Advisory Commission on Childhood Vaccines (ACCV)
Teleconference
March 7, 2024

Members Present

Albert Holloway, Jr. MD (2024)
Dana DeShon, DNP, APRN, CPNP-PC (2024)
Daniel Boyle (2024)
Timothy Thelen, JD (2024)
Divya Poduri (2026)
Ramon (Ray) Rodriguez, III, JD, MD (2026)

Ex officio Members

Jonathon Duffy, MD, MPH, Centers for Disease Control and Prevention (CDC)
Claire Schuster, MPH, National Institutes of Health (NIH)
Sean Dade, MPA, Office of the Assistant Secretary for Health (OASH)
Jay Slater, MD, Food and Drug Administration (FDA), (not in attendance – submitted recorded presentation)

Advisors

Heather Pearlman, Department of Justice (DOJ)
Lynn Ricciardella, Office of General Counsel (OGC)
Jocelyn McIntosh, United States Court of Federal Claims (CFC)

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, MPH, Director, DICP, Chair, ACCV
Pita Gomez, Principal Staff Liaison, ACCV
Andrea Herzog, Program Analyst

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

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

Public Comment on Agenda Items, CDR Reed Grimes, MD, MPH, Director, DICP and

Chair, ACCV

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

Approval of September 7, 2023, and September 8, 2023, Meeting Minutes, CDR Reed Grimes, MD, MPH, Director, DICP and Chair, ACCV

Commander Grimes invited a motion to approve the September 7, 2023, Meeting Minutes. On motion duly made and seconded, the ACCV voted and unanimously approved the September 7, 2023, ACCV Meeting Minutes.

Commander Grimes invited a motion to approve the September 8, 2023, Meeting Minutes. On motion duly made and seconded, the ACCV voted and unanimously approved the September 8, 2023, ACCV Meeting Minutes.

Report from National Vaccine Injury Compensation Program (VICP), CDR Reed Grimes, MD, MPH, Director, DICP and Chair, ACCV

Commander Grimes provided an update on the VICP. Commander Grimes stated that the purpose of the VICP is to provide an alternative to the traditional tort system by providing compensation to people found to be injured by certain vaccines. The VICP ensures an adequate supply of vaccines, stabilizes vaccine costs, and establishes/maintains an accessible and efficient forum for individuals found to be injured by certain vaccines.

For a vaccine to be covered by VICP, it must meet certain criteria so that the CDC will recommend the vaccine for routine administration to children or pregnant people. It must also be approved by Congress through an excise tax. The Vaccine Injury Compensation Trust Fund pays for the administration of the program as well as compensable expenses. The Secretary of Health and Human Services must add the vaccine to the program through a notice of coverage posted in the Federal Register, which assists in the adjudication of claims.

The Vaccine Injury Table is used to list injuries and/or conditions associated with covered vaccines. If the first symptom of these injuries and/or conditions occurs within the specified time period and the injury meets the definition included in the table, it is presumed that the vaccine caused the injury or condition unless another cause is proven. If an injury and/or condition is not on the table, or if the injury and/or condition does not meet the table requirements, the petitioner must prove that the vaccine caused the injury.

Commander Grimes showed a Vaccine Injury Table. On the left under item seven, it describes the vaccine covered, vaccines containing the polio inactivated virus (IPV). The table then shows a qualification in aids to interpretation or QAI. In the example, it shows the QAI for anaphylaxis on the right, which defines the injuries and conditions listed.

The ACCV guiding principles for recommending changes to the Vaccine Injury Table (borrowed

from an earlier presentation given to the ACCV) include that the table should be scientifically and medically credible. Where there is credible scientific and medical evidence to both support and reject a proposed change to the table, the change should be made to the benefit of petitioners whenever possible. If the Institute of Medicine, now known as the National Academy of Medicine (NAM), has studied the possible association between a vaccine and an adverse effect, the conclusions should be considered by the ACCV and deemed credible. However, those conclusions should not limit the deliberations of the ACCV.

Commander Grimes noted an effort underway for a review from the NAM, titled "*The Review of Relevant Literature Regarding Adverse Events Associated with Vaccines*." The review focuses on the state of the literature and providing causality assessments for certain shoulder injuries associated with intramuscular vaccination. The completion of these results should be available no later than the end of the fall.

A slide was shared that outlines the strength of data sources and guiding principles from 2006. There is a spectrum of various data sources, ranging from weaker sources such as non-peer-reviewed publications and case reports, to more robust ones like controlled clinical trials and clinical laboratory data.

Commander Grimes presented a graph showing VICP petitions filed by/for adults and children from fiscal year (FY) 2014 to FY2023. The graph shows a dark blue line representing the total petitions filed, with a light blue line just underneath it representing the adult petitions filed, and the maroon line representing the petitions for children towards the bottom of the horizontal axis. Over the last 10 full fiscal years, the number of petitions filed has generally increased, though it has plateaued around the 1,100 to 1,200 range, with the overwhelming majority of petitions being filed for adults.

The slide shared shows the number of VICP petitions filed for influenza vaccines as of March 1, 2024, from fiscal years 2020 through 2024. Influenza vaccines constitute a large proportion of the vaccines filed with the program, and this trend generally tracks with the overall number of claims filed, with a significant increase in FY2021 due to the bolus of shoulder injuries related to vaccine administration (SIRVA) claims.

Another slide shows the number of VICP petitions awaiting activation as of March 1, 2024. Activation refers to the pre-assignment review (PAR) process at the U.S. Court of Federal Claims, managed through the Office of the Special Master. The PAR allows the court to process petitions more efficiently by ensuring that cases are not assigned until the record is substantially complete and ready for a medical review. Currently, about 585 petitions are awaiting activation.

Additional slides show the number of activated petitions awaiting a HRSA medical review, covering the full fiscal year of 2023. From October 1, 2022, to March 1, 2024, there were over 1,100 petitions awaiting a HRSA medical review, meaning they had been activated by the court and were awaiting review. As of March 1, 2024, that number has been substantially reduced to 54 petitions, representing a 95 percent decrease. This indicates a substantial increase in the throughput of petitions awaiting a HRSA medical review.

The award amounts paid as of March 1, 2024, for the past five fiscal years range from $173 million to $244 million in total outlays. This is broken down by the overall petitioner's award paid versus the attorney's fees and costs paid. For cases brought forth with a reasonable basis for filing and in good faith, the VICP pays for all attorney's fees and costs.

A brief summary of the accounts for the Vaccine Injury Compensation Trust Fund was shared. As of December 31, 2023, the balance was a little over $4.5 billion. Interest on investments for that quarter was a little over $37 million, with excise tax revenue a little over $70 million, and a total income of about $108 million.

In summary, some DICP updates include the NAM review of the relevant literature regarding adverse events associated with vaccines, likely to be released in April. Approximately 91 percent of petitions filed over the last five fiscal years were for adults, indicating a higher proportion of claims filed for adults versus children. Additionally, the number of activated petitions awaiting medical review has been significantly reduced.

There was a discussion on the positions for nominations. Members were encouraged to recommend qualified individuals to apply. The program is seeking three members who are health professionals with expertise in the healthcare of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines. At least two of these health professionals should be pediatricians. Additionally, they are seeking three members from the general public, with at least two being legal representatives of children who have suffered a vaccine-related injury or death. There is also a need for three members who are attorneys, with at least one specializing in representing individuals who have suffered a vaccine-related injury or death, and one specializing in representing vaccine manufacturers. A website was provided for sending nominations, and members were encouraged to forward this information to interested parties.

Commander Grimes invited questions.

Ray Rodriguez had two questions, noting that there are 54 matters awaiting review with the division. He asked how many matters are currently in review as opposed to awaiting review, and what the average review time is for an individual matter undergoing review.

Commander Grimes noted that he did not have available data for the specific number of cases in the active review process, and that and that each case requires a detailed review of the medical records and time to evaluate the full medical merits of the claim.

Dan Boyle noted a significant reduction in FY2023 of both total outlays and, more significantly, the percentage of outlays going to the petitioner versus total outlays. It seems like there is a 14% decrease compared to the prior three years. In other words, 14% less of the total payments are going to the petitioners. He asked if there was a trend causing this change and noted that the amount per case in FY2023 was significantly lower. He inquired if there was something noticeable in the types of cases that caused this change.

Commander Grimes explained that there was a substantial backlog of claims reviewed by

medical providers, and significant efforts were made to work through that backlog. Some of those claims dated back to FY2021 and FY2022 and were sitting in the queue for a while. DOJ colleagues will provide more information about adjudications. It's not a direct correlation, as some cases span multiple fiscal years between filing and payment.

Regarding the overall number, this has been noticed too. Many compensable claims during that period were for SIRVA, especially from the FY2021 bolus. These generally involve lower dollar amounts because they don't incur high medical expenses after the fact.

Dan Boyle acknowledged Commander Grimes's explanation but noted the large increase in attorney's fees per case compared to past years.

Commander Grimes explained that there isn't a specific answer for the attorney's fees part, but it will be looked into with additional information available.

Dana DeShon commented that being only a third of the way into the year, there is a trend upwards, which means that petitioners' awards could be higher than those seen in 2020, 2021, and 2022.

Ray Rodriguez asked how many practitioners are conducting reviews for the organization. Commander Grimes did not have this information available.

Dan Boyle circled back to the trends in FY2024, noting that it looks like the attorneys' fees would be well beyond prior rates per case. He questioned whether it was just a factor of inflation or trends. If it stays at that same rate, would it be almost double what they were in FY2020 through 2022? Is there some systemic factor about rates and fees affecting this?

Commander Grimes stated that he does not have a definitive answer, but that FY2024 will be assessed to see if this is a sustained trend or just a blip.

Report from the DOJ, Heather Pearlman, Deputy Director, Torts Branch

Heather Pearlman went over the statistics report covering a six-month period, from August 16, 2023, to February 15, 2024. There were 665 petitions filed at the Court of Federal Claims. Of those, 590 involved adults and 75 involved minors.

There were 546 petitions adjudicated during that time (446 were compensated, and 100 were not compensated or were dismissed). Of the compensated cases, 194 were conceded by the Department of Health and Human Services (HHS). Most were SIRVA cases. There were also thirty-three cases involving the flu vaccine and GBS, one case each involving: a flu vaccine and anaphylaxis: a flu vaccine and syncope; a measles, mumps, and rubella (MMR) vaccine and immune thrombocytopenia purpura (ITP); a flu vaccine and axillary neuropathy; an MMR vaccine and cellulitis; a varicella vaccine and varicella viral disease;, and one abscess case related to several different vaccines. In these conceded cases, all but 20 were adopted by proffer, meaning the parties agreed on the value of the case. The others were resolved by a decision of

the Special Master.

For the cases not conceded by HHS, there were 252, and almost all (203) were resolved via settlement. Of the remaining 49 cases, 32 were resolved via proffer, and 17 were resolved by a decision of the Special Master. During the reporting period, there were also 96 petitions that were voluntarily withdrawn.

The Court of Appeals for the Federal Circuit decided three cases during the reporting period. All were appealed by petitioners: two were affirmed (*Cottingham v. HHS*, an attorneys' fees case, and *Winkler v. HHS*, appealing an entitlement decision), and one was dismissed (*Ling v. HHS*).

There were 17 appeals to the Federal Circuit brought by petitioners: 16 involved entitlement issues, and one involved an attorneys' fee issue. There are currently two appeals pending at the Federal Circuit brought by the respondent: one attorneys' fees case and one case regarding entitlement.

Regarding the Court of Federal Claims, there were 17 cases decided where petitioners sought review, and no decisions in cases where respondent sought review. Of those, 15 were affirmed, one was affirmed in part and denied in part, and one was dismissed.

There are 9 cases at the Court of Federal Claims brought by petitioners. Eight involve entitlement issues, and one involves an attorneys' fees issue. There are no pending cases brought by the respondent at the Court of Federal Claims at this time.

There was one oral argument scheduled—*Kalajdzic v. HHS*—at the Federal Circuit, scheduled for April 4 at 10 a.m. There were no oral arguments scheduled at the Court of Federal Claims.

The next several slides show all of the adjudicated settlements over the six-month period. The vast majority were SIRVA cases, and most involved the flu vaccine. The shortest adjudication time between filing and resolution was a SIRVA case that took one year and six days. The longest case took seven years and three months. Most cases fell in between.

The appendix was the same as in past meetings.
Commander Grimes opened the floor for questions. Dan Boyle expressed his appreciation that DOJ began providing data on the vaccine and injury information in conceded cases.

Update on NIAID, NIH Vaccine Activities, Claire Schuster, MPH, Communications Team Lead for Division of Microbiology and Infectious Diseases, NIAID

Influenza research
A Phase I trial of a new investigational universal flu vaccine is underway at the NIH Clinical Center in Bethesda, Maryland. The vaccine candidate, known as FluMoS-v2, was designed by researchers at NIAID's Vaccine Research Center. It is an adaptation of an earlier universal flu vaccine candidate called FluMoS-v1, which began first-in-human testing in 2021. FluMoS-v2, the new candidate, is designed to induce antibodies against many different influenza virus strains

by displaying part of the influenza virus hemagglutinin protein (HA) in repeating patterns on self-assembling nanoparticle scaffolds. While FluMoS-v1 displays HA from four strains of influenza virus, FluMoS-v2displays HA from six. Researchers anticipate that this will further broaden vaccine immunity, providing protection against a wider array of influenza viruses.

HIV/AIDS
A trial of a preventive HIV vaccine candidate has begun enrollment in the United States and South Africa. The Phase I trial will evaluate a novel vaccine, known as VIR-1388, for its safety and ability to generate an immune response. The investigational vaccine includes NIH-funded technology in development since 2004. Initial results are expected in late 2024.

Update on STIs
In September, NIH released the 2023-2028 Strategic Plan for Herpes Simplex Virus (HSV) Research. The plan was developed by an NIH-wide HSV working group and was informed by feedback from the research and advocacy communities. The plan will advance fundamental knowledge of HSV biology, pathogenesis, and epidemiology, and accelerate the development of diagnostics, vaccines, and therapies.

Dengue update
In October, WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recommended the use of Takeda's dengue vaccine, called Qdenga, in areas with a high dengue disease burden and high transmission in children ages 6 to 16 years. NIAID provided extensive support to advance the preclinical and clinical development of this vaccine, including first-in-human clinical testing.

Updates on the NIH All of Us Research Program
Researchers have discovered more than 275 million previously unreported genetic variants identified from data shared by nearly 250,000 participants in the NIH *All of Us* Research Program. Half of the genomic data are from participants of non-European genetic ancestry. The collection of variants provides researchers new pathways to better understand the genetic influences on health and disease, especially in communities that have been left out of research in the past. Nearly 4 million of the newly identified variants are in areas that may be tied to disease risk. To date, more than 750,000 people have enrolled in the *All of Us* Program. Ultimately, the program plans to engage at least 1 million people who reflect the diversity of the United States and will contribute data from DNA, electronic health records, wearable devices, surveys, and more over time.

To help tackle health disparities, NIH-supported scientists have devised new ways to improve a genetic testing method called a polygenic risk score. Polygenic risk scores are tools for assessing many genomic variants across the genome to determine a person's risk for disease. Since polygenic risk scores have not been effective for all populations, researchers recalibrated these genetic tests using ancestrally diverse genomic data from the *All of Us* Research Program. The researchers selected polygenic risk scores for 10 common health conditions, including breast cancer, prostate cancer, chronic kidney disease, coronary heart disease, asthma, and diabetes. Many of these health conditions are also associated with health disparities.

Cytomegalovirus
Cytomegalovirus, or CMV, has been present in the global population for centuries. Most people with CMV don't experience any symptoms and may be unaware that they're living with the virus. CMV is dangerous for people who are immunocompromised and for babies. It's the most common infectious cause of birth defects in the United States. Congenital CMV affects about 1 out of every 200 children in the U.S. Of babies with CMV, about 1 in 5 will experience long-term health effects, including hearing or vision loss, developmental or motor delays, seizures, or microcephaly. There's no preventive vaccine for CMV and treatment options are limited. In a recent laboratory study, NIAID-supported researchers found that an mRNA vaccine designed to prevent human CMV elicited long-lasting CMV-specific responses from several types of immune cells, outperforming a previous vaccine concept in multiple measures.

COVID-19
Researchers funded through the NIH Researching COVID to Enhance Recovery (RECOVER) Initiative have published a review of current knowledge about post-acute sequelae of SARS-CoV-2 (PASC) in children, including areas such as prevalence, epidemiology, risk factors, and clinical characteristics. They also highlight RECOVER's pediatric efforts, which seek to characterize the natural history of PASC in children and young adults, its underlying mechanisms, and long-term health effects to inform future treatment and prevention. For risk factors, one study found that the incidence of PASC was smaller after asymptomatic versus symptomatic infections, 15% versus 45%. Other risk factors include pre-Omicron variant periods, increasing child's age, higher severity of illness, the number of organ systems involved during acute infection, underlying chronic medical conditions, and increased weight status. RECOVER is enrolling up to 19,500 children and young adults at over 100 sites throughout the United States.

Ms. Schuster also discussed an ongoing community-based study of adults that began in October 2020. In this study, researchers identified SARS-CoV-2 infections among the study participants and examined the impact of vaccination on PASC, also known as long COVID. They found that vaccination was associated with lower prevalence and lower severity of long COVID symptoms.

Ms. Schuster highlighted a few papers related to COVID-19 and preterm birth. By late 2022, widespread COVID-19 vaccination of pregnant people likely halted a spike in the preterm birth rate that began at the start of the pandemic, according to an analysis of State of California health data funded in part by NIH. As part of this study, researchers classified vaccination rates according to zip code. Before May 2021, when vaccines were first made available, the effect of COVID-19 on preterm birth was similar across zip codes. After vaccines were made available, the effect of COVID-19 on excess risk of preterm birth declined sharply in those zip codes where vaccination was the highest. The authors note that their findings underscore the importance of keeping COVID-19 vaccinations current to guard against future resurgence of the virus. Another study found that preterm infants born to people who had been vaccinated for COVID-19 had roughly the same levels of antibody to the SARS-CoV-2 spike protein as term infants born to vaccinated people. Moreover, in all infants, antibodies to the spike protein were higher among those born to individuals who had received three or more vaccine doses before delivery compared to those who had only received two prior doses. The findings provide assurance that preterm infants received similar levels of maternal antibody protection as term infants after

maternal COVID-19 vaccination.

Multi-site Observational Maternal and Infant COVID-19 Vaccine Study (MOMI-VAX)
The study showed that women who received an mRNA-based COVID-19 vaccination or booster during pregnancy can provide their infants with strong protection against symptomatic COVID-19 infection for at least six months after birth. Based on blood samples from infants in the study, researchers found that newborns with high antibody levels at birth also had greater protection from COVID-19 infection during the first six months. While infants of mothers who received two COVID-19 vaccine doses had a robust antibody response at birth, infants whose mothers had received an additional booster dose during pregnancy had both higher levels of antibodies at birth and greater protection from COVID-19 infection during their follow-up visits. During the course of the study, none of the infants required hospitalization for COVID-19. The findings from the study reinforce the importance of receiving both a COVID-19 vaccine and booster during pregnancy to ensure that infants are born with robust protection that lasts until they are able to get vaccinated.

Pandemic preparedness
A special supplement to the Journal of Infectious Diseases was published last October with articles summarizing a pandemic preparedness workshop that NIAID hosted in November 2021. The supplement features articles from scientific experts on 10 viral families with high pandemic potential. Many of the viruses in these 10 families have no vaccines or treatments licensed or in advanced development for use among people. Rather than developing medical countermeasures for each individual virus, one strategy is to use the "prototype pathogen" approach. This approach characterizes representative viruses within viral families so that knowledge gained can be quickly applied to other viruses in the same family.

NIH Leadership updates
In November 2023, Dr. Monica Bertagnolli started as the 17th director of NIH. She is the first surgeon and the second woman to hold the position. Dr. Bertagnolli has been a cancer surgeon for more than 35 years. Nominated by President Biden, Dr. Bertagnolli was confirmed on a bipartisan basis by the U.S. Senate. She transitioned from her role as the 16th director of the National Cancer Institute, a position she held since October 2022.

Q&A
Claire Schuster concluded her presentation, and Commander Grimes opened the floor for questions.

Commander Grimes asked for examples of the 10 viruses that have been slated for pandemic preparedness research.

Ms. Schuster responded that the viruses are listed by families. She highlighted several examples, including arenaviruses (e.g., Lassa virus), hantaviruses, flaviviruses (such as West Nile virus and dengue virus), and filoviruses (like Ebola virus). Other viruses of interest include, but are not limited to, Chikungunya virus and enteroviruses.

Update on ISO, CDC Vaccine Activities, Jonathan Duffy, MD, MPH, Medical Officer, National Center for Emerging and Zoonotic Infectious Diseases

The first update relates to V-safe. V-safe is a vaccine safety monitoring system run by the CDC that allows individuals to respond to surveys about how they feel after receiving vaccines. This is a reminder that v-safe is a system where the person has to register, and then the V-safe system will send personalized and confidential health check-ins by either text or email, asking how people feel. The update here is that there are now additional vaccines being monitored in V-safe as of 2023. The two vaccines currently being monitored are the 2023-2024 updated COVID-19 vaccines and the RSV vaccines for both older adults and pregnant people.

The first paper is titled "Post-Marketing Safety Surveillance of Hexavalent Vaccine in the Vaccine Adverse Event Reporting System (VAERS)." The hexavalent vaccine is a combination vaccine that includes antigens for six different diseases. This paper summarizes and reviews reports of adverse events following this vaccine to VAERS over a four-year period. During this time, there were 501 reports of adverse events identified with this vaccine, with 4% being serious. The most frequently reported adverse events were fever and injection site erythema. It was noted that during the period of this review, a total of two million doses of the hexavalent vaccine had been distributed in the U.S. The conclusion was that the reports to VAERS were consistent with what was known from the pre-licensure studies.

The next paper is titled "The Epidemiology of Upper Limb Complex Regional Pain Syndrome in a Retrospective Cohort of Persons Aged 9 to 30 Years during the Time Period of 2002 to 2017." Complex regional pain syndrome (CRPS) is something that has had case reports following HPV vaccination. This study was done in response to that to learn more about it using the Vaccine Safety Datalink (VSD) system. The study looked at patients aged 9 to 30 years over this 15-year period from before and after HPV vaccines were available. They identified 113 cases that were verified through medical record abstraction and adjudication. They found that most cases had some other precipitating event, such as a non-vaccine related injury. They only identified one case in which the treating practitioner attributed the diagnosis to the HPV vaccination. They concluded that the incidence of CRPS over time showed no significant increases in rates after HPV vaccines became available in 2006. This does not support an increased risk of this condition since the vaccine became available.

The next paper is about Tetanus, diphtheria, and acellular pertussis (Tdap) vaccination during pregnancy and the risk of chorioamnionitis and related infant outcomes. Chorioamnionitis is an infection that had been reported as potentially an increased risk in people receiving Tdap during pregnancy. This was a follow-up study looking at this hypothesis in the Vaccine Safety Datalink. This retrospective observational cohort included people aged 15 to 49 years over a two-year period and included 118,000 pregnant individuals, 87% of whom had received the Tdap vaccine during pregnancy. The main result was that the risk of chorioamnionitis in the Tdap vaccine-exposed group was no different than in the group that had not received the Tdap vaccine.

The next paper is titled "Safety of Measles, Mumps, and Rubella Vaccine in Adolescents and Adults in the VSD." MMR is most commonly given to children, but it can also be given to adolescents and adults. The VSD looked at people aged 9 to 17 years and those over 18 years

who had received at least one dose of MMR over an eight-year period, identifying 276,000 doses of MMR given to adolescents and adults. They found that clinically serious outcomes were rare, and the common non-serious outcomes included arthropathy, injection site reaction, and rash.

The CDC continues to do a lot of work related to COVID-19 vaccines, and there have been many publications related to that. In the interest of time, I'll just list the titles here, and again, these citations are available on the CDC website. Topics include background rates of adverse events, post-menopausal bleeding, simultaneous administration of COVID-19 vaccines with influenza vaccines, data mining to look at adverse events after COVID-19 vaccines, and a report on Novavax vaccine safety monitoring.

These are more publications that have come out over the last several months or recently. Topics include the safety of simultaneous vaccination with COVID-19 vaccines, safety in pregnant people, a report describing deaths reported to VAERS following COVID-19 vaccination, safety among young children in the VSD, and an update on the CDC's COVID-19 vaccine pregnancy registry.

Recent highlights from recent Advisory Committee on Immunization Practices (ACIP) meetings
There were sessions on the COVID-19 vaccines. In summary, the bivalent COVID-19 vaccines, which were used from September 2022, were no longer matched to the currently circulating variants. In September and October 2023, the FDA approved and the CDC recommended the use of the updated COVID-19 vaccine for the 2023-2024 period for all persons aged six months and older.

ACIP had sessions on meningococcal vaccines. In October, ACIP approved the following recommendation by a majority vote: Pfizer's MenABCWY vaccine may be used when both MenABCWY and MenB are indicated at the same visit. This is a new combination vaccine that can be given as a single injection instead of the two separate vaccines that previously existed.

There was a session on Mpox vaccines. ACIP approved the following recommendation by a majority vote in October: ACIP recommends vaccination with the two-dose JYNNEOS vaccine series for persons aged 18 years and older at risk for Mpox. The footnotes explain who is at risk, generally relating to sexual-related risk factors.

ACIP also discussed the respiratory syncytial virus (RSV) vaccine in the maternal or pregnant people setting. In August 2023, the FDA approved the Pfizer RSV vaccine for pregnant persons at 32 to 36 weeks gestational age to prevent RSV in infants aged less than six months. The CDC's ACIP followed up with a recommendation to use that vaccine in a seasonal administration, meaning administered between September and January.

There were several updates on influenza vaccines. The titles of the presentations give a sense of the topics discussed. There was a session on influenza vaccines in pregnancy, including updates and information about the safety of the quadrivalent recombinant influenza vaccine in pregnant women and their infants. There was a presentation on pregnancy outcomes with the cell-cultured influenza vaccine, which was a post-marketing study. There was also a presentation on the effectiveness of maternal influenza vaccination during pregnancy against influenza-associated

hospitalizations and emergency room visits in infants less than six months of age.

The influenza session also included additional presentations on the co-administration of vaccines in adults. Presentations covered the safety of simultaneous versus sequential administration of the mRNA COVID-19 vaccines with the quadrivalent inactivated influenza vaccines, the safety of simultaneous vaccination with the recombinant zoster vaccine and the quadrivalent adjuvanted influenza vaccine, and an update on COVID-19 and influenza vaccine safety.

Vaccination coverage
The CDC has been tracking respiratory illness vaccination trends during the 2023-2024 respiratory virus season. These numbers are updated weekly based on the National Immunization Survey. This slide shows data through February 8. On the left graph, you can see the cumulative percentage vaccinated for COVID-19 vaccines and influenza vaccines in children aged six months to 17 years. Influenza is the upper line on that graph, and COVID-19 vaccines are the lower line. Similar data for adults aged 18 and older are shown for influenza, COVID-19, and RSV vaccines. RSV vaccines are recommended only for people aged 60 and older. Additional information and more recent data are available through the provided link.

Divya Poduri inquired whether all newly approved vaccines are added to the V-safe monitoring system and if there is a criterion for how long the vaccines are monitored through V-safe.
Dr. Duffy responded, noting that v-safe is a relatively new surveillance system. Currently, it is not used for vaccines other than the two he mentioned. There is potential for additional vaccines to be added in the future, but there are no definitive details on which vaccines or when that might occur. With the COVID-19 vaccines, the current modules are for the currently available vaccines. If the COVID-19 vaccine recommendation changes in the future, that might determine the period of monitoring. There hasn't been any predetermined end date for the current monitoring.

Dan Boyle asked if the CDC is looking at lessons learned from using V-safe with the two vaccines to potentially include other vaccines in the future.

Dr. Duffy mentioned that there is definitely consideration for adding other vaccines, particularly new vaccines or new recommendations from ACIP, in the future. However, there are no more details available on those plans at this time.

Dan Boyle further stated that the role of the ACCV is to survey federal, state, and local programs related to gathering information on injuries associated with the administration of childhood vaccines. He noted that v-safe is the newest system and appears to be less passive than VAERS, given its user-friendly approach and promotion at vaccine sites. He emphasized the importance of the ACCV's role in surveying these activities and considering how v-safe might be applied to vaccines on the vaccine injury table.

Update on the CBER, FDA Vaccine Activities, Jay E. Slater, MD, Medical Officer (recorded presentation)

FDA's vaccine activities between October 2023 and February 2024.
On October 3, FDA amended the emergency use authorization of the Novavax COVID-19 vaccine for use in individuals 12 years of age and older to include the 2023-2024 formula. The updated vaccine addresses circulating variants to provide better protection against serious consequences of COVID-19, including hospitalization and death.

On October 20, FDA approved Penbraya for the prevention of invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y in individuals 10 through 25 years of age.

On November 9, FDA approved Ixchiq, the first chikungunya vaccine. Ixchiq is approved for individuals 18 years of age and older who are at increased risk for exposure to chikungunya virus. The chikungunya virus is primarily transmitted to people through the bite of an infected mosquito. Chikungunya is an emerging global health threat with at least 5 million cases of chikungunya virus infection reported over the last 15 years. The highest risk for infection is in tropical and subtropical regions of Africa, Southeast Asia, and parts of the Americas where the chikungunya virus-carrying mosquitoes are endemic. However, chikungunya virus has spread to new geographical areas, causing a rise in the global prevalence of the disease.

On October 5, the Vaccines and Related Biological Products Advisory Committee met in open session to discuss strain selection for the influenza virus vaccine for the 2024 Southern Hemisphere influenza season.

FDA continues to maintain a website dedicated to its COVID-19 activities, including pandemic response activities pertaining to vaccines, testing, therapeutics, and devices. The website is frequently updated and is a resource for the public, including healthcare providers and industry.

Update on OASH OIDP National Vaccine Program, Sean Dade, Public Health Advisor, MPA

The National Vaccine Program was established in 1986 and complies with Section 2105 of the Public Health Service Act. The Secretary of the Department of Health and Human Services originally established this program to achieve optimal prevention of human infectious diseases, immunizations, and adverse reactions to vaccines. The program's responsibilities are outlined in the Vaccine National Strategic Plan, currently released for 2021 to 2025, provides a framework of goals, objectives, and strategies to coordinate vaccine development and use in the United States.

Priorities within the National Vaccine Program
The first priority is to increase vaccine uptake, especially among high-risk populations. In coordination with CDC, Immunize.org, and the National Vaccine Program leads the National Adult Influenza Immunization Summit, which consists of over 700 partners whose goal is to improve the use of all ACIP-recommended vaccines. The second priority is to work with the communication team and other community partners to dispel vaccine misinformation by developing sound vaccine education materials and resources that lead to more accurate vaccine knowledge, focusing on reducing vaccine hesitancy while also increasing vaccine uptake. The

third priority is to reduce disparities and inequities in access to and use of routinely recommended vaccines across the lifespan. They currently fund a cooperative agreement with six recipients to develop community-based projects throughout the nation to increase vaccine confidence among underserved populations with historically low vaccination rates. In the third year of the project, promising practices include using trusted messengers to provide vaccine information, developing culturally competent education materials, and increasing access to vaccines, especially in rural and hard-to-reach areas.

Key Initiatives in the National Vaccine Program
The first initiative focuses on vaccine innovation, particularly the evaluation of vaccination innovation. Within this scope, the program ensures vaccines are safe for distribution by working with federal agencies to ensure timely detection of vaccine safety signals. Once vaccines are ready for distribution to the public, the program aims to increase access to and use of routinely recommended vaccines, especially among underserved populations, to increase vaccine equity and limit disparities. The fourth initiative is to rebuild vaccine confidence, which has declined pre- and post-COVID-19 pandemic. They work closely with community-based organizations and partners to build public trust in vaccines, policies, and providers, to mitigate the spread of infectious disease outbreaks, such as recent measles outbreaks.

They are currently spearheading a Summer Pride Mpox Equity Pilot, aiming to increase Mpox vaccine equity for populations overrepresented in an outbreak. They work with community-based organizations to identify 25 to 30 LGBTQI events to support these populations. This pilot combines a comprehensive strategy to bring awareness and promote Mpox vaccination through various public health service channels.

The National Vaccine Program also collaborates with the vaccine communication team to promote national vaccine campaigns aimed at increasing vaccine coverage levels throughout the lifespan. For this presentation, two vaccine observances in April were highlighted. From April 1st to the 5th, Adolescent Immunization Action Week targets adolescents and highlights the importance of adolescent immunizations, urging healthcare providers and parents to ensure adolescents are up to date on their vaccines. National Infant Immunization Week, observed in the last week of April, emphasizes the importance of protecting children two years or younger from vaccine-preventable diseases. The program works closely with federal partners to promote these observances through various HHS social media platforms.

The National Vaccine Program provides strategic leadership and guidance to the National Vaccine Advisory Committee (NVAC). This federal advisory committee, established in 1987, convenes 15 members three times a year and recommends ways to achieve optimal prevention of human infectious diseases through vaccine development and provides direction to prevent adverse reactions to vaccines. This advice is presented to the Assistant Secretary for Health, who serves as the Director of the National Vaccine Program. NVAC recently held a virtual meeting on February 22nd and 23rd, discussing topics such as measles outbreaks, the use of artificial intelligence in vaccines, and childhood immunizations and state policies for school entries. The next NVAC meetings are scheduled for June 13th-14th and September 12th-13th, which are free to the public and can be watched online at hhs.gov/live.

Sean Dade concluded his presentation, and Commander Grimes opened the floor for questions.

Daniel Boyle expressed interest in the initiatives slide, particularly the four initiatives under vaccine safety. He asked for an example of how stakeholder input is obtained for the detection of safety signals and inquired about the NVAC meeting presentation on artificial intelligence and its use in detecting vaccine injuries.

Sean Dade explained that federal partners work to ensure there are safety mechanisms in place. While they aren't the lead agency for detecting safety signals, they coordinate with agencies like the CDC, which uses systems like V-safe to monitor safety signals. Their role is to ensure that these efforts align with the National Vaccine Strategic Plan. Additionally, Mr. Dade mentioned that artificial intelligence (AI) is primarily used in vaccine design and genetic molecule analysis. Daniel Boyle then asked about efforts to connect communities with health disparities to systems like V-safe.

Sean Dade responded that Dr. Duffy mentioned articles and data being used to develop reports, and exploring health disparities in relation to adverse events is a valuable topic.

Ray Rodriguez posed questions related to efforts to build public trust in vaccination and decrease vaccine hesitancy, as well as examples of what is being done to achieve this and improve vaccine access.

Sean Dade stated that they have six awardees throughout the nation working on community-based projects to improve vaccine confidence among underserved populations. Examples include Seattle, Denver, and some tribal nations. These projects focus on using trusted messengers to provide vaccine information, developing culturally competent education materials, and increasing access to vaccines, especially in rural and hard-to-reach areas. In the first year, they assessed some of the barriers their populations faced and then developed strategies to increase vaccine confidence. The approach varies depending on the organization and the specific issues the community faces. For example, Hennepin Healthcare in Minneapolis, Minnesota, uses socially vulnerable index data to identify underserved communities by zip code and then uses a mobile van to vaccinate individuals, thereby increasing vaccine access. Other agencies partner with organizations hosting community events to provide vaccines, aiming to find easy ways to immunize communities.

Ray Rodriguez had a follow-up question regarding discussions about the VICP and its benefits in the event of an adverse reaction.

Sean Dade mentioned that the regional health operations team within OASH has more access to community-based groups and providers. They hear concerns about vaccine safety and access from these groups. At the regional offices, they try to provide relevant information to providers and community-based organizations for distribution. At the national level, they work to identify gaps and coordinate with different federal agencies to address these issues. Their position allows them to see and address gaps that individual agencies might not see because they work in silos. As a coordinating body, they can recognize these issues and provide resources to mitigate them.

Future Agenda Items/New Business

Commander Grimes invited discussion of future agenda items and new business. Commander Grimes addressed a question raised by an ACCV member about how and when to discuss potential future items of interest for presentations or discussions at these meetings. He shared that this was the ideal time to raise items of interest. He noted that with back-to-back meetings, there would be another opportunity tomorrow after some planned presentations.

Commander Grimes provided a preview of the next ACCV meeting, highlighting several upcoming presentations. Dr. Alam Chandani from the FDA would present an overview of post-marketing safety monitoring, covering the Vaccine Adverse Event Reporting System (VAERS) and the FDA Adverse Event Reporting System (FAERS). Captain Sarah Shilley would present on the epidemiology of meningococcal disease in the U.S. and updates on meningococcal vaccines, which was timely given the new pentavalent strain of the meningococcal vaccine. Additionally, Dr. James Sejvar would give a talk on chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) and demyelinating conditions.

Commander Grimes then opened the floor to see if anyone on the Commission had potential future agenda items to raise.

Daniel Boyle noted that the minutes from the last meeting included a discussion about reviewing the decision not to send a request to the Secretary to add brachial neuritis to the vaccine table for the influenza vaccine. He inquired if this topic was on the agenda for the next day.

Commander Grimes apologized for the oversight and confirmed it was not on the agenda but agreed to discuss it in the upcoming meeting. He explained that at the previous ACCV meeting, the Commission voted not to recommend adding brachial neuritis to the table, and there was a request to review literature cited in some of Mr. Boyle's questions. Those references were sent out, and additional references were communicated by some ACCV members. Commander Grimes suggested using the new business section of tomorrow's meeting to discuss the references and the CIDP talk information.

Daniel Boyle expressed interest in additional information about V-safe, its current use, and potential application to vaccines on the injury table. Dr. Duffy responded that it would be best to have someone directly involved with the V-safe program give a standalone presentation at a future meeting.

Dana DeShon suggested that a broader overview of all vaccine safety systems, including V-safe, would be beneficial. Commander Grimes agreed, noting that the FDA's overview the next day would cover VAERS and FAERS, but a broader discussion encompassing systems like the VSD would be valuable.

Commander Grimes then called for any objections to moving forward with the proposed topics. Seeing unanimous agreement, he confirmed they would proceed with these plans. Dr. Holloway and other members expressed their support.

Daniel Boyle suggested making the survey of state and local vaccine injury monitoring efforts a regular section of the meetings, in line with the ACCV's charter duties. Commander Grimes appreciated the comment and agreed that incorporating these duties into routine updates would help inform future agenda items.

Commander Grimes then invited any additional agenda items from ACCV members.

Public Comment

Commander Grimes invited public comment. One comment was made by Theresa Wrangham, the Executive Director for the National Vaccine Information Center (NVIC). Theresa Wrangham addressed some of the comments made by commissioners during the meeting. She noted that Commissioner Boyle had expressed concerns about the adequacy of compensation, given some disparities highlighted in the earlier presentation. Ms. Wrangham reminded the ACCV that several years ago, a report by either the Banyan or Altarum group recommended that the VICP undertake an ongoing review of the adequacy of compensation. The report questioned whether the awards given by VICP were sufficient for the injuries for which petitioners were filing and being compensated. Despite this recommendation, Ms. Wrangham observed that no mechanism for such a review has been established, and in her nearly 20 years of monitoring the committee, she has seen no action taken on this report or any efforts to ensure that compensation is indeed adequate.

Ms. Wrangham suggested that in terms of the ACCV's charter to survey federal, state, and local levels for monitoring adverse events, a better question might be what infrastructure is in place at state and local levels. She mentioned that immunization information systems were envisioned to help monitor such events at the local level. A report on the status of these systems would be helpful.

Regarding the quality of research presented to the committee, Wrangham appreciated Commander Grimes' overview of the guiding principles used by the ACCV. However, she reminded the commissioners of the Institute of Medicine's report on public trust in vaccine safety research, specifically the data-sharing program from the VSD.

Commander Grimes invited a motion to adjourn. On motion duly made and seconded, the meeting was adjourned.