



Centers for Disease Control and Prevention (CDC) Immunization Safety Office (ISO) Update

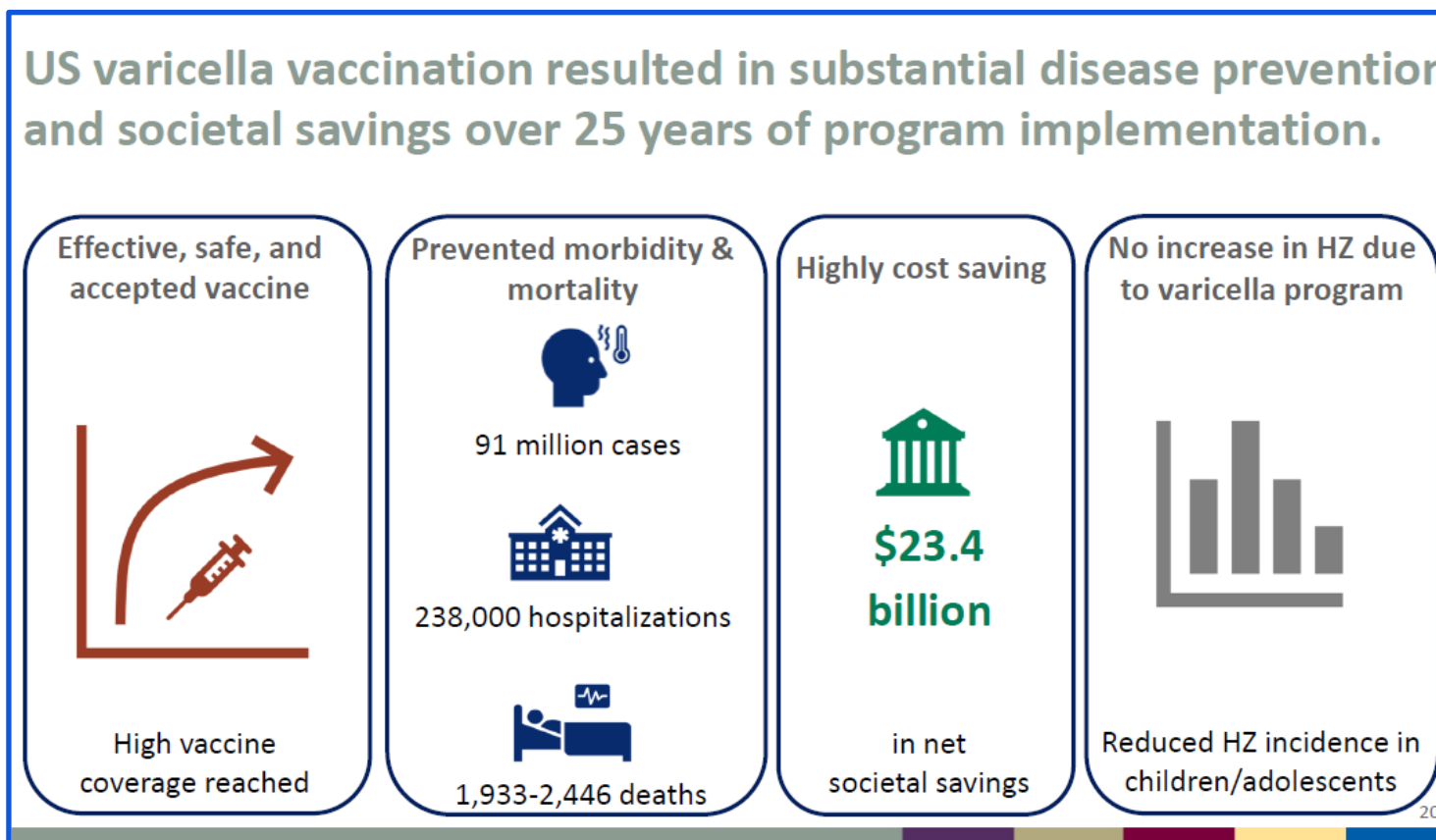
Advisory Commission on Childhood Vaccines (ACCV) meeting
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Advisory Committee on Immunization Practices (ACIP) meetings highlights

Varicella Vaccine

- 25 Years of Varicella Vaccination Program in the United States: Health and Economic Impact during 1995–2019



Mpox Vaccine

- ACIP approved the following recommendation by majority vote at its February 22-24, 2023 meeting:
 - ACIP recommends the 2-dose* JYNNEOS vaccine series for persons aged 18 years and older at risk of mpox during an mpox outbreak§.
- * Dose 2 administered one month after dose 1
- § Public health authorities determine whether there is an mpox outbreak; a single case may be considered an mpox outbreak at the discretion of public health authorities. Other circumstances in which a public health response may be indicated include ongoing risk of introduction of mpox into a community due to disease activity in another geographic area.

Polio Vaccine

- ACIP approved the following recommendations by majority vote at its June 21-23, 2023 meeting:
 - Adults who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with inactivated polio vaccine (IPV).(1)
 - (1)Important context in clinical considerations: In general, unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children.
 - Adults who have received a primary series of trivalent oral polio vaccine (tOPV) or IPV in any combination and who are at increased risk of poliovirus exposure may receive another dose of IPV. Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults.

Influenza Vaccines

- ACIP approved the following recommendations by majority vote at its June 21-23, 2023 meeting:
 - All persons ages ≥ 6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.
 - Affirm the updated *MMWR Recommendations and Reports*, “Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2023-24 Influenza Season”.

Pneumococcal Vaccines

- ACIP approved the following recommendations by majority vote at its June 21-23, 2023 meeting:
 - Use of either pneumococcal conjugate vaccines (PCV) PCV15 or PCV20 is recommended for all children aged 2–23 months according to currently recommended PCV dosing and schedules.
 - For children with an incomplete PCV vaccination status, use of either PCV15 or PCV20 according to currently recommended PCV dosing and schedules is recommended for:
 - Healthy children aged 24–59 months
 - Children with specified health conditions⁽²⁾ aged 24 through 71 months
 - For children aged 2–18 years with any risk condition who have received all recommended doses of PCV before age 6 years
 - Using ≥1 dose(s) of PCV20: No additional doses of any pneumococcal vaccine are indicated. This recommendation may be updated as additional data become available.
 - Using PCV13 or PCV15 (no PCV20): A dose of PCV20 or PPSV23 using previously recommended dosing and schedules is recommended.
 - For children aged 6–18 years with any risk condition who have not received any dose of PCV13, PCV15, or PCV20, a single dose of PCV15 or PCV20 is recommended. When PCV15 is used, it should be followed by a dose of PPSV23 at least 8 weeks later if not previously given.

⁽²⁾Risk conditions include: cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome, which are included in immunocompromising conditions); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; diabetes mellitus; immunocompromising conditions (on maintenance dialysis or with nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; and sickle cell disease and other hemoglobinopathies).

Respiratory Syncytial Virus (RSV) Vaccines – Adult

- ACIP approved the following recommendations by majority vote at its June 21-23, 2023 meeting:
 - Adults 60 years of age and older may receive a single dose of Respiratory Syncytial Virus (RSV) vaccine, using shared clinical decision-making.

Respiratory Syncytial Virus (RSV) Prevention in Infants

- ACIP approved the following recommendation by majority vote at its August 3, 2023 meeting:
 - Infants aged <8 months born during or entering their first Respiratory Syncytial Virus (RSV) season are recommended to receive one dose of nirsevimab (50 mg for infants <5 kg and 100 mg for infants \geq 5 kg).
 - Children aged 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one dose of nirsevimab (200 mg).

Pfizer Maternal RSVpreF Vaccine

- RSVpreF is a bivalent recombinant stabilized prefusion F protein subunit vaccine
- Policy Question: Should vaccination with Pfizer RSVPreF vaccine (120 μ g antigen, 1 dose IM given 24–36 weeks gestation) be recommended for pregnant people to prevent RSV disease in infants?

Coronavirus Disease 2019 (COVID-19) Vaccines

- COVID-19 continues to cause substantial morbidity and mortality across the population, particularly in groups like older adults and persons with immunocompromising conditions
- Anticipate updated vaccine doses will be broadly available in the fall
- Following updated vaccine authorizations, ACIP will review evidence to inform updated recommendations

V-safe after vaccination health checker

- Implemented December 2020
- Data collection for COVID-19 vaccines concluded on June 30, 2023
- Next generation v-safe is under development
 - Plans to collect data on new vaccines
 - Will allow greater flexibility for surveys and use CDC IT infrastructure
 - Designed to permit longer-term support for collecting data rapidly from a large number of vaccine recipients

Vaccine safety update at June 2023 ACIP meeting - 1

- The Childhood Immunization Schedule and Safety: Studies in the Vaccine Safety Datalink
- VSD Study: Antigens and Non-Targeted Infections
 - Public concern: early childhood immunization “overloads” immune system
 - Conclusions: No association between number of antigens young children receive through vaccines and likelihood of ED or inpatient encounters for infections
- VSD Study: Schedule and Type 1 Diabetes
 - Public concern: vaccine antigens and ingredients (including aluminum, used as adjuvant) interfere with immune function, increase risk of autoimmune disease
 - Conclusions: Vaccine schedule not associated with increased risk of T1DM

Vaccine safety update at June 2023 ACIP meeting - 2

- Vaccine Aluminum and Risk of Asthma
 - VSD Study: Aluminum and Asthma
 - Public concern: vaccine ingredients (specifically aluminum, used as adjuvant) increase risk of allergic disorders including asthma
 - Interpretation: Small positive association between cumulative vaccine-associated aluminum before 24 months and persistent asthma 24-59 months
 - The first step of a multi-step research process
 - An additional study in VSD is planned
 - Preliminary evaluation of aluminum content in childhood vaccines and risk of asthma in a Danish nationwide cohort
 - No support for an association between aluminum in vaccines and asthma by 5-yr-of-age in Denmark

Vaccine safety update at June 2023 ACIP meeting - 3

The Schedule and Safety: Broader Context

- Totality of available evidence continues to support the safety of the routine childhood vaccination schedule
- Existing federal vaccine safety surveillance systems robust and responsive to concerns expressed by parents of young children
- Precipitated by 2013 IOM Report on schedule, new field of study is being developed:
 - Examine cumulative, repeated exposures to vaccines and vaccine ingredients
 - Examine long-term health outcomes
- At time of IOM Report, few studies of the safety of the schedule “as a whole”
- Evidence accumulating around specific testable hypotheses; results which can be communicated to parents
- Additional studies related to aluminum and asthma risk planned and ongoing
- Benefits of vaccination strongly outweigh known and potential risks

Recent CDC vaccine safety publications

CDC COVID-19 vaccine safety publications

- Post-authorization safety surveillance of Ad.26.COV2.S vaccine: Reports to the Vaccine Adverse Event Reporting System and v-safe, February 2021-February 2022.
- Evaluation of association of anti-PEG antibodies with anaphylaxis after mRNA COVID-19 vaccination.
- COVID-19 vaccine safety inquiries to the Centers For Disease Control And Prevention Immunization Safety Office.
- COVID-19 Booster Vaccination in Early Pregnancy and Surveillance for Spontaneous Abortion.
- COVID-19 Vaccine Safety Surveillance in Early Pregnancy in the United States: Design Factors Affecting the Association Between Vaccine and Spontaneous Abortion.
- Surveillance For Multisystem Inflammatory Syndrome in US Children Aged 5-11 Years Who Received Pfizer-BioNTech COVID-19 Vaccine, November 2021 through March 2022.

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

