**October 2023 ACIP Meeting - Combined Immunization Schedules**

<https://www.youtube.com/watch?v=Xqfp9Cuh2-w&list=PLvrp9iOILTQb6D9e1YZWpbUvzfptNMKx2&index=3&ab_channel=CentersforDiseaseControlandPrevention%28CDC%29>

0:00

>> Good morning and welcome everyone to the second day of our ACIP meeting today is October 26.

0:05

And I'm pleased to call our ACIP Meeting to order. I will now take roll call for our members only.

0:11

As a reminder, we are going to ask that you state your conflicts because we do have a vote later today.

0:17

And I will go in alphabetical order. So we'll start with Ms. Bahta.

0:24

>> Good morning, Lynn Bahta immunization clinical consultant at the Minnesota Department of Health and I have no conflicts.

0:32

>> Thank you, Dr. Bell. >> Beth Bell, Clinical Professor,

0:37

Department of Global Health University of Washington, no complex.

0:43

>> Thank you. Dr. Chen. >> Wilbur Chen Professor of Medicine at the Center

0:50

for Vaccine Development and Global Health at the University of Maryland School of medicine.

0:55

I have no conflicts. >> Thank you, Dr. Cineas.

1:00

>> Sybil Cineas, Associate Professor of Medicine and Pediatrics at the Warren Alpert Medical School

1:05

of Brown University and I have no conflicts. >> Thank you Dr. Daley.

1:11

>> Good morning. Matt Daley, senior investigator Institute for Health Research Kaiser Permanente Colorado no conflicts

1:18

of interest. Thank you. >> Thank you, Dr. Kotton. >> Good morning, Camille Kotton.

1:25

I'm the Clinical Director of Transplant and Immunocompromised Host Infectious Diseases at Massachusetts General Hospital and associate professor

1:33

at Harvard Medical School. I have no conflicts. Thank you. >> Dr. Loehr.

1:39

>> Jamie Loehr private practice family medicine is a New York I have no conflicts.

1:44

>> Thank you, Dr. Long. >> Good morning Sarah Long Professor of Pediatrics

1:51

in pediatric infectious diseases at Drexel University College of Medicine. I have no conflict.

1:57

>> Thank you, Miss McNally. >> Good morning, Veronica McNally president of the Franny Strong Foundation based in Michigan

2:03

and I have no conflicts. >> Thank you Dr. Poehling.

2:09

>> Kathy Poehling professor of pediatrics and Epidemiology

2:14

and Prevention at Atrium Health Wake Forest, Wake Forest School of Medicine. I have no conflicts.

2:20

Thank you. >> Thank you, Dr. Sanchez. >> Good morning, Pablo Sanchez. I'm Professor of Pediatrics at The Ohio State University,

2:28

and neonatologist and pediatric infectious diseases at Nationwide Children's Hospital,

2:33

and I have no conflict. >> Thank you Dr. Talbot. >> Good morning Keipp Talbot, Professor of Medicine

2:41

and Health Policy at Vanderbilt University Medical Center, think for a second division

2:46

of infectious diseases, no conflict. >> Thank you. And this is Grace Lee, Professor of Pediatrics

2:52

at Stanford University School of Medicine. And I have no conflicts.

2:57

So next, we will move on to our agency updates, we will begin with the Centers for Disease Control and Prevention.

3:07

>> Good morning, my name is Demetre Daskalakis. And greetings on day two of ACIP.

3:14

I'm the director -- the Acting Director of the National Center for Immunization and Respiratory diseases.

3:19

And again, it's a pleasure to see you for day two. So I'll start by just talking a little bit

3:25

about what our primary focus is at this time of year, which is our respiratory virus season.

3:30

So I think as you all are aware, and your partnership is so important in this protecting people

3:35

against respiratory diseases, this fall or winter is really not a top priority for the agency

3:40

but also a top priority for the nation. It's important to protect people and important

3:46

to also protect health care so that we have the capacity to do to treat and care for people who don't have respiratory diseases.

3:55

It's good news, we are thankfully in our strongest position that we've ever been

4:01

for fighting these respiratory conditions, COVID-19 respiratory syncytial virus or RSV and flu.

4:09

So of course, with such an erudite group, it's really important to note we know that there's more than three that we work

4:15

with during the season and other seasons. But because there are many exciting interventions

4:21

that we have for these, we have a lot of focus, as well as the fact that these three tend to be the ones

4:27

that are detectably causing the largest strain on healthcare and burden of disease. So in terms of where we are today,

4:34

currently COVID-19 activity continues to decline in most parts of the country.

4:39

But when you look at the overall story, it remains the principal cause at this time of year

4:45

of respiratory virus associated hospitalizations and deaths. Influenza activity does also remain relatively low,

4:54

but not for long. We're seeing activity starting to increase in the country and right now some areas, particularly Alaska

5:02

and the Mariana Islands, are actually seeing a pretty significant increase in influenza.

5:07

Also, we are officially now in RSV season, we've hit the 3% threshold. And we are seeing the normal progression of RSV

5:15

in the country starting in the south, and slowly making its way up north with the expectation that we will be in RSV land

5:23

in the United States the whole way in about one to two months. A couple of important things to highlight, on October 23,

5:30

CDC published a health care provider toolkit, preparing your patients for the fall and winter season. This toolkit is great.

5:37

It provides clinical and other partners talking points. So we're all really on the same page of how to talk to people,

5:44

other providers and people that you care for about flu, COVID-19, and RSV, as well as their interventions,

5:50

including vaccines and treatments. Also, with some focus on coadministration, and some print materials that can go to patients

5:58

so that we can really be on the same page for communicating. So not shockingly, I will tout the importance of vaccines here,

6:05

that vaccines remain the safest protection to avoid hospitalization, also long-term health impacts and death.

6:12

It's again, as you all know, especially important for people who are at higher risk of developing serious complications.

6:18

That includes older adults and folks who have weakened immune systems. Though it's a campaign that focuses on flu,

6:24

so much of this deaths sort of fall into the wild to mild category, that these vaccines are taming these

6:30

infections, really an effective way of communicating what the role of these vaccines are in people's health, as well as in public health.

6:38

So bottom line is that we encourage everyone and really appreciate your help in being frontline warriors

6:44

in this, we encourage people to stay up to date on their vaccinations. Another really important piece

6:50

of what's happening this season is that we've had a very significant change in the way COVID-19 vaccine is distributed

6:57

in the United States. So we have had the experience of the largest U.S. government implemented vaccination program

7:07

in U.S. history, 700 million doses of COVID-19 vaccination that have been administered to over 270 million people.

7:14

That's amazing. On September 15, something changed, a switch was flipped,

7:20

in effect, where we went from U.S. government distribution of COVID 19 vaccine into distribution

7:25

through commercial networks. And I think that's been really instructive in terms of some

7:31

of the very important observations that strategies for public health distribution of vaccine tend to be different

7:36

than strategies for commercial distribution of vaccine. And I think, despite, you know, a year plus of planning,

7:42

definitely some very important lessons learned about how public health can potentially better influence how

7:47

commercial vaccine moves in the country. So what we also learned is

7:53

that we don't have a vaccines for adult program. And so as we see COVID-19 vaccine going

8:00

on to the commercial market, there was a significant concern that we really needed to make sure that uninsured

8:07

or underinsured people who live here are able to access vaccination,

8:12

regardless of their insurance status. And so thus was born bridge, a bridge to somewhere I hope.

8:19

CDC launched the COVID-19 vaccine bridge access program in mid-September, very accelerated, large,

8:27

large program that really created the possibility of access for 25 to 30 million Americans who are uninsured

8:35

and then additional people living in the country who are underinsured. The Bridge Program leverages unique public private

8:43

partnerships with pharmacies, as well as with manufacturers of vaccine to really create a two-channel system,

8:50

one that's a public health channel that really focuses on our vaccine partners that work in health departments, and the providers that they have that administer a vaccine

9:00

to their jurisdiction. But then also really great partnerships with the very important channel retail pharmacy channel

9:06

where we have three partners that are participating in really creating a sort of double headed net,

9:13

to be able to provide people access to vaccine. So I'm going to go back to the story of bridge and say,

9:21

It's great because it provides COVID-19 vaccination. It's temporary, and it only provides COVID-19 vaccination.

9:29

And so this is really sort of where I pivot for a moment to say, vaccines for adults is a really important strategy.

9:35

We know that vaccines for children is a game changer, you know, I come from many various infectious disease

9:43

spaces in my career. And I always step back and think that the two things that you see really having really enormously high impact

9:51

in terms of public health interventions, Ryan White and VFC. So these are just so important in the world in terms

9:58

of being able to provide people the prevention and services that they need to stay healthy.

10:04

So a bridge to somewhere I hope it's a bridge to VFA. And so really thinking about strategies

10:10

that we can create a program in the U.S., that is not a two-legged stool that's a little wobbly,

10:15

but a three-legged stool that includes the 317 program VFC and VFA.

10:20

So that we can actually, you know, create that prevention strategy that works so well,

10:26

since we know that vaccines prevent a lot of bad things. Speaking of that time to talk about VFC.

10:33

VFC is amazing. It is a federally funded mandatory entitlement program

10:39

that provides vaccines at no cost to children who might not otherwise get them. And so I'm sure you've heard these figures before.

10:46

But it's always good to remember. Imagine what we could do if we had both VFA and VFC.

10:52

In its 30-year history, happy anniversary VFC, it has prevented 472 million illnesses.

11:00

Over 1 million deaths and nearly 2.2 trillion, with a T, in societal costs.

11:07

Seems like a really good idea. Every dollar spent on saves $10,

11:14

almost $11 in projected health care costs. We know that since 1994 VFC has been critical

11:22

in increasing rates of vaccine uptake in us kids, reducing vaccine preventable diseases and as I said,

11:30

it is an equity intervention that really reaches the most vulnerable people who otherwise may not be able to get vaccine.

11:37

VFC is important because -- for lots of reasons, but one of its main purposes is to buy vaccine,

11:45

90% of that program funding comes from that. So I get asked frequently, what is the difference

11:51

between like VFC VFA and 317? 317, about 3% of its budget goes to purchasing vaccine

11:57

and it's kind of an emergency safety valve, provides infrastructure that supports VFC and could support VFA three legs to the stool are really critical

12:07

to be able to achieve the goal. Now I want to talk a bit about something

12:12

that is really important to be aware of, I think you all are tracking very closely, nirsevimab

12:17

and what we're seeing with some of the supply constraints, so as you know we're aware that nirsevimab,

12:24

which is a very important lung acting preventative antibody, that is to prevent RSV illness

12:31

in newborns has some limited supply. And on October 23, CDC issued a health alert or a HAN

12:39

that advises health care providers to prioritize the antibody to those who need it most.

12:45

So young infants birth age through five months, infants with high risk conditions.

12:51

And then also we know that it's really critical to have this reach American Indian

12:56

and Alaska Native infants given the burden of disease that we see in that population, especially if they're in remote settings.

13:04

Additionally, in that health alert, we also reminded people of alternatives for some babies and newborns between eight

13:13

to 19 months with certain medical conditions. So specifically palivizumab so that we are able to spare some

13:21

of the 100 milligram doses, which is where we're seeing some of the issue or most of the issue. So again, we also highlight that there is another way so a couple

13:30

of has to protection for newborns for RSV, and that includes vaccination in pregnant persons.

13:36

I think you all met about that on October 22. So you're all on top of it.

13:41

So again, we continue to be in really close contact with Sanofi to make sure that we have a chart forward

13:48

for the season just remembering again, commercial distribution and supply is different than public health

13:54

or U.S. government distribution or supplies. So it's really lucky that we have a strong partnership to be able to make sure that we are in close communication.

14:02

I do however, again want to uplift a point that we do have nirsevimab, we have palivizumab

14:07

and we also have vaccination in in pregnant persons reminding you that the

14:14

that the recommendation is 32 to 36 weeks of pregnancy. So again, vaccines critically important.

14:21

It's important to get them to people both from the manufacturing and distribution side, but also from the access and coverage side.

14:27

So I think that we are in a place of strength, but also we have some really important areas to continue

14:33

to address so that we maintain that strength and do it in an equitable way.

14:38

Thank you. >> Thank you very much, Dr. Daskalakis.

14:47

Next we will move on to the Centers for Medicare and Medicaid Services.

14:53

>> This is Mary Beth Hance and I have a few updates from CMS, which we'll touch -- be very consistent

15:00

with what we just heard from CDC. One thing we wanted to just highlight,

15:05

although I'm sure many people are aware is that the Inflation Reduction Act provision that would require

15:13

that traditional Medicaid cover all ACIP recommended vaccines

15:19

without cost sharing went into effect on October 1. These are adults who are in what we call traditional Medicaid,

15:28

which is the pre-expansion, Medicaid. Previously, vaccines were optional for states

15:35

and there could be cost sharing. We know that all states covered some, but most did not cover all ACIP recommended vaccines.

15:43

And this is a very exciting day that we're in from the Medicaid perspective and vaccines for adults.

15:51

Obviously, there's still a lot of work to do in this space. But this is an important step forward.

15:56

So again, that went into effect on October 1, we did issue guidance to states as well

16:02

as a fact sheet at the end of June. Moving on to recent vaccinations,

16:11

and most importantly, coordination with CDC. As you've just heard, there has been a lot

16:16

of things happening this fall, and we have worked very closely with CDC on all of them.

16:23

Obviously, the commercialization of COVID vaccines was a very important transition,

16:31

and CMS was in the middle of it. We worked really hard to amplify messaging to get information

16:38

out to be consistent with what CDC was sharing. And I really appreciate CDC colleagues coming and speaking

16:45

to Medicaid agencies about the Bridge Access Program and making sure that they were aware of that.

16:51

We also have worked very closely with CDC around the new products that are available for RSV, and amplifying important information

17:03

about them being available, including the supply issues that we just heard about and making sure everyone knows

17:09

of everything that is available in this space. It is also important that we don't lose sight

17:17

of our routine immunizations, with, you know, everything else that's happening in the space.

17:22

So we continue to amplify the importance of routine immunizations, and have reiterated

17:31

that message many, many times to states as we're also making sure that states are aware and other partners are aware

17:39

of all these important changes happening in this space. So thank you very much.

17:44

>> Thank you very much Miss Hance. Next we'll move to the Food and Drug Administration.

17:50

>> Thank you Dr. Lee, David Kaslow Office of Vaccines Research and Review CBER, FDA.

17:56

Since the last ACIP agency report in June of 2023 in apropos to yesterday and today's ACIP meeting,

18:05

FDA has approved or authorized 10 vaccine products issued an

18:10

updated guidance to industry and convened one vaccines and related Biologics products Advisory Committee.

18:20

On June 30, CBER approved a change to the prescribing information of Dengvaxia.

18:25

The dengue tetravalent vaccine live to include safety and efficacy data that support the use of Dengvaxia

18:33

in individuals six years through 16 years of age, with laboratory confirm previous dengue infection

18:40

and living in endemic areas. On July 20, CBER approved Cyfendus,

18:48

anthrax vaccine absorbed, adjuvanted indicated for post exposure prophylaxis of disease following suspected

18:55

or confirmed exposure to Bacillus anthracis in persons 18

19:00

through 65 years of age when administered in conjunction with recommended anti-bacterial drugs.

19:09

On July 27, CBER approved a change to the prescribing information of ERVEBO,

19:15

the Ebola Zaire Vaccine live vaccine to extend the indication

19:22

for use to individuals 12 months of age and older. On August 21st, CBER approved ABRYSVO,

19:31

the respiratory syncytial virus vaccine indicated for active immunization of pregnant individuals at 32

19:37

to 36 weeks gestational age for the prevention of lower respiratory tract disease

19:43

and severe lower respiratory tract disease caused by respiratory syncytial virus in infants from birth

19:50

through six months of age. On September 11, CBER approved Comirnaty

19:56

and Spikevax 2023/2024 formula COVID-19 mRNA vaccines for use

20:03

in individuals 12 years of age and older and amended the emergency use authorizations

20:09

of Moderna COVID-19 vaccine and Pfizer biotech COVID-19 vaccines

20:15

to include the 2023/2024 formula for use in individual six months through 11 years of age to prevent COVID 19.

20:23

Then on October 3, CBER amended the emergency use authorization of the Novavax COVID-19 vaccine adjuvanted

20:31

to include the 2023/2024 formula for use in individuals 12 years

20:36

of age and older to prevent COVID-19. On October 20, CBER approved Penbraya,

20:43

meningococcal groups A, B, C, W and Y vaccine indicated

20:48

for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups, A, B, C, W, and R,

20:56

the vaccine is approved for use in individuals 10 through 25 years of age.

21:02

And on October 19, CBRE issued an updated development and licensure of vaccines to prevent COVID-19 guidance

21:11

for industry to assist sponsors in the clinical development and licensure of vaccines for the prevention of COVID-19.

21:18

And then finally, on October 5, VRBPAC convened an open session

21:23

to discuss the strain selection for influenza virus vaccines for the 2024 Southern Hemisphere influenza season.

21:32

The committee unanimously recommended excluding the B/Yamagata lineage component

21:38

from quadrivalent influenza vaccines as soon as possible, as well as recommended the composition

21:44

for egg-based trivalent and quadrivalent 2024 Southern Hemisphere formulations

21:50

of influenza vaccines. And if I might, I'd like to personally thank the review

21:55

teams, the supervisors and the management at CBER who work diligently

22:00

to thoroughly review these 10 regulatory actions since the June 2023 ACIP meeting.

22:07

And I'd also like to thank the many CDC staff for their many contributions and their alacrity in these efforts.

22:15

That concludes the FDA Agency report ACIP. >> Thank you very much, Dr. Kaslow.

22:22

Next we'll move to Health Resources and Services Administration.

22:28

>> This is Commander Grimes with the Health Resources and Services Administration, couple of updates

22:36

for our Injury Compensation Programs. The National Vaccine Injury Compensation Program

22:42

or as we call the VICP continues to process a high volume of claims in fiscal year 2023.

22:49

Petitioners had filed 1129 claims with the VICP and nearly $174 million have been awarded including awards

22:58

to petitioners and their attorney's fees and costs. In addition, the VICP had a backlog

23:04

of 657 claims alleging vaccine injury that were awaiting review.

23:10

Previously, there had been nearly a 12 month wait time between when a petition was found

23:15

to have adequate medical records to review. By the time HRSA provider was able to review it.

23:23

And as of October 1, 2023, those wait times had been reduced significantly

23:29

to below a six month wait time. So we are working through the backlog in that VICP program.

23:36

More data about the VICP can be obtained at the VICPs website which is hrsa.gov /vaccinetechcompensation.

23:46

For our other injury compensation program, the Countermeasures Injury Compensation Program in the decade prior to COVID-19, only 500 claims have been filed

23:57

with the CICP, CICP received its first direct appropriation in fiscal year 2022.

24:03

And the program has used those funds to increase its capacity to conduct medical reviews.

24:08

By hiring and training new review staff and contractors as well as to pay compensable claims

24:13

and to improve information technology and other communication with requesters. The CICP recently made it improvements

24:21

to foster enhanced communication with requesters, allowing the requesters the capability

24:28

of checking their claim status in real time at injurycompensation.hrsa.gov and launching a chat function

24:35

on its website to assist requesters with frequently asked questions. As of October 1, 2023.

24:42

There have been 12,233 claims alleging injuries or death

24:47

from COVID-19 countermeasures that have been filed with the CICP including 9221 claims alleging injuries

24:55

from COVID-19 vaccines. CICP has rendered 1267 decisions on COVID-19 claims

25:02

and more information in depth data about the CICP can be found at www.hrsa.gov/cicpdata.

25:15

Over to you. >> Thank you very much Commander Grimes. Next we'll move on to the Indian Health Services.

25:23

>> Thank you, Doctor Lee this is Matthew Clark with IHS. The Indian Health Service continues to prioritize vaccination as our principal clinical

25:31

and public health prevention priority. As part of our IHS national E3 vaccines strategy,

25:37

we seek to ensure that every patient at every encounter is offered every recommended vaccine

25:42

when appropriate. In partnership with staff at our federal tribal and urban Indian organization facilities, we have collected

25:49

and shared best practices and lessons learned from dozens of E3 champions pilot sites across the country

25:56

for cross pollination of our IHS system of care. We are actively engaged

26:01

in our fall respiratory viral season vaccine campaign, with the goal to mitigate morbidity and mortality

26:07

from vaccine preventable illness in our vulnerable service population. Following approval of the 2023/2024,

26:15

monovalent COVID 19 vaccine, and RSV vaccines for elders and pregnant women.

26:21

The IHS distributed guidance to clinicians, public health staff, tribal leaders and tribal communities about the importance

26:29

of these countermeasures. Similarly coincided with the ACIP recommendations,

26:34

the Indian Health Service took quick action to add nirsevimab to the IHS National Core formulary

26:39

to further promote access to this immunization for infants and young children.

26:44

We have also reached out to our federal, tribal and urban Indian organization partners to provide guidance about the recommendation that all infants

26:53

under eight months of age and their first RSV season, and all American Indian and Alaskan Native children eight

26:59

to 19 months of age in their second RSV season, receive nirsevimab.

27:04

Currently, all ACIP recommended vaccines and long-acting monoclonal antibodies are listed

27:09

on the IHS National Core formulary. In addition, IHS continues as a long-term partner

27:15

with the Vaccines for Children program. And IHS also remains committed to providing support

27:20

to facilities interested in the CDCs Bridge Access Program for COVID vaccines for eligible persons.

27:27

Moving forward in collaboration with our partners and tribal communities, we will continue to promote access,

27:33

quality, value and equity related to immunizations in Indian country.

27:38

That concludes the IHS report. Thank you.

27:43

>> Thank you very much, Doctor Clark. Next we'll move on to the National Institutes of Health.

27:49

>> Yeah, good morning. This is John Beigel. From the National Institute of Allergy and Infectious Diseases. I have several updates from the National Institute of Health.

27:56

For COVID-19 several months ago, the National Institute of Allergy and Infectious Diseases and BARDA,

28:02

the Biomedical Advanced Research and Development Authority announced project NextGen.

28:07

This is a coordinated effort where federal government works with private sector to advance pipeline of new

28:13

and innovative vaccines and therapeutics for COVID-19. NextGen vaccines include those with an enhanced breath,

28:23

improved durability, and those that with the ability to block transmission

28:28

or infection including mucosal vaccines. And we're looking for ways

28:34

to improve upon the currently approved vaccines. And I have plans to leverage existing infrastructure

28:41

and networks to implement these studies. Evaluating multiple next generation COVID-19 links

28:48

to the program will be in the written updates but you can also run them by internet search.

28:54

For mpox we spoke yesterday about immunogenicity trial with JYNNEOS mpox vaccine.

29:00

This includes an evaluation of a lower intradermal dose and a non-inferiority adolescent safety and immunogenicity trial

29:08

that both stages have completed enrollment. The data for the initial results

29:15

for the intradermal stage are expected early 2024 with the adolescent data coming later.

29:21

For meningitis researchers from the NIAID funded infectious disease Clinical Research

29:28

Consortium provided an interim report on the pentavalent meningococcal serogroup, A, C, Y, W,

29:34

X conjugate vaccine in comparison to the A, C, W, W, Y conjugate vaccine that this was presented to the

29:41

WHO strategic advisory group of experts also known as sage.

29:47

This is different and just to be clear, this is different than the pentavalent the vaccine discussed yesterday including

29:53

serogroup X, which is seen in many African countries.

29:58

The study results showed that the pentavalent vaccine is safe, highly immunogenic. This pentavalent vaccine had already been shown immunogenic

30:09

and approved actually, for people's age one to 85.

30:15

But this was the pivotal study that extended that down into the infant age group so that that vaccine can be used

30:22

as part of routine immunization schedule in low- and middle-income countries. For HIV NIAID continues to support multiple programs

30:31

in pursuit of an HIV vaccine. One recent example to highlight the first and human trial

30:36

by HIV vaccine development by NIAID's Vaccine Research Center, which includes an engineered outer domain germline targeting

30:44

60mer nanoparticle. It's designed to prime VRC 01 class HIV specific B cells.

30:54

This is a strategy that is prime in B cells and then you refine them with additional antigens in order

31:02

to develop these broadly neutralizing antibodies. The result of this early phase clinical study was published

31:10

earlier in Science Translational Medicine and the links will be in the written comments.

31:16

Now for sexually transmitted disease in response to the persistent health challenges of HSV,

31:21

the NIH released a strategic plan on HSV research.

31:27

This includes a framework with a force strategic priorities,

31:33

including improving fundamental knowledge of HSV biology, pathogenesis and epidemiology, improving HSV diagnostics,

31:41

improving strategies to treat HSV. And while seeking curative therapeutic and advancing work

31:49

on preventative measures, including HSV vaccine. So hopefully this will help stimulate and lead

31:55

to effective HSV vaccines. And lastly, for leadership updates.

32:00

Dr. Tabak who was the Acting Director of the NIH named Jeanne Marrazzo as the Director of NIAID.

32:06

Dr. Marrazzo is well known by many people in this group. She's internationally recognized for her research

32:12

and education efforts in the field of STIs, especially as they affect women's health.

32:18

And we're very excited to have Dr. Marrazzo leading NIAID as we continue efforts for new and better vaccines.

32:23

So details and links for all these as well as additional updates will be provided in the written summary. This concludes the updates

32:29

from the National Institute of Health. >> Thank you very much Dr. Beigel.

32:34

Next we'll move on to the Office of infectious disease and HIV/AIDS policy.

32:42

>> This is Susan Farrall from the National Vaccine Program in HHSs Office. >> So sorry, we can't hear you very well.

32:49

Could you get closer to the mic? Thank you. >> Better now?

32:54

>> It's a little better. >> Hi, this is Susan Farrall

33:00

from the National Vaccine Program in the Office of Infectious Disease and HIV/AIDS Policy.

33:07

Our report today is that federal agencies comprising the inter agency vaccine Working Group have provided feedback

33:15

to inform the vaccines federal implementation progress report expected in December 2023.

33:22

The progress report will give an overview of progress from 2021

33:27

to 2023 towards achieving the goals of the vaccines National Strategic Plan,

33:33

which provides a roadmap for the coordination of vaccine development and use in United States.

33:40

The Office of the Assistant Secretary for Planning and Evaluation that is ASPE

33:45

and our office OIDP have jointly released an environmental scan

33:51

report titled, Environmental Scan of Best Practices for COVID Vaccination and Testing

33:57

for Underserved Populations. This document provides a comprehensive literature review,

34:03

and describes initiatives and interventions to improve COVID vaccination for people who are medically

34:10

or socially at disproportionate risk of COVID-19. This report can be found on the ASPE website.

34:18

Finally, the forthcoming National Vaccine Advisory Committee meeting is scheduled for February 22 and 23rd 2024.

34:28

Thank you. That concludes our report. >> Thank you very much for that report.

34:34

Dr. Daskalakis. >> Thank you so much. I want to apologize for not introducing our colleagues

34:43

from Sanofi who also would like to make a comment on the supply of nirsevimab. So Dr. Chen, thank you for allowing me

34:50

to grab the mic again to introduce them. Thank you. >> Thank you, Dr. Daskalakis.

34:56

Good morning. I'm Julian Ritchey, Head of Public Affairs and Patient Advocacy for Sanofi vaccines.

35:02

On behalf of Sanofi vaccines and our alliance partner AstraZeneca I appreciate the opportunity that NCIRD is providing for us to comment

35:10

on the current market situation for Beyfortus or nirsevimab. As Dr. Daskalakis shared,

35:16

we're experiencing unprecedented demand for Beyfortus in response to the unmet need that has existed in RSV prevention.

35:23

Despite an aggressive supply plan built with the goal of outperforming past pediatric immunization launches and built

35:31

to anticipate the demand of this season, the demand that has materialized has been much higher than forecasted across both the 50 milligram

35:37

and 100 milligram presentations. Both product dose presentations do continue to ship

35:43

to fulfill existing orders, however, for the 100 milligram presentation, we have stopped accepting new orders

35:49

as demand has consumed the supply currently available for the season. We will continue shipping doses of 100 milligram

35:56

to fulfill orders already on hand over the coming weeks, orders are still being accepted

36:01

for the 50 milligram presentation. We're working closely in collaboration with the Centers

36:07

for Disease Control and Prevention to ensure equitable distribution of available doses

36:12

through the VFC program. Our approach for fulfilling existing orders and in taking new orders for the 50 milligram product

36:19

across the private marketplace will also be done in a similar manner with equity in mind.

36:25

We appreciate the clinical guidance provided by CDC earlier this week via the HAN that was mentioned before.

36:32

Additionally, we're working with the FDA together with AstraZeneca, our partner in charge of the manufacturing

36:37

and supply to deliver all of the doses planned for this season. We appreciate the challenge that these supply constraints present

36:45

for providers and parents as well as for CDC, the FDA and AAP and others as we introduce Beyfortus.

36:53

We're thankful for your patience and your collaboration. We're already working to ensure

36:59

that will be sufficient supply available for next season as we continue to focus on making this season's doses available

37:05

as rapidly as possible. We will continue to update you and providers on the status

37:11

of orders and remaining shipments for any questions about the status of Beyfortus orders currently placed directly

37:18

with Santa Fe. Providers can reach out to their local Santa Fe representative or call 1855 Beyfortus regarding private sector doses.

37:27

For public sector doses providers can reach out to their state and local VFC program.

37:33

Again, thank you for this opportunity to comment. Sanofi and AstraZeneca appreciate the patience

37:39

of the immunization community as we work together through this introductory season. And as we prepare to meet demand in the future,

37:46

back to you, Dr. Daskalakis. >> I'll hand it back over to Dr. Chen.

37:54

>> Okay, actually, Dr. Kotton and Dr. Long, so Dr. Kotton, I see your hands is raised.

38:00

>> Thank you. I just have one question for Dr. Daskalakis. If you could address RSV vaccine availability

38:06

for pregnant people and how that's going. Thank you. >> Thanks, Dr. Kotton.

38:13

So just briefly, I think we'll have sort of a better view of what's happening in terms of coverage,

38:19

as we go further in this season. But in general, I'll say that because this is a commercially distributed

38:26

vaccine, we've been really in close contact with manufacturers and distributors to have a sense of sort of what's happening

38:32

on the ground, as well as really close discussions with our shareholders around the country,

38:39

including professional organizations, et cetera. So I'll start by saying it does not appear to be a bottleneck

38:45

in production of the vaccine. So from the perspective of what we've heard from manufacturers

38:51

as well as from distributors, vaccine is flowing. What we are hearing is that there are some barriers related

38:57

to concerns around coverage. So CDC is actively engaging across, again, shareholders

39:05

that deal with coverage, both governmental, CMS and also others to make sure the message is clear,

39:13

the importance of this vaccine product for pregnant people and for their newborns.

39:19

Additionally, many engagements have happened and more are planned to be able to sort of tout the importance

39:26

of the vaccine and also to do some myth busting around sort of what is available, as well as what we sort

39:32

of forecast will be the coverage scenarios. There will be some coverage issues

39:38

because there are some limits to the speed at which a private insurer needs to cover this,

39:43

but we're engaging with them as well to again, highlight the importance of a public health view

39:49

into strategies that tend to be more on the commercial side of the fence. Thank you.

39:55

>> Thank you. Dr. Long. >> Yes, it's a question for Dr. Ritchey, Sanofi.

40:01

So we should be winding down on need for the 100 milligram vials

40:08

as we catch people who are a little older at the beginning of the season, and the next month, but the 50s will need

40:15

through March and they are the most vulnerable. Do you -- what level of uptake did you plan for?

40:25

And what do you anticipate as far as potential shortages of the 50s?

40:31

>> Thank you, Dr. Long. And as far as the 50s I don't have specific numbers

40:40

to share in terms of volume. But it's something we're watching very closely. At this point, seeing the level of ordering

40:47

that happened early on, we're still trying to understand how much of that ordering is early

40:53

and stocking ordering and the utilization that will go forward. So the CDC can speak to more of the specifics

41:02

of the VFC program details but for non VFC and private sector doses, we're monitoring

41:08

that 50 milligram order very closely, and we'll work to adjust any order quantities going forward

41:15

if we detect that --

41:25

>> Thank you. Dr. Sanchez. >> Thank you. And this is also a question for Sanofi.

41:32

I just had a question in terms, you know, I know that the 100 milligram supply is limited.

41:39

And I certainly don't want to give 250 milligram to those

41:46

who would normally get 100. But my question is, is the experience and the you know,

41:53

the content of the 50 milligram, if you get two of them,

42:01

are you giving too much of the -- whatever else is contained in that product?

42:08

Do you understand my question? >> I do, Dr. Sanchez, thank you for the question.

42:15

And I'll engage my colleague Dr. Rizzo also in the line here. At this point, of course, just want to note that use

42:24

of the two 50s is outside of indication and I think it consistent with the HAN not recommended

42:31

at this point given the fact that that's consuming two doses that would be used in otherwise young individuals.

42:39

And considering that there are other options, presumably for the individuals for whom

42:44

that you would use the 100 milligram formulation. But let me ask Dr. Rizzo to also comment.

42:52

>> Yeah. Hi, it's Chris Rizzo from a U.S. Medical Affairs at Sanofi.

42:57

Dr. Sanchez, to your question, the excipients that are --

43:03

include arginine, histidine, polysorbate, and sucrose.

43:09

So I don't know if we have any data on that. But just, you know, for the 100 milligrams, they are --

43:17

a baby is getting double that. So once they cross five kilos, they're getting double that amount, but I don't have any specific data on that.

43:25

But I will also support what Julian said is that, you know,

43:33

in the HAN it's not recommended to give two 50s, because of concerns potentially about the 50 milligram

43:39

and we could give it to two babies who are younger, rather than one baby who's older,

43:45

but I know that there are older babies who are at very high risk as well.

43:52

>> Okay, thank you. We're going to close this part of the session I did just

43:58

on behalf of our committee wanted to express our appreciation for the agency leadership

44:05

who spoke today at our meeting to provide these updates. It is really clear

44:11

and it demonstrates how cross agency partnership and collaboration can actually have such a tremendous impact

44:18

on the health of the U.S. population. And so I know all of us are extremely grateful that you are willing to serve and appreciate all that you do.

44:26

So thank you everyone. We will move on to the next session which is on combined immunization schedules and Dr. Sybil Cineas

44:34

who is Chair of the Adult and Child Adolescent Immunization Schedule Work Group

44:39

will be walking us through the introduction overview for today.

44:44

>> Thank you Dr. Lee and good morning. Next slide.

44:51

The combined immunization schedule work group updates the child and adolescent and adult immunization schedules annually.

44:57

The child and adolescent immunization schedule summarizes ACIPs vaccination recommendations

45:03

for persons 18 years of age or younger, and the adult immunization schedule summarizes ACIPs

45:09

vaccination recommendations for persons 19 years of age or older. Both immunization schedules represent current approved ACIP

45:17

policy and are designed to be a guide for healthcare providers to ensure individuals get all their vaccines

45:23

when they need them. Next slide. The goal of the combined immunization schedule work group

45:31

is to better harmonize the child adolescent schedule and the adult schedules, no new policy is established

45:37

by the schedule rather it reflects a summary of ACIP recommendations.

45:43

Next slide. I would like to remind the committee

45:48

and the audience why we present the schedule for a vote every fall. ACIP is approval is necessary prior to publication

45:55

of the immunization schedules by CDC. In addition, ACIPs approval is necessary before our partners

46:02

from the professional organizations listed on this slide approve the schedules. Next slide.

46:08

This slide depicts the traditional timeline we have

46:14

used to publish the immunization schedules, the accompanying MMWR article and the adult schedule

46:21

in the Annals of Internal Medicine. All publications occur on the same day in early February each year.

46:28

Next slide. The traditional timeline and process of updating the schedules has resulted

46:35

in a few significant challenges in implementation of routine vaccinations. This includes insurance reimbursements

46:42

to health care providers, the ability of certain health care providers such as pharmacists to administer vaccines

46:49

in some jurisdictions, and delays in updating health care providers knowledge and practices related to new vaccine recommendations.

46:58

Next slide. To mitigate some of these challenges,

47:03

we are proposing publishing the 2024 immunization schedules web

47:08

PDF and app versions -- and app versions in November 2023. The MMWR article summarizing the updates

47:16

to the 2024 schedule will then be published a few months later, but earlier than the current February dates.

47:26

Next slide. I would like to acknowledge the exceptional leadership

47:31

of our CDC colleagues, Dr. Patricia Wodi and Dr. Neil Murthy, in light of many additions and edits

47:37

to the schedules this year. I would also like to acknowledge the contributions of my ACIP colleagues, Veronica McNally and Dr. Matthew Daley,

47:45

and thank the many liaison representatives, ex officio members, consultants,

47:50

and CDC subject matters listed here and on the next slide

47:56

who have contributed to the work group activities. Next slide.

48:05

As a reminder, presentations and updates to both schedules may include the use of vaccine trade names.

48:11

This is for identification purposes only and does not imply endorsement by CDC.

48:16

The proposed edits that will be discussed are subject to change based on ACIPs discussion and vote.

48:24

Next slide. For today's presentation, Dr. Wodi will discuss the proposed edits

48:30

for the 2024 Child and Adolescent schedule, as well as the proposed edits for the 2024 Adult Immunization Schedule.

48:37

These edits are intended to incorporate ACIP recommendations that have occurred since October of 2022, improve readability

48:46

and utility of the schedule into a language that is easy to interpret for practitioners.

48:51

The session will conclude with discussion of the proposed edits followed by a vote on the adult schedule

48:57

and the child and adolescent schedule. I will now ask Dr. Wodi to begin our session

49:03

with the proposed edits to the child and adolescent schedule. Thank you.

49:12

>> Thank you Dr. Cineas, let me just share my slide. I'm just pulling u my slide, give me a minute.

49:27

Good morning everyone. My name is Dr. Wodi and together with Dr. Murthy we co-lead the combined immunization schedule

49:35

work group. I will begin by presenting the 2024 updates to the child

49:41

and adolescent schedule. I will walk through the proposed changes for the cover page

49:48

and the tables, then the vaccination notes and then the appendix and introduce the newly added addendum.

49:56

The 2024 updates include new and updated recommendations for vaccines and write texts.

50:02

Additionally, we've made clarifying edits to the other vaccines listed on the slide, I will present only the substantive updates

50:10

to the schedule, minor grammatical formatting edits to improve clarity will not be presented.

50:17

Now, beginning with the cover page of the child and adolescent schedule.

50:23

In the box for how to use the schedule we've added this six step for providers to review the addendum

50:30

for ACIP recommendations that will occur after the schedule is published.

50:38

The title for the table listing the names and abbreviation has been changed to vaccines

50:44

and other immunizing agents because we've added nirsevimab to the table.

50:51

Nirsevimab has been added in a separate section at the top to indicate that is a monoclonal antibody and not a vaccine.

51:00

In the table listing the vaccine names and abbreviations we have a new rule for RSV vaccine

51:05

and we've listed only the brand Abrysvo because this is the only brand approved for using pregnancy.

51:11

In the pneumococcal conjugate vaccine role, we've deleted PCV 13 and added PCV 20 to be consistent

51:21

with the current guidelines. And then we've added new rules for mpox vaccine JYNNEOS

51:29

and the pentavalent meningococcal vaccine.

51:34

Lastly, on the cover page, we've deleted some vaccines that are no longer distributed or recommended

51:40

for use in the United States. So we've deleted the bivalent mRNA vaccine.

51:46

The diphtheria tetanus vaccine is no longer available. So that row has been deleted and then from the meningococcal A,

51:53

C, W, Y row was deleted Menactra. Moving on to table one

51:59

which outlines the immunization schedule by age.

52:05

In table one, the column header has also been changed to vaccine and other immunizing agents to account

52:11

for adding nirsevimab to the table. We have a new row for nirsevimab and we've shaded the ages back

52:20

through eight months in yellow indicating the age for routine immunization.

52:26

We also have an overlay in texting. One does depending on maternal RSV vaccination status.

52:35

And then for ages eight through 19 months, we've shaded that in purple to indicate that it's for those eight

52:43

through 19 months who at increased risk of severe RSV disease, and we've added see notes

52:49

to direct healthcare providers to the notes section for more information for these two age groups.

52:57

We've added RSV vaccine to table one and we've shaded 11 years

53:03

to 18 years in purple. And we have an overlaying text in our administration during pregnancy and just you know.

53:14

In the pneumococcal conjugate row, again, we've taken out PCV 13, and added PCV 20.

53:23

And the pneumococcal polysaccharide row has been deleted because that vaccine is no longer recommended

53:29

for all children who are at increased risk for invasive pneumococcal disease.

53:37

In the meningococcal row, we've removed Menactra.

53:43

And in the COVID-19 row we've removed the mRNA bivalent

53:49

vaccine, and we've changed the overlaying text to indicate to use the 2023/24 formula.

53:58

And lastly, to table one, we've added a new row for mpox vaccine and we've shaded it in purple indicated it should be used

54:06

based on risk factors. Moving on to table two, which outlines the catch up schedule

54:15

for children and adolescents who are beginning their immunization later on more than one month behind.

54:22

We have two minor edits for table two. In the DTaP row for those four to five

54:30

with clarify the interval to put a note stating that the fifth dose is not necessary

54:36

if the fourth dose was administered at age four years or older, and at least six months after dose three.

54:43

And the other change is to remove Menactra from the meningococcal A, C, W, Y row.

54:50

Now table three lists the immunization schedule by medical indication.

54:57

This year, we've extensively revised table three to more closely aligned with the instructions, which is that is

55:06

to be used to assess additional vaccines that will be needed based on medical condition or indications.

55:13

And the reason we did this was because we've received feedback from lots of healthcare providers

55:19

that the legend definitions were unclear and they were used inconsistently across the row.

55:26

When we went the work group changed the color definitions and we harmonized this with the child schedule

55:32

and applied it to all the row. So for this 2024 table three looks a lot different.

55:40

These are the new legend color definitions, we've clarified

55:46

that yellow represents recommended for all age eligible children who lack documentation

55:53

of a complete vaccination series. Previously just said vaccinated according to the routine schedule, so we've explained what that means.

56:01

And then for purple, we've indicated that it's not recommended for all children, but some children can receive the vaccine based

56:09

on their increased risk for all severe outcomes from disease. The definition for brown did not change it indicates additional

56:18

doses are needed, but we changed the color from checked yellow to brown so that the overlaying text is more visible.

56:26

And then lastly, for gray we changed no recommendation not

56:32

applicable to no guidance or not applicable.

56:38

We've also changed the table header. We've revised it for clarity.

56:43

So we say always use this table -- always use the table in conjunction with table one and the notes section.

56:50

And we indicate that there's some medical conditions not listed on this table and to see notes.

56:56

Note section. Similar to table one with changing header to vaccine

57:03

and other immunizing agents. We've met the DTaP and Tdap rows into one row

57:14

and in the pregnancy column we've indicated that one dose of Tdap is recommended for each pregnancy.

57:22

We've also merged the pneumococcal rows into a single row. And indicated with a brown color that additional doses are needed

57:31

for those medical conditions.

57:36

For nirsevimab we've added it as a new row. And then for those children and adolescents

57:43

who are immunocompromised or have chronic lung disease, we've used the brown color to indicate

57:49

that additional doses are needed. And an overlaying text to say this is in the second RSV season

57:55

and an instruction to see the notes. For RSV vaccine, the pregnancy column is

58:02

in yellow indicating is recommended for all pregnant women. And then we have the overlaying text, seasonal administration.

58:11

For all the other medical conditions we have this in purple, because any pregnant person who has any

58:16

of these medical conditions can also receive the vaccine.

58:25

We have a new row for mpox vaccine and all the medical conditions as shaded in purple,

58:31

indicating that anyone who has this medical condition and has the sexual risk factors should be vaccinated.

58:41

Now I'll go over the edits to the notes. In the additional information and section in the bullet

58:50

for the National Vaccine Injury Compensation Program, we've added RSV vaccine as one of the vaccines

58:59

that is not covered by VICP. The COVID-19 vaccination notes have been extensively revised

59:07

to be in line with the current recommendation. The routine vaccination section lists the recommendations

59:13

for persons who are not moderately or severely immunocompromised, and we've outlined the recommendations by age group

59:21

and the number of previous COVID-19 doses received. The special situation section outlines the recommendations

59:29

for persons who are moderately or severely immunocompromised. And we've also outlined the recommendations by age group

59:37

and number of previous doses received.

59:42

At the end of the COVID-19 notes, we've included some information that we think will be helpful for healthcare providers,

59:49

including that is no preferential recommendation when more than one recommended age appropriate vaccine

59:56

is available. We included links to the age transition information,

1:00:02

the interim guidance EUA. We've also added the definition for previously vaccinated.

1:00:10

And then lastly, we have a note for additional doses in persons

1:00:17

who are moderately or severely immunocompromised.

1:00:23

Moving on to HPV, we've made some minor edits here, we deleted the bullet on interrupted HPV schedule

1:00:31

because this information is on the cover page and it applies to all vaccines.

1:00:36

For situations where no additional doses are recommended, we've clarified that persons

1:00:41

who have completed their HPV series with any HPV vaccine do not need additional doses.

1:00:48

And we did that by adding of any valency to the sentence.

1:00:56

For influenza vaccination, we've taken out all the bullets

1:01:01

for persons who have a history of egg allergy. And at the end of the section we've included a note saying

1:01:08

that persons with egg allergy can receive any influenza vaccine egg-based or non-egg based appropriate

1:01:14

for age and health status. And we've included a link to the current recommendation

1:01:20

for the 2023/24 season.

1:01:25

In the MMR vaccination notes, we have moved the bullet for the minimum interval between MMR doses to the end

1:01:34

of the section and we've used asterix to indicate that it applies to routine catch up in special situations.

1:01:43

Previously, it was in the catch up vaccinations section and some healthcare providers found that confusing.

1:01:53

For MenACWY we've deleted Menactra from all the sections and we've added the pentavalent meningococcal vaccine.

1:02:02

At the end of that section we have some information

1:02:08

for the newly recommended pentavalent vaccine.

1:02:14

And children aged 10 years or older may receive a single dose of the pentavalent vaccine as an alternative

1:02:21

to separate administration of MenACWY and MenB, when both vaccines will be given on the same day

1:02:28

on a single injection where the pentavalent vaccine is preferred.

1:02:35

In the MenB note we've added a link to the shared clinical decision making --

1:02:40

to a shared link for decision making resource.

1:02:46

And at the end of the note we also have information for the use of the pentavalent meningococcal vaccine.

1:02:54

Here we have a lot more information than in the MenACWY note. So children aged 10 years or older may receive a dose

1:03:02

of the pentavalent vaccine as an alternative to separate administration of MenACWY and MenB

1:03:08

when both vaccines will be given on the same clinic day and a single injection where the pentavalent vaccine

1:03:14

is preferred. For age eligible children who are not at increased risk if the pentavalent vaccine is used

1:03:21

for MenB dose one then remember should be administered for those two.

1:03:27

That's because MenB vaccines are not interchangeable. And then for children -- for age eligible children who are

1:03:34

at increased risk of meningococcal disease those who need additional MenACWY and MenB doses including

1:03:43

for booster doses can use the pentavalent vaccine, if both vaccines will be given on the same day,

1:03:51

and at least six months has elapsed since the most recent pentavalent dose. And then lastly, we'll clarify

1:03:57

that for those ideally reachable children recommended to receive booster doses of MenACWY and MenB less

1:04:04

than six months after the dose of a pentavalent vaccine they should get their doses separately.

1:04:22

We have a new section for mpox vaccine and we've listed the recommendations for persons aged 18 years and at risk

1:04:30

for mpox will be sexual risk factors listed.

1:04:35

We have a bullet for pregnancy stating there's currently no ACIP recommendation for JYNNEOS using pregnancy due to lack

1:04:42

of safety data in pregnant persons, while pregnant persons with any risk factor described above may receive JYNNEOS.

1:04:54

For pneumococcal vaccination, again, we've taken out PCV 13 and added PCV 20.

1:05:00

We've added a note stating that either PCV 15 or PCV 20 can be used where the PCV vaccine is indicated.

1:05:10

PCV 20 is not indicated for children who have received four doses of PCV 13 or PCV 15

1:05:16

or another age appropriate complete PCV series.

1:05:23

Where we have listed the non-immunocompromising conditions that increase the risk

1:05:29

for invasive pneumococcal disease we've added chronic kidney disease excluding maintenance dialysis

1:05:35

and nephrotic syndrome, because these are listed in immunocompromising section.

1:05:43

We've added back chronic liver disease and for chronic lung disease we've specified

1:05:49

that this includes moderate persistent or severe persistent asthma.

1:05:54

And the recommendations are outlined by each group. And for each age group we've outlined the recommendations

1:06:02

based on their previous pneumococcal vaccination history.

1:06:11

For polio virus in the catch up vaccination, based on the new recommendation, we've added language for those

1:06:19

who are age 18 years, known or suspected to be unvaccinated or incompletely vaccinated.

1:06:25

We've also clarified that unless there are specific reasons to believe they were not vaccinated,

1:06:31

most persons aged 18 years old or older were born and raised

1:06:37

in the United States can be assumed that they were vaccinated against polio as children.

1:06:42

And then in the special situations section, we've outlined the recommendation for those

1:06:47

who have completed their primary series were at increased risk of exposure to poliovirus.

1:06:54

And at the bottom we have a note that defines what a complete primary series means.

1:07:03

For RSV immunization with nirsevimab, we have a new note section

1:07:10

and in the routine immunization section we have two bullets.

1:07:16

One outlines the recommendations for infants from October through March in most of the continental United States

1:07:23

and the other for infants born April through September. And in each of these bullets,

1:07:29

we've outlined the recommendation based on maternal RSV vaccination history.

1:07:38

In the special situation section we've outlined the recommendations for children ages eight months

1:07:43

through 19 months who are at increased risk for severe RSV disease. In that section we also have a bullet for age eligible children

1:07:53

who are undergoing cardiac surgery with cardiopulmonary bypass who need additional dose

1:07:59

of nirsevimab and we have the link to where more information is available.

1:08:07

And then at the end of the section, we've added some information on the timing of nirsevimab administration based on local RSV seasonality

1:08:17

and information on the use of nirsevimab in children who are eligible to receive palivizumab.

1:08:24

And we also added a resources which is a link to the nirsevimab frequently asked question web page.

1:08:34

For RSV vaccine, we've outlined the routine recommendation for pregnant women at age 32 through 36 week's gestation,

1:08:44

from September through January most of the United States. We've also indicated that either maternal RSV vaccination

1:08:51

or infant immunization with nirsevimab is recommended to prevent RSV disease in the infant.

1:08:58

And then, just like in the nirsevimab section, we have information on the timing of RSV vaccine based

1:09:06

on local RSV seasonality.

1:09:14

In the notes for Tdap, we've made some edits, mainly to clarify that 11

1:09:20

to 12 year Tdap dose is the adolescent booster.

1:09:28

Now we'll go over the appendix which leaves the contraindications and precautions for each vaccine listed in the schedule.

1:09:36

At the header, we've added the link to where you can find the contraindications

1:09:43

and precautions for COVID-19 vaccine, the most recent influenza recommendations for 23/24

1:09:52

and also for JYNNEOS vaccination. We've also changed the header to vaccines

1:09:59

and other immunizing agents. This year, the contraindications and precautions

1:10:05

for COVID-19 vaccines have been incorporated into the table. We have a one row for mRNA COVID-19 vaccines

1:10:14

and a separate row the protein subunit vaccine.

1:10:20

We've also added in a server map and RSV vaccine to the table

1:10:27

and in the footnotes we've included the link to the package insert for nirsevimab.

1:10:35

We've also added the pentavalent meningococcal vaccine

1:10:40

to the table listing the contraindications and precautions.

1:10:46

And mpox vaccine JYNNEOS. Lastly, we've deleted some information from this table

1:10:54

in the DTaP row we've removed the diphtheria tetanus vaccine

1:11:01

because that's no longer distributed in the United States. And in the Haemophilus influenzae row,

1:11:08

we've removed the bullet for severe allergy to not dry natural latex because that's no longer included

1:11:14

in the package insert. And in the meningococcal row, we've removed the information for Menactra.

1:11:24

Lastly, I will go over the addendum it's currently blank. And what we intend to do is

1:11:30

after this schedule is published, any ACIP vote or recommendation will be listed in the addendum.

1:11:37

Thank you and I will now take any questions.

1:11:44

>> Thank you, this presentation is now open for questions and Dr. Poehling. >> So thank you, Dr. Wodi and Murthy and the entire team,

1:11:54

you have taken enormous amounts of data and modifications

1:12:00

and really put it in a very coherent and understandable way. So thank you to the entire team.

1:12:06

I've got three questions that you're probably three steps ahead of me.

1:12:13

The first one is polio. Did we include the recommendation for 18 and older

1:12:22

for those who are unvaccinated? >> Yes, and I'll just go back to the slide.

1:12:32

Yes. In one second.

1:12:41

Yeah. So in the catch up vaccination section, we've included a bullet for those who are suspected

1:12:47

to be unvaccinated or incompletely vaccinated. >> Perfect. Thank you. I knew you were ahead.

1:12:53

The second one is on Slide 51. About the pentavalent meningococcal vaccine.

1:13:00

And it's about the wording. >> I'm sorry. >> Okay. No problem.

1:13:06

Oh, maybe I've got the wrong number. I apologize.

1:13:19

>> This one? >> If you go back to the previous one, wait.

1:13:26

Yes, this one. I was -- I'm wondering about the wording.

1:13:33

Because at the end, we talk about how you can have -- when both of them are going to be administered on the same day

1:13:41

in a single injection with connector is preferred, it kind of sounds like we prefer that

1:13:47

and we did not make a preferential recommendation. And so I worried that this would be misinterpreted.

1:13:56

>> Yeah, we went back and forth with if indicated. Well, we wanted to -- we wanted to communicate

1:14:03

that if the patient or the provider had a preference we weren't sure how

1:14:09

to word that. >> I think that it's okay, because you said

1:14:14

that they may receive a single dose as an alternative to separate administrations when both would be given

1:14:21

in the same day and I would a period. Because I think that clearly communicates

1:14:27

that both are equally reasonable options. >> Okay. We can do that.

1:14:36

>> Okay. And yay, all right, and then PCV 15 and 20.

1:14:44

>> PCV, so. >> Okay, this is going to be okay.

1:14:49

[ Laughter ] All right, stop, backup. >> Back up.

1:14:55

>> For routine. All right, so, I do appreciate the routine and special,

1:15:03

but what I'm worried about is that people will look at the routine and not realize

1:15:08

because we've changed the recommendations for the special. And so I've liked this sentence or --

1:15:15

but it kind of says that if you've received the complete

1:15:21

photo series you're done, unless you have a condition listed

1:15:27

in special situations, and I'm thinking you want to add that so people look at the next page.

1:15:35

And that is the end of my suggestions, and only three is really good. [ Laughter ]

1:15:45

>> Excellent, thank you, Dr. Poehling, Ms. Bahta? >> Dr. Poehling, you always beat me to the hand raising.

1:15:54

I also had similar concerns about the language of preferred

1:16:00

and actually went to the thesaurus and looked at desired or chosen, but I don't even think it's an important part

1:16:08

of the sentence. It doesn't need to be said. And then I know that we do not make policy with a schedule

1:16:16

but I wanted to raise an issue that seems to be kind

1:16:21

of bubbling up related to HPV and giving HPV

1:16:26

and a more routine recommendation starting at nine rather than -- well, it can be given as early as nine.

1:16:35

So that's just a -- put it on --

1:16:40

in the parking lot for an HPV work group. The question is -- there's data that --

1:16:51

growing data that shows better completion of HPV

1:16:56

when you start the series at age nine, it kind of removes some

1:17:02

of the sexual implications and it's easier to talk

1:17:07

about cancer prevention. But I know that the data is conflicting to some degree,

1:17:14

but I would just -- I'm hoping that the work group could look at that more closely.

1:17:22

>> So I know that there is interest in reconvening the HPV work group to address,

1:17:28

I believe this issue as well as probably some others. Given the large amount of -- the large number of work groups

1:17:36

that committee has currently had to support we've been delayed on getting that started, but hopefully we'll be able to do that soon.

1:17:46

>> Is there anything else Ms. Bahta? >> No, thank you. >> Thank you, Dr. Kotton.

1:17:55

>> Thank you. I just wanted to go -- I think it's Slide 40

1:18:00

which is table three. And I am not a pediatrician, but I wanted to --

1:18:12

Well, okay, I'll take that one. Okay, so it's for the RSV vaccine. So, right, perfect.

1:18:19

So obviously, this is for pregnant children and adolescents, right?

1:18:26

But the fact that it's in purple for all those other indications, I know that you mean pregnant people with those indications.

1:18:34

But when I look at this, I see purple. So if somebody has chronic heart, lung or whatever disease,

1:18:42

they should -- they could consider getting this vaccine even if they're not pregnant.

1:18:49

So I would actually make that a different -- I would not keep that purple.

1:18:54

I think that means that you should be giving RSV vaccine to a lot of people for whom it's definitely not approved,

1:19:00

does that make sense? >> Makes sense. >> So I think the purple is erroneous.

1:19:06

>> This has been a recurring issue with table three and whether to limit the information for each column

1:19:17

to only the vaccine that is recommended, or if to also communicate that people

1:19:24

with those conditions should receive other vaccines based

1:19:29

on routine recommendation or their risk. And so to try to address that problem,

1:19:37

the work group leans towards communicating to providers

1:19:42

that people who have this medical condition should also get their routine vaccines.

1:19:49

And so when we revise the column, the color legend, we wanted to leave yellow for those

1:19:57

that are routinely recommended for everyone who has that condition. And then purple, recommended based on their increased risk

1:20:09

for infection or severe outcomes. We struggle with maternal RSV vaccine

1:20:15

because it doesn't really fit into any of these colors, because we're not giving it to the mother

1:20:22

to prevent RSV disease it's for the infants that was --

1:20:28

none of the other colors fit. >> So I would advocate for turning the purple to gray

1:20:33

because there's no guidance or not applicable and just keeping it yellow for pregnant people, because we actually haven't made this a risk based vaccine

1:20:42

for pregnant people. So all of the other groups here, and I say this out of love,

1:20:48

because this indication schedule is my absolute favorite thing ever.

1:20:53

And I include it in virtually every talk I give. Because these are the people that I take care of.

1:20:59

So I would just advocate for flipping that purple to gray to make it obvious to everybody

1:21:05

that this is not recommended outside of pregnancy,

1:21:12

for children, for children. Yes, sorry. We're only talking about children, children and adolescents.

1:21:18

Pregnant children and adolescents. Thank you.

1:21:26

>> Thank you. Dr. Kimberlin.

1:21:35

>> David Kimberlin AAP Red Book question for you about the new final page that you presented,

1:21:46

the addendum page, which course is empty right now, because everything's included in what you just presented.

1:21:53

But let's say a new vaccine is approved. And ACIP recommends use, between now and October,

1:22:01

latter part of October 2024 it will be listed in the addendum page, correct?

1:22:09

And will it also result in a change to one of the tables in that hypothetical?

1:22:16

Or will it only be listed here and the change to the tables will go through the standard process

1:22:24

that has been done, you know, out infinitum, and that you just went through today for the current year?

1:22:31

>> Yeah, if a new recommendation comes out after the schedule is published, say let's say

1:22:37

in February or March, it will be listed on this page. We are currently working on a transition

1:22:45

to have a more responsive schedule. And we're hoping to have that plan finalized

1:22:50

in the next few months. So at this time, our plan is to list any new recommendations

1:22:58

that are caught after the schedule is published on this page and not change the other tables until we come

1:23:06

up with a new process for having a responsive schedule.

1:23:11

>> Thank you I personally would support that I think otherwise it becomes a real beast

1:23:18

to constantly be trying to redo everything. And as long as it's listed here that in my judgment should be enough.

1:23:26

Thank you. >> Thank you. Dr. DeShon. >> Hi, I'm Dana DeShon from NAPNAP,

1:23:33

thank you for your presentation. Any new changes on the schedule this year, a lot of work.

1:23:39

Any thought on adding page numbers? It's just a practical helpful suggestion. I just know I've dropped the pages and it's very cumbersome

1:23:47

to put them back in order. And my other question is also, any thought about alphabetizing the vaccines on the tables

1:23:55

and the catch up schedules? Like they do on the notes in the appendix just for ease of use.

1:24:01

Thank you. >> Thank you for your comment. We'll see if we can add page numbers,

1:24:08

regarding the listing the schedule in alphabetical order,

1:24:15

in table one, and they're actually listed according to when they will be given.

1:24:22

So Hepatitis B comes first because it's the first -- it's given at birth.

1:24:27

And that's why we have that order, so the vaccines for younger kids, are listed earlier, then those that became

1:24:35

in adolescence are listed later. >> Thank you, Dr. Daley.

1:24:42

>> Yeah, thanks so much. So I have a question about how the schedule is used.

1:24:49

And I would like to propose that we need a research agenda, some modest research agenda.

1:24:56

But to know this is a tremendous amount of information that we're trying to convey.

1:25:02

It's getting more and more detailed, we're going to run into the situation where we can't fit the schedule

1:25:07

on one page, I happen to be color challenged. And I use the -- and this is a visual representation of a ton

1:25:20

of information, and I use the schedule a little bit less than I did 20 years ago, if I have somebody --

1:25:27

for myself, if I'm looking something up, or if I'm in clinic with a student, I use it a little bit less.

1:25:37

And I'll make two other quick points. One is that we often are operating in a circumstance

1:25:44

where there's an electronic health record. Some of these are amenable to electronic health record prompts.

1:25:50

And some of these aren't, naturally, something like special situations. And I say this with all the love that Dr. Kotton expressed

1:25:57

about the schedule, about the visual representation of the schedule here. But the second point is that I'm often looking

1:26:04

up a specific vaccine, because there's some detail that I need there.

1:26:11

But here, you have to go from one table to the notes, to then get the additional information you're seeking

1:26:20

versus some other strategy where you're able to find a vaccine

1:26:25

with those recommendations very quickly, could be app based and should be factored in whether you're operating

1:26:32

in an EHR environment or not. That to me suggests we need research on how best to convey this information to frontline providers, thanks.

1:26:49

>> I'm going to ask for the next few comments if we can be concise. And if there's a response that you can be concise

1:26:55

on a response, Dr. Long. >> Yes, if you go to slide 35.

1:27:01

Again, we're not making policy but I don't believe there's a varicella work group currently,

1:27:07

is there, we're doing well with varicella. So here is the question, you have listed as red.

1:27:19

>> Is it the varicella notes? >> Maybe it's different, it's -- with the red and yellow

1:27:25

and green it's Slide 35 on my handout, but it must not be slide 35 anymore.

1:27:31

It's immunization table three, immunization by medical indication.

1:27:36

>> Okay. >> With the red and yellow and purple and gray. >> This one? >> Okay, there it is, that'll do.

1:27:42

So, it says here for MMR and V with an asterix contraindicated during pregnancy.

1:27:50

And then it says, I can hardly read it. It says vaccinate after pregnancy,

1:27:55

I think is the word, if indicated. So I have recently seen two children in the first month

1:28:02

of life, who I recognize this very mild varicella

1:28:10

who I then asked the question of the mother, tell me about where you've been,

1:28:15

and these were immigrant families. The mother delivered.

1:28:21

The mother is from South America, one central America, one South America didn't have varicella as a child,

1:28:28

undoubtedly baby has no antibody, mother gets a vaccine in the postpartum period day that she delivers and goes home,

1:28:36

and she got a few lesions, the baby got skin disseminated varicella, both of them not severely ill.

1:28:42

But led to spinal tap treatment with Acyclovir thinking it was herpes.

1:28:49

And happily, I was there. None of the other people in the whole place had seen varicella

1:28:56

to know that that's what that looked like. So I just don't think the postpartum time --

1:29:03

I'm sure it's a public health measure, gets people vaccinated but it's not a good time for this vaccine

1:29:11

which is a little bit skin transmissible if the mother gets lesions.

1:29:17

And maybe mothers from South America who never had varicella are more likely to get lesions

1:29:22

than all the people we give it to in the United States who had varicella. However, as I thought about it, we're getting to the point

1:29:29

where we're having babies born with only maternal vaccine protection.

1:29:34

And I don't know, you know, if that will be adequate for this kind of transmission.

1:29:41

So I just wondered, I bet you struggled with not saying in the postpartum period, but you say, after pregnancy,

1:29:50

and I suspect that some people are translating this to postpartum.

1:29:55

And so I think some group ought to look at that and see if that's still the right thing to do, I would be fine.

1:30:05

You know, the first month and like baby is not immunologically normal. And although we know varicella is very bad

1:30:12

in the first two weeks, it's probably not perfect if you get it in this third week, or the fourth week.

1:30:18

And then the other thing that I think is a public health measure too that isn't

1:30:24

on these things is what you do for people, when they come to the border.

1:30:30

You give them a lot of vaccines, there was just a child presented at our ID week, who was 15/16 months old, who got MMRNV

1:30:41

and 10 days later had the diagnosis of a severe malignancy. Now, did somebody not --

1:30:48

did somebody miss that this child didn't look healthy 10 days before? But ended up with enormously complicated course

1:30:57

and terrible varicella, pneumonia, and then measles,

1:31:02

both vaccine virus pneumonia. So I don't know what to do about that.

1:31:08

It's still a good idea to vaccinate people, but maybe it is just education.

1:31:14

For people that ask the questions nobody thought about this -- >> Dr. Long?

1:31:20

Sorry to ask, but do you have a specific recommendation for the notes for the section? Or are you asking if this could be revisited sort of generally?

1:31:28

>> Yes, I would like them to think about the note on this pregnancy after pregnancy.

1:31:36

>> And how would it be different just so for clarification?

1:31:42

>> What did she say? >> Clarify. What do you recommend?

1:31:52

>> Probably not in the first days postpartum.

1:31:57

I don't think you should change this schedule. But I don't want to see it again next year with the same question

1:32:05

without someone modeling, you know, what would it do if you didn't immunize all those people compared

1:32:11

with immunizing a mom on the first postpartum day?

1:32:17

>> Dr. Morton, would it be okay, if we deal that question

1:32:22

and ask the SMEs for varicella to perhaps work offline with Dr. Long just to make sure we are not changing the

1:32:29

recommendation, but it's consistent? I'm actually going to ask, sorry, I'm going to move on, the next few.

1:32:35

I'm just going to ask if you can quickly state what you would suggest for the schedule. That will be extremely helpful.

1:32:41

And then Dr. Wodi at the end, we'll just ask if you have any comments about all of the comments.

1:32:46

Commander Grimes. >> Yes, thank you. And really appreciate all the excellent work done on this.

1:32:54

Can you go to Slide 33. Just want to make a quick note here, with the inclusion

1:33:03

of mpox being added to the child and adolescent immunization schedule, mpox is a vaccine,

1:33:09

JYNNEOS is a vaccine that is covered under the countermeasures Injury Compensation Program. So this section will just need to be tweaked to recognize that.

1:33:19

Thank you. >> Thank you. Dr. Poehling. >> Okay, two things. One, as I was thinking about Dr. Long's question, one option is

1:33:28

to remove the asterix from the red. And that would make it maybe clear, just a consideration

1:33:36

for the workgroup that's going to discuss it and then the second was to highlight under the pentavalent there were two paragraphs side by side

1:33:44

that had the same -- is preferred wording and just making sure we remove that on both.

1:33:49

I'm done. Thank you. >> Yeah. Ms. Hayes. >> Yes, Carol Hayes with ACNM.

1:33:56

Dr. Long I just wanted to point out that the vast majority of women that have not been vaccinated are immigrants

1:34:02

and they are covered during their hospitalization for or the birth by Medicaid.

1:34:08

But once they leave the hospital, they are uninsured. And they are lost to follow up many times and they are lost to care.

1:34:14

And so it's one of the reasons why we have always recommended, as long as I've been a midwife, we have always recommended

1:34:19

that they are vaccinated immediately postpartum. >> Thank you.

1:34:26

And then I just have -- while we're on this table, I just have one quick comment, which is looking at the RSV nirsevimab line,

1:34:33

you'll see that the second RSV season, it has heart disease or chronic lung disease, I guarantee the question will come

1:34:39

up whether or not heart disease could be included for the second season. And I will just express my opinion

1:34:46

that as we move towards a respiratory viral prevention platform, I do think perhaps we should think

1:34:54

about how we can harmonize across flu COVID and RSV, some of the conditions, because I don't necessarily --

1:35:01

there's like unusual circumstances like CSF leaks, for example, with pneumococcal vaccine. But other than that, I certainly am suggesting

1:35:09

that this schedule actually highlights some of the minor differences, but they can be significant to patients.

1:35:16

And I do think we need to start to harmonize some of the conditions as evidence allows and as is reasonable

1:35:23

from an implementation standpoint, for our providers, given the complexity of the schedule. Is there anything else specific to the schedule

1:35:29

that would be useful for Dr. Wodi and team to review?

1:35:36

Okay, Dr. Wodi, is there anything else? >> Yeah. Thanks, everyone for your comment.

1:35:42

I just wanted to comment on removing the asterix. And just as a reminder that we added that because we wanted

1:35:51

to encourage pregnant women who are on vaccine -- providers to vaccinate pregnant women after the pregnancy

1:35:59

for these vaccines that are contraindicated. So I think if you took three years ago,

1:36:05

we did not have the asterix and we felt that people would not think about vaccinating the pregnant woman after the pregnancy.

1:36:13

And so that was why we added it as the background. >> Thank you, Dr. Wodi. Dr. Poehling.

1:36:19

>> I was wondering, do I need to make a motion to accept this guy schedule based

1:36:25

on the recommendations that have been added? >> Yes. Thank you, Dr. Poehling.

1:36:33

>> I believe we have -- we were planning a combined vote. So we want to wait on that motion

1:36:38

until after the adult schedule is presented. >> Thank you, Dr. Morton. Okay, let's please move ahead to Dr. Neil Murthy, who will speak

1:36:47

about the 2024 updates to the adult schedule. And again, we really appreciate the work on this.

1:36:52

This is very detailed and complicated. >> Thank you, Dr. Lee, Dr. Neil Murthy so I'm going

1:36:59

to present the updates to the adult schedule. >> Okay. Thank you.

1:37:05

>> All right, so most of the updates to the adult schedule are similar to the child

1:37:11

and adolescent schedule. So I'll go over the changes to the cover page tables,

1:37:17

vaccination notes, appendix, and the addendum. So on the 2024 updates includes new and updated recommendations

1:37:25

for the vaccine in red -- for the vaccines list in red. And then for the others, we've made clarifying edits just

1:37:32

like we did for the child. So, on the cover page for how to use the schedule,

1:37:41

we have a fifth step instructing providers to review the addendum where we're going to list the recommendations that we'll call

1:37:48

after the schedule is published. In the table listing the names

1:37:53

and abbreviations we've added the pentavalent meningococcal vaccine, mpox and RSV vaccine.

1:38:01

And here for RSV vaccine, we have the two brands listed as opposed to the child schedule.

1:38:08

And then we've deleted the bivalent mRNA COVID-19 vaccine and Menactra from this table.

1:38:17

I'll table one list the recommended vaccines by age.

1:38:24

For COVID-19, we've changed the overlaying text to specify that the 2023/24 formula should be used.

1:38:36

For RSV we have age 19 to 49 years in purple indicated

1:38:44

that is recommended for some adults not all adults, and we have the overlaying text seasonal administration during

1:38:51

pregnancy, see notes. And then for 60 years and older we have the blue bar indicating

1:38:57

that this is a shared clinical decision making recommendation. For the pneumococcal row, we have removed the overlaying text

1:39:07

that said either use PCV 15 plus PPSV 23 or PCV 20

1:39:15

because the recommendations have been outdated and it's a lot more nuances than what we had.

1:39:24

And we've added mpox and all the ages are shaded in purple indicating that if you have a risk factor,

1:39:31

you should be vaccinated. Now table two list the recommendations

1:39:39

by medical indications and is similar to table three in the child schedule.

1:39:44

And we did the same thing we wanted to align more closely to the instructions for how to use the schedule,

1:39:50

so identify additional doses recommended based on the medical condition.

1:39:56

And we also revise the color legends for this table and harmonized it with the child's schedule.

1:40:05

But here for the yellow, we now have that is recommended for all adults who lack documentation of vaccination

1:40:12

or lack of evidence of past infection. Those are slight revisions from the 2023 wording,

1:40:20

we just took the age and put it in a purple. So the purple now represents that it's not recommended

1:40:26

for all adults, but it's recommended for some adults based on either their age or their risk

1:40:32

for infection of severe outcome. Brown is new to the table. And we wanted to indicate that for some

1:40:39

of these medical conditions, additional doses of vaccines will be needed. And this was to harmonize with the child's schedule

1:40:47

and the gray we now have no guidance or not applicable.

1:40:52

And we've added the same header to table two like we did

1:40:58

for the table three in the child's schedule, just letting providers know that you use this table

1:41:03

with table one and the notes. And that there's some medical conditions that are not listed

1:41:09

on the slide to see the notes section and that individuals could have made multiple medical conditions.

1:41:18

And in the Hepatitis B row for diabetes, we've indicated that for those aged 60 years

1:41:24

and older the recommendation is shared clinical decision making.

1:41:31

And for RSV we have -- for pregnancy we have a yellow indicator that is recommended

1:41:38

for all pregnant women and the overlaying text is null administration. And for the other medical conditions we had --

1:41:47

we use the blue because of the shared clinical decision making

1:41:53

in older adults. But now looking at this and based on the previous conversations maybe it should be gray

1:41:59

to change it to gray. And then for mpox we have all the medical conditions

1:42:06

in purple. Because anyone with this medical conditions can have the sexual risk factors recommended for vaccination.

1:42:15

For pregnancy we've added see notes, and for men who have sex with men see notes and healthcare personnel see notes

1:42:22

because [inaudible] to the recommendation.

1:42:27

Now moving to the notes section. This year we've added the Additional Information section

1:42:34

to the adults schedule to harmonize with the child's schedule. In the bullet for the National Injury Compensation program.

1:42:43

We've added RSV and would add mpox like previously noted for this CICP program.

1:42:51

COVID-19 vaccination has been extensively revised to align

1:42:57

with the new recommendation for routine vaccination. This is for persons who are not moderately

1:43:03

or severely immunocompromised. And the special situation section lists the

1:43:09

recommendations for people who are moderately or severely immunocompromised based

1:43:14

on their previous COVID-19 vaccination history. And just like we did in the child's schedule,

1:43:22

we have some information that we think will be helpful for healthcare providers that know professional recommendations,

1:43:29

links to more information of the schedule and the EUA. The definition for what previously vaccinated means

1:43:38

and then some information for additional doses and those who are moderately or severely immunocompromised.

1:43:44

Now for Hepatitis A for routine vaccination,

1:43:49

we wanted to clarify that people who are not fully vaccinated they don't have a risk factor

1:43:56

but are requesting the vaccine can get the vaccine, so we revised that bullet to say any person

1:44:01

who is not fully vaccinated and requests vaccination, identification of risk factors is not required they can

1:44:10

be vaccinated. And then for those who are at risk, we just changed the wording just to match what we have

1:44:17

in the routine vaccination section. For Hepatitis B we added a new bullet that adults 60 years

1:44:26

of age and older who request Hepatitis B vaccine should receive the vaccine.

1:44:32

And for the -- for those who are diabetes --

1:44:37

those living with diabetes and 60s and older, we've added a notation to say

1:44:44

that this is shared clinical decision making recommendation. We made similar -- for HPV vaccination we made similar

1:44:54

changes to the child's schedule which was to revamp the bullet on interrupted schedule. And then to clarify that if you've completed your HPV

1:45:02

vaccination series with any of the HPV vaccines, you do not need additional doses.

1:45:12

For influenza vaccination, we've taken out all the bullet for persons with a history of egg allergy.

1:45:18

And we've added a note that they can now receive any influenza vaccine appropriate for their age and health status.

1:45:24

And we have the link to the 2023/24 recommendation. We also had a bullet here for persons who had a history

1:45:33

of Guillain-Barre syndrome within six weeks of influenza vaccine. We took that out because we already have

1:45:39

that in the appendix. For meningococcal vaccination, we've added information

1:45:47

for shared clinical decision making resource.

1:45:53

And we've also added the pentavalent meningococcal vaccine at the end and we will also remove the preferred

1:46:03

language from this section too.

1:46:09

For mpox vaccine, we've listed -- we have a special situation section for those that risk

1:46:15

and we've listed what the risk factors are. We also have the same bullet for pregnancy

1:46:20

like we had in the child. In addition to that we have a bullet

1:46:26

for healthcare personnel stating that except in rare circumstances, such as when no available personnel protective equipment,

1:46:34

healthcare personnel do not have -- who do not have any of those sexual risk factors describable

1:46:39

should not receive JYNNEOS. And we added this because there's been a few questions

1:46:46

about if healthcare personnel providing clinical care for patients with input should be vaccinated.

1:46:55

The meningococcal section was extensively revised just

1:47:00

to clarify -- primarily to clarify the minimum intervals based on which product is used.

1:47:12

And then for polio vaccination. Based on the new recommendation, we now have a routine vaccination wording

1:47:20

which says adults known or suspected to be unvaccinated or incompletely vaccinated should complete the series.

1:47:27

And in the special situation section we have adults who are

1:47:32

at increased risk of exposure to polio who have completed the series may receive one lifetime

1:47:39

booster, and we have included the definition of what a complete primary series is.

1:47:48

For RSV vaccination, the routine section addresses the recommendations for pregnant persons.

1:47:56

We have that pregnant persons should be vaccinated at 32 through 36 weeks gestation, from September

1:48:03

through January most of the United States. And we've also included the language based on time and based

1:48:11

on local RSV seasonality. We also thought it was important to refer

1:48:17

to nirsevimab in this section. So we have the language that either maternal RSV or infant immunization with nirsevimab is recommended.

1:48:26

And we refer -- we refer to the child's schedule for recommendations for nirsevimab in infants.

1:48:37

The special situation section here addresses the shared link or decision making for those 60 years or older.

1:48:44

We've listed the two vaccines brand that can be used here. And we've also provided some information for persons

1:48:51

that are considered at increased risk for severe RSV disease.

1:48:59

And then for the Tdap notes, we've clarified that a Tdap dose administered at 10 years may be counted

1:49:08

as the adolescent dose recommended at age 11 through 12 years.

1:49:14

Now moving on to the appendix which lays the contraindications and precautions.

1:49:19

Similar to the child's schedule we've revised the header to include the links to the contraindications for JYNNEOS

1:49:26

and COVID-19 vaccine and we've updated the link to the -- for influenza vaccine to the current recommendation.

1:49:35

We have incorporated COVID-19 vaccines into the table.

1:49:42

And we have a different row for mRNA COVID-19 vaccines and then

1:49:47

for the protein subunit vaccine. We've added RSV vaccine, contraindications

1:49:55

and precautions to the table. And in the -- we've also added the pentavalent meningococcal

1:50:04

vaccine to the table. And mpox. And similar

1:50:14

to the child's schedule we've deleted the bullet for severe allergic to latex from the hip vaccine rule.

1:50:22

And we've also deleted Menactra from the meningococcal vaccine row.

1:50:29

And lastly to the addendum, which is currently blank,

1:50:36

here's where we're going to list all the recommendations that will occur after the schedule is published.

1:50:44

Thank you, and I'll now take questions. >> Thank you, this presentation is open for questions.

1:50:56

Dr. Long. >> Yes, it's regarding table one any of the slides around 79,

1:51:04

80 on my handout 77, 78. Anyone that have these -- the colors.

1:51:11

>> Table one? Sorry. >> No, one that has a color.

1:51:18

I think it's early, there you go. There you go. >> This one? >> Before that. >> Or the one before that.

1:51:24

>> Table one. >> Table one. Thank you. Table one.

1:51:30

The question is about the third -- the last phrase in the color,

1:51:40

the color definition at the bottom. So it's hard to read but recommended vaccine,

1:51:48

no table one, you were there. >> Oh table one? >> Yeah, table one.

1:51:53

You were there. >> Here? >> The bottom thing. The orange is supposed to be recommended vaccination

1:51:59

for adults who meet age requirements, fine. Lack documentation of vaccination, fine,

1:52:06

or lack of evidence of past infection. Now, that doesn't apply to most of those.

1:52:14

So I wonder why that's there. It certainly doesn't apply to pneumococcus, you know, past infection with what?

1:52:20

There are lots of them. I wonder what -- am I misunderstanding something?

1:52:26

And there's nothing in the notes that helps with that. >> You're right that it doesn't apply to all the vaccines,

1:52:32

but it applies to like, measles. >> I can't understand.

1:52:38

>> And varicella. So it applies to some and with that -- we've struggled with that a lot because it really --

1:52:45

>> It applies to varicella, but it's the only one I can think it applies to,

1:52:51

so why do you -- I would put that under varicella rather than applying it to all oranges because you don't say anything

1:52:59

about it in the notes. >> Camille Kotton. It applies to Hepatitis A, Hepatitis B, measles,

1:53:05

others we use it all the time in the adult world. >> Do they lack evidence of past infection?

1:53:13

So you do Hepatitis B, surface antibodies positive you don't give it and you do that before you give it?

1:53:19

Is that right? >> Yes. Commonly.

1:53:25

>> The general works allows serologic evidence for past infections and is consistent with some

1:53:32

of the policy notes for some of the infections and are measles, mumps, rubella, varicella, Hepatitis A.

1:53:43

>> I might put that in the notes on a few of them that it applies to but I mean, coronavirus, well Coronavirus is different thing.

1:53:53

Influenza, it certainly doesn't pertain to, RSV it won't pertain to, tetanus it clearly doesn't

1:54:00

because you don't make antibodies. So if you have evidence of past infection, you'd still give those, I mean, we could go down the line.

1:54:08

We don't trust it for MMR. >> I like it. >> Why?

1:54:13

>> Because -- >> We're open to suggestions on how to handle these support tables because it's very --

1:54:19

it applies to some and not others, and -- >> The internists like it.

1:54:26

>> [ Laughter ] >> Thank you.

1:54:31

Why don't we go down the line and then Dr. Wodi if we could collect up some of these comments,

1:54:39

and if you could respond cumulatively, that'd be great. Dr. Long was there anything else you wanted to bring up?

1:54:47

>> No. >> Okay, thank you. Dr. Kotton.

1:54:53

>> Thank you. Thank you. So for -- can we go to Slide 85, please, table two.

1:55:01

And RSV, where it's in blue, which is great for shared clinical decision making.

1:55:08

Could we put 60 years of age and over rather than see notes, see notes means click again.

1:55:15

And any time a clinician has to click again, it enhances burnout, frustration and fatigue.

1:55:23

The CDC had a very nice release yesterday about mental health in clinicians.

1:55:29

And I would like to link that advocacy to the see notes.

1:55:35

I do realize that we may be considering 50 to 59. So then there may need to be a change.

1:55:41

But rather than see notes, I would just advocate for greater than or equal to 60 years of age with blue shared clinical decision making.

1:55:48

>> That would be similar to the Hepatitis B item on the Hepatitis B row. >> Yes, yeah.

1:55:55

Take a copy and paste that. Yeah, I like that. Yeah, make it the same. In fact, when you start making things similar,

1:56:01

it gets a lot easier. We like that. Me and the interns mentioned by Dr. Talbot.

1:56:08

>> Thank you. Any additional comments, Dr. Kotton? >> No, thank you. >> Thank you.

1:56:15

Doctor Goode. >> Yes. Hi, thank you. Just a couple of comments.

1:56:21

On the very first page, it looks like for influenza vaccine, we have inactivated and recombinant,

1:56:28

but there's not a cell culture listed.

1:56:35

-- as well as on the table. >> Lisa, can you --

1:56:41

>> Hi, this is Lisa Grohskopf the flu work lead. Essentially, for all intents and purposes,

1:56:47

we regard the cell culture based vaccine as one of the inactivated influenza vaccines, it is different

1:56:53

in that, it is cell culture based as opposed to egg-base like the other ones are. But they're essentially interchangeable

1:56:58

from a policy perspective. We do in our recommendations in the R&R, sometimes call out CCIB

1:57:05

where we have to talk specifically about characteristics of that vaccine, but essentially, would not be treated any differently

1:57:11

from a policy perspective. >> Okay, great. Thank you. >> I hope that helps. Thank you.

1:57:17

>> And then the other thing on table -- the polio is listed everywhere, but not in the table.

1:57:24

And I don't know if that's by design, because it's not necessarily a recommendation, but just an observation.

1:57:30

And then the last thing is on the pneumococcal table two,

1:57:35

that we have -- maybe to have see notes I know that burnout was just talked about, but since it is

1:57:42

so complicated, maybe there should be see notes there for the pneumococcal vaccines.

1:57:48

>> Thank you. >> Thank you, Dr. Cineas. >> Thank you, we can stay on table two,

1:57:55

I noticed that there isn't pentavalent meningitis on there,

1:58:01

and it would be indicated for patients with asplenia who would need both MenB and MenACWY potentially

1:58:09

at the same visit if they're under age 25.

1:58:14

>> Thank you. Any additional observations?

1:58:22

Okay. Dr. Williams? >> Yes, I wanted to say that the LAIV

1:58:28

on table one makes sense where you have four between the IV or IV four, the LAIV but when you go to table two,

1:58:36

it gets very confusing to me. It looks like it's a separate vaccine and in line three looks

1:58:46

like it's separate from the other two vaccines. >> Sorry, I'm just looking at table one.

1:58:52

>> Table one makes complete sense because you have the or there. >> Okay.

1:58:57

>> Ones, two and three. And then going to that one if you look

1:59:05

at the LAIV four I don't quite understand what the message is

1:59:11

trying to be there and the or has disappeared. >> Okay.

1:59:22

>> Thank you. I'll keep going. Dr. Wodi, please feel free to collect up these comments and then respond at the end, Dr. Poehling.

1:59:31

>> I'll go after the commander. >> Commander Grimes.

1:59:37

>> Thank you. And Dr. Wodi, appreciate you calling out on Slide 82

1:59:42

That you would adjust the mpox. Just want to also make a note on Slide 67 cover

1:59:49

for the adult schedule. There needs to be adjustment

1:59:55

of the language around injury claims. And we're happy to help with that adjustment, over.

2:00:02

>> Thank you, Dr. Poehling. >> I would like to reiterate my appreciation to the work group

2:00:10

for the tremendous work that they have done. This is a lot of information that is really well described.

2:00:18

And so I'd like to make a motion if the time is good to say

2:00:24

that I'd like to move this forward with the recommendations that had been shared.

2:00:30

>> Thank you. Just hold for one moment. Dr. Wodi. Is there anything you'd like to respond to?

2:00:36

Or do you have any concerns about the comments and suggestions that have been given? >> I have a few comments and for the pentavalent vaccine not

2:00:46

added to table ones or two. That's because it doesn't change the recommendation.

2:00:51

So when we discuss this with the SMEs, we decided to put the information in the notes because the recommendation is the same

2:00:59

for -- it doesn't change. And then for the comments on LAIV

2:01:06

and IV we didn't quiet listen, we didn't quite understand the comment.

2:01:12

So in table one, we have a one row for IIV four or our IV

2:01:18

and then we have the separate row for LAIV. And then in table two, we have the same theme.

2:01:26

A different row for, sorry, just one separate row for IIV

2:01:34

for RIV four and then a different row for LAIV. >> Yes, my question was it looks

2:01:42

like there are two separate standalone vaccines but you wouldn't get two, you wouldn't get IIV and LAIV.

2:01:51

And the other table it had an or IIV or LAIV they're both flu vaccines.

2:01:57

And then the other thing was -- this is Dr. Williams, and then the purple, under one dose annually looks

2:02:04

like it's applying to men who have sex with men. I was not aware of that as an indication for LAIV.

2:02:13

Personally, and it's just gets -- I work with LAIV. So the indications there are confusing to me.

2:02:20

>> Okay. All right, go ahead, Lisa >> So the reason that men have sex with men is called

2:02:30

out for LAIV, I'm not sure. Actually, I can't read the slide now that I think of it.

2:02:39

>> Sorry. I can answer that. We wanted to -- you would notice that for some of the --

2:02:45

now that we have age in the purple, we wanted to call out that for that group there's an age indication.

2:02:54

So you can't use it for all men who have sex with men, they have to be between the ages of 19 and 49.

2:03:00

And we did the same thing for the other. So if you look at the -- had the orange

2:03:06

where there's a precaution and also health care worker, we also have the one dose annually

2:03:12

if you're aged 19 to 49 years. So we wanted to let people know that yes,

2:03:19

actually for LAIV there's actually a maximum age for which you can use it.

2:03:26

>> Okay, okay, thank you. And then maybe should there still be an or in between rows two and three?

2:03:32

Since they wouldn't be getting both IIV and LAIV in a season? >> Yes, we can add or, now I understand what --

2:03:42

to make it similar to the blue or with the --

2:03:48

yeah, we can add that, yeah. >> Thank you. >> Thank you.

2:03:54

Anything else? Dr. Wodi? >> No, thank you. >> Thank you so much.

2:04:00

So Dr. Poehling thank you for the motion on the table. Dr. Loehr. >> I'd like to second that motion.

2:04:07

>> Thank you so it has been moved and seconded that we accept the updated adult

2:04:13

and childhood immunization schedules and we will vote on this after public comment.

2:04:18

Thank you everyone for now let's take a just a five-minute break,

2:04:25

plan to reconvene at 10 minutes after the hour, thank you very much.