COVID-19 Vaccine Update

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Disclosures

- Commercial vaccine products will be discussed
- No other disclosures relevant to today's presentation

Objectives

- Review data supporting COVID-19 vaccination in children and adults
- Provide an overview of the current CDC recommendations for COVID-19 vaccination*
- Discuss frequently encountered questions surrounding COVID-19 vaccination

*Current as of May 5, 2023

COVID-19 Vaccines

COVID-19 Vaccine Basics – mRNA Vaccines

Moderna

Pfizer

- Two vaccine manufacturers – 5 products
- Lipid-encapsulated mRNA encoding Spike protein
- Body produces Spike protein which generates an immune response
- Following protein production, the body degrades the vaccine mRNA
- Does not contain live virus
- Does not interact with recipient's DNA in any way

Source: CDC

COVID-19 Vaccine Basics – Protein Subunit

Novavax

- One vaccine product available
- Synthetic nanoparticle coated with Spike protein
- Body generates an immune response to protein
- Contains adjuvant to enhance immune response
- Does not contain live virus

Source: CDC

COVID-19 Vaccine Basics – Viral Vector

Janssen
(Johnson & Johnson)

- Adenoviral vector containing gene to encode for Spike protein
- Body produces Spike protein which generates an immune response
- Does not contain live SARS-CoV-2 virus
- Adenoviral vector cannot replicate inside body and is destroyed
- Production limited – all remaining Janssen vaccine doses expire by May 6, 2023

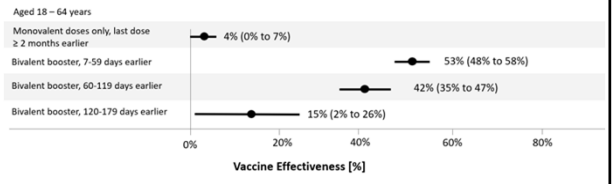
Source: CDC

Vaccine Effectiveness & Safety Data

Adults 18 years and older

Vaccine Effectiveness – 18 – 64 years

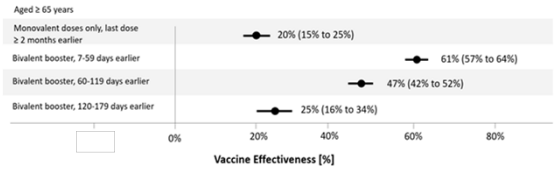
- VISION Network: *September 2022 – March 2023*
- Absolute vaccine efficacy of monovalent and bivalent booster against **emergency department/urgent care** encounters in immunocompetent adults



Source: CDC

Vaccine Effectiveness – ≥ 65 years

- VISION Network: *September 2022 – March 2023*
- Absolute vaccine efficacy of monovalent and bivalent booster against **emergency department/urgent care** encounters in immunocompetent adults



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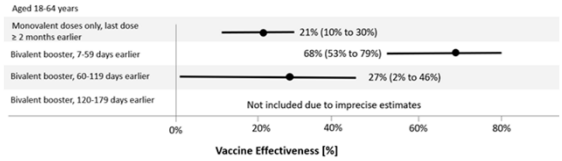

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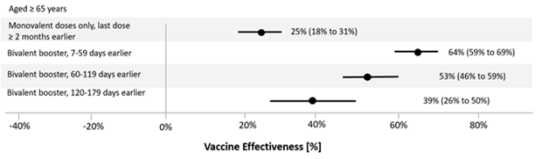
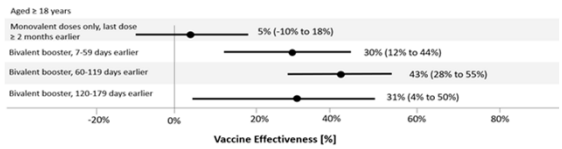


Source: CDC

Vaccine Effectiveness – 18y and older

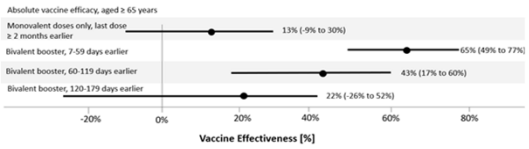
- VISION Network: *September 2022 – March 2023*
- Absolute vaccine efficacy of bivalent booster against **hospitalizations** in immunocompromised adults



Source: CDC

Vaccine Effectiveness – ≥ 65 years

- IVY Network: *September 2022 – April 2023*
- Absolute vaccine efficacy against **hospitalizations** in immunocompetent adults ≥ 65 years



Source: CDC

Vaccine Data Summary – Adults

- Vaccine efficacy does wane over time
- Bivalent boosters provide additional protection against emergency department/urgent care visits and hospitalizations
- Vaccines provide durable protection against severe disease (mechanical ventilation) and death

Source: CDC

Vaccine Safety – 18y and older

- Vaccine Safety Datalink (VSD) partnership between CDC and 9 integrated healthcare organizations, ~12.5 million patients
- VAERS
- CMS data and Department of Veterans Affairs

- No evidence of any safety signals for ischemic stroke following COVID-19 mRNA bivalent boosters in past 10 weeks

Vaccine Recommendations
Adults 18 years and older

Vaccine recommendations – 18y and older

- One dose of a bivalent mRNA COVID-19 vaccine, regardless of completion of (monovalent) primary series
- 65 and older:
  - One optional additional bivalent mRNA vaccine dose at least 4 months after last bivalent booster
- Immunocompromised:
  - May receive an optional additional bivalent mRNA dose at least 2 months after the last bivalent dose
  - Additional bivalent mRNA doses may be administered spaced at least 2 months apart per healthcare provider discretion
    - i.e., Stem cell transplant, CAR-T therapy, B-cell depletion, other high-risk conditions

Source: CDC

Vaccine recommendations – 18y and older

- Novavax booster: available if you are unable or unwilling to receive a Pfizer or Moderna bivalent COVID-19 booster and you meet the following requirements:
  - You are 18 years of age or older
  - You completed a COVID-19 vaccine primary series at least 6 months ago
  - You have not gotten any other booster dose

Source: CDC

Common questions regarding COVID vaccines
Adults 18 years and older

Can COVID-19 vaccine types be mixed?

- While not recommended, the vaccine type can be mixed under the following circumstances:
  - The same vaccine product is not available
  - The previous dose was given, but the product administered is unknown.
  - The person would otherwise not complete the primary series
  - The person starts but is unable to complete a primary series with the same COVID-19 vaccine due to a contraindication

Source: CDC

Will an annual vaccine be needed?

- Possibly - In June, the FDA will hold a meeting to discuss the strain composition of the COVID-19 vaccines for fall of 2023.
- The FDA does this yearly with the influenza vaccines.
- The agency will seek input from the ACIP committee on which SARS-CoV-2 variants and lineages are most likely to circulate in the upcoming year.
- Once the specific strains are selected, the FDA expects manufacturers to make updated formulations of the vaccines for availability this fall.

Source: FDA

When will vaccines be commercialized?

- Likely early Fall – dependent upon what will be authorized by the FDA and recommended by CDC, and what will align with a strain change for potential variants
- After commercialization, vaccines will remain free for most people through the Vaccines for Children Program, Children's Health Insurance Program, most commercial insurance, Medicare, and Medicaid programs

Source HHS.gov

COVID-19 Vaccine Updates

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Vaccine Effectiveness & Safety Data
Children 6 months through 17 years

Vaccine Effectiveness – Children 6m to 23m

- Subset of data evaluated by FDA for Pfizer and Moderna clinical vaccine trials
  - Randomized, blinded, placebo-controlled clinical trial enrolling immunocompetent infants and young children
  - Analysis period: *December 2021 through April 2022*
    - Includes early Omicron (Moderna) and BA.2 subvariant (Pfizer)
  - Reflects vaccine effectiveness from monovalent vaccines against **mild symptomatic infection**

Source: FDA, CDC

Vaccine Effectiveness – Children 6m to 23m

- Comparable neutralizing antibody levels to adolescents and young adults:
  - Moderna Geometric Mean Ratio (GMR) = **1.28** (1.12, 1.47)
  - Pfizer GMR = **1.19** (1.00, 1.43)
- Vaccine effectiveness comparable to older children:
  - Moderna vaccine effectiveness = **51%**
  - Pfizer vaccine effectiveness = **76%**
  - **Wide confidence intervals** due to relatively low numbers of cases

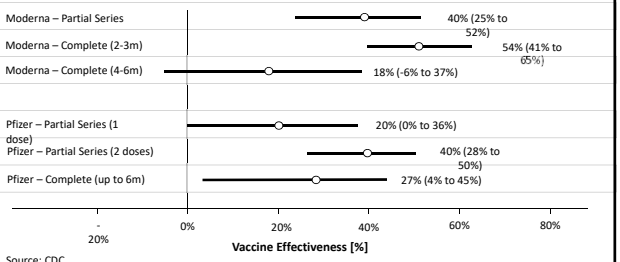
Source: FDA, CDC

Vaccine Effectiveness – Children 3yr to 5yr

- Increasing Community Access to Testing (ICATT) Program
  - Test-negative, case-control analysis to estimate VE against **symptomatic, mild disease** in immunocompetent children ages 3-5yr
  - Analysis period: *July 2022 through April 2023*
    - Omicron subvariants BA.4/BA.5 and XBB predominant
  - Reflects vaccine effectiveness from monovalent mRNA vaccines

Source: CDC

Vaccine Effectiveness – Children 3yr to 5yr



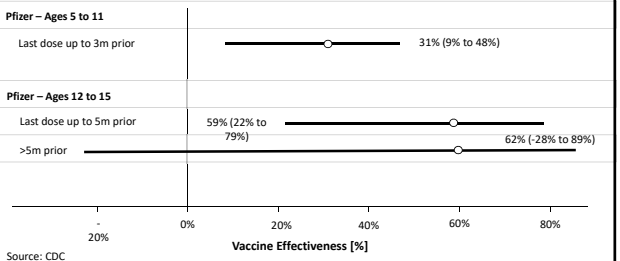
Source: CDC

Vaccine Effectiveness – Children 5yr to 15yr

- Pediatric Research Observing Trends and Exposures in COVID-19 Timelines (PROTECT) cohort
  - Conducted in Arizona, Florida, Texas, and Utah
  - Prospective cohort of immunocompetent children and adolescents ages 5-15 years
  - Included routine weekly SARS-CoV-2 testing, irrespective of symptoms
  - Analysis period: *December 2021 through February 2022*
    - Includes early Omicron variant transmission
  - Reflects monovalent Pfizer vaccine effectiveness against **mild symptomatic and asymptomatic infection**

Source: CDC

Vaccine Effectiveness – Children 5yr to 15yr



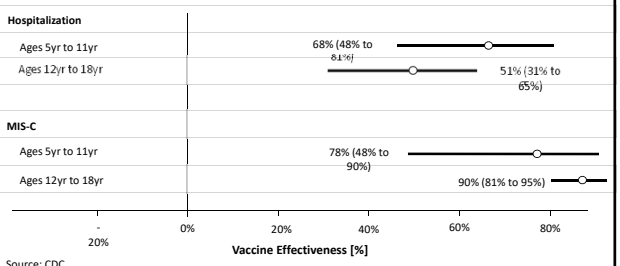
Source: CDC

Vaccine Effectiveness – Severe Disease

- Overcoming COVID-19
  - Test-negative, case-control analysis to estimate vaccine effectiveness against **hospitalization and multisystem inflammatory syndrome in children (MIS-C)** in immunocompetent children ages 5-18yr
  - Analysis period: *July 2021 through April 2022*
    - Includes Delta, Omicron, and early Omicron subvariant transmission
  - Reflects vaccine effectiveness from monovalent Pfizer vaccine

Source: CDC

Vaccine Effectiveness – Severe Disease



Source: CDC

Vaccine Safety – Children 6m to 5 yr

- Mild or moderate local and systemic reactions common
  - ~25% have any injection site reaction
  - ~50% have any systemic reaction
- Serious adverse events rare
- No reports of myocarditis for data analyzed through Aug 2022
  - Reflects data from ~1 million vaccinated young children
- Vaccination errors are most common event reported to VAERS

Source: CDC

Vaccine Safety – Children 5yr to 11 yr (Booster)

- Mild or moderate local and systemic reactions common
  - ~70% have any injection site reaction
  - ~50% have any systemic reaction
- Serious adverse events rare
- No reports of myocarditis for data analyzed through Jan 2023
  - Reflects data from ~1 million bivalent booster doses
- Vaccination errors are most common event reported to VAERS

Source: CDC

Vaccine Safety – Children 12yr to 17yr (Booster)

- Mild or moderate local and systemic reactions common
  - ~70% have any injection site reaction
  - ~60% have any systemic reaction
- Serious adverse events rare
- 5 cases of myocarditis for data analyzed through Oct 2022
  - Not all occurring in children – age range 12yr to 78yr
  - Reflects data from ~22 million bivalent booster doses
- Vaccination errors are most common event reported to VAERS

Source: CDC

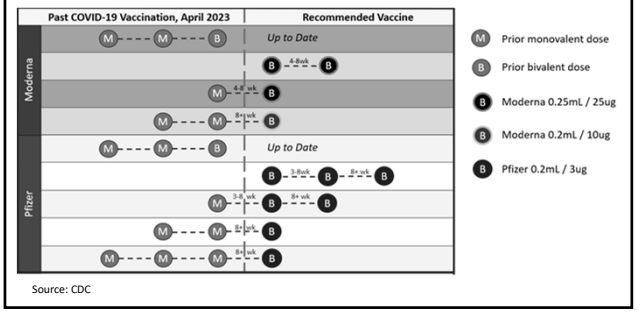
Vaccine Data Summary – Children

- Completing vaccine series provides protection against mild and severe COVID-19 infection in children
- Durability of protection wanes over 4-6 months following last dose
  - Initial protection and waning patterns are similar to adults
  - Protection against severe disease is more durable
- Serious adverse events are very rare

Source: CDC

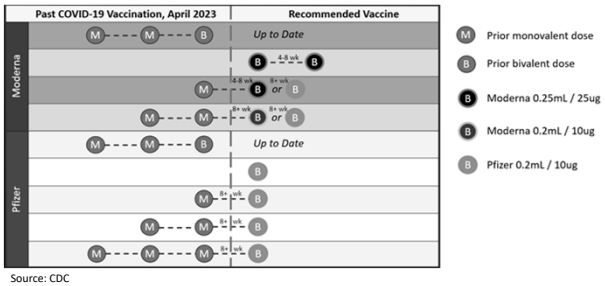
Vaccine Recommendations
Children 6 months through 17 years

Vaccine Schedule – Children 6m to 4yr



Source: CDC

Vaccine Schedule – Children 5yr



Source: CDC

Vaccine Schedule – Children 6m to 17yr

- Children 6 months of age and older follow adult schedule
- Immunocompromised children:
  - May receive an optional additional bivalent mRNA dose at least 2 months after the last bivalent dose
  - Additional bivalent mRNA doses may be administered spaced at least 2 months apart per healthcare provider discretion
    - i.e., Stem cell transplant, CAR-T therapy, B-cell depletion, other high-risk conditions
- Recent updates do not change Novavax recommendations
  - Two-dose primary series separated by 3-8 weeks (ages 12yr and older)
  - Receive bivalent mRNA dose at least 2 months following primary series

Source: CDC

Common questions regarding COVID vaccines
Children 6 months through 17 years

Which dose should a child receive who turns 5 years old between doses?

- In general, patients should receive the age-appropriate product and dosage based on their age on the day of vaccination
- Exception: Pfizer primary series for children
  - Children younger than 5 years old starting the three-dose vaccination series with Pfizer must complete the series they start
    - i.e., must receive the 0.2mL / 3ug maroon cap dose rather than 0.2mL / 10uG orange cap dose even if now 5 years old

Source: CDC

When is the optimal time to administer the 2nd dose of Novavax in an adolescent male?

- The 2nd dose of Novavax may be administered as soon as 3 weeks following the 1st dose
- While risk remains small, cases of myocarditis and pericarditis have been reported during post-authorization use outside the US
- Extending the interval to 8 weeks may reduce the rare risk of vaccine-associated myocarditis and pericarditis, particularly in males ages 12 to 39 years

Source: CDC

Should children who recovered from MIS-C undergo vaccination?

- Individual vaccination decisions should be made in consultation with the multi-disciplinary medical team
- In general, the benefit of vaccine outweighs the theoretical risk of an MIS-like illness in the following:
  1. Clinical recovery has been achieved, including return to baseline cardiac function
  2. At least 90 days has passed since diagnosis of MIS-C

Source: CDC

COVID-19 Vaccine Update Summary

- Vaccination is effective in preventing infection and disease due to SARS-CoV-2
- Effectiveness wanes over time, though is most durable for severe disease
- Serious adverse events from vaccination are rare in children and adults
- Remaining up to date with the bivalent vaccine is important to ensure ongoing protection
- Vaccination guidance can change; refer to CDC and FDA for the latest guidance and recommendations

Thank You