whose mother has an unknown hepatitis B status, and 4) the removal of lenient language for delaying the birth dose until after hospital discharge. Vaccine safety information was updated to include data from the pre- and post-licensure studies and report information from the Vaccine Adverse Events Report System from 2005 to 2015.

Newcomer SR, Kulldorff M, Xu S, Daley MF, Fireman B, Lewis E, Glanz JM. Bias from outcome misclassification in immunization schedule safety research . *Pharmacoepidemiol. Drug Saf*. 2018 Feb; 27(2): 221-228. Epub 2018 Jan 2.

The Institute of Medicine in 2013 recommended conducting observational studies of the childhood immunization schedule safety. However, these studies present a methodical challenge because of bias from misclassification of outcomes in electronic health record data. Using simulations, researchers evaluated the percent of valid diagnoses (positive predictive values, PPVs) as indicators of bias of an exposure-outcome association, and quantitative bias analyses methods used for bias correction. Overall outcome PPVs did not reflect the distribution of false positives by exposure and are poor indicators of bias in individual studies. Quantitative bias analysis was effective in correcting outcome misclassification bias and should be considered in immunization schedule research.

Moro PL, Zheteyeva WY, Barash F, Lewis P, Cano M. Assessing the Safety of Hepatitis B Vaccination During Pregnancy in the Vaccine Adverse Event Reporting System (VAERS), 1990-2016. *Vaccine*. 2018 Jan 2;26(1):50-54.

Few studies have been done on the safety of hepatitis B vaccine in pregnant women. This review describes adverse events after Hepatitis B vaccination of pregnant women reported to the Vaccine Adverse Event Reporting System (VAERS). During the period from January 1, 1990 to June 30, 2016, VAERS received 192 reports involving pregnant women following Hepatitis B vaccination. No new or unexpected safety concerns were found.

Tamez RL, Tan WV, O'Malley JT, Broder KR, Garzon MC, LaRussa P, Lauren CT. Influenza B Virus Infection and Stevens-Johnson Syndrome. *Pediatr Dermatol.* 2018 Jan;35(1);e45-e48.

Stevens-Johnson Syndrome (SJS) is a rare, serious disorder that affects the skin and the areas that creates and releases mucus. It starts as flu-like symptoms, and leads to a rash and blisters. Patients who develop SJS require hospitalization to manage the symptoms and identify the cause. This case reviewed SJS in a 2-year-old boy with influenza B infection. He was up to date on his immunizations, including the influenza vaccine 3 months prior to coming to coming to the hospital. He was treated with antiviral oseltamivir and IV treatment', and his symptoms cleared up. With his diagnosis of influenza type B and SJS, there were still concerns of re-exposure to influenza B antigen during next season's vaccination. The boy received the quadrivalent inactivated influenza vaccine the following season, was monitored and tolerated the vaccine well without reports of adverse reactions. Medical evaluation concluded that the patient's influenza B infection was the most likely cause of SJS.

2017

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