NEW YORK STATE IMMUNIZATION ADIVSORY COUNCIL MINUTES OF MARCH 3rd, 2022 MEETING

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

NYSDOH Staff Members: Dr. Elizabeth Rauch-Phung, Ms. Robin Suitor, Ms. Kara Connelly, Dr. Dina Hoefer, Ms. Loretta Santilli, Ms. Barbara Joyce, Ms. Stephanie Ostrowski, Ms. Sarah Hershey, Mr. Dileep Sarecha, Ms. Carolyn Perry, Ms. Lyndsey Hoyt, Ms. Alexandra Hamburg, Ms. Kate Sorensen, Ms. Olga Lawrence, Mr. Johnathan Karmel, Ms. Shainza Noor, Ms. Anike Shaw

NYCDOHMH Staff Members: Dr. Jane Zucker

Other: Christine Hayes (GSK), Michelle Monnier (GSK), Thomas Dumas (GSK), Tobey Snyder (GSK), Molly Ortolani Walsh (MERC), Robert Zullo (MERC), Gregory Honsberger (PFI), Sagar Shah (PAS), Scott Eden (PAS), Andrew Rannekamp (SEQ), Karen Oles (Dynavax), Natalie Taylor (Dynavax), Natasha Loojune-Sookman (Schenectady County PH)

Invited Guest:	Discussion	Follow-Up
Agenda Item		
Welcome / Chair's	The meeting was called to order by Dr. Tristram at 12:30 pm.	Send suggestions for
Remarks:	 Introductions of those in attendance were completed. 	members to Dr. Tristram,
Dr. Debra Tristram	 Dr. Tristram stated that the council is missing 2 voting members 	will discuss next meeting
	 Would like to open it up to other voting members for suggestions; looking for geographic and experience spread, maybe someone in Western part of the state? Would like more broad participation. Discussion Dr. Tristram - Misinformation/disinformation/propaganda, providing every aspect of our society, mostly the internet. How do we combat this in new ways? What is the state doing? 90% of children hospitalized that I'm seeing in the hospital aren't immunized or the parents aren't immunized. Need to be clear on messaging. Elie Ward - The state is working on helping parents understand the latest information, both through social media and working with providers. We will go through this in more detail in the presentations. 	or circulate beforehand for discussion

NYS Covid19 Vaccination Program Update: Loretta A. Santilli, MPH

• Information is current as of 3/2/22 and is subject to change as the pandemic evolves

Covid-19 vaccines timeline

- Slide 3 goes through 12/20-7/21, slide 4 7/21-10/21, skipped to slide 5
- 11/2/21 Pfizer authorized for children 5 thru 11 years
- 11/17/21 Emergency Use Instructions (EUI) issued for individuals who received a non-FDA authorized or approved COVID-19 vaccine authorizing a 3rd additional primary dose for moderately/severely immunocompromised persons 12+ and a booster dose for 18+
- 11/19/21 CDC recommends boosters for anyone 18+ (6 mos after mRNA, 2 mos after J&J)
- 12/9/21 CDC recommends Pfizer booster for 16 and 17 year olds
- 12/16/21 CDC states clinical preference for mRNA COVID-19 vaccine over Janssen/J&J
- 12/23/21 new formulation of Pfizer adult/adolescent (12+) vaccine (Tris, Gray Cap, no diluent)
- Jan 22 CDC recommends Pfizer (1/4) and Moderna (1/7) booster dose at least <u>five</u> months after completing primary series (instead of 6)
- 1/4/22 CDC recommends moderately/severely immunocompromised 5-11 year olds receive an additional primary dose of vaccine 28 days after their second dose.
- 1/5/22 CDC recommends Pfizer boosters for 12-15 year olds (5 months after series)
- 1/7/22 Pfizer EUI updated for persons who received incomplete primary vaccination with vaccines not approved/authorized in the U.S. (no need to restart series)
- 1/31/22 FDA approves Spikevax, Moderna's COVID-19 vaccine for individuals 18+
- 2/8/22 J&J pauses Janssen production at Dutch manufacturing plant not sure what the supply chain for that product will look like going forward
- 2/9/22 Pre-ordering opened for Pfizer vaccine 6 mos thru 4 yrs
- 2/11/22 FDA pauses review of Pfizer vaccine for 6 mos thru 4 yrs pending additional data
- 2/11/22 CDC clarified recommendation for mRNA vaccine 3-dose primary series and booster dose for a total of 4 doses for persons who are moderately/severely immunocompromised and shortened interval between the primary series and booster dose from 5 months to 3 months.
- Janssen/J&J receive additional dose and booster dose for a total of 3 doses.
- 2/22/22 CDC updated <u>clinical considerations</u> for an 8-week interval between the first and second mRNA vaccine doses for certain individuals

Provider Channels

- 5,246 providers fully enrolled as of 2/23/22 (up 89 from Nov). 494 are pediatric offices.
- 14 NYS operated vaccination sites "State PODs" remain operational
- NYS #VaxForKids 261 sites established over 6-week <u>campaign</u>

Vaccines:

Monitor new products or changes in authorization or approval of existing products
Coming soon: Pfizer EUA for children 6 months through 4 years

Program:

The primary focus continues to be vaccinating the unvaccinated (including hard to reach adults, adolescents and children 5-11) while supporting ongoing booster efforts.

Monitoring expiration dates, beyond use dates, proper storage and inventory to prevent avoidable waste.

- Community based vaccination events in partnership with local provider partners (LHDs, pharmacies, hospitals, FQHCs)
- Community- and faith-based pop ups continued focus on ZIP codes with lower vaccination coverage rates.
- Healthcare provider booster requirement February 21, 2022
- Enforcement paused will reevaluate in 3 months

Provider Education

- COVID-19 Vaccine Information for Providers
- Comprehensive website with guidance, trainings, resources
- NYSDOH COVID-19 Vaccine Webinars for Healthcare Providers
 Recorded and available for viewing
- 11/4/21 COVID-19 Pediatric Vaccine and Boosters
- 2/4/22 COVID-19 Epidemiology, Vaccinations, Oral Anti-Virals and other Treatments, Revised Isolation and Quarantine, and Influenza

Public Education #VaccinateNY

(links to many social media resources and materials)

- Dedicated workgroup to **promote vaccine confidence** and quickly **address misinformation** that may spread on social media and in other media forms
- Intensive campaigns including media buys featuring Dr. Bassett encouraging vaccinations for kids and boosters
- <u>#GettheVaxFacts</u> Campaign to counter misinformation and disinformation with <u>downloadable</u> toolkits
- <u>Frequently Asked Questions</u> Answers to common questions about the COVID-19 vaccine.

Data and Systems

- NYSIIS (CIR in NYC) continues to support all data reporting needs
- COVID-19 <u>Vaccine Finder</u> tool remains active for determining vaccine provider locations
- <u>Excelsior Pass, Excelsior Pass Plus</u> New York's free, voluntary and secure platform to retrieve digital proof of COVID-19 vaccination.
 - New York State's Excelsior Pass Blueprint is a national framework to aid in the development and implementation of digital health credentials.

COVID-19 Data Hub

• Centralized COVID-19 data access page with information related to testing, hospitalization, fatalities, vaccination, etc.

NYS COVID-19 Vaccine Tracker

	 37,045,391 doses have been administered (as of 3/2/21,11 am) Additional Doses and Boosters administered: 7,126,471 Vaccination Coverage (NYSIIS/CIR data) Race/Ethnicity of People Vaccinated with at Least One Dose Compared to Total Population Aged 15+ years Percent of People with COMPLETE Vaccination Series by Age Group Discussion	
	Dr. Tristram – hopes the campaign effects vaccination rates	
Approval of November 2021 Minutes	Will get the minutes out today. It appears they were not sent out in advance.	Meeting minutes were sent out shortly after the meeting.
Legislative Update Ellie Ward	 Not much right now because the legislature is focused on the budget Adolescent consent to vaccinate Broader consent to healthcare as well as immunization for adolescents Legislation requiring the flu vaccine for school and childcare The academy has a new statement supporting immunizations required by law Will let us know if there is a time for this council to take a position on legislature Discussion – mentioned there's a movement to have adult reporting to Immunization Information systems the way it is for pediatric regarding consent Dr. Tristram – is this something we should take up as an Advisory Council? Ellie Ward – it's way too early, we should wait for a final version of a bill Dr. Kenneth Rowin – but when the time is right it sounds like this is something we should definitely do 	
Advisory Committee	Overview of Booster Dose Recommendations	Dr. Betsy will work with
on Immunization	COVID-19 Work Group Interpretation	the public affairs group
Practices Meeting	Top priority should be continued vaccination of unvaccinated individuals	to see if there is any good
Summary	Balance of benefits and risks varies by age	accurate information for
Dr. Rausch-Phung	Older adults have clearest benefit/risk balance	those who did have
	 In the setting of Omicron variant, likely lower vaccine effectiveness in all populations, compared to effectiveness seen with original strain and Delta variant However, in the setting of increasing cases this winter, even moderate reductions in transmission could increase the relative benefits of booster doses Myocarditis data after booster doses reassuring to date, continue to closely monitor 	myocarditis or other adverse reactions to address their specific needs / concerns and hopefully counter the

Preferential	Recommend	lation f	or mRNA	Vaccines

- Ongoing surveillance of thrombosis with thrombocytopenia syndrome (TTS) following Janssen vaccine has observed higher reporting rates than those previously estimated in spring/summer 2021
 - Highest reported rates in women age 30-49 years (9.79 cases per million doses administered)
- 100% of reported cases of TTS were hospitalized, two-thirds admitted to ICU, 15% died
- In CDC's analysis, mRNA COVID-19 vaccines had a better relative benefit-risk balance compared to Janssen vaccine
 - However, the benefits of Janssen COVID-19 vaccination still markedly exceed the risks when compared to no COVID-19 vaccine at all
- Among people ages 18 years and older, mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine

Benefits and Risks after Janssen and mRNA COVID-19 vaccine, Females

- COVID-19 associated hospitalizations prevented by Janssen COVID-19 vaccine (1 dose) compared with TTS and GBS cases expected
- COVID-19 associated hospitalizations prevented by mRNA COVID-19 vaccines (2 dose) compared with myocarditis cases expected
- Presented by age groups for females
- Expected benefits of the mRNA expected the expected benefits of the Janssen
- All female age groups pose a higher risk for the Janssen than the mRNA vaccine
- Benefits still out way the risks

Benefits and Risks after Janssen and mRNA COVID-19 vaccine, Males

- Similar results with this distinction; males 18 49 have the highest incidences of myocarditis, higher than anticipated than Janssen vaccine
- Overall, all ages and genders, the benefits of either vaccine out way the risks
- ACIP decided not to make gender based recommendation for 18 and over, mRNA vaccine is recommended over the Janssen
- The Janssen is still available especially for individuals unable to get the mRNA due to myocarditis, allergies, or personal preference

Department of Health made a handout to explain the risk/benefits

Moderna COVID-19 Vaccine FDA Approval

On January 31, 2022, the FDA approved a 2-dose primary series of Moderna COVID-19 Vaccine (Spikevax) for ages 18 years and older

misinformation that's out there

- Moderna COVID-19 vaccine remains under EUA for additional primary doses for immunocompromised people and booster doses
- Spikevax has the same formulation as the Moderna COVID-19 vaccine under EUA and both may be used interchangeably
- On February 4, 2022, the ACIP and CDC reaffirmed previous recommendations for use of Moderna (Spikevax) COVID-19 vaccine

COVID-19 Vaccination Schedule for People who are Moderately or Severely Immunocompromised

- People with moderate to severe immunocompromise who received a primary series of mRNA COVID-19 vaccines should receive an additional dose at least 28 days after the second dose, followed by a booster dose 3 months after the additional dose
- People with moderate to severe immunocompromise who received a primary dose of Janssen COVID-19 vaccine should receive an additional dose of mRNA COVID-19 vaccine at least 28 days after the Janssen dose followed by a booster dose 2 months after the additional dose
- Additional details, including information on persons in this population who received the booster dose before the additional dose are available at https://www.cdc.gov/vaccines/covid-19-vaccines-us.html#vaccination-people-immunocompromised

People Who Received Passive Antibody Products

- On February 11, 2022, the CDC updated clinical guidance on receipt of COVID-19 vaccine among people who received passive antibody products
 - COVID-19 vaccination should **not** be delayed following receipt of passive antibody products
 - However, in people who already received a COVID-19 vaccine, administration of tixagevimab/cilgavimab (EVUSHELD) should be deferred at least 2 weeks postvaccination
- Although some reduction in vaccine-induced antibody titers were observed in people who
 previously received passive antibody products, the balance of benefits vs. risks favors
 proceeding with vaccination

Myocarditis and Pericarditis

- On February 11, 2022, the CDC made a history of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine a **precaution** to further doses of mRNA COVID-19 vaccines
- Rates are highest following dose 2 in adolescent and young adult males
- In most reporting systems, myocarditis/pericarditis risk appear higher following dose 2 of Moderna vs. dose 2 of Pfizer COVID-19 vaccine

 However, the benefits of vaccination still markedly exceed the risks even among adolescent and young adult males

Benefits and risks after mRNA COVID-19 vaccines among males ages 18-39 years

- Benefits of mRNA COVID-19 vaccines (e.g., COVID-19 associated hospitalizations prevented)
 markedly exceed the myocarditis cases expected
- Presented by product Moderna and Pfizer-BioNTech
- https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/12-COVID-Oliver-508.pdf
- If someone is at risk for myocarditis, then the Janssen vaccine may be a good alternative

Ontario, Canada: Reporting rate of myocarditis/pericarditis per million doses among males ages 18-24 years by vaccine product and interval

- Several other countries rolled out the vaccine in different ways. In the US we prioritized having people get both doses on schedule, many other countries prioritized maximizing the 1st dose before getting the 2nd dose
- There's an opportunity to study people who got that primary series of the 1st, 2 doses at various different intervals
- A study of incidence of myocarditis and pericarditis following Moderna and Pfizer COVID-19 vaccines in young men in Ontario, Canada found that young men who received vaccines with the 2nd dose at least 8 weeks after the 1st dose had lower reporting rates of myocarditis and pericarditis than those who got it 3 or 4 weeks after the 1st dose.

British Columbia and Quebec, Canada: Vaccine effectiveness of any two doses of mRNA vaccines by primary series interval

• People who received the 2nd dose at least 7 to 8 weeks after the 1st dose had higher vaccine effectiveness than people who got it 3 to 4 weeks after the 1st dose

Extended Interval Between Primary Series Doses

- Some people ages 12 through 64 years especially males ages 12 through 39 years may benefit from getting their second mRNA COVID-19 vaccine dose 8 weeks after receiving their first dose
- Providers should continue to recommend the 3-week (Pfizer-BioNTech) or 4-week (Moderna) interval for patients who:
 - o Are age 5-11 years
 - o Are age 65 years or older
 - o Are moderately to severely immunocompromised, or
 - Need rapid protection, such as during high levels of community transmission

• https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#primary-series

Tick-Borne Encephalitis (TBE) Vaccine

- First U.S. TBE vaccine (Ticovac) FDA-approved in August 2021 for use in persons age ≥ 1 year
- Used in other countries for > 20 years
- TBE is endemic to parts of Europe and Asia; seasonal from April to November
- Disease case fatality 1-20% with sequelae in 10-50%
- Risk factors
 - Laboratory work (< 10 U.S. labs work with TBE) virus
 - Travel to endemic countries: < 1 case per 30 million trips overall, but risk increases to ~
 1 in 2 million trips during transmission season and while undertaking activities with risk of tick exposure
- ≥ 94% seropositivity 3 years after 3-dose primary series
 - ≥85% seropositivity 10 years after booster dose
- No serious safety concerns observed

TBE Vaccine Recommendations

- Laboratory workers
 - TBE vaccination is <u>recommended</u> for laboratory workers with a potential for exposure to the TBE virus
- Persons who travel abroad
 - TBE vaccine is <u>recommended</u> for persons who are moving abroad or traveling to a TBEendemic area and will have extensive exposure to ticks based on their planned outdoor activities and itinerary
 - TBE vaccine <u>might be considered</u> for persons traveling or moving to a TBE-endemic area who might engage in outdoor activities in areas where ticks are likely to be found. The decision to vaccinate should be based on an assessment of their planned activities and itinerary, risk factors for a poorer medical outcome, and personal perception and tolerance of risk

Cholera Vaccine

- Currently recommended for adult travelers age 18-64 years to an area with active cholera transmission
- December 2020 FDA approval for ages 2-17 years
- Limited data to date on pediatric vaccine efficacy, based on immunobridging to adults, but suggests moderate benefit

	 No serious adverse events were judged to be related to the vaccine; non-serious adverse events were not meaningfully different among vaccine vs. placebo recipients Recommendation: Lyophilized CVD 103-HgR is recommended for children and adolescents aged 2–17 years traveling from the United States to an area with active cholera transmission Discussion Allison Singer – I think there is a lot we can learn from the autism community in regard to anti-vaxxers. The data showing low risk of myocarditis notwithstanding, a person with an adverse reaction is a story, it's a real person who tweets and goes on social media, whereas a person who didn't die as a result of being vaccinated is hypothetical There really no information for people who have adverse reaction, when you go online, all you get is that the risk of myocarditis is low and you should be vaccinated, but for people who have experienced that, there's nothing for them so they are turning towards non-scientific channels that say they should never be vaccinated ever again We should focus on this issue, it's going to come up again Dr. Betsy – thank you for sharing that helpful insight Allison Singer - Do we know any websites that provide information for people that have had myocarditis? Dr. Betsy – Not sure, we will do some research, we should boost the good accurate information if it's out there, if not we should create it Dr. Tristram – lot of disinformation out there, one site said 90% of people who experienced myocarditis went to the hospital, which is not true Dr. Betsy – made note of that and will discuss with Public Affairs Group Dr. Rowin – seems that we shoot ourselves in the foot when we come out with vaccines by changing recommendations and the schedule so quickly, the optics look terrible when there are reversal of decisions. 	
Vaccines for Children Update: Kara Connelly Lyndsey Hoyt	Kara Connelly: Lyndsey Hoyt has a new title as Vaccine Program Manager. During the last meeting, I gave a quick update on data loggers that were being sent out to all VFC providers. All VFC providers received a new refrigerator and freezer data logger between August and finishing up in December. Opened up reenrollment for VFC, VFA and Birthdose providers on Valentines Day. To date, over 500 providers have submitted their reenrollment. The deadline is March 31.	

	Recently submitted their prebook for flu vaccine. However they are still continuing to fufill orders for this year from providers requesting doses. They have approved approx. 400,000 doses since ordering opened in late August. Lyndsey Hoyt: A couple of new products added this summer; MenQuadFi, which is a quadrivalent conjugate vaccine for menignoccal. Sanofi is transitioning to MenQuadFi, away from Menactra vaccine later this year. Introduced VaxCelis, a hexavalent vaccine that contains Dtap, Polio, Hepatitis B and Hib components. Next week, 2 new adult pneumococcal vaccines (Prevnar 20 and Vaxnavance) will become available to order for VFA providers.
NYSIIS Update: Dina Hoefer	 An amendment to 2168 was recently signed. Not changing why or who can access NYSIIS, but they updated the language in how schools access the immunization registry. Schools are looking for an automated batch process. Hopefully next meeting there can be a quick overview of this. Fraudulent data entry in to NYSIIS. There is a very robust program at the state with Division of Legal Affairs that are working on those investigations. NYSIIS will support that and pull what is needed. One side effect from this is that they are being more cautious of access to the registry. Turnaround times on setting people up have been longer. Not really seeing a full return to pre-pandemic levels of vaccine administration. Coverage took a hit and has not rebounded. Overall doses administered is still down. Pediatric flu vaccine is way down compared to previous seasons. 2021 influenza season was better than 2020-2021. Because the pediatric population were getting COVID immunizations during the fall push for flu vaccine. Flu took a backseat to COVID.
NYC DOHMH Update: Dr. Jane Zucker	 Pediatric Vaccination At the end of 2021, the aggregate number of routine vaccinations that were given to children under 18 was 16% lower than compared to pre-pandemic. 450,000 fewer pediatric doses being administered Up to date coverage for the vaccine series for 19-35 month olds has decreased substantially. MMR vaccine

	Adolescent vaccination rates were less impacted; HPV coverage did not change.
	 Flu Vaccine 43% more adult influenza doses reported to the registry. Some of this is due to more reporting and some of it is an actual increase in vaccination. 9% decrease in pediatric flu vaccine. Fewer VFC orders for flu vaccine Have heard a lot of feedback about competing priorities in pediatric care practice: COVID-19 vaccine, limited storage capacity, limited number of appointments, limited staffing and fatigue. School Compliance
	 Better than last year, have not reached pre-pandemic levels of compliance Public schools have been querying the immunization registry via the webservice
	 COVID Response 96 ½% of NYC adults have received at least one dose, 87% are fully vaccinated. 65% of children 5-17 received one dose, 56% fully vaccinated. Coverage is high in older adolescents compared to ages 5-11.
	Dr. Rowin: Do you think that the flu problem for this year has been due to the fact that there was virtually no influenza? And do you think that really affected the uptake of the vaccine this year?
	Dr. Zucker: It did not seem to impact adults. It impacted the pediatric side. Providers are seeing greater vaccine hesitancy about flu than they've had in the past. Parents may not want to administer to their kids and there is more hesitancy than before. The daycare population did not rebound which was surprising.
New Business: Dr. Debra Tristram	Dr. Tristram asked how the councilmembers felt about having a hybrid in-person/remote meeting for the next meeting. Dr. Rowin said he would be willing to attend in-person June if there is not another variant.
	An attendee asked the date of the June meeting. The June ACIP meeting is June 22 nd and 23 rd . There was a discussion for a July 7 th meeting.

Elie Ward: Something to consider if you are interested in a group weighing in on any legislation that date is too late. We would have to meet and agree to what to do sometime in April or early May.

Robin Suitor added that though the bylaws say that they are allowed to meet 3 times a year, that doesn't preclude the council from having its own separate meetings without the state or with the state.

Dr. Tristram: When would they need to have submit their input on legislation?

Elie Ward: The budget is done April 1st, somewhere near the end of March they should have a clear indication of which piece of legislation would actually be moving and which ones they would want to discuss and make a decision about whether they support a proposal or remain neutral. There is an issue as to who will write the memo of support or opposition.

Dr Tristram: Would that have to be the entire group?

Elie Ward: It is who you would want to meet and want to vote. If the advisory council wishes to take a position on legislation, they will have to meet.

Dr. Rowin: When is the budget going to be finalized and voted on?

Elie Ward: I cannot guarantee anything, but the schedule is that the budget is due April 1st.

Dr. Tristram: Is it possible to have copies of what's being worked on or what the propositions are so that we know what they are?

Elie Ward: Some of them yes, and some of them are being changed.

Dr. Zucker: Suggested putting a legislation discussion meeting on the calendar

Elie Ward: That makes sense, I think the group needs to make a decision, what is the mechanism to do it and who is going to write the memo of support or opposition. Who is going to dilute how it is going to be delivered? There are certain things a department can and cannot do. I would suggest that our chair talk carefully with the department about what kind of support.

Dr. Tristram: I think we certainly have to write a letter. Joe wrote a letter in the past that we all signed off on to move forward with getting rid of some of the impediments to vaccination for kids. Can meet in early April.

Dr. Tristram: Is anyone at the state able to collect legislation?

Dr. Betsy: We could reach out to Governmental Affairs and try to find out what bills are proposed for information gathering purposes. But I agree it would not be appropriate for the state to be part of the discussion about potential lobbying efforts.

Dr. Tristam suggested sending out a doodle poll to choose a date for the April legislative meeting.

	The council voted to keep the next IAC meeting on June 2 nd . November 2021 Meeting minutes to be reviewed and approved after meeting.	
Adjournment:	The meeting was adjourned at 2:01pm.	