Advisory Commission on Childhood Vaccines (ACCV)

Teleconference

December 2, 2022

Members Present

Albert Holloway, Jr. MD (2024)
Dana DeShon, DNP, APRN, CPNP-PC (2024)
Daniel Boyle (2024)
Timothy Thelen, JD (2024)

Division of Injury Compensation Programs (DICP), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS)

CDR Reed Grimes, MD, Director, DICP, Chair, ACCVA
Pita Gomez, Principal Staff Liaison, ACCV
Andrea Herzog, Program Analyst

Welcome Remarks and Chair Report, CDR Reed Grimes, MD, Director, DICP and Chair, ACCV

Dr. Grimes called the meeting to order and welcomed everyone. Dr. Grimes announced that all current active commissioners and ex officio members were present which constituted a quorum.

Public Comment on Agenda Items

Dr. Grimes invited public comment on the meeting agenda and there were none.

Overview of CDC's Clinical Immunization Safety Assessment (CISA) Project, CAPT Karen Broder, MD, Medical Officer, CDC ISO

Dr. Broder began with including a disclaimer slide that the findings and conclusions in this presentation are of the presenter and do not necessarily represent the official position of the CDC. Dr. Broder explained that the Immunization Safety Office (ISO) has responsibility for monitoring the safety of vaccines after they are licensed or authorized for emergency use. ISO has three long-standing vaccine safety infrastructures including: the Vaccine Adverse Event Reporting System (VAERS), comanaged by CDC and FDA; the Vaccine Safety Datalink (VSD); and CISA, the focus of the presentation. The newly added system, V-safe, was added during the COVID pandemic and is a smartphone-based active safety monitoring system.

CISA's mission is to improve understanding of adverse events following immunization (AEFI) at the individual patient level. There are three main goals, which include: to serve as a vaccine safety resource for U.S. healthcare providers with answers to complex vaccine safety questions at the individual patient level to assist with immunization decision-making; to assist CDC in evaluating emerging vaccine safety issues; and conducting clinical research to identify preventive strategies for AEFI. CISA is a collaboration with CDC and seven medical research

centers. These medical research centers contain world experts in vaccine safety, as well as other areas of medicine, including infectious diseases across both pediatric and adult populations. Dr. Broder acknowledged that Vanderbilt University Medical Center is the lead site for the clinical consultation service.

Dr. Broder demonstrated how clinicians can request a CISA consultation for any COVID-19 or routine vaccine concerns. Health departments can request a CISA consultation for complex COVID-19 vaccine questions. Most clinical inquiries come through CDC Emergency Operations Center (EOC) Watch Desk, CDC-INFO, or internal and external sources. CDC CISA clinicians assess inquiries or requests to see how to best handle them. For inquiries that are straightforward or have been seen multiple times, CISA clinicians work back and forth with the requester. The more complex inquiries may have a structured CISA case consultation. This process includes scheduling the consult with healthcare providers, health department and other federal partners; encourage the health care provider to take advantage of existing resources (like VAERS, medical record review, literature review and review of existing surveillance data); conduct discussions with subject matter experts; provide guidance for clinical decision making; and follow-up to see how the patient did with the information from the consultation.

Dr. Broder described the CISA algorithm that is used to assess causality after AEFI, which may result in one of three outcomes: indeterminant, inconsistent with a causal association, and consistent with a causal association. (*Additional information on algorithm is available at *Halsey NA, et al. Algorithm to Assess Causality after Individual Adverse Events Following Immunizations. Vaccine. 2012 Apr 13.)*

Dr. Broder showed a record of events from October 2012 through January 2018 (all pre-pandemic). There were 114 cases, 86% AEFI and 16% no AEFI. The median age of patients was 5.0 years, and the mean age of patients was 12.9 years. The influenza vaccine was involved in more than a third of the cases.

Dr. Broder presented a data summary of consultations from October 2012 – January 2018, which reflects what CISA consults looked like prior to the pandemic. Dr. Broder presented an interesting case consult example, involving a two-year-old who suffered an adverse reaction to influenza vaccine. The provider asked if the patient with a history of Stevens-Johnson Syndrome (SJS) after influenza B infection should receive a seasonal influenza vaccine. The child was hospitalized in intensive care for severe SJS involving more than 10% body surface area, and influenza B virus was the only pathogen available. By applying the algorithm, the subject matter experts advised the patient to be vaccinated with quadrivalent inactivated influenza vaccine (IIV4) and not the live attenuated influenza vaccine (LAIV4). The child received IIV4 and experienced no AEFI. (*A detailed discussion of the issues involved may be found at Tamez RL et al. Influenza B virus infection and Stevens-Johnson syndrome. PediatrDermatol. 2018 Jan;35(1): e45-e48).*

CISA also contributes to the Advisory Committee on Immunization Practices (ACIP) safety evidence reviews, clinical guidance pertinent to vaccine safety, and to assess vaccine safety signals identified after COVID-19 vaccines.

Dr. Broder described the third goal of CISA clinical research. CISA conducts prospective clinical research designed to address real world public health needs that may use randomized clinical trial (RCT) designs and allows for clinical data and laboratory specimen collections. Between 2012 and 2022, CISA has conducted 22 clinical studies, and 14 of these clinical studies enrolled participants aged less than 18 years of age.

Dr. Broder highlighted three study examples with RCT design. Duke University site led the fever and water study, while the Vanderbilt University site led the asthma study. These included studies on fever after simultaneous vs. sequential vaccination; safety of LAIV in children with asthma; and drinking water to prevent post-vaccination presyncope in adolescents.

Dr. Broder offered five summary points including:

- CDC's ISO has a robust infrastructure for vaccine safety monitoring; uses complementary systems, including CISA
- CISA clinical consultations provide a valuable service to U.S. healthcare providers and health departments
- CISA has provided clinical expertise for CDC vaccine guidance pertaining to safety
- CISA-sponsored clinical research studies fill a unique role in providing evidence for vaccine safety across the life stages, including pregnancy
- Experience during COVID-19 pandemic has demonstrated that CISA can adapt to meet urgent public health needs

Dr. Broder concluded their remarks and invited questions. Dana Deshon shared that she works in primary care pediatrics and asked if primary care providers ask for an assessment or does their team actively monitor VAERS and reach out to healthcare providers for further follow-up. Dr. Broder responded that healthcare providers should request a CISA clinical consultation and encourages the filing of a VAERS report, but that these are parallel processes. There are too many different VAERS reports from different sources, so it would be difficult to know which ones to pursue. However, if someone calls or it is very clear in the VAERS report that the clinician is looking for a consult, then CDC staff would reach out to offer a CISA consultation. Daniel Boyle mentioned his personal experience with a vaccine injury 13 years before, that involved both confirming the injury and identifying resources and information needed to take appropriate actions, and finally what to do about future events such as COVID that are similar. There is also a need to be aware of other injuries that may occur. Daniel Boyle asked if CISA sees themselves as a surveillance program. Dr. Broder responded that one of the functions of CISA is to provide technical expertise to enhance surveillance. CISA really focuses on the cases that are most helpful and can make a difference, where providers need to make an actual decision.

Overview of National Academy of Sciences, Engineering, and Medicine (NASEM) Contracts, Kathleen Stratton, NASEM

Dr. Stratton mentioned that the NASEM was established in 1863 as a private not-for-profit organization, but is not supported by a line item in the Congressional budget. Congress often mandates involvement in important topics, as it did in the matter of charging the Academies with reporting a review of the science on adverse events in the 1986 National Childhood Vaccine Injury Act. NASEM has been involved in three comprehensive reports on the safety of vaccines for VICP in 1992, 1994 and 2012, that were done specifically with the purpose of providing the scientific foundation for the compensation program and has never been to make specific recommendations for which injuries should be on the Vaccine Injury Tables. Previous work done for VICP was consensus committee work, where experts are convened to come to a

consensus around a topic of science, engineering, or medicine. Dr. Stratton clarified that these committees operate under Section 15 of the Federal Advisory Committee Act. They reviewed the rules under which the NASEM operates, including the ability to work in closed sessions. Any information given to the committee for their deliberations must be made available to the public, so the work can be transparent. The final report will be released to the public for free download from the National Academic Press.

This contract is funded with funds from both CDC and DICP. NASEM came to an agreement for their statement of task, which is for NASEM to establish a committee of experts who will assess the biological, clinical, and epidemiological literature and include a causality assessment of shoulder injuries that may be related to vaccine administration, and specific adverse events related to COVID-19 vaccines. The committee will issue one report in March 2024.

The committee has been asked to review the following list of COVID-19 vaccine related adverse events:

- Guillain-Barrè Syndrome (GBS)
- chronic inflammatory demyelinating polyneuropathy (CIDP)
- transverse myelitis (TM)
- Bell's palsy
- hearing loss
- chronic headaches
- infertility
- sudden death
- myocarditis/pericarditis
- thrombosis with thrombocytopenia syndrome (TTS)
- immune thrombocytopenic purpura (ITP)
- thromboembolic events (e.g., cerebrovascular accident (CVA),
- myocardial infarction (MI), pulmonary embolism, deep vein thrombosis (DVT)
- capillary leak syndrome

The process involves formation of the committee, an information gathering phase, writing the report with an external peer review of the report, and finally a distribution of the report. Currently, the committee membership is being finalized. The biographies will be posted for a public comment period before the committee meets for the first time in January or February 2023. The committee will meet virtually and in hybrid fashion multiple times for this project.

Dr. Stratton concluded their remarks and invited questions. Dr. Grimes expressed appreciation for the good report, and clarified that the funding will come from the CDC, VICP, and additionally the Countermeasures Injury Compensation Program (CICP). Daniel Boyle asked if the ACCV will be getting status updates on the progress of this causality assessment. Due to mandates regarding NASEM operations, Dr. Stratton clarified that they are unable to share developing work products, approaches, or preliminary conclusions, but could provide some updates at a future meeting, if helpful, to the ACCV. Dr. Stratton will follow-up and provide the website for their public comment period, once it is live on their website.

Future Agenda Items and New Business.

Dr. Grimes commented that these topics from December 1, 2022, meeting have been discussed previously and recorded in the minutes. Daniel Boyle shared his appreciation for Dr. Grimes listening to areas of interest where additional information is needed and finding a way to bring this to the ACCV.

Public Comment

Dr. Grimes invited public comment. There were no requests to make a public comment. Dr. Grimes invited a motion to adjourn. On motion duly made and seconded, the meeting was adjourned.