Immunization Update 2023

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Disclosure Statement

- Donald Bennett has no relevant financial relationship(s) with ineligible companies to disclose.

  and

- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Disclosure Statement #2

This presentation was current at the time of preparation—something has probably already changed

Learning Objectives

At the completion of this activity, the participant will be able to:

1. discuss the Centers for Disease Control and Prevention (CDC) identified trends in vaccine-preventable disease prevalence this past year;
2. describe the recent changes in recommendations from the CDC Advisory Committee on Immunization Practices with an emphasis on COVID-19 vaccines;
3. discuss the impact of the 2022-2023 influenza season and review vaccine effectiveness factors; and
4. describe initiatives to improve vaccine hesitancy and increase immunization rates including examples of misinformation and disinformation.

General Vaccination Trends

- The COVID-19 pandemic contributed to a decrease in pediatric well visits and a decrease in vaccinations in general
- Well visits are up, and vaccinations are trending up
- Some vaccine hesitancy persists
- “Catch-up vaccinations” continue to lag

Factors Contributing to Decreased Pediatric Vaccinations

- Well visits postponed because of fear of COVID-19 infection
- With virtual learning, some required school vaccines not enforced
- Same with sports physicals
- Lack of health insurance or other financial concerns
- State legislative changes making opting out easier

- During the 2021-2022 school year:
  - National kindergarten vaccine coverage 93%
  - Lowest rate in a decade
  - Drop consists of a 1% decline since the 2019-2020 school year and a 2% drop since the start of the pandemic.
  - Example of what this means: ~250,000 kindergartners potentially are not protected against measles.

CDC Vaccine Schedules

- Available on CDC website
  - Child (birth-6 years)
  - Adolescent (7-18 years)
  - Catch-up (4 months-18 years)
  - Adult
  - Adult with conditions
- Free mobile apps

References—Free Phone Apps

CDC Immunization Schedules

Purple Book

Measles, Mumps, Rubella Trends

- Measles & Rubella considered eliminated in US in 2000 (measles) & 2004 (rubella)
- Mumps experienced a >99% reduction in cases due to achieving and maintaining high MMR coverage
- These viruses continue to cause locally acquired and importation-related cases and outbreaks.
- In the United States during 2016 – 2021:
  - Measles cases: 13 – 1282 cases per year
    Mumps cases: 154 – 6366 cases per year (primarily locally acquired)
  - Rubella cases: <10 cases per year (all imported)

Measles Central Ohio

- First reported cases early November 2022
- Total of 85 cases
  - 80 unvaccinated
  - 4 partially vaccinated (1 of 2 doses)
  - 1 unknown vaccination status
- Columbus Department of Health outbreak over February 23, 2023
- No cases for 42 days (2 x incubation period)

New MMR Vaccine

- New MMR vaccine (PRIORIX, GSK) approved by FDA June, 2022
- Has been licensed in Germany since 1997
- Data demonstrate equivalence to the currently licensed MMR (M-M-R II, Merck).

MMR II (Merck)

- 2023 approved for IM injection in addition to subcutaneous (0.5mL)
- IM injection slightly fewer local reactions
  - Erythema
  - Swelling
  - Pain
- Systemic reactions similar

Other Injection Changes

- Varicella vaccine (Varivax-Merck)
  - Now IM in addition to subcutaneous
- Measles, Mumps, Rubella, Varicella (ProQuad-Merck)
  - Now IM in addition to subcutaneous

Clostridium difficile (C. diff)

- Gram positive bacteria causing over 200,000 GI infections annually with ~12,000 deaths
- Usually in institutional settings
- Antibiotic use contributory
  - Fluoroquinolones, clindamycin, cephalosporins
- High priority for a vaccine
- Pfizer ended vaccine study March 2022 because it did not meet goals

Pneumococcal Conjugate Vaccine 15-valent (PCV-15) & 20-valent (PCV-20)

- Pneumococcal polysaccharide conjugated to nontoxic diphtheria toxin (15 or 20 serotypes)
- Both originally indicated for adults ≥ 18 years and dosed as 0.5 mL I.M.
- Replaces PCV-13 in adults
- Merck PCV-15 (Vaxneuvance™) approved 7/2021
- Pfizer PCV-20 (Prevnar 20™) approved 6/2021

Pneumococcal Conjugate Vaccine 15-valent (PCV-15) & 20-valent (PCV-20)

- Merck PCV-15 (Vaxneuvance™) approved in June 2022 for use in children 6 weeks through 17 years.
- Pfizer PCV-20 (Prevnar 20™) projected to be approved for children in 2023

Pneumococcal Polysaccharide Vaccine 23-valent (PPSV23)

- Pneumovax® 23 (Merck) approved 1983
- Purified capsular polysaccharide antigen from 23 types of pneumococcus
- Covers 85%+ of serotypes causing disease
- More effective against preventing bacteremia than pneumonia
- Not effective in children < 2years
- Dose = 0.5mL given IM or SC

Adults Age ≥ 65 years

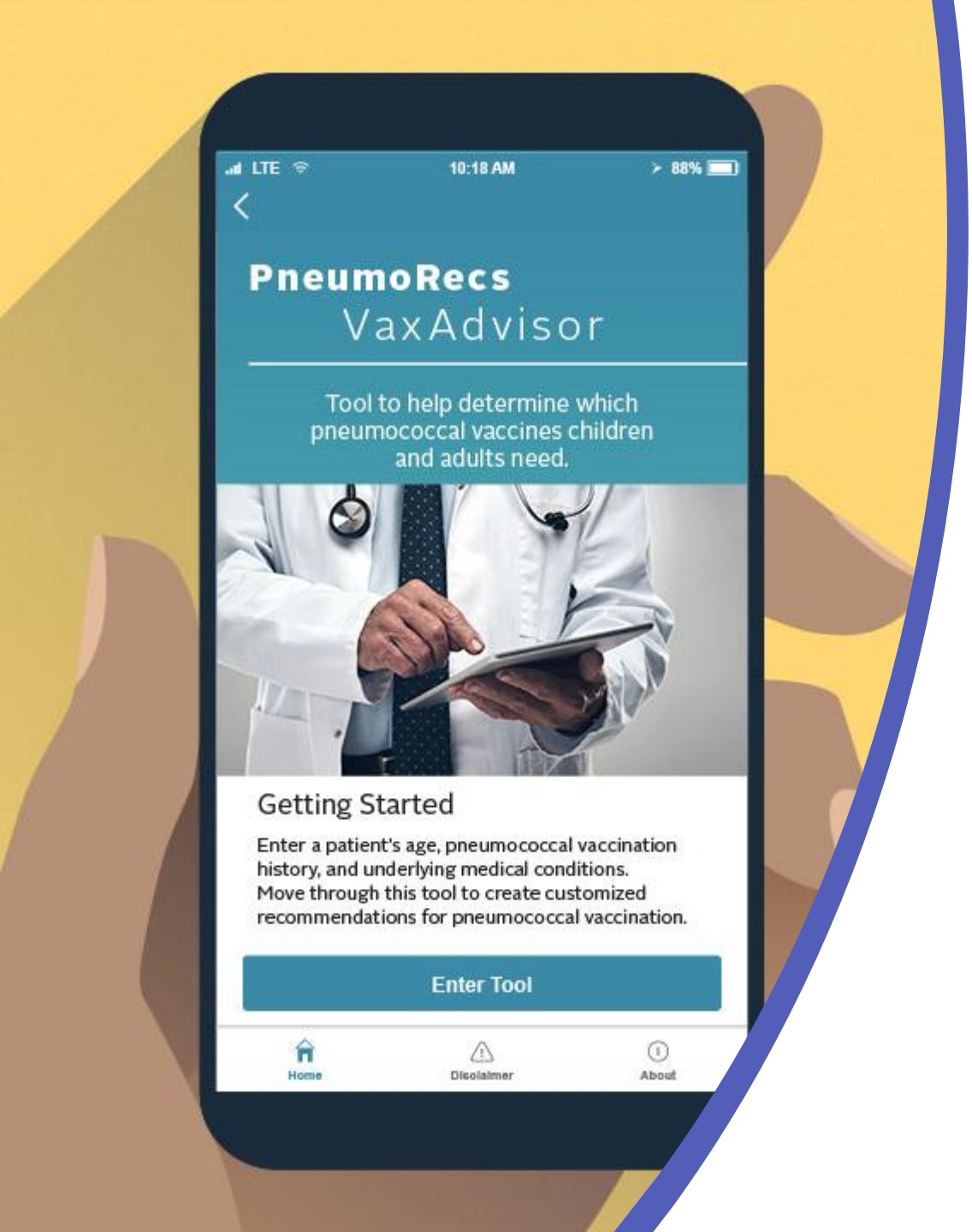
- If no previous dose of PCV or unknown history
  1. Give PCV-20 or
  2. Give PCV-15 followed by PPSV23

     Preferably 1 year later . May give at 8-week interval if immunocompromised, cochlear implant, CSF leak

ACIP Recommendations *MMWR* January 28, 2022

Adults Age ≥ 65 years

- If previous dose of PCV-13 and PPSV23, no additional doses are needed.
- If previous dose of PCV-13 and no PPSV23, finish this sequence
- If previous dose of PPSV23 only, give either PCV-15 or PCV-20
- ACIP has determined that these changes are cost effective



PneumoRecs VaxAdvisor

Pneumococcal Vaccines Practical Approaches

- Vaccine naïve: Consider PCV 20 over PCV 15 + PPSV23
  - Simpler regimen
  - May streamline your inventory
  - Both PCV products cost ~$240/dose
  - PPSV23 costs ~$120/dose
  - All 3 vaccines covered by Medicare

Tdap and Pregnancy

- Tdap: ACIP recommendations October 24, 2012
  - Give during every pregnancy regardless of Tdap history.
  - Give between weeks 27-36 to maximize maternal antibody response and passive antibody transfer
  - Women not previously vaccinated with Tdap, give immediately postpartum if not given during pregnancy

“Cocooning”

- Concept of vaccinating pregnant women and all others who will have close contact with an infant before the infant can develop natural immunity from vaccinations.
  - Pertussis (12 months)
  - Influenza (6 months)
- Endorsed by CDC and Academy of Pediatrics

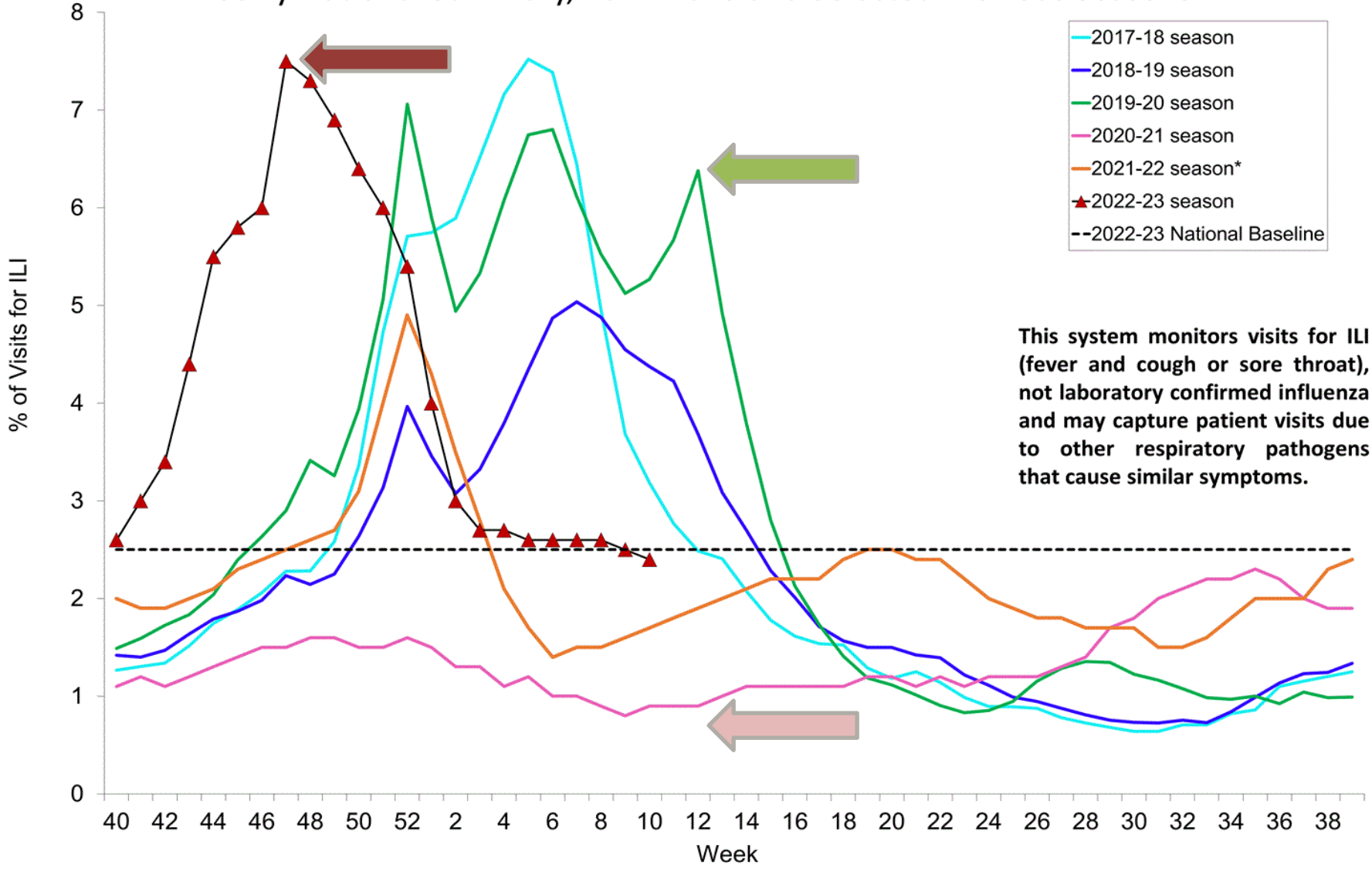
Pertussis

- Recent study covering 2000-2019 effect of Tdap during 3rd trimester and infants up to 2 months of age
  - Prevents 75% of cases
  - Protects 90% against hospitalization

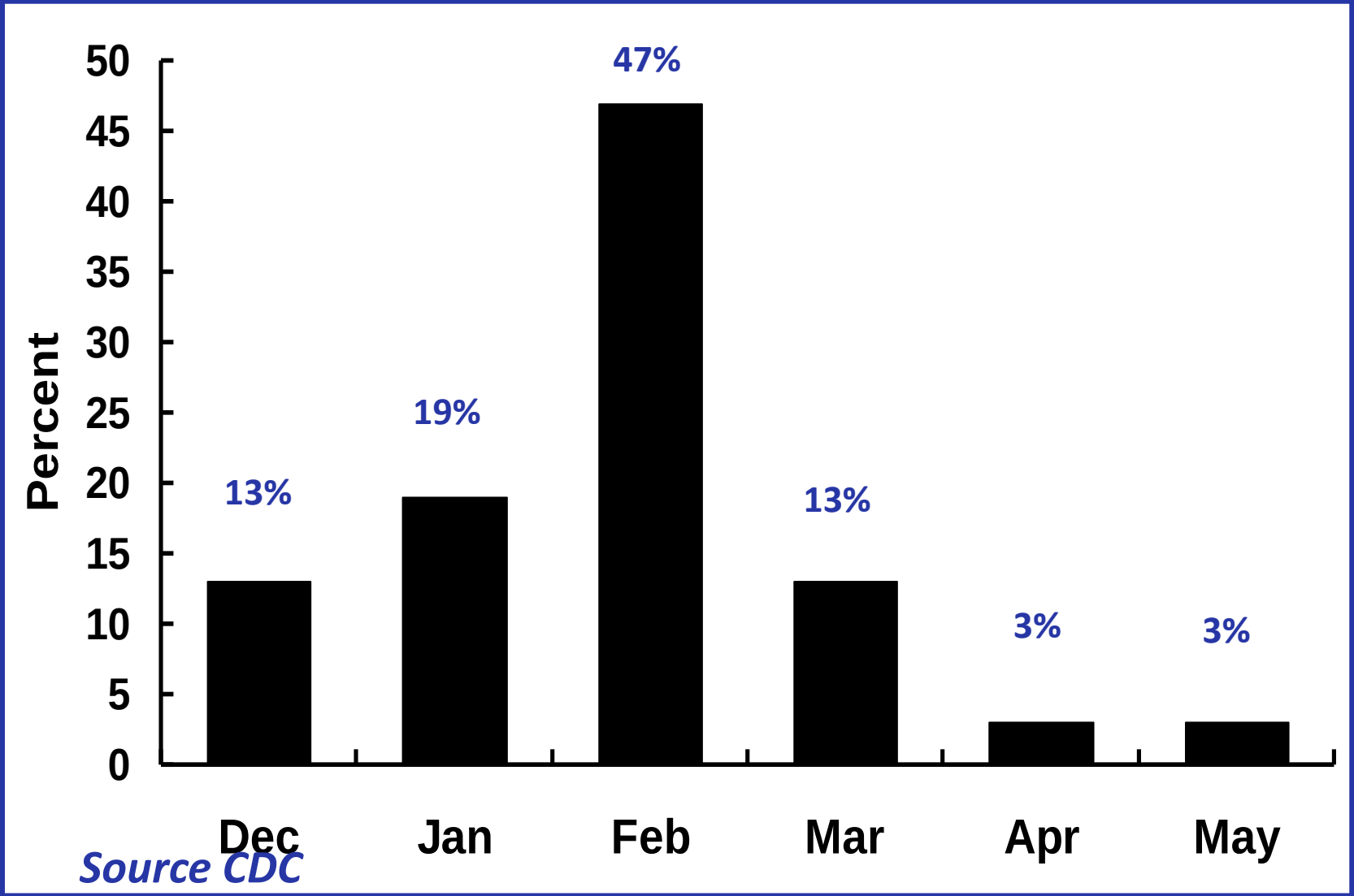
ACIP October, 2019

- Tdap approved as a substitute for Td
  - Every 10 years Td booster
  - Tetanus prophylaxis for wound management
  - Catch-up immunization schedule for those age 7+

Percentage of Outpatient Visits for Respiratory Illness Reported By The U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2022-2023 and Selected Previous Seasons



Month of Peak Influenza Activity United States, 1976-2018



Source CDC

Influenza Vaccine 2022-2023

- A/Victoria/2570/2019 (H1N1)pdm09-like virus;
- A/Darwin/9/2021 (H3N2)-like virus;
- B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and
- B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

Vaccine Effectiveness 2022-2023

- From February ACIP meeting
- Influenza A Children
  - Overall 45% (usually 30%)
  - 42% against ED visit
  - 68% against hospitalization
- Influenza A Adults
  - 43% against hospitalization

Pediatric Flu Vaccinations 2022-2023

- Down from 55.3% to 53%
- Rural vs Urban Disparity
  - Urban 56.7%
  - Rural 37.5%

Pediatric Deaths by Season

Season	Deaths
2022-2023	132
2021-2022	6
2020-2021	2
2019-2020	192
2018-2019	144
2017-2018	188
2016-2017	110

Consistently those eligible for vaccine and die:
ONLY 20-25% received it!!

Where Do People Get Influenza Vaccinations

- Pharmacies ~ 40%
  - 47.5 million doses in 2020-2021
  - 43 million doses in 2021-2022
- Provider offices ~ 20% (higher for peds)
- Work ~ 8%

Influenza Vaccine Recommendations

- All 6 months and older
  - Changed and simplified in 2009 because 19–49-year-olds hit hard by H1N1
  - And high risk groups did not know they were high risk

Groups at Increased Risk of Complications of Influenza (slide1/2)

- All children 6 months--5 years old
- All ≥ 50 years old
- Chronic diseases (CV, pulmonary, metabolic)
- American Indians/Native Alaskans
- Morbidly obese (BMI ≥ 40)

Groups at Increased Risk of Complications of Influenza (slide 2/2)

- Immunosuppression
- Long-term care residents
- 6 month-18 year old on chronic ASA
- Pregnant women

Pregnancy and Influenza Vaccine

- Unvaccinated Moms who have influenza
  - Increased rates of premature births
  - Decreased birth rates
  - Increased rates of Cesarean sections
- 2022-2023 vaccinations lagging
  - 44% vs 55.3% last season
  - 2020-2021 was 62%+

Pregnancy and Influenza Vaccine

- Risk of hospitalization 4 times higher than nonpregnant women
- Risk of complications comparable to nonpregnant women with high risk medical conditions
- for ALL women who will be pregnant during influenza season, ACIP recommends vaccination with inactivated influenza vaccine
- Vaccination can occur during any trimester

Pregnancy and Influenza Vaccine

- Cannot vaccinate infants younger than 6 months
- June, 2011 study, American Journal of Obstetrics and Gynecology
  - 1550 hospitalized infants over 7 flu seasons (2002-2009)
  - Infants 45% less likely to get the flu in their first flu season if mother received the vaccine

Influenza Vaccine Recommendations

- Health care providers, including home care
- Employees of long-term care facilities
- Household members of high-risk persons (including children 0-59 months)

Source: *MMWR* 2007; 56 (RR-6)

Influenza Vaccines
Inactivated Influenza Vaccines

- IIV3 = Trivalent inactivated influenza vaccine
- IIV4 = Quadrivalent
- RIV4 = Recombinant influenza vaccine (Flublok)
- ccIIV4 = cell cultured (Flucelvax)
- aIIV4 = adjuvanted (Fluad)

- Note: Not all vaccines are indicated for all age groups! Read product literature closely.

Influenza Vaccines: 2022-2023

Ages	Products	Manufacturers
6-35 months=0.25 mL ≥ 6 months=0.5ml	Fluzone IIV4 FluLaval IIV4 Fluarix IIV4 FluLaval IIV4	Sanofi-Pasteur GSK GSK ID Bio (GSK)
≥ 4 years	Fluvirin IIV4	Seqiris
≥ 6 months	Flucelvax ccIIV4	Seqiris
≥ 6 months	Afluria* IIV4	Seqiris
≥18 years	Flublok RIV4	Protein Sciences
≥ 65 years	Fluzone High-Dose IIV4 Fluad aIIV4	Sanofi-Pasteur Seqiris
2-49 years	FluMist LAIV4	AstraZeneca

* Approved for jet injector for 18 through 64 years

Pediatric Dosing

- For children younger than 9 years of age who have not received influenza vaccine before
  - Give two doses spaced 4 weeks apart
- If during the first vaccination year, they only received one dose, then you need to give 2 doses this year
- Check your specific vaccine product-- the dose may be 0.25 mL or 0.5 mL

Recommended for Age 65+

- Fluzone HD Quadrivalent
- Fluad Quadrivalent (Seqirus)
  - Same adjuvant (MF59) as IIV3 Fluad
- Flublok Quadrivalent
- ACIP: no preference

Bird Flu

- 1997 Hong Kong H5N1 birds to mammals
- 2004 Vietnamese family
- 2005 North Africa, Turkey and Europe poultry to wild birds
- 2015-2017 Egypt 250 human cases; 93 deaths
- World confirmed cases with ~50% death rate
- U.S. 2022-2023 detected in chickens, bears, foxes, skunks (some H9N2)

Avian Flu H5N1

- Global activity 2023
  - Two cases in Cambodia (February)
  - Two cases China (February)
- Work begun on H5N1 vaccine
- CDC: low risk in U.S. at this time

Respiratory Syncytial Virus (RSV)

- Pediatrics ages 5 years and younger
  - Millions outpatient visits/year
  - 80,000 hospitalizations/year
  - 300 deaths/year
- Transmission increases in winter months

Respiratory Syncytial Virus (RSV)

- Nirsevimab monoclonal antibody provides passive immunity
- Given IM once
- ACIP evaluating for annual recommendation
- Also being evaluated for pregnant women at 24-36 weeks to protect mom and newborn

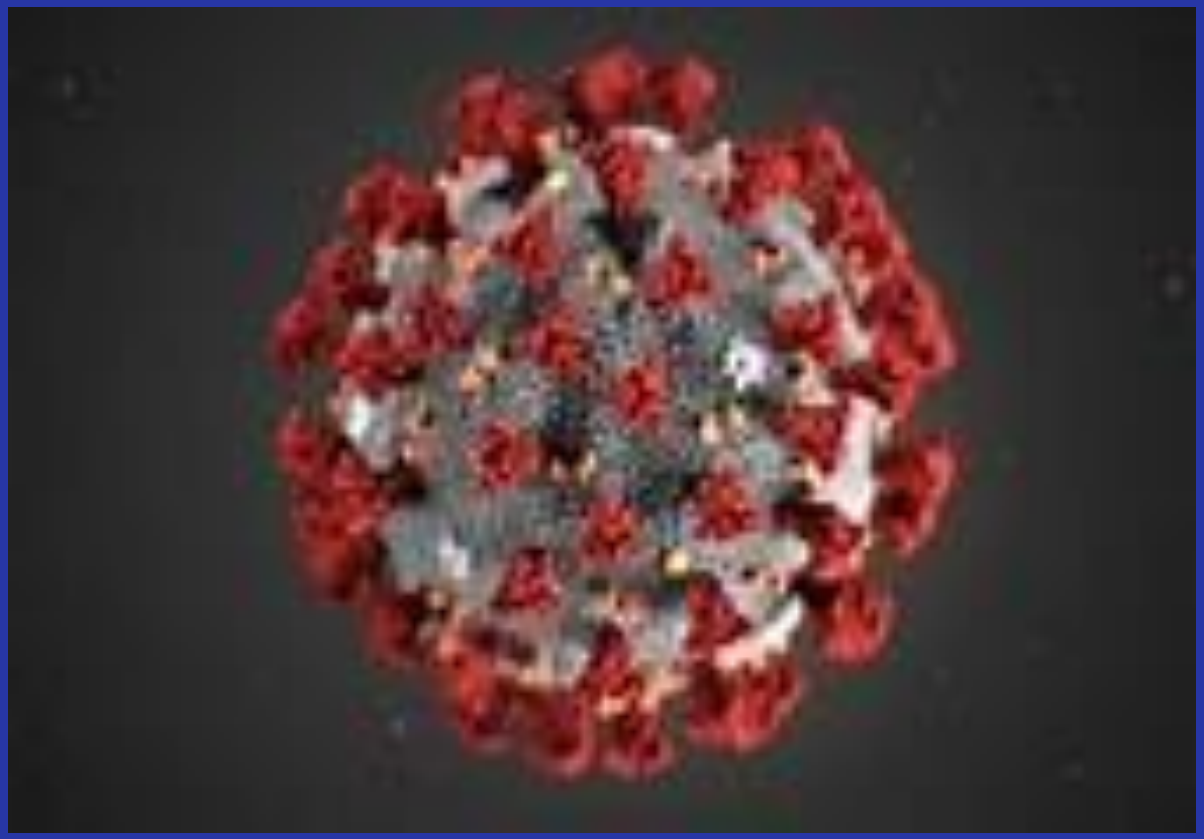
Respiratory Syncytial Virus (RSV)

- Adults 65 and older
- Often unrecognized cause of respiratory disease
- ~6,000-10,000 deaths/year
- FDA evaluating two vaccines (Pfizer; GSK)
  Look for additional information later in 2023

Polio

- Look for update after June, 2023 ACIP
- Evaluating primary booster doses with inactivated vaccine in adults
- CDC monitoring waste waters in select communities

SARS-CoV-2



- COVID-19 no longer deemed a health care emergency, but it needs to be a health care priority

Confirmed COVID-19 Statistics as of March 10, 2023

- Global Confirmed 676,609,000+
- Global Deaths 6,881,000+
- U.S. Confirmed 103,800,000+
  - Estimated to be over 150,000,000
- U.S. Deaths 1,119,792

Source Johns Hopkins COVID Resource Center

www.coronavirus.jhu.edu

JHU has stopped the tracking system

- US continues reporting 4000 deaths and 35,000 hospitalizations/week

COVID Vaccinations

- U.S. : 270 million have received at least one vaccination
- Results since January 2022
  - Daily COVID-19 reported cases are down 92%
  - Deaths have declined 80%
  - New hospitalizations are down nearly 80%

As of March 5, 2023

- Since January 1 in Ohio
  - Over 65,000 cases
  - 2700 hospitalizations
  - 448 deaths
- Ohio vaccinations
  - 60% received Primary series; includes 87% over 65
  - Updated boosters = 15%
    - 33% for ages 60-79
    - 40% of 80+

COVID-19 Vaccine Effectiveness

- Unvaccinated hospitalization rate 16 times higher than those with one bivalent booster
- Vaccinated adults without booster hospitalization rate 2.6 times higher than those with one bivalent booster

Pharmacists

- Have given ~300 million COVID-19 Vaccinations
- Averted 1 million deaths
- Prevented 8 million hospitalizations
- Saved $450 billion in health care costs
- Also pharmacy teams vaccinated disproportional share Asian, Hispanic or Latinos
- 70% of vaccinating pharmacies located in communities with moderate to high social vulnerability

COVID Vaccinations

- ~70% received primary series
- Only 16% have received bivalent booster
- ACIP February 2023
  - Not recommending routine annual vaccinations
  - In Fall, may recommend boosters for older adults and those immunocompromised

- The U.S. has the highest COVID-19 death rate among high-income countries, at 3,000 deaths in every 1 million cases between Jan. 22, 2020, and Jan. 18, 2023.

Vaccine Safety
Summary from February ACIP

- Multiple safety monitoring systems
  - Vaccine Adverse Event Reporting System (VAERS)
  - V-Safe
  - Vaccine Safety Datalink (VSD)
- VSD reported slight increase in ischemic stroke in 65 years and older November 2022
  - Only a blip; not in other systems
  - Frequent complication of COVID-19
- No increase of myocarditis in adolescent males

Factors for High Risk of Disease Progression

1. Age $\geq$ 65 years of age
2. Obesity (BMI > 30)
3. Diabetes
4. Cardiovascular disease
5. Chronic lung disease

March 2023

- Omicron subvariant XBB.1.5 accounts for 90% of COVID-19 cases
- Up from late February of 85%
- Hospitalizations and deaths are down

Current Vaccine Recommendations

- Primary Series
  - Moderna: 2 doses at 0 and 4-8 weeks
  - Pfizer-BioNTech, Novartis: 2 doses 0 and 3-8 weeks
- Moderate to severe immunocompromised
  - Moderna: 3 doses at 0, 4 and 8 weeks
  - Pfizer-BioNTech: 3 doses at 0, 3 and 7 weeks
  - Novavax: 2 doses at 0 and 3 weeks

Booster Doses as of December 2022

- Recommend one dose of bivalent mRNA vaccine (Moderna or Pfizer-BioNTech) at least 2 months after last primary dose
- Give even if history of COVID-19 disease
- Although not required, may want to defer until 3 months post infection

February 2023

- Omicron subvariants XBB and XBB 1.5
  and BQ and BQ1.1
  account for >95% of new cases
- Current bivalent vaccines have some effectiveness at protecting against symptomatic disease
- More effective at preventing hospitalizations and deaths

January 27, 2023

- FDA's Vaccine and Related Biological Products Advisory Committee (VRBPAC) unanimous vote:
- Replace previous authorized regimen with bivalent for primary vaccinations
- Reformulated bivalent Pfizer-BioNTech and Moderna protect against Omicron BA.4 and BA.5 subvariants

Pediatric Update

- Ages 6 months-4 years who have completed primary series should get Pfizer-BioNTech bivalent booster at least 2 months after last primary done
- Vaccine providers now required to report myocarditis and pericarditis after Janssen vaccine to Vaccine Adverse Event Reporting System (VAERS)

Post-COVID Conditions
Long COVID
("Long Haulers")

- Various symptoms persist for weeks and months
- Symptomatic COVID may result in one-third having some symptoms 1 month later
- Some asymptomatic individuals may develop lingering long-term symptoms

Long COVID

- Ohio: ~488,900 children had COVID
- NIH: ~4% will develop Long COVID
- Result ~20,000 children

Long COVID Symptoms

- Exhaustion/Fatigue
- Respiratory: SOB, coughing
- Cardiac: Chest pain, palpitations
- Joint or muscle pain
- “Brain fog”
- Headaches, dizziness, trouble sleeping
- Changes in smell/taste
- Depression/Anxiety
- Gastrointestinal

Long COVID
Types

- Basically two types*
  1. Severely ill requiring hospitalization
     - Intensive care: 74% physical symptoms 1 year later
     - Lingering mental symptoms 26%
     - Cognitive symptoms 16%
  2. Mild infections (No hospitalizations). May be from overactive immune system
     - “Brain fog”
     - Endless headaches
     - Unusual tingling sensations

Long COVID
Risks

- Age
- History of asthma
- Severity of infection
- Number of symptoms (5 or more create high risk of lingering symptoms
- Vaccination helps prevent Long COVID
- Do not know if different variants have different effects on Long COVID

Isolation Guidelines
If Test Positive

- Day 0 is the day of symptom onset.
- Day 1 is first full day after the day of symptom onset.
- Stay home at least 5 days; isolate from others in the home.
- Use separate bedroom and bath if possible.
- Do not share personal items.
- May end isolation after 5 days if symptom free and no fever.

Removing Your Mask

- Feeling better and no fever , wear your mask through day 10

OR

- Two negative tests 48 hours apart, may remove your mask

Nirmatrelvir/ritonavir (Paxlovid)

- March 16, 2023
- FDA advisory panel votes 16-1
  - Move from EUA (since late 2021) to full approval
  - Could prevent 1500 deaths/week
  - Could prevent 13,000 hospitalizations/Week
- Focus on individuals
  - Unvaccinated/partially vaccinated
  - Elderly
  - Immunocompromised

COVID Rebound

- After Paxlovid or Molnupiravir (Legevrio)~5%
- Can occur 2 days to 30+days later
- Appears more common with new variants

Combination COVID-19/Flu Vaccine

- Will not be available for Fall 2023

Mpox

- The public health emergency (PHE) for the mpox outbreak ended on January 31, 2023, as the number of reported cases continues to fall since the PHE was first declared in August 2022. The PHE was renewed only once in November.

Mpox (Monkeypox)

- Orthopoxvirus (related to smallpox)
- First identified in 1958
- First human case 1970
- Central and West African countries

Mpox (Monkeypox) Symptoms

- Fever
- Headaches
- Muscle or back pain
- Swollen lymph glands
- Chills
- Fatigue
- Rash with Lesions form
- Lasts 2-4 weeks

Mpox (Monkeypox)

- Infectious until rash gone & lesions healed (fresh layer of skin forms)
- Respiratory droplets, exposure to lesions, body fluids or contaminated clothing
- Sexually transmitted
- If HIV/AIDS, higher risk for more severe disease
  - Increased death rates
  - Lesions spread greater on body
- No proven treatment

Mpox (Monkeypox)
At Risk Populations

- Traveled to endemic area
- Direct contact with infected person
- Men who have sex with men

Mpox Public Health Emergency

- Declared August 2022
  - Peak 400+ cases/day
  - Total cases 30,000+
  - 26 deaths
- Cases have fallen dramatically
- PHE ended January 31. 2023

Mpox Vaccine (Jynneos)

- Smallpox and Monkeypox, Live, Non-Replicating
- Approved September 2022
- 18 years and older
- Suspension 0.5mL vials (swirl before use)
- Must be frozen
  - Refrigerated 12 hours after thawing

Mpox Vaccine (Jynneos)

- 0.5mL dose subcutaneously in triceps area (was initially given intradermally)
- Two dose regimen given 4 weeks apart ~80% effective
- Considered protected 2 weeks after second dose
- Protects against mpox and smallpox

Mpox Vaccine Side Effects

- Injection site reactions
  - Pain 85%
  - Redness 61%
  - Swelling 51%
- Systemic
  - Muscle pain 43%
  - Headache 35%
  - Fatigue 30%

Vaccines Do Not Prevent Deaths, Vaccinations Do!

World Health Organization

- In 2019: “Vaccine hesitancy is one of the TOP 10 threats to global health”

Vaccine Hesitancy versus Vaccine Confidence

- Confidence: May apply to educating someone who does not have an opinion yet and is still open.
- Hesitancy-: May apply to someone who is opposed to the vaccine and may have been exposed to misinformation or disinformation
- May take more than just education.

Former U.S. Surgeon General Dr. Jerome Adams:

(Paraphrased)

The CDC does a great job of providing good scientific information for health care providers and scientists, but not such a good job of communicating with the public.

- Our public debate seems increasingly driven by what people want to be true rather than what is actually true.
- “Echo Chamber”


VACCINE RESEARCH
ANTI VAX MOM RESEARCH

Accuracy of the Internet "Info-demic"

"On the Internet, nobody knows you're a dog."

Examples

- Italian study 2007-2017 YouTube
  - MMR-autism negative videos outnumbered positive by factor of 3
  - Negative also viewed more times
- HPV dizziness and fainting
  - 2014 Japan suspended vaccination recommendation for 9 years
  - Hesitancy increased in other countries
  - Estimated results of 25,000 preventable cases occurred with 5000 deaths

Vaccine Hesitancy

- 1. Opposed to all vaccines
- 2. Opposed to specific vaccines
  - MMR and Autism
  - HPV dizziness & fainting
  - Vaccine ingredients, thimerosal, adjuvants
- 3. Opposed to schedule “overwhelms child’s immune system”

Vaccine Hesitancy

- Regional and local variations
- Health professions still the most trusted for accurate information
- Build trust—community outreach
- Strategy?
  - Initially, do not correct misperceptions
  - Pivot to focus on the disease

References

Centers for Disease Control and Prevention
www.cdc.gov
Treatment Guidelines NIH
www.covid19treatmentguidelines.nih.gov
World Health Organization
www.who.int
Immunization Action Coalition (IAC)
www.immunize.org

Need More Information?

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