NEW YORK STATE IMMUNIZATION ADIVSORY COUNCIL
MINUTES OF April 3, 2023 MEETING
12:30 pm-2:00 pm

Invited Guest: Agenda Item	Discussion	Follow-Up
Welcome / Chair's Remarks: Dr. Debra Tristram	Introductions and thank you to Kara Connelly for speaking with the lawyers to determine that the meeting can be held as a virtual meeting. Business: we are trying to fill 2 open seats on the Council. 2 candidate names were submitted and we are waiting on word from the Legislature. Ellie Ward advised that it can take time to hear back and offered to look into the status if there is a direct ask for her to do so. A direct ask was made. (It was noted that Phil Kaplan is one of the candidates being considered.)	
New Business: Dr. Debra Tristram	The Council is hopeful about this year's budget. There is good support of pediatrics included in the budget proposal. No final budget at this time, still negotiating. Budget includes money for Medicaid and public health in general but no money specifically vaccine related in the budget. The adult consent bill to have immunizations automatically put into NYSIIS for 19+ is asked for every year and has not passed. Dr. Tristram briefly touches on the plans for Bureau of Immunization to become a Division with some focus on vaccine hesitancy. Hopes there will be stakeholder input as the plans move forward. Notes it is very important for advocates to be out on social medial to reach the younger generation when it comes to vaccine confidence. 21 States are rolling back vaccine mandates for children, hope this is not a new trend and we will not see anything like this in New York. Let's Get Immunized NY Home | Let's Get Immunized NY (letsgetimmunizedny.org) resource shared as a good resource	
Covid-19 Vaccination Commercialization: Lyndsey Hoyt	• Vaccine is still currently available through the CDC for ordering. Talk about combining strain selection for future use (possible for the Fall) • Supply issues for Moderna 6+ Monovalent, all expiring no more will be ordered • ACIP voted to add Covid vaccine to VFC	

	(Slides available upon request)	
ACIP Meeting discussion: Dr. Jessica Kumar	• RSV was bad this year, population 60+ was especially at high risk • 117 pediatric deaths • Nirsevimab drug looks promising (Slides available at the end of meeting notes)	
Influenza: Sarah Hershey	• 24 weeks of wide-spread flu, peaked in mid Dec with and increase in Flu B this year • 138 pediatric deaths from flu nationwide • Vaccination provided substantial protection among all ages. High protection for immuno-compromised • Flu vaccine was low among pregnant women • Race and ethnic disparities were present	
NYSIIS update: Dina Hoefer	• Still a lot going on with Polio in regard to NYSIIS reporting • April 1 numbers were 79.8% with 85.2% coverage in school age kids • Kids are still delaying vaccines and not hitting the benchmarks • Lots of updates behind the scenes in NYSIIS trying to improve functionality for schools • Training and Outreach team is working on education	
Closing remarks:	Minutes for this meeting are informal and can't be approved because there was not a quorum. Next meeting will be June/July and then again in Nov.	

Key slides from Dr. Kumar's presentation

What Is Happening in NYS as of 4/6/23

Preliminary VPD Surveillance Data - 2022	
Disease	Case Count
Haemophilus influenzae type b	2
Mumps	11
Pertussis	212
Polio	1
Streptococcal pneumoniae (infections in children <5 years of age)	53
Varicella (outbreaks only)	0

RSV

- Viruses often co-circulate seasonally
- **F** and G are targets of neutralizing antibodies
- Natural RSV infection does not provide durable or complete protection from re-infection
- Re-infection can occur as early as 2mo past the last infection
- Anti-RSV antibodies return to pre-infection levels within 6 mo post infectic
- No treatments for adults
- 80,000 hospitalizations, and up to 300 deaths in U.S. children less than 5 years of age each year
- The most common cause of hospitalization in U.S. infants

FDA evaluates RSV vaccine for older adults > or = to 60 or 65 yrs

- Applied for Biologic License Application (BLA); for 65 and older adults
- 0.mL IM dose

Abrysvo (RSVPreF) Pfizer:
- 86% (lower respiratory infection and acute respiratory infection)
- Rare potential reactions
- VE in high risk patients
- AE profile showed no safety concerns

Arexvy (RSVPreF3+AS01E) GSK:
- 82.6% VE for RSV LRTD in 60 yrs+

- FDA has not yet completed review of safety and efficacy data for the GSK adjuvanted RSVpreF3 vaccine and the Pfizer bivalent RSVpreF vaccine.
- ACIP recommendations would be made only if the vaccines are approved and licensed by FDA

Nirsevimab Drug (CDER) for infants

- AstraZeneca/Sanofi
- Long acting monoclonal antibody
- Single-dose preventative immune therapy IM dose
- Accepted application for biologics license application
- Used up to 24 months of age
- Intervention for <8 mo and children <20 months that are high risk and entering their second RSV season
  - Same groups eligible for palivizumab while entering the 2nd RSV season (AAP)
  - 74.5% reduction in lower respiratory tract infections
- Possible inclusion into VFC
- FDA adverse event reporting system (FAERS)
- Most commonly, rash (0.7%) within 14d of dose, pyrexia (0.5%) and injection site reactions (0.3%) within 7d post dose

Evidence to Recommendations (EtR) Framework: Policy Questions

- Should one dose of nirsevimab be recommended
  - At birth for all infants born during October to March
  - When entering first RSV season
  - <8 months of age for all infants born during April through September

  - During the first RSV season: Feasiblity, equity (inclusion into VFC) and cost
  - During the second RSV season: limited data/efficacy, recommended for those eligible for palivizumab in the second season

Maternal/Pregnant Person RSV Vaccine, RSVpreF or PF-06928316

- Pfizer maternal bivalent RSV vaccine
- Use at 24-36 weeks gestation
- Given to infants up to 6mo post birth
- Vaccine efficacy of 81.8% against severe medically attended lower respiratory tract illness due to RSV in infants from birth through the first 90 days of life
- Highest efficacy of 69.4% demonstrated through the first six months of life
- Continue discussion at the June ACIP meeting
- AMA involved, await for licensing before vote or discussion

ACIP: RSVpreF or PF-06928316

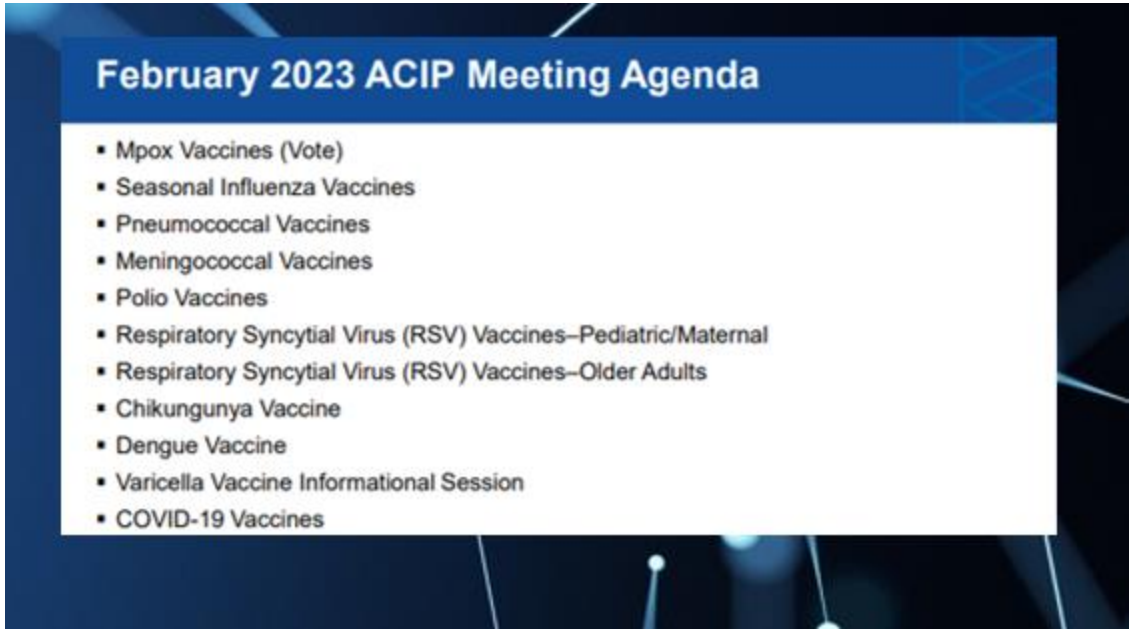
- Should the Pfizer RSV bivalent prefusion F vaccine be recommended for all pregnant people as a single dose given at 24-36 weeks gestation?
- Context of the current standard of care for prevention of RSV disease in infants at the time of ACIP vote
- No data available on efficacy stratified by gestational age at time of administration
- All pregnant people in the trial received their first and only dose of RSV vaccine
- Currently there are no data available on:
  - Efficacy of the 1st lifetime dose during subsequent pregnancies
  - Safety of additional doses given in subsequent pregnancies

Continued questions

- Disease burden: functional loss/cardiovascular complications
- Impact on the healthcare system
- Duration of vaccine efficacy
- VE in immunocompromised and frail elderly
- VE with severe infections
- Effect of administration with concomitant vaccines

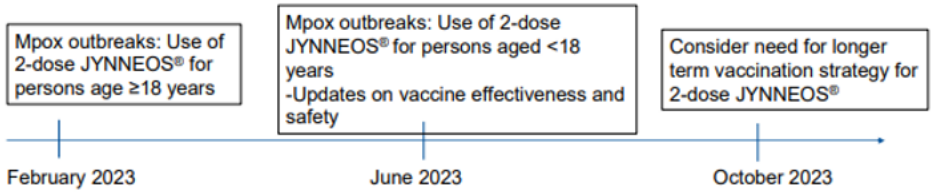
Resources

- RSV Nat. Center for Immunization & Respiratory Disease: https://www.fda.gov/media/165732/download
- RSV Immunity: https://www.fda.gov/media/165733/download
- RSV virology: https://www.fda.gov/media/165734/download
- GSK ppt: https://www.fda.gov/media/165649/download
- Pfizer ppt: https://www.fda.gov/media/165737/download
- Abrysvo: https://www.fda.gov/media/165728/download; https://www.fda.gov/media/165730/download
- Arexvy: https://www.fda.gov/media/165729/download ; https://www.fda.gov/media/165731/download


February 2023 ACIP Meeting Agenda
Mpox Vaccines (Vote)
Seasonal Influenza Vaccines
Pneumococcal Vaccines
Meningococcal Vaccines
Polio Vaccines
Respiratory Syncytial Virus (RSV) Vaccines–Pediatric/Maternal
Respiratory Syncytial Virus (RSV) Vaccines–Older Adults
Chikungunya Vaccine
Dengue Vaccine
Varicella Vaccine Informational Session
COVID-19 Vaccines

MPOX

- Use of orthopoxvirus vaccine, JYNNEOS®,
  - (licensed in 2019) for pre-exposure vaccination of people at occupational risk for orthopoxvirus exposures
  - 2-dose series, subcutaneous administration
  - Recommendations published June 3, 2022: www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm
  - Currently no ACIP recommendation for use of JYNNEOS® during outbreaks



Source: Vaccination | Mpox | Poxvirus | CDC

MPOX

- MPOX: ACIP voted unanimously to recommend the 2-dose Jynneos series for people age 18 years and older at risk of mpox during an mpox outbreak
- Subcutaneous administration will be recommended unless supply constraints necessitate intradermal administration
- ACIP will consider use of the vaccine in people younger than age 18 years during its June 2023 meeting
- Longer-term vaccination strategy for 2-dose Jynneos will be considered at the October 2023 meeting

COVID Booster Dose

- Everyone ages 5 and older, if it has been at least 2 months since your last dose
- Children ages 6mo to 5 years who completed the 2-dose Moderna primary series and if it has been at least 2 months since their last dose
- For children ages 6mo to 4 years who completed the 3-dose Pfizer primary series with Pfizer monovalent vaccine for all three doses and if it has been at least 2 months since their last dose
- All children ages 6mo through 4 years who start a new Pfizer primary series should receive monovalent vaccine for dose 1 and 2 and a bivalent vaccine for dose 3

COVID Vaccine in the Future

- Simplifying the COVID vaccine recommendations
  - 2-dose primary series for children and in immunocompromised adults
  - Adopt a 1-dose annually scheduled for all other children and adults
  - To use bivalent vaccines for both the primary series and booster doses (maybe as early as May 2023)
  - Commercialization of vaccines/treatments (Fall 2023)
    - VFC and services for uninsured adults
- November 2022: VSD detected a safety signal for ischemic stroke in adults age 65 years and older after the Pfizer-BioNTech bivalent COVID-19 vaccination which was stronger following simultaneous administration of the Pfizer-BioNTech bivalent booster and influenza vaccine
- Vaccine coverage remains low in all ages particularly children and adults

Influenza Vaccines

- Flu peaked early, peak was in Nov and early Dec
- Increased activity compared to the last 2 seasons

- Mostly Influenza A (H3N2), co-circulation with A (H1N1)
- Flu vaccine efficacy >50% for the whole (peds/adult population) for this past season
- Significant protection from hospitalization in high risk groups and over all ages
- Provided the most protection in high risk groups which includet he >65 year old group and immune compromised

Polio Vaccines

- Adults known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series
- Unless there are specific reasons to believe they were not vaccinated, most adults who were born in the US can assume can assume they were vaccinated against polio as children

Proposed Language:

- Adults who have received a primary series of 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.

Things to consider:

- Vaccination before a person is at increased risk; consistency with other adult recommendations, make recommendations more simple
- Risk stratification and vaccine supply

Original Recommendation

- Need for supplementary dose?
- Assessing protection when exposure is expected in high risk situations
- 2 cases of paralytic polio in adult travelers who completd a primary polio vaccine series with Salk IPV and/or tOPV
- Vaccine efficacy against paralytic polio ranges from 36-89% for one dose and 89-98% for 2 doses
- No data on vaccine efficacy of primary series + boosters vs primary series only
- Research shows 98-100% of adults with heterogenous pre-booster vaccine histories/seropositivity 1 month after an IPV-containing booster and another study followed trial participants 10 years post booster and found a 98-100% seropositive rate

Source: https://www.cdc.gov/mmwr/preview/mmwrhtml/00025216.htm; https://pubmed.ncbi.nlm.nih.gov/25131729/ https://pubmed.ncbi.nlm.nih.gov/15882526/

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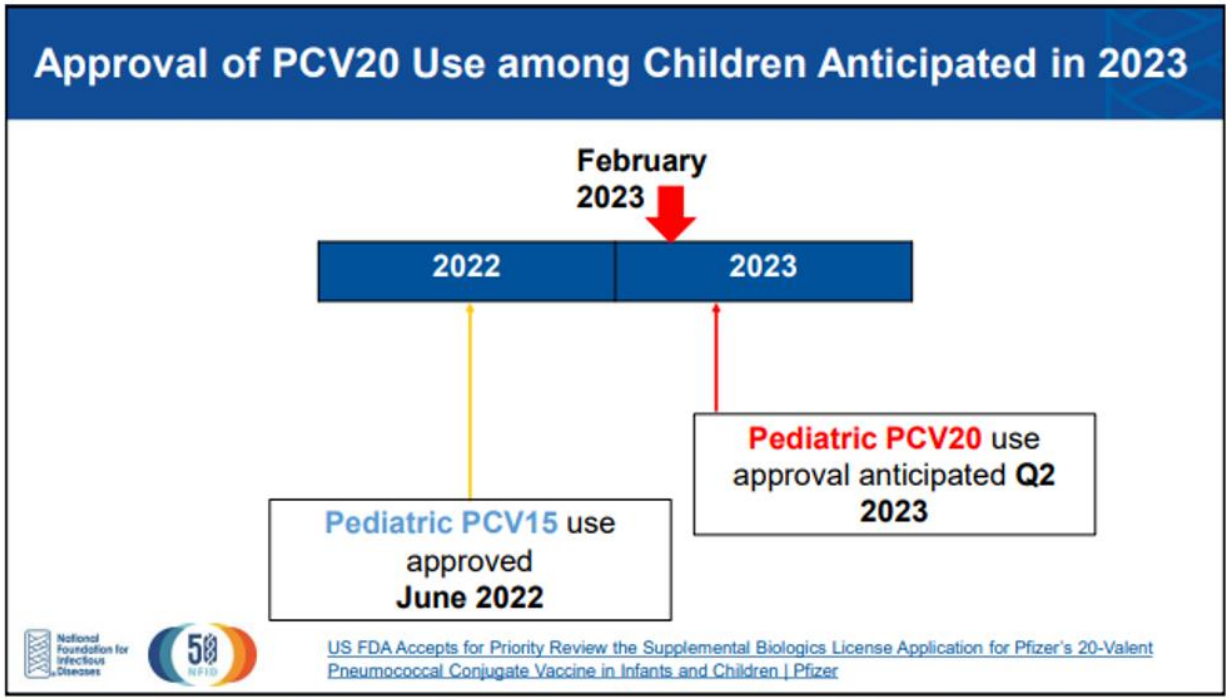
Pneumococcal Vaccines Currently Recommended for Use in the US

	Recommended for children	Recommended for adults
Pneumococcal conjugate vaccines		
PCV13	✓	
PCV15	✓	✓
PCV20		✓
Pneumococcal polysaccharide vaccine		
PPSV23	Risk-based recommendations	If previously received PCV13 or PCV15

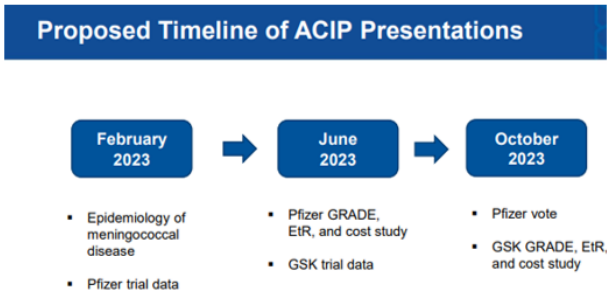
Pneumococcal Vaccines

- Invasive pneumococcal disease is higher in children <5 years
- Pneumococcal vaccines (PCV-20) for kids (may be licensed in 4/2023)
- PCV20 dosing schedules for children younger than age 2 years
- Considerations for using PCV20 in children ages 2-18 years instead of PPSV23 in older children who have underlying medical conditions and increased risk of invasive disease
- Stay tuned for the ACIP meeting in June


Approval of PCV20 Use among Children Anticipated in 2023
February 2023
2022
2023
Pediatric PCV20 use approval anticipated Q2 2023
Pediatric PCV15 use approved June 2022
US FDA Accepts for Priority Review the Supplemental Biologics License Application for Pfizer's 20-Valent Pneumococcal Conjugate Vaccine in Infants and Children | Pfizer

Meningococcal

- Meningococcal
  - Meningitis pentavalent vaccine (MenABCWY) which includes MenB (Pfizer/GSK)
  - Pfizer MenABCWY vaccine appears to be noninferior to MenACWY+MenB based on clinical trial data presented
  - May be included in the adolescent schedule
  - TBA in June at ACIP with a vote in Oct 2023



Resources

- ACIP: ACIP February 22-24, 2023 Presentation Slides | Immunization Practices | CDC
- NFID: 23.03.22-Webinar-Slides-Handout.pdf