Immunization Update and ACIP Highlights – June 2023

July 5, 2023

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) met on June 21, 22, 23 for its regular triennial vaccine meeting. For archives of minutes and slides, go to the ACIP meeting website and click on "Meeting Materials." COVID vaccine recommendations are available on the CDC's Clinical Considerations website. Below are the key highlights:

- **Influenza Vaccines Vote:** Influenza Vaccine Recommendations for the 2023–2024 season were approved including removal of any special considerations for egg allergic patients. Safety protocols should be the same for egg allergic and non-egg allergic patients.
- **Polio Vaccine Vote (Adult)**
  - All adults who are unvaccinated or incompletely vaccinated in the U.S. should complete their primary polio vaccination series with inactivated polio vaccine (IPV).
  - Adults who are at increased risk for poliovirus exposure may receive a single lifetime booster of IPV.
- **Pneumococcal Conjugate Vaccine 20-Valent Vote (Child):** Pneumococcal conjugate vaccine 20-valent (PCV20:Prevnar20) was recommended for the standard pneumococcal series in children age <2 years and for children ages 2-18 years with chronic medical conditions.
- **Respiratory Syncytial Virus (RSV) Vaccine Vote (Older Adult):** Adults ages 60 years and older may receive a single dose of RSV vaccine, using shared clinical decision-making.
- **RSV Vaccines (Maternal and Infant):** Maternal RSV bivalent prefusion F (RSVpreF) vaccine administered to pregnant women at 27 to 36 weeks gestation and Nirsevimab RSV monoclonal antibody (mAb) administered to infants prior to RSV season are both effective strategies but are extremely cost prohibitive when both are used for the same child. When providing maternal RSVpreF vaccine, it should be offered from June through February.
- **COVID-19 Vaccines**
  - CDC is preparing for the transition to a monovalent XBB.1.5 COVID vaccine booster in the fall.
  - Following updated FDA vaccine authorizations, ACIP will review evidence to inform updated recommendations.
- **Mpox Vaccine:** Clinical guidance for the administration of Mpox vaccine in pregnant women and persons less than 18 years was discussed.
- **Meningococcal Vaccine:** Cost-effectiveness of various meningococcal schedule strategies were presented substituting Pfizer pentavalent (subtypes A, B, C, W, Y) meningococcal vaccine for doses of quadrivalent (subtypes A, C, W, Y) meningococcal vaccine, MenB vaccines or both.
- **Other Topics:** Evidence concerning Dengue vaccine, and Chikungunya vaccine and Vaccine Safety was presented.

Influenza Vaccines Vote

The ACIP voted to approve the Influenza Vaccine recommendations for the 2023-2024 season. Vaccine composition is the same as last season with the exception of the Influenza A/H1N1 pdm09-like subtype which has been updated to the 2022 circulating subtype.

Recommendations on timing of vaccination remain the same as last season. Most adults and pregnant women in their 1st and 2nd trimester should not receive vaccine in July or August unless it is likely they will not receive a vaccine later. The optimal time to offer influenza vaccine is in the September through October time frame, although vaccination should continue until vaccine has expired. Women in their 3rd trimester during July and August should receive vaccine prior to delivery. Children needing two doses should get the first dose as soon as possible and children needing just one dose and pregnant women in the third trimester can consider getting their influenza vaccine as early as July or August.

After a full review of the literature on safety of vaccination of those with egg allergy, recommendations for those with egg allergy have been modified to be the same as with other vaccines, namely:

- All persons ages 6 months and older with egg allergy should receive an 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.
- Egg allergy necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg.
- Severe and life-threatening reactions to vaccines can rarely occur with any vaccine and in any vaccine recipient, regardless of allergy history. Providers are reminded that all vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available. All vaccine providers should be familiar with their office emergency plan and be certified in cardiopulmonary resuscitation.

Polio Vaccine Vote – Adults

In response to the recent vaccine-derived poliovirus, type 2 (VDPV2) outbreak in New York State, the ACIP evaluated the 2000 recommendation to vaccinate adults who were who were at increased risk of exposure and were unvaccinated or incompletely vaccinated and voted to update it with a universal adult recommendation. The new recommendation states:

- "Adults who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with IPV", and
- "Adults who have received a primary series of trivalent oral polio vaccine (tOPV) or IPV in any combination 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 dose with IPV for adults."

One committee member raised the point that there is no data regarding booster doses in immunocompromised persons and that more than one booster might be necessary for immunocompromised persons. The work group is continuing to examine the use of polio vaccine in these persons at higher risk.

Clinical considerations: Definition of fully vaccinated is receipt of a primary series of 3 or more doses of tOPV or IPV in any combination administered at least 4 weeks apart and the last dose in the series was given on or after their 4th birthday and was given at least 6 months after the prior dose.

Unless there are specific reasons to believe they were not vaccinated, adults who were born and raised in the U.S. can assume they were vaccinated against polio as children. Polio vaccination has been part of the routine childhood immunization schedule for decades and IPV is still part of the routine childhood immunization schedule. Most adults in the U.S. have protective polio antibodies. However, unvaccinated and incompletely vaccinated adults remain susceptible to paralytic polio if exposed to poliovirus.

Those at increased risk of exposure include:

- Travelers who are going to countries where polio is epidemic or endemic
- Laboratory and healthcare workers who handle specimens that might contain polio
- Healthcare workers or other caregivers who have close contact with persons who could be infected with poliovirus.

Pneumococcal Conjugate Vaccine 20-valent (PCV20) Vote - Child

Pneumococcal conjugate vaccine 20-valent (PCV20), [Pfizer:Prevnar20®] was approved for use in children by the FDA prior to the June 2023 ACIP meeting. Four recommendations were voted on and approved by the ACIP regarding its use in children ages 18 and younger:

1. PCV15 and PCV20 are recommended for children ages 2 through 23 months according to current recommended pneumococcal vaccine dosing and schedule.

2. For children with an incomplete PCV vaccination status, use PCV15 or PCV20 according to the current recommendation schedule:
    a. Healthy children ages 24 through 59 months should receive 1 dose at least 8 weeks after the most recent PCV dose. No supplemental PCV20 is recommended if children have completed their full series with PCV13 or PCV15.
    b. Children with any risk condition ages 24 through 71 months:
        i. If previous receipt of 2 or fewer doses of a PCV, give 2 doses of PCV15 or PCV20 at least 8 weeks apart.
        ii. If 3 doses all given before 12 months of age, give 1 dose of PCV15 or PCV20 at least 8 weeks after the most recent PCV dose.
        iii. Risk conditions were expanded to include asthma, chronic kidney disease regardless of stage and chronic liver disease.

3. Children ages 2-18 years with a risk condition who completed their PCV series prior to age 6 years:
    a. If at least 1 of those doses was PCV20, then no further doses recommended.

    b. If PCV 13 or PCV15 were used and no PCV20 doses administered, a dose of PCV20 or PPSV23 using the previously recommended schedule should be given at age 2 years or greater, at least 8 weeks after the previous PCV dose.

    c. If immunocompromised and already received a dose of PPSV23, give either a dose of PCV20 or PPSV23 at least 5 years after that first dose of PPSV23.

4. Children ages 6-18 years with any risk condition who have not received any doses of PCV should receive either a dose of PCV15 followed by a dose of PPSV23 separated by at least 8 weeks, or a dose of PCV20.

Replacing PCV13 and PCV15 with PCV20 in healthy children increases the cost per quality adjusted life year (QALY) but is a cost-saving strategy in children with chronic medical conditions and immunocompromising conditions. In 2018-2019, the proportion of invasive pneumococcal disease (IPD) caused by PCV20, non-PCV13 types was approximately 30% of IPD cases. The proportion of IPD cases caused by PCV15, non-PCV13 types was approximately 15% of IPD cases. And the proportion IPD cases caused by PPSV23, non PCV20 types was 1-5% of IPD cases. The use of PPSV23 in addition to PCV20 would be cost prohibitive in the range of several hundred thousand to several million dollars per QALY. While PCV20 did not meet IgG geometric mean concentration non-inferiority criteria for several serotypes after dose 3, it met non-inferiority for all serotypes after dose 4.

Recommendations for children who have received **hematopoietic stem cell transplant** (HSCT) has been harmonized with the adult recommendation. They are to receive three doses of PCV20, 4 weeks apart starting 3 to 6 months after HSCT. A fourth PCV20 dose is recommended at least 6 months after the third PCV20 dose, or at least 12 months after HSCT, whichever is later. HSCT recipients who have started their pneumococcal vaccine series with PCV13 or PCV15 may complete their 4-dose pneumococcal vaccine series with PCV20 without giving extra doses.

If PCV20 is not available, three doses of PCV15, followed by a dose of PPSV23 at least 12 months after HSCT may be given. For patients with chronic graft-versus-host disease who are receiving PCV15, a fourth dose of PCV15 can be given in place of PPSV23 since these children are less likely to respond to PPSV23. A patient's clinical team is best positioned to determine the appropriate timing of vaccination.

Respiratory Syncytial Virus (RSV) Vaccine Vote - Adult

Two Respiratory Syncytial Virus (RSV) vaccines covering RSV A and RSV B have been licensed for adults ages 60 years and older:

- GSK's adjuvanted F protein vaccine (RSVpreF3 vaccine) AREXVY, containing 120mcg antigen and an ASO1 adjuvant
- Pfizer's non-adjuvanted F protein vaccine (bivalent RSVpreF vaccine) ABRYSVO™, containing 120mcg antigen and no adjuvant

The ACIP voted to recommend that adults ages 60 years and older MAY receive a single dose of RSV vaccine, using shared clinical decision-making.

GSK studied vaccine efficacy (VE) for both only one dose of AREXVY and when a second dose is given 12 months later. VE was 94.1% in the first season for severe RSV lower respiratory disease (RSV-LRTD) and 84.6% Mid-season 2. VE was 82.6% and 77.3% respectively against less severe RSV-LRTD. For one dose administered, the VE for Season 2, was 64.2% in preventing severe RSV-LRTD, and when a second dose was administered, the VE for that same Season 2 was essentially the same at 64.1%. It is estimated:

- For 1 million adults ages 60-64 years vaccinated given one dose of AREXVY, 890 hospitalizations and 35 deaths would be averted, and
- For 1 million adults ages 65 years and older vaccinated given one dose of AREXVY, 2,300 hospitalizations and 120 deaths would be averted.

GSK's AREXVY data did not show improved immunogenicity with a second booster dose, raising the issue of the need for boosters and whether the one dose should be timed for providing protection when the individual is most at risk. With a second dose, there were no higher antibody titers than with the first dose and no prolonged

effect. The neutralizing titer levels declined as quickly after the second dose as after the first dose. Pfizer did not present booster data and is still testing their booster dose. Vaccine efficacy did persist for two seasons.

Pfizer provided efficacy data into mid-season 2 after 1 dose of ABRYSVO™ which showed VE of 88.9% in Season 1 and 78.6% VE in Mid-season 2 for RSV-LRTD with 3 or more symptoms and VE of 65.1% in Season 1 and 48.9% in Mid-season 2 for RSV-LRTD with 2 or more symptoms. It is estimated:

- For 1 million adults ages 60-64 vaccinated given one dose of ABRYSVOTM, 960 hospitalizations and 37 deaths would be averted, and
- For 1 million adults ages 65 and older vaccinated given one dose of ABRYSVOTM, 2,500 hospitalizations and 130 deaths would be averted.

Trial data were inadequate due to low enrollment of persons ages 75 and older, nursing home residents and immunocompromised participants. VE against hospitalizations was not available.

There were three inflammatory neurologic events (2 Guillain-Barré Syndrome (GSB), 1 motor-sensory axonal polyneuropathy) reported within 42 days of vaccination with Pfizer's ABRYSVO™ among 20,255 older adults across all clinical trials. There were three inflammatory neurologic events in trials of GSK's AREXVY within 42 days of vaccination, (1 case of GSB within an open label trial and 2 cases acute demyelinating encephalomyelitis (ADEM) in a coadministration trial with influenza vaccine), but there were no unvaccinated comparators in those GSK studies. Study reported cases of ADEM did not have substantiating CSF or imaging tests to confirm the diagnosis. All studies were not powered enough to determine if there was an increased risk or if the findings occurred by chance.

Clinical guidance

- **Shared Clinical Decision-making** – those most likely to benefit from the vaccine are those with chronic lung diseases such as COPD and asthma, those with chronic cardiovascular diseases, those who are immunocompromised, have hematologic disorders, neurologic disorders, endocrine disorders such as diabetes, kidney and liver disorders, and residents of nursing homes and long-term care facilities. Studies were not conducted on immunocompromised participants and while it is possible that they could have reduced response to the vaccine, ACIP is still recommending it in those persons under shared clinical decision-making.
- **Timing** – give as soon as the vaccine is available and continue to administer throughout the RSV season. Since only one dose is recommended at this time, providing the vaccine when a person is at increased risk due to their age or comorbidities may lend the greatest protection.
- **Coadministration** – coadministration with other vaccines is acceptable, but committee members expressed reservations about coadministration for vaccines which have not been studied. Coadministration was studied with regular dose, high-dose and adjuvanted influenza vaccines. When vaccines were coadministered there was a slightly lower antibody titers against influenza subtypes and RSV types compared to when the vaccines were given sequentially. There are no data on COVID vaccine, Td/Tdap, or Shingrix coadministration. The GSK RSV vaccine contains the same adjuvant as Shingrix, although in half the amount, and committee members expressed caution in coadministering RSV vaccine with Shingrix.
- **Viral transmission** – since this is a parenteral injection, it may not have an impact on mucosal colonization and spread.

RSV vaccines will be Medicare Part D vaccines, so those patients covered by Medicare Part D will not be able to obtain the vaccine in a clinic setting but will need to receive it at a pharmacy. There is currently not a Vaccines for Adult funding program as a safety net for uninsured patients.

ACIP members were distressed that they were making recommendations regarding the adult RSV vaccines without knowing their price. When asked, GSK committed to a guaranteed price range somewhere between $200-295/dose and Pfizer quoted a range of $180-270/dose but would not guarantee that range.

Respiratory Syncytial Virus (RSV) Vaccine – Infant and Maternal

ACIP is anticipating voting on recommendations for Pfizer's RSV vaccine RSVpreF for pregnant mothers and Sanofi's RSV monocolonal antibody Nirsevimab for infants this fall if both products are approved. GSK halted its trials of Maternal RSV vaccine in February 2022 due to concerns of an imbalance in preterm deliveries and neonatal deaths of premature infants in vaccine recipients in low- and middle-income countries.

Nirsevimab potentially will be approved to administer to all infants <8 months of age entering their first RSV season and all infants born during the RSV season, and to children <24 months of age who remain at increased risk of severe disease entering their second RSV season to prevent lower respiratory tract infections.

Cost-effectiveness of maternal vaccination, infant mAb therapy and a combination using both products was reviewed. For Pfizer's RSVpreF maternal vaccine, VE against medically attended lower respiratory tract infection was 57.1% during the first 90 days of life and 51.3% at 6 months. Maternal RSV vaccination averts 2 hospitalizations/1,000 births and 5 ICU stays/10,000 births. Maternal RSV vaccination increases costs, but if vaccine is not administered from March through May, it becomes more cost-effective. There have been concerns about an imbalance in preterm births in those vaccinated during the Pfizer trials (although this occurred primarily in one country and was not statistically significant). It is too early to decide whether additional doses should be given in subsequent pregnancies given the lack of data on safety or efficacy beyond the first dose.

Due to concerns about preterm deliveries, ACOG representatives recommended the vaccine should be given in weeks 32-36 weeks, but that is a very short window to complete maternal vaccinations, and there needs to be time for maternal antibodies to be produced and passed to the fetus. The most optimal VE of 67.4% occurred when the vaccine was given at gestational ages 28 to 32 weeks, with the VE from 32 to 36 weeks at 57.3%. The ACIP RSV Work Group is proposing a recommendation for gestational ages 27-36 weeks for maternal vaccination.

Combinations of both RSVpreF vaccine and Nirsevimab add marginal effectiveness at very high cost in the general population. While it may be cost effective to administer one or the other, it is not cost effective to give both. Neither product is cost saving.

Adding Nirsevimab to all infants born to previously vaccinated mothers provides very little impact at a cost of $668,735/QALY. Adding Nirsevimab for infants only born during April through September born to previously vaccinated mothers is also not cost effective at $486,882/QALY. The benefit of adding maternal RSVpreF on top of a strategy of giving every child Nirsevimab costs more than $10million/QALY.

There are potential advantages to either maternal vaccination or infant monoclonal antibody administration, but both strategies should only rarely be used together.

Potential advantages of maternal vaccination over monoclonal antibody (mAb) include:

- A maternal vaccine may be lower in price (although resulting in a higher cost/QALY).
- An mAb is not a traditional vaccine which results in many complex implementation issues such as insurance coverage, vaccine schedule, immunization registries, safety monitoring.

- Maternal vaccination provides protection from birth when infants are at highest risk.
- An mAb must be timed correctly to provide protection during the RSV season, and atypical seasonal transmission may lead to unprotected infants.
- Maternal vaccine induces a polyclonal antibody response, which should be more resilient to mutations than a monoclonal antibody
- Tying Nirsevimab recommendations to maternal vaccination can be problematic as the vaccination status may be difficult to obtain especially during birth hospitalization, and outpatient primary care providers for the infant may not have good access to maternal prenatal vaccine records.

The potential advantages of Nirsevimab mAb over maternal vaccination include:

- Concern about an imbalance for preterm birth observed after RSVpreF vaccine.
- No head-to-head data to support this supposition, but protection from maternal vaccination is estimated to wane more quickly. The half-life of Nirsevimab is 63–73 days, and the half-life of infection-induced maternal RSV antibodies is 36–38 days.
- Nirsevimab administration can be timed to be given when the infant is entering the RSV season.
- Maternal transplacental antibodies may be reduced in infants born prematurely or soon after maternal immunization, or due to maternal disease.
- Maternal uptake of other recommended vaccines is substantially lower than routine childhood vaccines, although influenza vaccine among children is only mildly higher than among pregnant people.

Proposed clinical considerations:

- Either maternal vaccination with RSVpreF or Nirsevimab is recommended to prevent RSV disease, but both products are not needed for most infants
- Risks and benefits of both RSVpreF and Nirsevimab should be considered when deciding on maternal vaccination.
- Scenarios where Nirsevimab should be considered when a mother has been previously vaccinated include an infant born prematurely or within 14 days of vaccination or an infant at high-risk of severe disease (especially if born greater than 3 months prior to RSV season).
- RSVpreF vaccine should be offered to pregnant people during June through February in the continental United States. Providers can consider offering it year-round for ease of implementation if RSV seasonality is unpredictable or in jurisdictions with different RSV seasonality than the continental united states.
- Coadministration data is needed with other maternal vaccines, especially for Tdap which is administered in the same time frame.

COVID-19 Vaccines

For the latest CDC COVID vaccine recommendations, visit the CDC's Clinical Considerations website.

The FDA's Vaccine and Related Biological Advisory Committee (VRBPAC) met in June 2023 and advised manufacturers to produce a monovalent booster containing XBB.1.5 antigen. CDC is preparing for the transition to the new formulation and to commercialization of the vaccine in the fall. Following updated FDA vaccine authorizations, ACIP will review evidence to inform updated recommendations. Uninsured and under-insured children will be covered through VFC. Uninsured adults will be covered by the Bridge Access Program which will provide free vaccine first at local health departments and will then expand access to contracted retail pharmacies. Manufacturers will donate vaccine to the program and the administration fee will be paid through the federal government.

COVID-19 vaccines continue to be the most effective tool to prevent serious illness, hospitalization and death from COVID-19. Most of the population has not received a bivalent vaccine dose. It is anticipated that benefits will be realized from receiving an updated vaccine prior to a possible increase in COVID-19 cases in the winter. Antibodies against different XBB variants have good cross-protection between them.

The work group is supportive of additional simplification for children ages 2 through 4 years in the future, such as recommending only a single dose as is recommended for those ages 5 years and older.

COVID-19 vaccination is important for pregnant people for the protection of themselves and for their infants. Rates of hospitalization of infants ages 0 through 5 months with a COVID infection increased during the

Omicron period and are similar to the rates of hospitalization for those ages 65 to 75 years. Maternal vaccination at any point during pregnancy appears to be beneficial to infants ages 6 months and younger. Vaccine should be given to the mother early in her pregnancy to protect her from poor outcomes during pregnancy

Data during the Omicron variant period shows that compared with protection from infection or vaccination alone, hybrid immunity likely protects better against infection and severe disease. Current protection is influenced by cumulative number of vaccine doses, number of times infected, timing of most recent vaccination or infection, and how closely the circulating variant matches the vaccine or prior infection.

Mpox Vaccine

In the February 2023 ACIP meeting, recommendations for administration of JYNNEOS vaccine in persons ages 18 and older during an outbreak were approved and will be published in MMWR this summer. Additional clinical guidance was discussed during the June meeting.

Breakthrough cases in a new cluster in Chicago have been observed in men who have received only 1 dose of JYNNEOS, are HIV positive or with a higher number of sex partners in the 3 weeks prior.

While protection is seen with 1 or 2 doses, the highest rate of protection is seen with 2 doses regardless of route of administration. Adverse events are rare, with 49 cases of syncope per million doses and 2 reports of anaphylaxis per million doses.

Pregnant women have contracted Mpox through close contact with a confirmed case. Two neonates developed lesions within a week of their mother becoming symptomatic. One breastfeeding neonate developed lesions on their face and chest after the mother developed lesions on her breast. No adverse events have been reported in pregnant women. JYNNEOS is not contraindicated in pregnant women or breastfeeding women.

Less than 1% of Mpox cases were in persons under age 18 years. Most were in the 13- to 17-year age range with male-to-male sexual contact as a risk factor. For younger children, cases are predominantly from household contact. For children and adolescents, JYNNEOS should be administered to those ages 6 months through 17 years for pre-exposure prophylaxis or post exposure prophylaxis if an exposure has occurred during an outbreak. For children younger than 6 months, VIVIG should be administered in lieu of JYNNEOS. While antibodies to Mpox virus are likely low in VIVIG, temporal administration of vaccine should be avoided. Ideally, administration of JYNNEOS should be delayed if VIVIG was recently administered.

Meningococcal Vaccines

Economic modeling of the incremental cost-effectiveness of vaccinating healthy adolescents ages 11 to 12 years and age 16 years with Pentavalent MenABCWY vaccine relative to using Quadrivalent MenACWY and MenB was presented. Current recommendations are for 2 doses of Quadrivalent MenACWY for all at ages 11 to 12 and at age 16, and after shared clinical decision-making, 2 doses of MenB at age 16 years. Pentavalent MenABCWY vaccine trials have been conducted with 2 doses given 6 months apart.

The meningococcal work group examined whether Pentavalent vaccine should be administered when both Quadrivalent and MenB vaccine are indicated, whether Pentavalent vaccine should be administered when only Quadrivalent is indicated, and whether Pentavalent vaccine should be administered when only MenB vaccine is indicated.

Most Pentavalent strategies would save more or the same number of cases as the standard of care, but they would do so at a much higher cost per QALY. The exception is giving a dose of Quadravalent at age 11 to 12 years, a dose of Pentavalent at age 16, and then a dose of MenB, which could be incrementally cost saving relative to the standard of care. Another strength of this strategy is the reduction from 4 doses to 3 doses. Weaknesses of this schedule include not matching the dosing used in clinical trials. It would require stocking three vaccine types (MenACWY, Men ABCWY, and MenB) and could increase the risk of provider vaccine administration error. If ACIP does not recommend a second dose of Pentavalent Men ABCWY, insurance companies might not cover it in lieu of MenB.

The committee asked if it would be feasible to rethink the whole meningococcal schedule and possibly recommend 2 doses of MenABCWY or two doses of MenACWY and MenB at ages 16 to 18 years. Giving the vaccine at ages 11 to 12 years was thought to be not necessary. The work group will continue to evaluate potential dosing schedules prior to making a recommendation.

Other Topics

Dengue – The workgroup is evaluating four questions to inform the recommendation once the Takeda TAK-003 dengue virus vaccine is approved by the FDA. Approval is anticipated in Quarter 3 of 2023. The group is considering whether TAK-003 should be recommended in persons living in dengue endemic areas ages 4 through 16 years who are seronegative prior to vaccination, and in that age group who are seropositive prior to vaccination and whether it should be recommended in persons ages 17 through 60 years who are seronegative or seropositive. Immunobridging data is used to evaluate its use in the older age group. Three of seven Evidence to Recommend (EtR) framework domains were presented: Public Health Problem, Benefits and Harms and Resource Use.

The Takeda TAK-003 dengue vaccine is a live-attenuated quadrivalent vaccine with a dengue virus serotype 2 backbone given in a two-dose series separated by 3 months.

Chikungunya – Chikungunya causes long term joint pain in 1 in 4 infected persons. It can cause blurred vision and headaches as well. In a recent outbreak in Paraguay, 9% of cases were hospitalized, <1% of cases resulted in death with the highest case fatality rate in neonates. Valneva's chikungunya vaccine is anticipated for approval in fall of 2023. The ACIP will review EtR in the October 2023 meeting with potential recommendation in February 2024.

Vaccine Safety – Several safety studies were presented. Vaccination does not result in higher rates of non-vaccine targeted infections, refuting the theory that vaccinations cause an "overload" of the immune system. Type I Diabetes Mellitus is not associated with vaccination or aluminum. Prevention of RSV does not reduce the rate of the development of Asthma. Aluminum content in vaccine was not associated with an increase in rates of asthma in a Danish National cohort, but a Kaiser Permanente study showed a small positive association between cumulative vaccine-associated aluminum prior to age 24 months and persistent asthma at ages 24 to 59 months. This is a multi-step trial that has not yet been completed. The totality of available evidence continues to support the safety of the routine childhood vaccination schedule.

Questions regarding immunization?

Contact Tamara Sheffield, MD, MPA, MPH, Senior Medical Director, Preventive Medicine, Intermountain Healthcare, at **801-442-3946**.