Centers for Disease Control and Prevention Immunization Safety Office Update

Advisory Commission on Childhood Vaccines (ACCV)
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Disclaimer

- The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of CDC

- The use of any product trade names is for identification purposes only

Recent Publications

Recent Publication: Advisory Committee on Immunization Practices

- Havers FP et al. ***Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccines – Updated Recommendations of the Advisory Committee on Immunization Practices, United States, 2019*** MMWR Morb Mortal Wkly Rep 2020;69:77–83.
- Summary: 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.

  - Available at https://www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm

Recent Publication: Vaccine Adverse Event Reporting System (VAERS)

- Haber P et al. ***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
  - Summary: Since 2011, the Advisory Committee on Immunization Practices (ACIP) has recommended tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) vaccination for adults ≥ 65 years of age. 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 - 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.

  - Available at https://www.ncbi.nlm.nih.gov/pubmed/31883809

Recent Publication: Vaccine Adverse Event Reporting System(VAERS)

- Su JR et al. ***Erythema multiforme, Stevens Johnson syndrome, and toxic epidermal necrolysis reported after vaccination, 1999–2017.*** *Vaccine*. 2019 Dec 20. pii: S0264-410X(19)31670-6.
  - Summary: Erythema multiforme (EM), Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and SJS/TEN after vaccination 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.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/31883809

Recent Publication: Vaccine Adverse Event Reporting System(VAERS)

- Hibbs et al. ***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.
  - Summary - 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 - 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.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/31784231

Recent Publication: Vaccine Injury Compensation Program (VICP)

- Hesse et al. ***Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner claims to the National Vaccine Injury Compensation Program, 2010-2016.*** Vaccine. 2020 Jan 29;38(5):1076-1083.
  - Summary: Since 2010, petitioner claims of shoulder injury related to vaccine administration (SIRVA) to the National Vaccine Injury Compensation Program (VICP) have been increasing. The authors reviewed alleged medical reports and VICP clinician reviewer diagnosis of SIRVA and SIRVA-like injuries in the VICP's Injury Compensation System database. 476 petitioner claims recommended for concession were identified. Claims per year increased from two in 2011 to 227 in 2016. Most claims (83%) were women, the median age was 51 years and 84% involved influenza vaccine. A suspected administration error ('injection too high') was reported in 36% of cases. Common initial diagnoses were shoulder pain, rotator cuff problems, and bursitis. Most (80.0%) cases received physical or occupational therapy, 60.1% had at least one steroid injection, and 32.6% had surgery. Most (72%) healthcare providers who gave opinions on causality considered the injury was caused by vaccination. 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.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/31771864

Recent Publication: Clinical Immunization Safety Assessment Project (CISA)

- Walter EB et al. ***Fever after Influenza, Diphtheria-Tetanus-Acellular Pertussis, and Pneumococcal Vaccinations*** Pediatrics. 2020;145(3):e20191909
  - Summary: 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 2017-18 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.
  - Available at https://pediatrics.aappublications.org/content/pediatrics/early/2020/02/04/peds.2019-1909.full.pdf

Recent Publication: Vaccine Safety Datalink (VSD)

- Yu W, et al. ***The use of natural language processing to identify vaccine-related anaphylaxis at five health care systems in the vaccine safety Datalink.*** Pharmacoepidemiol Drug Saf Feb 2020 29 (2), 182-188.
  - Summary: 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.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/31797475

Recent Publication: Vaccine Safety Datalink (VSD)

- Li R, et al. ***A Bayesian approach to sequential analysis in post-licensure vaccine safety surveillance.*** Pharm Stat. 2019 Dec 22. doi: 10.1002/pst.1991.
  - Summary: 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.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/31867860

Thank you

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