

NEW YORK STATE IMMUNIZATION ADVISORY COUNCIL
MINUTES OF August 24th, 2023 MEETING

Council Members: Dr. Debra Tristram, Dr. Kenneth Rowin, Paul Macielak, Elie Ward, Alison Singer

NYSDOH Staff Members: Kara Connelly, Dr. Dina Hoefler, Dr. Deb Blog, Dr. Jessica Kumar, Alexandra Hamburg, Anike Shaw, Sarah Hershey, Kiersten Westbrook, Deborah Sobieszak, Jeremy Heisey, Theresa Nichols, Victoria Ervin

NYCDOHMH Staff Members: Dr. Bindy Crouch

Invited Guest: Agenda Item	Discussion	Follow-Up
Welcome / Chair's Remarks: Dr. Debra Tristram	<ul style="list-style-type: none"> • The meeting was called to order by Dr. Tristram at 12:31 pm. • Introductions of those in attendance were completed. <p>Discussion</p>	
Approval of June 2022 Minutes	<ul style="list-style-type: none"> • The meeting minutes from April will be provided via email 	
Legislative Update Elie Ward	<ul style="list-style-type: none"> • Change in NYSIIS to opt out instead of Opt in • Passed assembly, died in the senate • It will likely come back <p>Discussion</p> <ul style="list-style-type: none"> • Huge opposition, despite how small this change would be • Politicians don't really want to get behind this • Omnibus bill a6761 coming out to support mature minors to allow them control over their healthcare without parental consent 	
ACIP Meeting Summary and Clinical Updates Dr. Jessica Kumar	<p>Clinical Updates</p> <ul style="list-style-type: none"> • Introduce reporting for RSV (lab reporting, pediatric deaths) and individual cases of varicella • RSV updates and campaign: Link <ul style="list-style-type: none"> • Pharmacists and immunizers: Link • Polio updates: Link with advisory Link • Public Health live: HPV (8/16) and adult immunizations (3/2023) 	

- <https://www.albany.edu/cphce/hpv-vaccine-cancer-prevention-changing-narrative-improve-vaccination-rates>
- <https://www.albany.edu/cphce/adult-immunization-recommendations-and-strategies-to-improve-coverage-rates>

- “Start at 9” for HPV vaccination: [Link](#) on 8/2
- Webinar series: Meningococcal Disease: [Link](#)

FDA approves Abrysvo for 32-36 wks gestational age of pregnancy (8/21)

- Prevent lower respiratory tract disease (and severe illness) in infants from birth to 6 months of age
- Approved for 32-36 wks gestational age
- Single injection intramuscularly
- Same vaccine approved for older adults in May
- Reduced the risk of severe LRTD by 81.8% within 90 days after birth and 69.4% within 180 days after birth
- AE’s: injection site pain, headache, muscle pain and nausea
- Preterm births, pre-eclampsia, low birth weight and jaundice

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

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

- Applied for Biologic License Application (BLA); for 60 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

	<p>Arexvy (RSVPreF3+AS01E) GSK:</p> <ul style="list-style-type: none"> • 82.6% VE for RSV LRTD in 60 yrs+ • <i>Limited data available on immunogenicity of coadministration of adult RSV vaccines and other vaccines, the General Best Practice Guidelines for Immunization provides that coadministration of RSV vaccines with other adult vaccines is acceptable including giving RSV vaccines to adults simultaneously with seasonal influenza vaccines.</i> <p>RSV in Adults: Abrysvo (Pfizer) and Arexvy (GSK)</p> <ul style="list-style-type: none"> • Significant efficacy over at least 2 seasons • Prevent severe morbidity and mortality (frail, co-morbid conditions) • AE: inflammatory neurologic events 42 d post each vaccine (GBS) • Cost-effectiveness: Current assumptions: \$200 Pfizer RSVpreF, \$270 GSK RSVPreF3, priority to older age groups due to uncertainty of illness/hospitalization and duration of protection of vaccine • Vote: Adults 60 years of age and older may receive a single dose of Respiratory Syncytial Virus (RSV) vaccine, using shared clinical decision-making <p>Palivizumab Drug for infants</p> <ul style="list-style-type: none"> • Palivizumab (RSV protein F) monoclonal antibody product is limited to children under 24 months of age with certain conditions that place them at high risk for severe RSV disease. <ul style="list-style-type: none"> • Given once a month during RSV season, 15mg/kg • born prematurely (at or before 35 weeks) and who are 6 months of age or less at the beginning of RSV season • who have a chronic lung condition, called bronchopulmonary dysplasia (BPD), that needed medical treatment within the last 6 months, and who are 24 months of age or less at the beginning of RSV season • Born with certain types of heart disease and who are 24 months of age or less at the beginning of RSV season • https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/ • https://www.synagis.com/index.html <p>Nirsevimab Drug (CDER) for infants</p> <ul style="list-style-type: none"> • AstraZeneca/Sanofi monoclonal antibody product • Passive immunization. While not technically a “vaccine” in a traditional sense (active immunization), it is being used in a manner like routine childhood vaccines 	
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- FDA announcement: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-prevent-rsv-babies-and-toddlers>
- Single-dose preventative immune therapy IM dose
- Used up to 24 months of age
- Infants aged <8 months born during or entering their first RSV season are recommended to receive one dose of Beyfortus (50 mg for infants <5 kg and 100 mg for infants ≥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 Beyfortus (200 mg)

Nirsevimab Drug (CDER) for infants

Beyfortus is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in:

- Neonates and infants born during or entering their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.
- VFC: <https://www.cdc.gov/vaccines/programs/vfc/index.html>
- CDC: <https://www.cdc.gov/rsv/high-risk/infants-young-children.html>
- AAP: Comparing Monoclonal Antibodies for RSV Prevention:7/1
 - Comparing Monoclonal Antibodies for RSV Prevention. *AAP Grand Rounds* July 2023; 50 (1): 4. <https://doi.org/10.1542/gr.50-1-4>

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

Discussion

- For infants born shortly before and during the RSV season,
 - providers should target administration during the birth hospitalization or shortly after discharge, and by one week of age
- For infants born before the RSV season,
 - providers should target administration just before the start of the RSV season, such as during a scheduled well child visit

- Based on pre-pandemic patterns, nirsevimab could be administered in most of the continental US from October through the end of March
 - Providers in jurisdictions with altered seasonality should consult state, local, or territorial guidance on timing of nirsevimab administration
- The ACIP added American Indian and Alaska Native Children to those recommended by the AAP who are at increased risk of severe disease in children aged 8-19 months entering their second RSV season based on documented increased incidence of RSV-associated hospitalizations in these groups
- Other risk factors include children with chronic lung disease of prematurity who required medical support any time during the 6-month period before the start of the second RSV season, severe immunocompromise, cystic fibrosis who have manifestations of severe lung disease or weight-for-length <10th percentile

Polio Virus

- Risk for importation
- Most US born adults have serologic evidence to poliovirus types 1-3
- Unvaccinated or incompletely vaccinated adults are susceptible to polio if exposed
- Plan to move toward a uniform polio vaccine recommendation allowing unvaccinated adults to get vaccinated and bring adult polio vaccine policy in line with mmr/varicella for adults
- Uniform recommendation regardless of wastewater or other surveillance measures
- 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 they were vaccinated against polio as children

Polio Vaccines

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 completed 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

Recommendations

- Adults (age ≥ 18 years) who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with IPV
- Adults who have received a primary series of trivalent OPV (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
- NYS advisory: https://www.health.ny.gov/diseases/communicable/polio/docs/2023-07-31_advisory.pdf

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 included the >65 year old group and immune compromised
- Vaccination of all person's age ≥ 6 months who do not have contraindications continues to be recommended
- Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.
- Recommendations regarding timing of vaccination are unchanged from 2022-2023

Influenza Changes

Updated US influenza vaccine composition for 2023-2024

- Proposed changes to the recommendations for vaccination for persons with egg allergy

	<ul style="list-style-type: none"> • If a vaccine other than cclIV4 or RIV4 is used, the selected vaccine should be administered in an inpatient or outpatient medical setting, including but not necessarily limited to hospitals, clinics, health departments, and physician offices. • Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions with no specific observation period • Approved age indication for the cell culture–based inactivated influenza vaccine, Flucelvax Quadrivalent (ccIV4), was changed in October 2021 from ≥ 2 years to ≥ 6 months • ACIP recommends that adults aged ≥ 65 years preferentially receive any one of the following higher dose or adjuvanted influenza vaccines: quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4). If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used • All seasonal influenza vaccines expected to be available in the United States for the 2022–23 season are quadrivalent <ul style="list-style-type: none"> • hemagglutinin (HA) derived from one influenza A(H1N1)pdm09 virus • one influenza A(H3N2) virus • one influenza B/Victoria lineage virus • one influenza B/Yamagata lineage virus. • Inactivated influenza vaccines (IIV4s) • Recombinant influenza vaccine (RIV4) • Live attenuated influenza vaccine (LAIV4) are expected to be available • Trivalent influenza vaccines are no longer available <p>Pneumococcal Vaccine Updates</p> <ul style="list-style-type: none"> • Both PCV15 and PCV20 Were Approved Based on Safety and Immunogenicity Data Compared with PCV13 • serotype 3 had higher antibody responses • 3 primary series and a booster=“3+1” schedule: Currently, either PCV13 or PCV15 can be used <p>Votes</p> <ul style="list-style-type: none"> • 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: 	
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	<ul style="list-style-type: none"> • Healthy children aged 24–59 months • Children with specified health conditions 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 <ul style="list-style-type: none"> • 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 <p>Chikungunya/Dengue</p> <ul style="list-style-type: none"> • Feb 2023: Valneva BLA for Chikungunya vaccine <ul style="list-style-type: none"> • Consideration of chikungunya vaccine use among residents of US territories and states at risk for outbreaks • New Dengue vaccine TAK-003 • Currently on ACIP: Three doses of Dengvaxia™ are indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3, and 4 in people 9–16 years old with: <ul style="list-style-type: none"> • laboratory confirmation of previous dengue virus infection <p>AND</p> <ul style="list-style-type: none"> • living in endemic areas <p>MPOX/Combined Meningitis Vaccine</p> <ul style="list-style-type: none"> • ACIP recommends the 2-dose (administered one month after dose 1) JYNNEOS® vaccine series for persons aged 18 years and older at risk of mpox during an mpox outbreak • Discuss a longer-term vaccine strategy <p>New CDC Page updates:</p> <ul style="list-style-type: none"> • Mpox Vaccine Recommendations: https://www.cdc.gov/poxvirus/mpox/vaccines/vaccine-recommendations.html • Mpox Vaccination Basics: https://www.cdc.gov/poxvirus/mpox/vaccines/index.html <p>Combined Meningitis Vaccine</p> <p>Comprised of Trumenba® (serogroup B) and Nimenrix® (serogroups ACWY) – Trumenba®</p> <ul style="list-style-type: none"> • Consists of two purified recombinant lipidated FHbp antigens, one from each FHbp subfamily (A and B) 	
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	<ul style="list-style-type: none"> • Currently licensed and available in US (10–25 years) – Nimenrix® • Meningococcal group A, C, W, and Y polysaccharide tetanus toxoid conjugate vaccine • Not licensed in US but used extensively in Europe and elsewhere for over a decade • <i>For individuals aged 10 years or older, Pfizer’s MenACWY vaccine may be used as an alternative to MenACWY and MenB vaccines only when both vaccines are indicated to be given at the same time.</i> • <i>This proposal applies to healthy individuals (routine schedule) and those at increased risk for meningococcal disease</i> <p>Resources</p> <ul style="list-style-type: none"> • 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 • ACIP: ACIP February 22-24, 2023 Presentation Slides Immunization Practices CDC • NFID: 23.03.22-Webinar-Slides-Handout.pdf <p>Discussion</p> <p>Any push to recommended RSV vaccine in nursing home ACIP is pushing clinical joined decision making Should be included for free in nursing homes</p>	
<p>Vaccine Program Update Kara Connolly</p>	<ul style="list-style-type: none"> • Seasonal flu ordering is open, for VFC/A providers, opened on 8/21 • Can order menvio now, as 1 vial doesn’t require reconstitution • Prevnar 20 will be available starting September • RSV pending addition to CDC contract, once available vaccine program is considering making them available in the VFA program, need more funding in order to purchase • Monoclonal antibody will be added to VFC soon 	

	<ul style="list-style-type: none"> • New covid monovalent should be available soon (this fall) ordering for existing vaccines ended 8/2 • Covid 19 updated office hours for providers, discuss the transition between bridge access program and VFC and current vaccination program • CDC working with production <p>Discussion How will the new Covid vaccine be presented publicly? Not really sure, the messaging will be that it's updated and targeted for new variants, everyone is eligible, the old monovalent is no longer relevant Gonna be a hard sell</p>	
<p>Influenza Update Sarah Hershey</p>	<p>Showed map of NYS displaying flu rates, highest in New York City, and capital Peaked early last year, around Nov and Dec Adults 65+ more likely to be hospitalized 13 pediatric deaths in NY this year</p> <p>Summary of CDC's Influenza Vaccine Coverage Estimates Updates: January 6, 2023</p> <ul style="list-style-type: none"> • Earlier observed drops in overall adult coverage has narrowed as the season has progressed. • Coverage among pregnant people has remained low. • Coverage in children overall has remained similar to last season with an increase seen among Hispanic children. • Racial and ethnic disparities persist despite some improvement seen in coverage among Black adults and Asian American adults. Coverage in urban and suburban areas continues to be higher than rural areas. • The CDC continues to recommend influenza vaccine while influenza viruses continue to circulate. <p>2023-2024 Influenza Vaccine Recommendations</p> <ul style="list-style-type: none"> • MMWR is pending, but is expected by the end of August • CDC director adopted ACIP recommendations and this was posted on the CDC's "Flu News and Spotlights" which included recommendations for: <ul style="list-style-type: none"> ○ Updated language regarding persons with egg allergy will remove additional safety measures. All persons with egg allergy are recommended to receive any influenza vaccine that is appropriate for their age and health status. Recommended safety measures will be the same as receipt of any vaccine. 	

NYSIIS Update Dina Hoefer	<ul style="list-style-type: none"> • New functionality • Data and trends • Monitoring RSV monoclonal antibody guidance for reporting to IIS <p>Discussion What was the influenza vaccine intake for last year? Data not available at this time</p>	
New York City Dept. of Health and Mental Hygiene Update Dr. Crouch	<ul style="list-style-type: none"> • Very busy with vaccination of children who have newly arrived in NYC as asylum seekers • 56,000 people in city housing, 2-3 shelters per weekend, and all pediatric immunizations are offered and link them to a primary care providers • Adult RSV NYC is working on incorporating older adults talking to their provider <ul style="list-style-type: none"> ○ Standing order with pharmacies support by NYC DOH MH • Concerned about providing accurate information on Covid vaccination, working hard on plans for uninsured adults and where they will have access to vaccines <p>Discussion The RSV vaccine sounds expensive</p>	
New Business: Dr. Debra Tristram	Organization called vaccinate NY Next meeting will be 11/9	
Adjournment:	The meeting was adjourned at 2pm.	