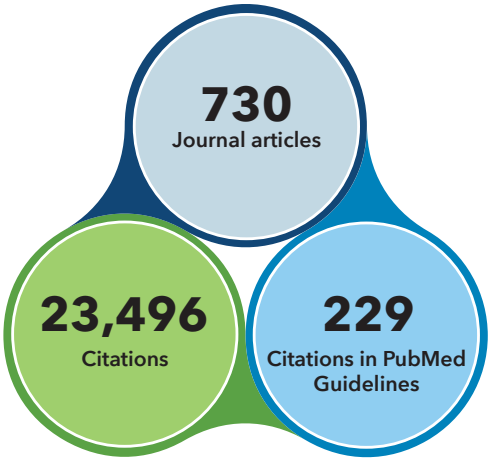
Kaiser Permanente Research Brief

Vaccines

This brief summarizes the contributions of Kaiser Permanente Research since 2007 on the topic of vaccines. This includes vaccinations delivered in early childhood as well as those delivered to adolescents and adults.

Although the development of vaccinations against communicable diseases dates back to the 18th century, the creation of modern vaccines and their widespread use in the United States began in the 20th century.[1] Today, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention provides national recommendations for vaccines, including pertussis (whooping cough) shots for pregnant women and numerous vaccinations delivered to children, adolescents, and adults (see figure below).[2] Although vaccination has largely eliminated diseases such as measles and rubella in the United States,[1] these and other diseases are still found frequently in countries with lower rates of vaccine coverage,[3] and the ease of global travel has led to cases in which unvaccinated people from well-vaccinated nations have contracted these infections.[4] Moreover, diseases such as pertussis,[1] varicella (chicken pox)[5], and human papillomavirus (HPV)[6] still occur frequently in the United States.

Kaiser Permanente publications related to vaccines since 2007



Source: Kaiser Permanente Publications Library and Scite metrics, as of April 22, 2022 .

In addition to the direct effect of immunizing patients against dangerous diseases, vaccination also benefits society more broadly through so-called "herd immunity" effects. Through herd immunity, higher rates of effective vaccination for a given illness at a population level confer protection to unvaccinated individuals by making encounters with infected individuals increasingly rare. For example, increased uptake of the pediatric pneumococcal vaccine has been associated with decreased rates of the disease among adults, many of whom have not, until recently, received this vaccine.[7,8] The level of vaccination coverage required to create herd immunity for a given disease depends on both the vaccine's effectiveness and how easily the disease is transmitted between unvaccinated people.

This brief summarizes a selection of the publications contained within the Kaiser Permanente Publications Library, which indexes journal articles and other publications authored by individuals affiliated with Kaiser Permanente. The work described in this brief originated from across Kaiser Permanente's 8 regions and was supported by a wide range of funding sources including internal research support as well as both governmental and nongovernmental extramural funding.

Vaccination is an active area of study for Kaiser Permanente Research. Scientists across the organization have used our rich, comprehensive, longitudinal data to advance knowledge in the areas of understanding risk, improving patient outcomes, and translating research findings into policy and practice. We have published more than 700 articles related to vaccines since 2007.[9] Together, these articles have been cited approximately 23,500 times. These articles are the product of observational studies, randomized controlled trials, meta-analyses, and other studies led by Kaiser Permanente scientists. Our unique environment, which includes our fully integrated care and coverage model, lets our research scientists, clinicians, medical groups, and health plan leaders collaborate to contribute generalizable knowledge on vaccines, and many other research topics.

Understanding Risk

Who is at risk of acquiring vaccine-preventable communicable diseases?

Any person who has not been vaccinated against a particular disease and encounters a person infected with that disease is at risk of infection. Additionally, no vaccine is 100% effective in preventing disease transmission, so vaccinated people may continue to be at risk.[10;11] In children, undervaccination (either delaying or not receiving vaccines) appears to be increasingly common.[12] Parental refusal of vaccines has been associated with outbreaks of measles, pertussis, varicella, Haemophilus influenzae type b (Hib), and pneumococcal disease,[13] and our recent studies have linked parental hesitancy with significantly higher rates of pertussis,[14] varicella,[15] and pneumococcal disease.[16] Another study conducted by our scientists found lower rates of vaccination in children diagnosed with autism spectrum disorder, as well as their younger siblings.[17] Our researchers also have found higher rates of infection in children who failed to complete all courses of multicourse vaccines.[18] In some instances, delaying vaccinations can increase the risk of side effects. For example, delayed receipt of measles-mumps-rubella (MMR) or measles-mumps-rubella-varicella (MMRV) vaccine has been associated with a higher risk of febrile seizures.[19] Infants too young to be vaccinated against particular diseases are also at risk of acquiring those diseases; research has found that preterm infants may have lower immune responses to vaccines,[20] while neonatal intensive care unit-treated infants may not receive all appropriate vaccines.[21]

The CDC's Advisory Committee on Immunization Practices sets national guidelines for recommended vaccines.[2]

Childhood

(BIRTH TO 10 YEARS)

- Pertussis (during pregnancy)
- Diphtheria, tetanus and pertussis
- Hepatitis A, hepatitis B
- Polio
- Pneumococcal disease
- Haemophilus influenza type B (Hib)
- Measles, mumps, rubella and varicella
- Rotavirus
- Annual flu (beginning at 6 months and older)
- COVID-19 (ages 5 and older)

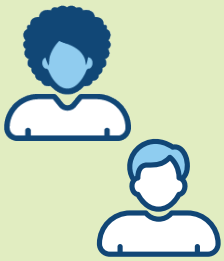
Adolescence

(11 TO 18 YEARS)

- Human papillomavirus (HPV)
- Meningococcal conjugate
- Tetanus, diphtheria and pertussis
- Annual flu
- COVID-19

Adulthood

(19+ YEARS)



- Annual flu
- Tetanus and diphtheria (with/without pertussis)
- COVID-19
- Hepatitis B (ages 19-59)
- Herpes zoster (at age 50)
- Pneumococcal (at age 65)

Kaiser Permanente scientists have developed and tested programs that address parental concerns about vaccinating their young children.

Beginning during pregnancy and continuing through infancy, physicians should provide information about vaccines, and work actively to build trust with hesitant parents[116-118]

A website featuring vaccine information and social capabilities that allows parents to communicate and share information is associated with improved vaccination rates[123-125]

In adults, our research has found higher risks of herpes zoster[22] and influenza[23] among the unvaccinated, and cervical cancer may be more common among women who do not receive HPV vaccination during adolescence.[24] Individuals with weakened immune systems also are at higher risk of acquiring vaccine-preventable diseases. For example, reactivation of latent herpes zoster infection is more likely to occur in patients using immunosuppressive drugs.[25]

How safe are vaccines?

Because vaccines are, by definition, delivered to large numbers of healthy individuals, they are judged by very strict standards of safety, and regulatory approval is only granted to vaccines with extremely low observed risks. Kaiser Permanente researchers have been involved in studying the safety of meningococcal,[26-36] pneumococcal,[37-40] HPV,[41-46] MMR,[47] MMRV,[48-50] tetanus-diphtheria-pertussis (Tdap),[51-54] diphtheria-tetanus-pertussis (DTaP)-polio,[55-57] flu,[58-72] shingles,[73;74] pertussis,[75] hepatitis A[76;77], and hepatitis B[78;79] vaccines, among others.[80-85]The rarity of problems with vaccine safety makes the prediction of risks challenging, and requires considerable research expertise[86;87] and ongoing surveillance.[88-90]

Allergic reactions such as swelling or soreness at the vaccination site[91-95] and complications such as febrile seizures[96,97] or fevers[98;99] are known side effects of vaccines, though these are rarely associated with long-term health problems.[100] Our scientists have led studies linking febrile seizure risks to specific vaccines, including the MMRV[101-104] and influenza[105] vaccines. Elderly patients have also experienced higher rates of adverse effects from the shingles[92] and tetanus-diphtheria-pertussis (Tdap)[106] vaccines, although these risks are arguably outweighed by the benefits of these vaccines, such as prevention of neuralgic pain and tetanus or diphtheria infection.

Improving Patient Outcomes

What strategies are effective in increasing vaccination rates?

Despite the importance of routine vaccination, compliance with many recommendations is inconsistent, and research conducted by our scientists has demonstrated racial and socioeconomic disparities in receipt of early childhood,[107;108] flu,[109] and COVID-19[110] vaccines, as well as suboptimal rates of flu vaccination among pregnant women.[111] In addition, our research has highlighted the challenges of completing recommended vaccinations during the COVID-19 pandemic, in light of disrupted access to medical care.[112-114] Kaiser Permanente researchers have explored a variety of approaches for increasing vaccination rates. In general, the approaches used for early-childhood vaccination are very different from those used for other types of vaccines. Successful interventions for increasing vaccine uptake in young children include physician-oriented approaches to address parental hesitancy,[115-122] tailored messages delivered via social and other media,[123-129] automated reminders,[130] school-based vaccination,[131-135] and community-based education (for example, public service announcements).[136;137] In contrast, outreach approaches that have been shown to increase adolescent and adult uptake of vaccines include workplace vaccination programs,[138;139] reminders placed in the electronic health records of patients or parents,[131;140-142] and use of vaccine series requiring fewer doses for completion.[79;143,144]

How effective is vaccination in preventing the transmission of communicable diseases?

Kaiser Permanente researchers have been actively involved in research on vaccine effectiveness, including herd immunity effects[14;145-147] and protection of vulnerable populations, including the elderly,[148-155] infants,[156-162] people with suppressed immune systems,[25;163] and people with certain chronic diseases.[164;165] Recent work by our scientists has explored the mechanisms by which zoster and pneumococcal vaccination in older adults appears to protect against other infectious illnesses.[166;167] Other Kaiser Permanente research has identified shortcomings in vaccine effectiveness. Numerous studies of annual flu vaccinations have identified waning effects over time,[168-170] differences in effectiveness between vaccine types,[171-173] and variable effectiveness from year to year.[23;174;175] More recently, we have repeatedly found evidence of the waning effectiveness of the pertussis[176-181] and herpes zoster[182;183] vaccines. This work contributed directly to changes in the ACIP's recommendations regarding immunization for these conditions. Finally, our scientists are actively involved in randomized trials evaluating the effectiveness of simultaneous administration of multiple vaccines to adolescents[83] and adults.[85]

The Vaccine Safety Datalink demonstrated increased seizure risk with MMRV versus delivering MMR and varicella in separate injections.[101]

MMR and V separately at 12-23 months	MMRV at 12-23 months
376,354 vaccine recipients	83,107 vaccine recipients
Seizure rate per 1000 person-years 7 to 10 days after vaccination	
MMR + V **42**	MMRV **85**
Relative risk	
1.98 (95% CI 1.43-2.73)	

CDC RECOMMENDATION:
Deliver MMR and varicella separately.

How does vaccination affect a person's health?

Vaccine-preventable diseases carry serious and well-known health risks, including cervical cancer from HPV, liver failure from hepatitis, meningitis from Hib, and death from illnesses such as influenza, pertussis, or hepatitis.[184;185] Vaccination affects health in numerous ways beyond the transmission of communicable diseases. For example, vaccination in pregnant women has been shown to transmit immunity to their children,[186-188] and annual flu vaccinations appear to have small but statistically significant effects on mortality and hospitalization rates,[148;189-192] and on numbers of outpatient visits.[193]

Translating Research Findings Into Policy and Practice

As part of a learning health care organization that uses research to inform and improve practice, our research, clinical, and operational partners have tested a range of interventions to increase uptake of recommended vaccines. Pediatricians in Kaiser Permanente have worked to address parental vaccine hesitancy,[116;194;195] leading to the development and evaluation of messaging interventions.[117;124] This work was subsequently expanded to flu and HPV vaccination. Reminders placed in Kaiser Permanente's electronic health record system have been used to inform changes in vaccination policies,[90;196-199] including a change in herpes zoster vaccines. Our scientists have also explored multicomponent programs for increasing rates of HPV vaccination.[200]

Collectively, research from Kaiser Permanente authors has been cited more than 220 times in recent practice guidelines, including the vaccination guidelines for influenza,[201] HPV,[202] herpes

zoster,[203] Tdap[204] and MMRV [205] published by the CDC's Morbidity and Mortality Weekly Report. More recently, our scientists have contributed to COVID-19 vaccine recommendations published by the CDC's Advisory Committee on Immunization Practices,[206-210] as well as the American College of Rheumatology.[211-213] Our research has also directly influenced national vaccine policies. One study of febrile seizure risks associated with the first injection of MMRV versus MMR separately from varicella found that people receiving MMRV were twice as likely to experience seizures 7 to 10 days after vaccination.[101] This led the CDC to recommend that the first MMR and varicella shots be given separately (unless the parent wishes their child to receive MMRV).[19;205] Work questioning the durability of the pertussis vaccine delivered to children[177;181] led to increased emphasis on prenatal vaccination,[186] and other work[182] prompted uptake of a newer zoster vaccine.[183]

Kaiser Permanente has also shown considerable leadership in the field of vaccine research. Our researchers are leaders in the CDC's Vaccine Safety Datalink, or VSD, an ongoing effort to use data from large health care organizations to evaluate vaccine safety.[214-217] In the VSD, which began in 1990, 6 of our regions contribute electronic patient data that are used to study rare but serious adverse reactions, the safety of new vaccines, and changes in vaccine recommendations. Vaccine safety in pregnancy is an emphasis of VSD research, along with the development of new research methods and rapid cycle analysis techniques for promptly notifying the public of possible risks.[218-222] We are also involved in the U.S. Flu Vaccine Effectiveness Network, which provides interim and annual estimates of the effectiveness of each year's flu vaccine by studying individuals entering health care facilities during flu season.[223-236] Our researchers continue to be involved in early-stage vaccine development through the large, long-standing vaccine clinical trials program in the Northern California Vaccine Study Center, and through the National Institutes of Health's Vaccine and Treatment Evaluation Units (VTEU) network.[237;238] The VTEU, based in Kaiser Permanente's Washington Region, is the only such unit in the country housed in an integrated health organization. Our researchers have also participated in a recent workshop on pertussis vaccine waning, organized by the National Institute of Allergy and Infectious Diseases,[239] as well as a Brighton Collaboration effort aimed at standardizing the case definition of multisystem inflammatory syndrome.[240]

Finally, our scientists are part of ongoing research efforts to develop vaccines in response to COVID-19.[241] The VTEU was the lead site for the first-ever trial of a COVID-19 vaccine, evaluating the vaccine developed by Moderna Therapeutics and the National Institute of Allergy and Infectious Diseases.[242;243] Our researchers have been involved in several late-phase efficacy trials, including trials of the vaccines developed by Pfizer and BioNTech, Moderna and NIAID, and Johnson & Johnson.[244] This work has continued with our participation in clinical trials and evaluations of the real-world effectiveness of these vaccines.[245-259] Our researchers have also taken part in studies of booster dose effectiveness,[260-264] as well as studies exploring the waning effects of COVID-19 vaccines over time,[265-267] and safety concerns such as myocarditis,[268;269] adverse birth outcomes,[270;271] hypersensitivity reactions,[272-275] and other adverse events.[276-278] Kaiser Permanente scientists have also conducted extensive research on public perceptions and hesitancy regarding COVID-19 vaccination in a variety of populations, including young adults,[279] pregnant women,[280] parents,[281] essential workers,[282] health care workers,[283;284] members of ethnic minorities,[285] and homeless people.[286]

Kaiser Permanente's 185 research scientists and 1,530 support staff members are based at 9 research centers. There are currently 2,355 studies underway, including clinical trials. Since 2007 our research scientists and clinicians have published more than 20,000 articles. Kaiser Permanente currently serves approximately 12.5 million members in 8 states and the District of Columbia.

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References

1. Ventola CL. Immunization in the United States: Recommendations, Barriers, and Measures to Improve Compliance: Part 1: Childhood Vaccinations. *P t.* 2016;41(7):426-436.
2. Centers for Disease Control and Prevention. ACIP Vaccine Recommendations. 2022; https://www.cdc.gov/vaccines/hcp/acip-recs/index.html. Accessed June 3, 2022.
3. World Health Organization. Global Allia nce for Vaccines and Immunization (GAVI). 2018; http://www.who.int/mediacentre/factsheets/fs169/en/. Accessed July 6, 2018.
4. Gautret P, Botelho-Nevers E, Brouqui P, Parola P. The spread of vaccine-preventable diseases by international travellers: a public-health concern. *Clin Microbiol Infect.* 2012;18 Suppl 5:77-84.
5. Centers for Disease Control and Prevention. Monitoring the Impact of Varicella Vaccination. 2016; https://www.cdc.gov/chickenpox/surveillance/monitoring-varicella.html. Accessed July 6, 2018.
6. Centers for Disease Control and Prevention. Human Papillomavirus (HPV) Statistics. 2017; https://www.cdc.gov/std/hpv/stats.htm. Accessed July 6, 2018.
7. Stephens DS, Zughaier SM, Whitney CG, et al. Incidence of macrolide resistance in Streptococcus pneumoniae after introduction of the pneumococcal conjugate vaccine: population-based assessment. *Lancet.* 2005;365(9462):855-863.
8. Whitney CG, Farley MM, Hadler J, et al. Decline in invasive pneumococcal disease after the introduction of protein-polysaccharide conjugate vaccine. *N Engl J Med.* 2003;348(18):1737-1746.
9. KPPL Search, conducted on April 22, 2022: (dc.title:immunis* OR dc.title:immuniz* OR dc.title:vaccin* OR dc.subject.mesh:immunization OR dc.subject.mesh:vaccination OR dc.subject.mesh:vaccines) AND dc.type:"-Journal Article" AND dc.date.issued:[2007 2022].
10. Chu L, Daganzo S, Aronowitz P. Chickenpox in a Vaccinated Adult. *J Gen Intern Med.* 2019;34(3):479-480.
11. Zerbo O, Bartlett J, Goddard K, et al. Acellular Pertussis Vaccine Effectiveness Over Time. *Pediatrics.* 2019;144(1):e20183466.
12. Glanz JM, Newcomer SR, Narwaney KJ, et al. A Population-Based Cohort Study of Undervaccination in 8 Managed Care Organizations Across the United States. *JAMA Pediatr.* 2013;167(3):274-281.
13. Salmon DA, Dudley MZ, Glanz JM, Omer SB. Vaccine Hesitancy: Causes, Consequences, and a Call to Action. *Am J Prev Med.* 2015;49(6 Suppl 4):S391-398.
14. Glanz JM, McClure DL, Magid DJ, et al. Parental refusal of pertussis vaccination is associated with an increased risk of pertussis infection in children. *Pediatrics.* 2009;123(6):1446-1451.
15. Glanz JM, McClure DL, Magid DJ, et al. Parental refusal of varicella vaccination and the associated risk of varicella infection in children. *Arch Pediatr Adolesc Med.* 2010;164(1):66-70.
16. Glanz JM, McClure DL, O'Leary ST, et al. Parental decline of pneumococcal vaccination and risk of pneumococcal related disease in children. *Vaccine.* 2011;29(5):994-999.
17. Zerbo O, Modaressi S, Goddard K, et al. Vaccination Patterns in Children After Autism Spectrum Disorder Diagnosis and in Their Younger Siblings. *JAMA Pediatr.* 2018;172(5):469-475.
18. Glanz JM, Narwaney KJ, Newcomer SR, et al. Association Between Undervaccination With Diphtheria, Tetanus Toxoids, and Acellular Pertussis (DTaP) Vaccine and Risk of Pertussis Infection in Children 3 to 36 Months of Age. *JAMA Pediatr.* 2013;167(11):1060-1064.
19. Hambidge SJ, Newcomer SR, Narwaney KJ, et al. Timely Versus Delayed Early Childhood Vaccination and Seizures. *Pediatrics.* 2014;133(6):e1492-1499.
20. Klein NP, Gans HA, Sung P, et al. Preterm infants' T cell responses to inactivated poliovirus vaccine. *J Infect Dis.* 2010;201(2):214-222.
21. Navar-Boggan AM, Halsey NA, Escobar GJ, et al. Underimmunization at discharge from the neonatal intensive care unit. *J Perinatol.* 2012;32(5):363-367.
22. Tseng HF, Smith N, Harpaz R, et al. Herpes zoster vaccine in older adults and the risk of subsequent herpes zoster disease. *JAMA.* 2011;305(2):160-166.
23. Jackson ML, Chung JR, Jackson LA, et al. Influenza Vaccine Effectiveness in the United States during the 2015-2016 Season. *N Engl J Med.* 2017;377(6):534-543.
24. Silverberg MJ, Leyden WA, Lam JO, et al. Effectiveness of catch-up human papillomavirus vaccination on incident cervical neoplasia in a US health-care setting: a population-based case-control study. *Lancet Child Adolesc Health.* 2018;2(10):707-714.
25. Cheetham TC, Marcy SM, Tseng HF, et al. Risk of Herpes Zoster and Disseminated Varicella Zoster in Patients Taking Immunosuppressant Drugs at the Time of Zoster Vaccination. *Mayo Clin Proc.* 2015;90(7):865-873.
26. Jackson LA, Baxter R, Reisinger K, et al. Phase III comparison of an investigational quadrivalent meningococcal conjugate vaccine with the licensed meningococcal ACWY conjugate vaccine in adolescents. *Clin Infect Dis.* 2009;49(1):e1-10.

27. Reisinger KS, Baxter R, Block SL, et al. Quadrivalent meningococcal vaccination of adults: phase III comparison of an investigational conjugate vaccine, MenACWY-CRM, with the licensed vaccine, Menactra. *Clin Vaccine Immunol.* 2009;16(12):1810-1815.
28. Halperin SA, Gupta A, Jeanfreau R, et al. Comparison of the safety and immunogenicity of an investigational and a licensed quadrivalent meningococcal conjugate vaccine in children 2-10 years of age. *Vaccine.* 2010;28(50):7865-7872.
29. Baxter R, Baine Y, Ensor K, et al. Immunogenicity and safety of an investigational quadrivalent meningococcal ACWY tetanus toxoid conjugate vaccine in healthy adolescents and young adults 10 to 25 years of age. *Pediatr Infect Dis J.* 2011;30(3):e41-48.
30. Baxter R, Baine Y, Kolhe D, et al. Five-Year Antibody Persistence and Booster Response to a Single Dose of Meningococcal A, C, W, and Y Tetanus Toxoid Conjugate Vaccine in Adolescents and Young Adults: An Open, Randomized Trial. *Pediatr Infect Dis J.* 2015;34(11):1236-1243.
31. Klein NP, Reisinger KS, Johnston W, et al. Safety and Immunogenicity of a Novel Quadrivalent Meningococcal CRM-Conjugate Vaccine Given Concomitantly With Routine Vaccinations in Infants. *Pediatr Infect Dis J.* 2012;31(1):64-71.
32. Klein NP, Baine Y, Bianco V, et al. One or Two Doses of Quadrivalent Meningococcal Serogroups A, C, W-135 and Y Tetanus Toxoid Conjugate Vaccine is Immunogenic in 9-12 Month Old Children. *Pediatr Infect Dis J.* 2013;32(7):760-767.
33. Klein NP, Baine Y, Kolhe D, et al. Five-Year Antibody Persistence and Booster Response Following One or Two Doses of Meningococcal A, C, W, and Y Tetanus Toxoid Conjugate Vaccine in Healthy Children. *Pediatr Infect Dis J.* 2016;35(6):662-672.
34. Klein NP, Habanec T, Kosina P, et al. Immunogenicity and safety of the quadrivalent meningococcal ACWY-tetanus toxoid conjugate vaccine (MenACWY-TT) in splenectomized or hyposplenic children and adolescents: Results of a phase III, open, non-randomized study. *Vaccine.* 2018;36(17):2356-2363.
35. Tseng HF, Sy LS, Ackerson BK, et al. Safety of Quadrivalent Meningococcal Conjugate Vaccine in 11- to 21-Year-Olds. *Pediatrics.* 2017;139(1):e20162084.
36. Tartof SY, Sy LS, Ackerson BK, et al. Safety of Quadrivalent Meningococcal Conjugate Vaccine in Children 2-10 Years. *Pediatr Infect Dis J.* 2017;36(11):1087-1092.
37. Greenhow TL, Hung YY, Herz A. Bacteremia in Children 3 to 36 Months Old After Introduction of Conjugated Pneumococcal Vaccines. *Pediatrics.* 2017;139(4):e20162098.
38. Tseng HF, Sy LS, Qian L, et al. Pneumococcal Conjugate Vaccine Safety in Elderly Adults. *Open Forum Infect Dis.* 2018;5(6):ofy100.
39. Cannon K, Elder C, Young M, et al. A trial to evaluate the safety and immunogenicity of a 20-valent pneumococcal conjugate vaccine in populations of adults ≥65 years of age with different prior pneumococcal vaccination. *Vaccine.* 2021;39(51):7494-7502.
40. Klein NP, Peyrani P, Yacisin K, et al. A phase 3, randomized, double-blind study to evaluate the immunogenicity and safety of 3 lots of 20-valent pneumococcal conjugate vaccine in pneumococcal vaccine-naive adults 18 through 49 years of age. *Vaccine.* 2021;39(38):5428-5435.
41. Vichnin M, Bonanni P, Klein NP, et al. An Overview of Quadrivalent Human Papillomavirus Vaccine Safety - 2006 to 2015. *Pediatr Infect Dis J.* 2015;34(9):983-991.
42. Sy LS, Meyer KI, Klein NP, et al. Postlicensure Safety Surveillance of Congenital Anomaly and Miscarriage Among Pregnancies Exposed to Quadrivalent Human Papillomavirus Vaccine. *Hum Vaccin Immunother.* 2018;14(2):412-419.
43. Naleway AL, Mittendorf KF, Irving SA, et al. Primary Ovarian Insufficiency and Adolescent Vaccination. *Pediatrics.* 2018;142(3):e20180943.
44. Lipkind HS, Vazquez-Benitez G, Nordin JD, et al. Maternal and Infant Outcomes After Human Papillomavirus Vaccination in the Periconceptional Period or During Pregnancy. *Obstet Gynecol.* 2017;130(3):599-608.
45. Kharbanda EO, Vazquez-Benitez G, Lipkind HS, et al. Risk of Spontaneous Abortion After Inadvertent Human Papillomavirus Vaccination in Pregnancy. *Obstet Gynecol.* 2018;132(1):35-44.
46. Kharbanda EO, Vazquez-Benitez G, DeSilva MB, et al. Association of Inadvertent 9-Valent Human Papillomavirus Vaccine in Pregnancy With Spontaneous Abortion and Adverse Birth Outcomes. *JAMA Netw Open.* 2021;4(4):e214340.
47. Klein NP, Abu-Elyazeed R, Povey M, et al. Immunogenicity and Safety of a Measles-Mumps-Rubella Vaccine Administered as a First Dose to Children Aged 12 to 15 Months: A Phase III, Randomized, Noninferiority, Lot-to-Lot Consistency Study. *J Pediatric Infect Dis Soc.* 2020;9(2):194-201.
48. Blatter MM, Klein NP, Shepard JS, et al. Immunogenicity and Safety of Two Tetravalent (Measles, Mumps, Rubella, Varicella) Vaccines Co-Administered with Hepatitis A and Pneumococcal Conjugate Vaccines to Children 12 14 Months of Age. *Pediatr Infect Dis J.* 2012;31(8):e133-140.
49. Leonardi M, Bromberg K, Baxter R, et al. Immunogenicity and safety of MMRV and PCV-7 administered concomitantly in healthy children. *Pediatrics.* 2011;128(6):e1387-1394.

50. Klein NP, Weston WM, Kuriyakose S, et al. An open-label, randomized, multi-center study of the immunogenicity and safety of DTaP-IPV (Kinrix) co-administered with MMR vaccine with or without varicella vaccine in healthy pre-school age children. *Vaccine*. 2012;30(3):668-674.

51. DeSilva M, Vazquez-Benitez G, Nordin JD, et al. Maternal Tdap vaccination and risk of infant morbidity. *Vaccine*. 2017;35(29):3655-3660.

52. Jackson ML, Yu O, Nelson JC, et al. Safety of repeated doses of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine in adults and adolescents. *Pharmacoepidemiol Drug Saf*. 2018;27(8):921-925.

53. Becerra-Culqui TA, Getahun D, Chiu V, et al. Prenatal Tetanus, Diphtheria, Acellular Pertussis Vaccination and Autism Spectrum Disorder. *Pediatrics*. 2018;142(3):e20180120.

54. Becerra-Culqui TA, Getahun D, Chiu V, et al. The Association of Prenatal Tetanus, Diphtheria, and Acellular Pertussis (Tdap) Vaccination With Attention-Deficit/Hyperactivity Disorder. *Am J Epidemiol*. 2020;189(10):1163-1172.

55. Weston WM, Klein NP. Kinrix: a new combination DTaP-IPV vaccine for children aged 4-6 years. *Expert Rev Vaccines*. 2008;7(9):1309-1320.

56. Black S, Friedland LR, Ensor K, et al. Diphtheria-tetanus-acellular pertussis and inactivated poliovirus vaccines given separately or combined for booster dosing at 4-6 years of age. *Pediatr Infect Dis J*. 2008;27(4):341-346.

57. Sukumaran L, McCarthy NL, Kharbanda EO, et al. Infant Hospitalizations and Mortality After Maternal Vaccination. *Pediatrics*. 2018;141(3):e20173310.

58. Jain VK, Domachowske JB, Wang L, et al. Time to Change Dosing of Inactivated Quadrivalent Influenza Vaccine in Young Children: Evidence From a Phase III, Randomized, Controlled Trial. *J Pediatric Infect Dis Soc*. 2017;6(1):9-19.

59. Baxter R, Jeanfreau R, Block SL, et al. A Phase III evaluation of immunogenicity and safety of two trivalent inactivated seasonal influenza vaccines in US children. *Pediatr Infect Dis J*. 2010;29(10):924-930.

60. Lee GM, Greene SK, Weintraub ES, et al. H1N1 and seasonal influenza vaccine safety in the vaccine safety datalink project. *Am J Prev Med*. 2011;41(2):121-128.

61. Kawai AT, Li L, Kulldorff M, et al. Absence of associations between influenza vaccines and increased risks of seizures, Guillain-Barre syndrome, encephalitis, or anaphylaxis in the 2012-2013 season. *Pharmacoepidemiol Drug Saf*. 2014;23(5):548-553.

62. Li R, Stewart B, McNeil MM, et al. Post licensure surveillance of influenza vaccines in the Vaccine Safety Datalink in the 2013-2014 and 2014-2015 seasons. *Pharmacoepidemiol Drug Saf*. 2016;25(8):928-934.

63. Baxter RP, Lewis N, Fireman B, et al. Live Attenuated Influenza Vaccination Prior To Age 3 Years and Subsequent Development of Asthma: A 14-Year Follow-Up Study. *Pediatr Infect Dis J*. 2018;37(5):383-386.

64. Kharbanda EO, Vazquez-Benitez G, Romitti PA, et al. First Trimester Influenza Vaccination and Risks for Major Structural Birth Defects in Offspring. *J Pediatr*. 2017;187:234-239.

65. Baxter R, Eaton A, Hansen J, et al. Safety of quadrivalent live attenuated influenza vaccine in subjects aged 2-49years. *Vaccine*. 2017;35(9):1254-1258.

66. Zerbo O, Modaressi S, Chan B, et al. No association between influenza vaccination during pregnancy and adverse birth outcomes. *Vaccine*. 2017;35(24):3186-3190.

67. Ray GT, Lewis N, Goddard K, et al. Asthma exacerbations among asthmatic children receiving live attenuated versus inactivated influenza vaccines. *Vaccine*. 2017;35(20):2668-2675.

68. Vickers ER, McClure DL, Naleway AL, et al. Risk of venous thromboembolism following influenza vaccination in adults aged 50years and older in the Vaccine Safety Datalink. *Vaccine*. 2017;35(43):5872-5877.

69. Daley MF, Clarke CL, Glanz JM, et al. The safety of live attenuated influenza vaccine in children and adolescents 2 through 17 years of age: A Vaccine Safety Datalink study. *Pharmacoepidemiol Drug Saf*. 2017;27(1):59-68.

70. Donahue JG, Kieke BA, King JP, et al. Inactivated influenza vaccine and spontaneous abortion in the Vaccine Safety Datalink in 2012-13, 2013-14, and 2014-15. *Vaccine*. 2019;37(44):6673-6681.

71. Getahun D, Fassett MJ, Peltier MR, et al. Association between seasonal influenza vaccination with pre- and postnatal outcomes. *Vaccine*. 2019;37(13):1785-1791.

72. Munoz FM, Jackson LA, Swamy GK, et al. Safety and immunogenicity of seasonal trivalent inactivated influenza vaccines in pregnant women. *Vaccine*. 2018;36(52):8054-8061.

73. Grupping K, Campora L, Douha M, et al. Immunogenicity and Safety of the HZ/su Adjuvanted Herpes Zoster Subunit Vaccine in Adults Previously Vaccinated with a Live-Attenuated Herpes Zoster Vaccine. *J Infect Dis*. 2017;216(11):1343-1351.

74. Larson EB, Nelson JC. In older adults, use of a recombinant zoster vaccine was associated with Guillain-Barré syndrome. *Ann Intern Med*. 2022;175(3):JC35.

75. Chatterjee A, O'Keefe C, Varman M, et al. Comparative immunogenicity and safety of different multivalent component pertussis vaccine formulations and a 5-component acellular pertussis vaccine in infants and toddlers: A randomized, controlled, open-label, multicenter study. *Vaccine*. 2012;30(23):3360-3368.

76. Trofa AF, Klein NP, Paul IM, et al. Immunogenicity and Safety of an Inactivated Hepatitis A Vaccine When Coadministered With Diphtheria-tetanus-acellular Pertussis and Haemophilus influenzae Type B Vaccines in Children 15 Months of Age. *Pediatr Infect Dis J*. 2011;30(9):e164-169.
77. Groom HC, Smith N, Irving SA, et al. Uptake and safety of hepatitis A vaccination during pregnancy: A Vaccine Safety Datalink study. *Vaccine*. 2019;37(44):6648-6655.
78. Groom HC, Irving SA, Koppolu P, et al. Uptake and safety of Hepatitis B vaccination during pregnancy: A Vaccine Safety Datalink study. *Vaccine*. 2018;36(41):6111-6116.
79. Bruxvoort K, Slezak J, Qian L, et al. Association Between 2-Dose vs 3-Dose Hepatitis B Vaccine and Acute Myocardial Infarction. *JAMA*. 2022;327(13):1260-1268.
80. Glanz JM, Newcomer SR, Daley MF, et al. 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;319(9):906-913.
81. Hansen J, Zhang L, Klein NP, et al. Post-licensure safety surveillance study of routine use of quadrivalent meningococcal diphtheria toxoid conjugate vaccine. *Vaccine*. 2017;35(49 Pt B):6879-6884.
82. Wang SV, Abdurrob A, Spoendlin J, et al. Methods for addressing "innocent bystanders" when evaluating safety of concomitant vaccines. *Pharmacoepidemiol Drug Saf*. 2018;27(4):405-412.
83. Klein NP, Abu-Elyazeed R, Cheuvart B, et al. Immunogenicity and safety following primary and booster vaccination with a hexavalent diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliovirus and Haemophilus influenzae type b vaccine: a randomized trial in the United States. *Hum Vaccin Immunother*. 2019;15(4):809-821.
84. Klein NP, Abu-Elyazeed R, Baine Y, et al. Immunogenicity and safety of the Haemophilus influenzae type b and Neisseria meningitidis serogroups C and Y-tetanus toxoid conjugate vaccine co-administered with human rotavirus, hepatitis A and 13-valent pneumococcal conjugate vaccines: results from a phase III, randomized, multicenter study in infants. *Hum Vaccin Immunother*. 2019;15(2):327-338.
85. Thompson AR, Klein NP, Downey HJ, et al. Coadministration of 13-valent pneumococcal conjugate and quadrivalent inactivated influenza vaccines in adults previously immunized with polysaccharide pneumococcal vaccine 23: a randomized clinical trial. *Hum Vaccin Immunother*. 2019;15(2):444-451.
86. Williams SE, Pahud BA, Vellozzi C, et al. Causality assessment of serious neurologic adverse events following 2009 H1N1 vaccination. *Vaccine*. 2011;29(46):8302-8308.
87. Rowhani-Rahbar A, Klein NP, Dekker CL, et al. Biologically plausible and evidence-based risk intervals in immunization safety research. *Vaccine*. 2012;31(1):271-277.
88. Baggs J, Gee J, Lewis E, et al. The Vaccine Safety Datalink: a model for monitoring immunization safety. *Pediatrics*. 2011;127(Suppl 1):S45-53.
89. Lieu TA, Kulldorff M, Davis RL, et al. Real-time vaccine safety surveillance for the early detection of adverse events. *Med Care*. 2007;45(10 Suppl 2):S89-95.
90. Yih WK, Kulldorff M, Fireman BH, et al. Active surveillance for adverse events: the experience of the Vaccine Safety Datalink project. *Pediatrics*. 2011;127(Suppl 1):S54-64.
91. Glanz JM, Newcomer SR, Hambidge SJ, et al. Safety of trivalent inactivated influenza vaccine in children aged 24 to 59 months in the vaccine safety datalink. *Arch Pediatr Adolesc Med*. 2011;165(8):749-755.
92. Tseng HF, Liu A, Sy L, et al. Safety of Zoster Vaccine in Adults from a Large Managed Care Cohort: A Vaccine Safety Datalink Study. *J Intern Med*. 2012;271(5):510-520.
93. Loughlin AM, Marchant CD, Adams W, et al. Causality assessment of adverse events reported to the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 2012;30(50):7253-7259.
94. Jackson LA, Yu O, Nelson JC, et al. Injection site and risk of medically attended local reactions to acellular pertussis vaccine. *Pediatrics*. 2011;127(3):e581-587.
95. Hesse EM, Navarro RA, Daley MF, et al. Risk for Subdeltoid Bursitis After Influenza Vaccination: A Population-Based Cohort Study. *Ann Intern Med*. 2020;173(4):253-261.
96. Duffy J, Weintraub E, Hambidge SJ, et al. Febrile Seizure Risk After Vaccination in Children 6 to 23 Months. *Pediatrics*. 2016;138(1):e20160320.
97. Duffy J, Hambidge SJ, Jackson LA, et al. Febrile Seizure Risk after Vaccination in Children One to Five Months of Age. *Pediatr Neurol*. 2017;76:72-78.
98. Klein NP, Lewis E, McDonald J, et al. Risk factors and familial clustering for fever 7-10days after the first dose of measles vaccines. *Vaccine*. 2017;35(12):1615-1621.
99. Walter EB, Klein NP, Wodi AP, et al. Fever After Influenza, Diphtheria-Tetanus-Acellular Pertussis, and Pneumococcal Vaccinations. *Pediatrics*. 2020;145(3):e20191909.
100. Tartof SY, Tseng HF, Liu IL, et al. Inpatient admission for febrile seizure and subsequent outcomes do not differ in children with vaccine-associated versus non-vaccine associated febrile seizures. *Vaccine*. 2014;32(48):6408-6414.
101. Klein NP, Fireman B, Yih WK, et al. Measles-mumps-rubella-varicella combination vaccine and the risk of febrile seizures. *Pediatrics*. 2010;126(1):e1-8.

102. Klein NP, Lewis E, Fireman B, et al. Safety of Measles-Containing Vaccines in 1-Year-Old Children. *Pediatrics*. 2015;135(2):e321-329.

103. Jacobsen SJ, Ackerson BK, Sy LS, et al. Observational safety study of febrile convulsion following first dose MMRV vaccination in a managed care setting. *Vaccine*. 2009;27(34):4656-4661.

104. Rowhani-Rahbar A, Fireman B, Lewis E, et al. Effect of Age on the Risk of Fever and Seizures Following Immunization With Measles-Containing Vaccines in Children. *JAMA Pediatr*. 2013;167(12):1111-1117.

105. Tse A, Tseng HF, Greene SK, et al. Signal identification and evaluation for risk of febrile seizures in children following trivalent inactivated influenza vaccine in the Vaccine Safety Datalink Project, 2010-2011. *Vaccine*. 2012;30(11):2024-2031.

106. Tseng HF, Sy LS, Qian L, et al. Safety of a Tetanus-Diphtheria-Acellular Pertussis Vaccine When Used Off-Label in an Elderly Population. *Clin Infect Dis*. 2013;56(3):315-321.

107. Freeman RE, Thaker J, Daley MF, et al. Vaccine timeliness and prevalence of undervaccination patterns in children ages 0-19 months, U.S., National immunization Survey-Child 2017. *Vaccine*. 2022;40(5):765-773.

108. Williams JTB, Rice JD, Lou Y, et al. Parental Vaccine Hesitancy and Vaccination Disparities in a Safety-Net System. *Pediatrics*. 2021;147(2):e2020010710.

109. Wu MJ, Chung JR, Kim SS, et al. Influenza vaccination coverage among persons seeking outpatient medical care for acute respiratory illness in five states in the United States, 2011-2012 through 2018-2019. *Vaccine*. 2021;39(12):1788-1796.

110. Pingali C, Meghani M, Razzaghi H, et al. 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;70(28):985-990.

111. Irving SA, Ball SW, Booth SM, et al. A multi-country investigation of influenza vaccine coverage in pregnant individuals, 2010-2016. *Vaccine*. 2021;39(52):7598-7605.

112. Ackerson BK, Sy LS, Glenn S, et al. Pediatric Vaccination During the COVID-19 Pandemic. *Pediatrics*. 2021;148(1):e2020047092.

113. Santoli JM, Lindley MC, DeSilva MB, et al. Effects of the COVID-19 Pandemic on Routine Pediatric Vaccine Ordering and Administration - United States, 2020. *MMWR Morb Mortal Wkly Rep*. 2020;69(19):591-593.

114. Gaythorpe KAM, Abbas K, Huber J, et al. Impact of COVID-19-related disruptions to measles, meningococcal A, and yellow fever vaccination in 10 countries. *Elife*. 2021;10:e67023.

115. Sadaf A, Richards JL, Glanz J, et al. A systematic review of interventions for reducing parental vaccine refusal and vaccine hesitancy. *Vaccine*. 2013;31(40):4293-4304.

116. Glanz JM, Wagner NM, Narwaney KJ, et al. A mixed methods study of parental vaccine decision making and parent-provider trust. *Acad Pediatr*. 2013;13(5):481-488.

117. Glanz JM, Kraus CR, Daley MF. Addressing Parental Vaccine Concerns: Engagement, Balance, and Timing. *PLoS Biol*. 2015;13(8):e1002227.

118. Opel DJ, Zhou C, Robinson JD, et al. Impact of the Childhood Vaccine Discussion Format Over Time on Immunization Status. *Acad Pediatr*. 2018;18(4):430-436.

119. Lieu TA, Zikmund-Fisher BJ, Chou C, et al. Parents' Perspectives on How to Improve the Childhood Vaccination Process. *Clin Pediatr (Phila)*. 2017;56(3):238-246.

120. Eller NM, Henrikson NB, Opel DJ. Vaccine Information Sources and Parental Trust in Their Child's Health Care Provider. *Health Educ Behav*. 2019;46(3):445-453.

121. Hofstetter AM, Opel DJ, Stockwell MS, et al. Associations between Healthcare Professional Communication Practices and Influenza Vaccination of Hospitalized Children: Influenza vaccine communication during hospitalization. *Acad Pediatr*. 2021;21(7):1142-1150.

122. Williams JT, Rice JD, Lou Y, et al. Parental Vaccine Hesitancy and Risk of Pediatric Influenza Undervaccination in a Safety-Net Healthcare System. *Acad Pediatr*. 2021;21(7):1126-1133.

123. Glanz JM, Wagner NM, Narwaney KJ, et al. Web-based Social Media Intervention to Increase Vaccine Acceptance: A Randomized Controlled Trial. *Pediatrics*. 2017;140(6):e20171117.

124. Shoup JA, Wagner NM, Kraus CR, et al. Development of an Interactive Social Media Tool for Parents With Concerns About Vaccines. *Health Educ Behav*. 2015;42(3):302-312.

125. Daley MF, Narwaney KJ, Shoup JA, et al. Addressing Parents' Vaccine Concerns: A Randomized Trial of a Social Media Intervention. *Am J Prev Med*. 2018;55(1):44-54.

126. Shoup JA, Narwaney KJ, Wagner NM, et al. Social Media Vaccine Websites: A Comparative Analysis of Public and Moderated Websites. *Health Educ Behav*. 2019;46(3):454-462.

127. Ponce-Gonzalez IM, Perez K, Cheadle AD, et al. A Multicomponent Health Education Campaign Led by Community Health Workers to Increase Influenza Vaccination among Migrants and Refugees. *J Prim Care Community Health*. 2021;12:21501327211055627.

128. Dempsey A, Kwan BM, Wagner NM, et al. A Values-Tailored Web-Based Intervention for New Mothers to Increase Infant Vaccine Uptake: Development and Qualitative Study. *J Med Internet Res*. 2020;22(3):e15800.

129. Daley MF, Glanz JM. Using Social Media to Increase Vaccine Acceptance. *Acad Pediatr.* 2021;21(4S):S32-S33.

130. Wagner NM, Dempsey AF, Narwaney KJ, et al. Addressing logistical barriers to childhood vaccination using an automated reminder system and online resource intervention: A randomized controlled trial. *Vaccine.* 2021;39(29):3983-3990.

131. Daley MF, Curtis CR, Pyrzanowski J, et al. Adolescent immunization delivery in school-based health centers: a national survey. *J Adolesc Health.* 2009;45(5):445-452.

132. Gold R, Naleway AL, Jenkins LL, et al. Completion and timing of the three-dose human papillomavirus vaccine series among adolescents attending school-based health centers in Oregon. *Prev Med.* 2011;52(6):456-458.

133. Kjos SA, Irving SA, Meece JK, Belongia EA. Elementary school-based influenza vaccination: evaluating impact on respiratory illness absenteeism and laboratory-confirmed influenza. *PLoS ONE.* 2013;8(8):e72243.

134. Kempe A, Allison MA, Daley MF. Can School-Located Vaccination Have a Major Impact on Human Papillomavirus Vaccination Rates in the United States? *Acad Pediatr.* 2018;18(2S):S101-S105.

135. Benjamin-Chung J, Arnold BF, Mishra K, et al. City-wide school-located influenza vaccination: A retrospective cohort study. *Vaccine.* 2021;39(42):6302-6307.

136. Kepka D, Coronado GD, Rodriguez HP, Thompson B. Evaluation of a Radionovela to Promote HPV Vaccine Awareness and Knowledge Among Hispanic Parents. *J Community Health.* 2011;36(6):957-965.

137. Schoeppe J, Cheadle A, Melton M, et al. The Immunity Community: A Community Engagement Strategy for Reducing Vaccine Hesitancy. *Health Promot Pract.* 2017;18(5):654-661.

138. Kuntz JL, Holley S, Helms CM, et al. Use of a pandemic preparedness drill to increase rates of influenza vaccination among healthcare workers. *Infect Control Hosp Epidemiol.* 2008;29(2):111-115.

139. Naleway AL, Henkle EM, Ball S, et al. Barriers and facilitators to influenza vaccination and vaccine coverage in a cohort of health care personnel. *Am J Infect Control.* 2014;42(4):371-375.

140. Tom JO, Chen C, Zhou YY. Personal Health Record Use and Association with Immunizations and Well-Child Care Visits Recommendations. *J Pediatr.* 2014;164(1):112-117.

141. Henrikson NB, Zhu W, Baba L, et al. Outreach and Reminders to Improve Human Papillomavirus Vaccination in an Integrated Primary Care System. *Clin Pediatr (Phila).* 2018;57(13):1523-1531.

142. Kepka D, Christini K, McGough E, et al. Successful Multi-Level HPV Vaccination Intervention at a Rural Healthcare Center in the Era of COVID-19. *Front Digit Health.* 2021;3:719138.

143. Janssen RS, Bruxvoort K, Jacobsen SJ, et al. Considerations for estimating real-world outcomes and value in vaccination: A case study with adult hepatitis B virus vaccination. *Vaccine.* 2021;39(39):5666-5672.

144. Kamineni A, Blasi PR, Gundersen GD, et al. Barriers to Human Papillomavirus Vaccine Series Completion among Insured Individuals in an Integrated Healthcare Setting. *Infect Dis (Auckl).* 2021;14:11786337211018712.

145. Baxter R, Tran TN, Ray P, et al. Impact of Vaccination on the Epidemiology of Varicella: 1995-2009. *Pediatrics.* 2014;134(1):24-30.

146. Markowitz LE, Naleway AL, Lewis RM, et al. Declines in HPV vaccine type prevalence in women screened for cervical cancer in the United States: Evidence of direct and herd effects of vaccination. *Vaccine.* 2019;37(29):3918-3924.

147. Baxter R, Aukes L, Pelton SI, et al. Impact of the 13-Valent Pneumococcal Conjugate Vaccine on Invasive Pneumococcal Disease After Introduction Into Routine Pediatric Use. *J Pediatric Infect Dis Soc.* 2021;10(2):141-150.

148. Nichol KL, Nordin JD, Nelson DB, et al. Effectiveness of influenza vaccine in the community-dwelling elderly. *N Engl J Med.* 2007;357(14):1373-1381.

149. Tseng HF, Chi M, Smith N, et al. Herpes zoster vaccine and the incidence of recurrent herpes zoster in an immunocompetent elderly population. *J Infect Dis.* 2012;206(2):190-196.

150. Russell K, Chung JR, Monto AS, et al. Influenza vaccine effectiveness in older adults compared with younger adults over five seasons. *Vaccine.* 2018;36(10):1272-1278.

151. Jackson LA, El Sahly HM, George S, et al. Randomized clinical trial of a single versus a double dose of 13-valent pneumococcal conjugate vaccine in adults 55 through 74 years of age previously vaccinated with 23-valent pneumococcal polysaccharide vaccine. *Vaccine.* 2018;36(5):606-614.

152. Hsiao A, Hansen J, Timbol J, et al. Incidence and Estimated Vaccine Effectiveness Against Hospitalizations for All-Cause Pneumonia Among Older US Adults Who Were Vaccinated and Not Vaccinated With 13-Valent Pneumococcal Conjugate Vaccine. *JAMA Netw Open.* 2022;5(3):e221111.

153. Lewnard JA, Bruxvoort KJ, Fischer H, et al. Effectiveness of 13-valent pneumococcal conjugate vaccine against medically-attended lower respiratory tract infection and pneumonia among older adults. *Clin Infect Dis.* 2021;ciab1051.

154. Ackerson B, Qian L, Sy LS, et al. Completion of the two-dose recombinant zoster vaccine series in adults 50 years and older. *Vaccine.* 2021;39(6):926-932.

155. Sun Y, Jackson K, Dalmon CA, et al. Effectiveness of the recombinant zoster vaccine among Kaiser Permanente Hawaii enrollees aged 50 and older: A retrospective cohort study. *Vaccine.* 2021;39(29):3974-3982.

156. Shui IM, Baggs J, Patel M, et al. Risk of intussusception following administration of a pentavalent rotavirus vaccine in US infants. *JAMA*. 2012;307(6):598-604.

157. Yih WK, Lieu TA, Kulldorff M, et al. Intussusception Risk after Rotavirus Vaccination in U.S. Infants. *N Engl J Med*. 2014;370(6):503-512.

158. Eaton A, Lewis N, Fireman B, et al. Birth outcomes following immunization of pregnant women with pandemic H1N1 influenza vaccine 2009-2010. *Vaccine*. 2018;36(19):2733-2739.

159. Block SL, Klein NP, Sarpong K, et al. Lot-to-Lot Consistency, Safety, Tolerability, and Immunogenicity of an Investigational Hexavalent Vaccine in US Infants. *Pediatr Infect Dis J*. 2017;36(2):202-208.

160. Klein NP, Abu-Elyazeed R, Cornish M, et al. Lot-to-lot consistency, safety and immunogenicity of 3 lots of Haemophilus influenzae type b conjugate vaccine: results from a phase III randomized, multicenter study in infants. *Vaccine*. 2017;35(28):3564-3574.

161. Avalos LA, Ferber J, Zerbo O, et al. Trivalent inactivated influenza vaccine (IIV3) during pregnancy and six-month infant development. *Vaccine*. 2020;38(10):2326-2332.

162. Platt HL, Greenberg D, Tapiero B, et al. A Phase II Trial of Safety, Tolerability and Immunogenicity of V114, a 15-Valent Pneumococcal Conjugate Vaccine, Compared With 13-Valent Pneumococcal Conjugate Vaccine in Healthy Infants. *Pediatr Infect Dis J*. 2020;39(8):763-770.

163. Tseng HF, Tartof S, Harpaz R, et al. Vaccination Against Zoster Remains Effective in Older Adults Who Later Undergo Chemotherapy. *Clin Infect Dis*. 2014;59(7):913-919.

164. Henkle E, Lu M, Rupp LB, et al. Hepatitis A and B Immunity and Vaccination in Chronic Hepatitis B and C Patients in a Large United States Cohort. *Clin Infect Dis*. 2015;60(4):514-522.

165. Shang M, Chung JR, Jackson ML, et al. Influenza vaccine effectiveness among patients with high-risk medical conditions in the United States, 2012-2016. *Vaccine*. 2018;36(52):8047-8053.

166. Lewnard JA, Bruxvoort KJ, Fischer H, et al. Prevention of Coronavirus Disease 2019 Among Older Adults Receiving Pneumococcal Conjugate Vaccine Suggests Interactions Between Streptococcus pneumoniae and Severe Acute Respiratory Syndrome Coronavirus 2 in the Respiratory Tract. *J Infect Dis*. 2022;225(10):1710-1720.

167. Bruxvoort KJ, Ackerson B, Sy LS, et al. Recombinant Adjuvanted Zoster Vaccine and Reduced Risk of Coronavirus Disease 2019 Diagnosis and Hospitalization in Older Adults. *J Infect Dis*. 2022;225(11):1915-1922.

168. Bateman AC, Kieke BA, Irving SA, et al. Effectiveness of monovalent 2009 pandemic influenza A virus subtype H1N1 and 2010-2011 trivalent inactivated influenza vaccines in Wisconsin during the 2010-2011 influenza season. *J Infect Dis*. 2013;207(8):1262-1269.

169. Ferdinands JM, Fry AM, Reynolds S, et al. Intraseason waning of influenza vaccine protection: Evidence from the US Influenza Vaccine Effectiveness Network, 2011-12 through 2014-15. *Clin Infect Dis*. 2017;64(5):544-550.

170. Ray GT, Lewis N, Klein NP, et al. Intra-season Waning of Influenza Vaccine Effectiveness. *Clin Infect Dis*. 2019;68(10):1623-1630.

171. Poehling KA, Caspard H, Peters TR, et al. 2015-2016 Vaccine Effectiveness of Live Attenuated and Inactivated Influenza Vaccines in Children in the United States. *Clin Infect Dis*. 2018;66(5):665-672.

172. Klein NP, Fireman B, Goddard K, et al. Vaccine effectiveness of cell-culture relative to egg-based inactivated influenza vaccine during the 2017-18 influenza season. *PLoS ONE*. 2020;15(2):e0229279.

173. Dawood FS, Naleway AL, Flannery B, et al. Comparison of the Immunogenicity of Cell Culture-Based and Recombinant Quadrivalent Influenza Vaccines to Conventional Egg-Based Quadrivalent Influenza Vaccines among Healthcare Personnel Aged 18-64 Years: A Randomized Open-Label Trial. *Clin Infect Dis*. 2021;73(11):1973-1981.

174. Cochran LW, Black S, Klein NP, et al. Vaccine effectiveness against laboratory-confirmed influenza in infants: A matched case control study. *Hum Vaccin*. 2010;6(9):729-735.

175. Flannery B, Smith C, Garten RJ, et al. Influence of Birth Cohort on Effectiveness of 2015-2016 Influenza Vaccine Against Medically Attended Illness Due to 2009 Pandemic Influenza A(H1N1) Virus in the United States. *J Infect Dis*. 2018;218(2):189-196.

176. Witt MA, Katz PH, Witt DJ. Unexpectedly Limited Durability of Immunity Following Acellular Pertussis Vaccination in Pre-Adolescents in a North American Outbreak. *Clin Infect Dis*. 2012;54(12):1730-1735.

177. Tartof SY, Lewis M, Kenyon C, et al. Waning immunity to pertussis following 5 doses of DTaP. *Pediatrics*. 2013;131(4):e1047-1052.

178. Klein NP, Bartlett J, Fireman B, Baxter R. Waning Tdap Effectiveness in Adolescents. *Pediatrics*. 2016;137(3):e20153326.

179. Klein NP, Bartlett J, Fireman B, et al. Waning protection following 5 doses of a 3-component diphtheria, tetanus, and acellular pertussis vaccine. *Vaccine*. 2017;35(26):3395-3400.

180. Briere EC, Pondo T, Schmidt M, et al. Assessment of Tdap Vaccination Effectiveness in Adolescents in Integrated Health-Care Systems. *J Adolesc Health*. 2018;62(6):661-666.

181. Klein NP, Bartlett J, Rowhani-Rahbar A, et al. Waning protection after fifth dose of acellular pertussis vaccine in children. *N Engl J Med*. 2012;367(11):1012-1019.

182. Tseng HF, Harpaz R, Luo Y, et al. Declining effectiveness of herpes zoster vaccine in adults 60 years and older. *J Infect Dis*. 2016;213(12):1872-1875.

183. Baxter R, Bartlett J, Fireman B, et al. Long-Term Effectiveness of the Live Zoster Vaccine in Preventing Shingles: A Cohort Study. *Am J Epidemiol*. 2018;187(1):161-169.

184. Toor J, Echeverria-Londono S, Li X, et al. Lives saved with vaccination for 10 pathogens across 112 countries in a pre-COVID-19 world. *Elife*. 2021;10:e67635.

185. Li X, Mukandavire C, Cucunubá ZM, et al. Estimating the health impact of vaccination against ten pathogens in 98 low-income and middle-income countries from 2000 to 2030: a modelling study. *Lancet*. 2021;397(10272):398-408.

186. Baxter R, Bartlett J, Fireman B, et al. Effectiveness of Vaccination During Pregnancy to Prevent Infant Pertussis. *Pediatrics*. 2017;139(5):e20164091.

187. Henkle E, Steinhoff MC, Omer SB, et al. The Effect of Exclusive Breastfeeding on Respiratory Illness in Young Infants in a Maternal Immunization Trial in Bangladesh. *Pediatr Infect Dis J*. 2013;32(5):431-435.

188. Coonrod DV, Jack BW, Boggess KA, et al. The clinical content of preconception care: immunizations as part of preconception care. *Am J Obstet Gynecol*. 2008;199(6 Suppl 2):S290-295.

189. Baxter R, Ray GT, Fireman BH. Effect of influenza vaccination on hospitalizations in persons aged 50 years and older. *Vaccine*. 2010;28(45):7267-7272.

190. Fireman B, Lee J, Lewis N, et al. Influenza vaccination and mortality: differentiating vaccine effects from bias. *Am J Epidemiol*. 2009;170(5):650-656.

191. Nelson JC, Jackson ML, Jackson LA. Effectiveness of influenza vaccination. *N Engl J Med*. 2007;357(26):2728-2729.

192. Thompson MG, Kwong JC, Regan AK, et al. Influenza Vaccine Effectiveness in Preventing Influenza-associated Hospitalizations During Pregnancy: A Multi-country Retrospective Test Negative Design Study, 2010-2016. *Clin Infect Dis*. 2019;68(9):1444-1453.

193. Jackson ML, Phillips CH, Benoit J, et al. Burden of medically attended influenza infection and cases averted by vaccination - United States, 2013/14 through 2015/16 influenza seasons. *Vaccine*. 2018;36(4):467-472.

194. Henrikson NB, Anderson ML, Opel DJ, et al. Longitudinal Trends in Vaccine Hesitancy in a Cohort of Mothers Surveyed in Washington State, 2013-2015. *Public Health Rep*. 2017;132(4):451-454.

195. Widdice LE, Hoagland R, Callahan ST, et al. Caregiver and adolescent factors associated with delayed completion of the three-dose human papillomavirus vaccination series. *Vaccine*. 2018;36(11):1491-1499.

196. McCarthy NL, Gee J, Weintraub E, et al. Monitoring vaccine safety using the Vaccine Safety Datalink: utilizing immunization registries for pandemic influenza. *Vaccine*. 2011;29(31):4891-4896.

197. Chao C, Silverberg MJ, Becerra TA, et al. Human papillomavirus vaccination and subsequent cervical cancer screening in a large integrated healthcare system. *Am J Obstet Gynecol*. 2017;216(2-151):e1-e9.

198. Hechter RC, Qian L, Luo Y, et al. Impact of an electronic medical record reminder on hepatitis B vaccine initiation and completion rates among insured adults with diabetes mellitus. *Vaccine*. 2019;37(1):195-201.

199. Bruxvoort K, Sy LS, Luo Y, Tseng HF. Real World Evidence for Regulatory Decisions: Concomitant Administration of Zoster Vaccine Live and Pneumococcal Polysaccharide Vaccine. *Am J Epidemiol*. 2018;187(9):1856-1862.

200. Groom HC, Irving SA, Caldwell J, et al. Implementing a Multipartner HPV Vaccination Assessment and Feedback Intervention in an Integrated Health System. *J Public Health Manag Pract*. 2017;23(6):589-592.

201. Grohskopf LA, Sokolow LZ, Broder KR, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices - United States, 2017-18 Influenza Season. *MMWR Recomm Rep*. 2017;66(2):1-20.

202. Markowitz LE, Dunne EF, Saraiya M, et al. Human papillomavirus vaccination: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2014;63(Rr-05):1-30.

203. Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines. *MMWR Morb Mortal Wkly Rep*. 2018;67(3):103-108.

204. Liang JL, Tiwari T, Moro P, et al. 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;67(2):1-44.

205. Marin M, Broder KR, Temte JL, et al. Use of combination measles, mumps, rubella, and varicella vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2010;59(Rr-3):1-12.

206. Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines - United States, 2021. *MMWR Morb Mortal Wkly Rep*. 2021;70(44):1545-1552.

207. Oliver SE, Wallace M, See I, et al. Use of the 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;71(3):90-95.

208. Woodworth KR, Moulia D, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5-11 Years - United States, November 2021. *MMWR Morb Mortal Wkly Rep*. 2021;70(45):1579-1583.

209. Dooling K, Gargano JW, Moulia D, et al. Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged ≥16 Years: Recommendations of the Advisory Committee on Immunization Practices - United States, September 2021. *MMWR Morb Mortal Wkly Rep*. 2021;70(38):1344-1348.

210. MacNeil JR, Su JR, Broder KR, et al. Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the 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;70(17):651-656.

211. Curtis JR, Johnson SR, Anthony DD, et al. American College of Rheumatology Guidance for COVID-19 Vaccination in Patients with Rheumatic and Musculoskeletal Diseases - Version 1. *Arthritis Rheumatol.* 2021;73(7):1093-1107.

212. Curtis JR, Johnson SR, Anthony DD, et al. American College of Rheumatology Guidance for COVID-19 Vaccination in Patients With Rheumatic and Musculoskeletal Diseases: Version 3. *Arthritis Rheumatol.* 2021;73(10):e60-e75.

213. Curtis JR, Johnson SR, Anthony DD, et al. American College of Rheumatology Guidance for COVID-19 Vaccination in Patients With Rheumatic and Musculoskeletal Diseases: Version 2. *Arthritis Rheumatol.* 2021;73(8):e30-e45.

214. Centers for Disease Control and Prevention. Vaccine Safety Datalink (VSD). 2018; https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/. Accessed July 6, 2018.

215. Hambidge SJ, Ross C, Shoup JA, et al. Integration of data from a safety net health care system into the Vaccine Safety Datalink. *Vaccine.* 2017;35(9):1329-1334.

216. Groom HC, Crane B, Naleway AL, et al. Monitoring vaccine safety using the vaccine safety Datalink: Assessing capacity to integrate data from Immunization Information systems. *Vaccine.* 2022;40(5):752-756.

217. Irving SA, Groom HC, Dandamudi P, et al. A decade of data: Adolescent vaccination in the vaccine safety datalink, 2007 through 2016. *Vaccine.* 2022;40(9):1246-1252.

218. McNeil MM, Gee J, Weintraub ES, et al. The Vaccine Safety Datalink: successes and challenges monitoring vaccine safety. *Vaccine.* 2014;32(42):5390-5398.

219. Li R, Weintraub E, McNeil MM, et al. Meningococcal conjugate vaccine safety surveillance in the Vaccine Safety Datalink using a tree-temporal scan data mining method. *Pharmacoepidemiol Drug Saf.* 2018;27(4):391-397.

220. Kharbanda EO, Vazquez-Benitez G, Romitti PA, et al. Identifying birth defects in automated data sources in the Vaccine Safety Datalink. *Pharmacoepidemiol Drug Saf.* 2017;26(4):412-420.

221. Donahue JG, Kieke BA, Lewis EM, et al. Near Real-Time Surveillance to Assess the Safety of the 9-Valent Human Papillomavirus Vaccine. *Pediatrics.* 2019;144(6):e20191808.

222. Naleway AL, Crane B, Irving SA, et al. Vaccine Safety Datalink infrastructure enhancements for evaluating the safety of maternal vaccination. *Ther Adv Drug Saf.* 2021;12:20420986211021233.

223. Centers for Disease Control and Prevention. Seasonal Influenza Vaccine Effectiveness, 2005-2018. 2018; https://www.cdc.gov/flu/professionals/vaccination/effectiveness-studies.htm. Accessed July 6, 2018.

224. Doyle JD, Chung JR, Kim SS, et al. Interim Estimates of 2018-19 Seasonal Influenza Vaccine Effectiveness - United States, February 2019. *MMWR Morb Mortal Wkly Rep.* 2019;68(6):135-139.

225. Flannery B, Chung JR, Monto AS, et al. Influenza Vaccine Effectiveness in the United States during the 2016-2017 Season. *Clin Infect Dis.* 2019;68(11):1798-1806.

226. Rolfes MA, Flannery B, Chung J, et al. Effects of Influenza Vaccination in the United States during the 2017-2018 Influenza Season. *Clin Infect Dis.* 2019;69(11):1845-1853.

227. Dawood FS, Chung JR, Kim SS, et al. Interim Estimates of 2019-20 Seasonal Influenza Vaccine Effectiveness - United States, February 2020. *MMWR Morb Mortal Wkly Rep.* 2020;69(7):177-182.

228. Flannery B, Kondor RJG, Chung JR, et al. Spread of antigenically drifted influenza A(H3N2) viruses and vaccine effectiveness in the United States during the 2018-2019 season. *J Infect Dis.* 2020;221(1):8-15.

229. Chung JR, Flannery B, Gaglani M, et al. Patterns of Influenza Vaccination and Vaccine Effectiveness Among Young US Children Who Receive Outpatient Care for Acute Respiratory Tract Illness. *JAMA Pediatr.* 2020;174(7):705-713.

230. Gaglani M, Vasudevan A, Raiyani C, et al. Effectiveness of Trivalent and Quadrivalent Inactivated Vaccines against Influenza B in the United States, 2011-2012 to 2016-2017. *Clin Infect Dis.* 2021;72(7):1147-1157.

231. Balasubramani GK, Nowalk MP, Sax TM, et al. Influenza vaccine effectiveness among outpatients in the US Influenza Vaccine Effectiveness Network by study site 2011-2016. *Influenza Other Respir Viruses.* 2020;14(4):380-390.

232. Balasubramani GK, Choi WS, Nowalk MP, et al. Relative effectiveness of high dose versus standard dose influenza vaccines in older adult outpatients over four seasons, 2015-16 to 2018-19. *Vaccine.* 2020;38(42):6562-6569.

233. Tenforde MW, Chung J, Smith ER, et al. Influenza vaccine effectiveness in inpatient and outpatient settings in the United States, 2015 - 2018. *Clin Infect Dis.* 2021;73(3):386-392.

234. Tenforde MW, Kondor RJG, Chung JR, et al. Effect of antigenic drift on influenza vaccine effectiveness in the United States - 2019-2020. *Clin Infect Dis.* 2021;73(11):e4244-e4250.

235. Kim SS, Flannery B, Foppa IM, et al. Effects of prior season vaccination on current season vaccine effectiveness in the US Flu VE Network, 2012-13 through 2017-18. *Clin Infect Dis.* 2021;73(3):497-505.

236. Chung JR, Kim SS, Kondor RJ, et al. Interim Estimates of 2021-22 Seasonal Influenza Vaccine Effectiveness - United States, February 2022. *MMWR Morb Mortal Wkly Rep.* 2022;71(10):365-370.

237. National Institute of Allergy and Infectious Diseases. Vaccine and Treatment Evaluation Units (VTEUs). 2017; https://www.niaid.nih.gov/research/vaccine-treatment-evaluation-units. Accessed July 6, 2018.

238. Munoz FM, Patel SM, Jackson LA, et al. Safety and immunogenicity of three seasonal inactivated influenza vaccines among pregnant women and antibody persistence in their infants. *Vaccine.* 2020;38(33):5355-5363.

239. Damron FH, Barbier M, Dubey P, et al. Overcoming Waning Immunity in Pertussis Vaccines: Workshop of the National Institute of Allergy and Infectious Diseases. *J Immunol.* 2020;205(4):877-882.

240. Vogel TP, Top KA, Karatzios C, et al. Multisystem inflammatory syndrome in children and adults (MIS-C/A): Case definition & guidelines for data collection, analysis, and presentation of immunization safety data. *Vaccine.* 2021;39(22):3037-3049.

241. Patel MM, Jackson ML, Ferdinands J. Postlicensure Evaluation of COVID-19 Vaccines. *JAMA.* 2020;324(19):1939-1940.

242. Jackson LA, Anderson EJ, Rouphael NG, et al. An mRNA Vaccine against SARS-CoV-2 - Preliminary Report. *N Engl J Med.* 2020;383(20):1920-1931.

243. Anderson EJ, Rouphael NG, Widge AT, et al. Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults. *N Engl J Med.* 2020;383(25):2427-2438.

244. Kaiser Permanente joins late-stage COVID-19 vaccine study [press release]. August, 12, 2020 2020.

245. El Sahly HM, Baden LR, Essink B, et al. Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase. *N Engl J Med.* 2021;385(19):1774-1785.

246. Frenck RW, Klein NP, Kitchin N, et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. *N Engl J Med.* 2021;385(3):239-250.

247. Thompson MG, Burgess JL, Naleway AL, et al. Prevention and Attenuation of Covid-19 with the BNT162b2 and mRNA-1273 Vaccines. *N Engl J Med.* 2021;385(4):320-329.

248. Thompson MG, Burgess JL, Naleway AL, et al. Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers - Eight U.S. Locations, December 2020-March 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(13):495-500.

249. Thompson MG, Stenehjem E, Grannis S, et al. Effectiveness of Covid-19 Vaccines in Ambulatory and Inpatient Care Settings. *N Engl J Med.* 2021;385(15):1355-1371.

250. Naleway AL, Grant L, Caban-Martinez AJ, et al. Incidence of SARS-CoV-2 infection among COVID-19 vaccinated and unvaccinated healthcare personnel, first responders, and other essential and frontline workers: Eight US locations, January-September 2021. *Influenza Other Respir Viruses.* 2022;16(3):585-593.

251. Chung JR, Kim SS, Belongia EA, et al. Vaccine effectiveness against COVID-19 among symptomatic persons aged ≥12 years with reported contact with COVID-19 cases, February-September 2021. *Influenza Other Respir Viruses.* 2022.

252. Tyner HL, Burgess JL, Grant L, et al. Neutralizing Antibody Response to Pseudotype SARS-CoV-2 Differs between mRNA-1273 and BNT162b2 COVID-19 Vaccines and by History of SARS-CoV-2 Infection. *Clin Infect Dis.* 2021;ciab1038.

253. Tartof SY, Slezak JM, Fischer H, et al. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. *Lancet.* 2021;398(10309):1407-1416.

254. Naleway AL, Groom HC, Crawford PM, et al. Incidence of SARS-CoV-2 Infection, Emergency Department Visits, and Hospitalizations Because of COVID-19 Among Persons Aged ≥12 Years, by COVID-19 Vaccination Status - Oregon and Washington, July 4-September 25, 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(46):1608-1612.

255. Bruxvoort KJ, Sy LS, Qian L, et al. Effectiveness of mRNA-1273 against delta, mu, and other emerging variants of SARS-CoV-2: test negative case-control study. *BMJ.* 2021;375:e068848.

256. Bruxvoort KJ, Sy LS, Qian L, et al. Real-world effectiveness of the mRNA-1273 vaccine against COVID-19: Interim results from a prospective observational cohort study. *Lancet Reg Health Am.* 2022;6:100134.

257. Bozio CH, Grannis SJ, Naleway AL, et al. Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19-Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity - Nine States, January-September 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(44):1539-1544.

258. Embi PJ, Levy ME, Naleway AL, et al. Effectiveness of 2-Dose Vaccination with mRNA COVID-19 Vaccines Against COVID-19-Associated Hospitalizations Among Immunocompromised Adults - Nine States, January-September 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(44):1553-1559.

259. Grannis SJ, Rowley EA, Ong TC, et al. Interim Estimates of COVID-19 Vaccine Effectiveness Against COVID-19-Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS-CoV-2 B.1.617.2 (Delta) Variant Predominance - Nine States, June-August 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(37):1291-1293.

260. Moreira ED, Kitchin N, Xu X, et al. Safety and Efficacy of a Third Dose of BNT162b2 Covid-19 Vaccine. *N Engl J Med*. 2022;386(20):1910-1921.

261. Atmar RL, Lyke KE, Deming ME, et al. Homologous and Heterologous Covid-19 Booster Vaccinations. *N Engl J Med*. 2022;386(11):1046-1057.

262. Tartof SY, Slezak JM, Puzniak L, et al. Effectiveness of a third dose of BNT162b2 mRNA COVID-19 vaccine in a large US health system: A retrospective cohort study. *Lancet Reg Health Am*. 2022;9:100198.

263. Thompson MG, Natarajan K, Irving SA, et al. Effectiveness of a Third Dose of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance - VISION Network, 10 States, August 2021-January 2022. *MMWR Morb Mortal Wkly Rep*. 2022;71(4):139-145.

264. Natarajan K, Prasad N, Dascomb K, et al. Effectiveness of Homologous and Heterologous COVID-19 Booster Doses Following 1 Ad.26.COV2.S (Janssen [Johnson & Johnson]) Vaccine Dose Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults - VISION Network, 10 States, December 2021-March 2022. *MMWR Morb Mortal Wkly Rep*. 2022;71(13):495-502.

265. Pegu A, O'Connell S, Schmidt SD, et al. Durability of mRNA-1273 vaccine-induced antibodies against SARS-CoV-2 variants. *Science*. 2021;373(6561):1372-1377.

266. Taylor SC, Hurst B, Martiszus I, et al. Semi-quantitative, high throughput analysis of SARS-CoV-2 neutralizing antibodies: Measuring the level and duration of immune response antibodies post infection/vaccination. *Vaccine*. 2021;39(39):5688-5698.

267. Ferdinands JM, Rao S, Dixon BE, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance - VISION Network, 10 States, August 2021-January 2022. *MMWR Morb Mortal Wkly Rep*. 2022;71(7):255-263.

268. Gargano JW, Wallace M, Hadler SC, et al. 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;70(27):977-982.

269. Simone A, Herald J, Chen A, et al. Acute Myocarditis Following COVID-19 mRNA Vaccination in Adults Aged 18 Years or Older. *JAMA Intern Med*. 2021;181(12):1668-1670.

270. Lipkind HS, Vazquez-Benitez G, DeSilva M, et al. Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth - Eight Integrated Health Care Organizations, United States, December 15, 2020-July 22, 2021. *MMWR Morb Mortal Wkly Rep*. 2022;71(1):26-30.

271. Kharbanda EO, Haapala J, DeSilva M, et al. Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy. *JAMA*. 2021;326(16):1629-1631.

272. Macy E, Pandya S, Sheikh J, et al. Population-based incidence, severity, and risk factors associated with treated acute-onset COVID-19 mRNA vaccination-associated hypersensitivity reactions. *J Allergy Clin Immunol Pract*. 2022;10(3):827-836.

273. Salzman MB, Huang CW, O'Brien CM, Castillo RD. Multisystem Inflammatory Syndrome after SARS-CoV-2 Infection and COVID-19 Vaccination. *Emerg Infect Dis*. 2021;27(7):1944-1948.

274. Yousaf AR, Cortese MM, Taylor AW, et al. Reported cases of multisystem inflammatory syndrome in children aged 12-20 years in the USA who received a COVID-19 vaccine, December, 2020, through August, 2021: a surveillance investigation. *Lancet Child Adolesc Health*. 2022;6(5):303-312.

275. Greenhawt M, Abrams EM, Shaker M, et al. The Risk of Allergic Reaction to SARS-CoV-2 Vaccines and Recommended Evaluation and Management: A Systematic Review, Meta-analysis, GRADE Assessment, and International Consensus Approach. *J Allergy Clin Immunol Pract*. 2021;9(10):3546-3567.

276. Xu S, Huang R, Sy LS, et al. 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*. 2021;70(43):1520-1524.

277. Klein NP, Lewis N, Goddard K, et al. Surveillance for Adverse Events After COVID-19 mRNA Vaccination. *JAMA*. 2021;326(14):1390-1399.

278. Rosenblum HG, Hadler SC, Moulia D, et al. 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;70(32):1094-1099.

279. Donin G, Erfányuková A, Ivlev I. Factors Affecting Young Adults' Decision Making to Undergo COVID-19 Vaccination: A Patient Preference Study. *Vaccines (Basel)*. 2022;10(2):265.

280. Razzaghi H, Meghani M, Pingali C, et al. 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;70(24):895-899.

281. Choi K, Becerra-Culqui T, Bhakta B, et al. Parent intentions to vaccinate children with autism spectrum disorder against COVID-19. *J Pediatr Nurs*. 2022;63:108-110.

282. Lutrick K, Groom H, Fowlkes AL, et al. COVID-19 vaccine perceptions and uptake in a national prospective cohort of essential workers. *Vaccine*. 2022;40(3):494-502.

283. Choi K, Chang J, Luo YX, et al. "Still on the Fence:" A Mixed Methods Investigation of COVID-19 Vaccine Confidence Among Health Care Providers. *Workplace Health Saf*. 2022;70(6):285-297.

284. Choi K, Rondinelli J, Cuenca E, et al. Race/Ethnicity Differences in COVID-19 Vaccine Uptake Among Nurses. *J Transcult Nurs*. 2022;33(2):134-140.

285. Cuellar NG, Cuellar MJ, McDiarmid A, et al. Social Determinants of Health and COVID-19 Behaviors and Beliefs Toward Immunizations Among Latinxs. *Hisp Health Care Int*. 2021;19(4):221-229.

286. Rogers JH, Cox SN, Hughes JP, et al. Trends in COVID-19 vaccination intent and factors associated with deliberation and reluctance among adult homeless shelter residents and staff, 1 November 2020 to 28 February 2021 - King County, Washington. *Vaccine*. 2022;40(1):122-132.