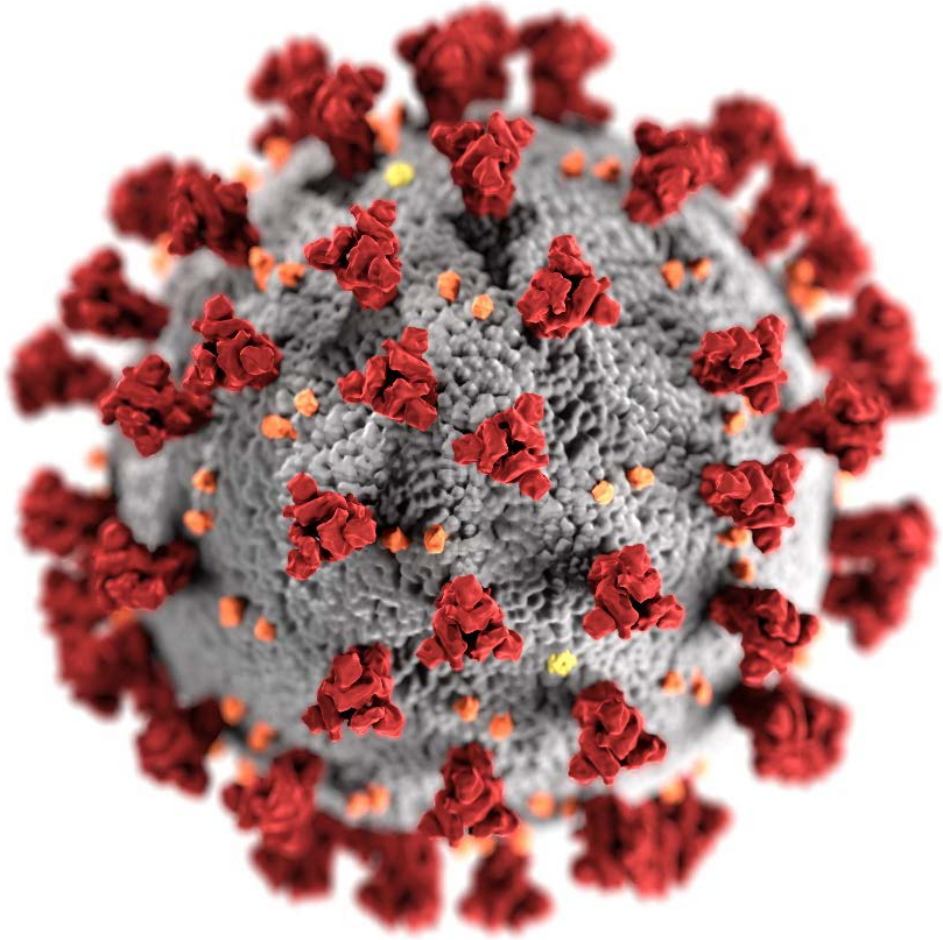
Work Group Summary



Sara Oliver MD, MSPH
ACIP Meeting
September 22, 2021

cdc.gov/coronavirus

Booster doses of COVID-19 vaccines

- Policy on booster doses will be coordinated with **FDA** for regulatory allowance, and **ACIP** for recommendations for use

Data to inform recommendations for booster doses of COVID-19 vaccines

- Safety and immunogenicity for a third dose of BNT162b2
- Immunity and SARS-CoV-2
- Vaccine effectiveness in the United States
- Modeling the potential impact of booster doses in nursing home residents
- Early safety monitoring for third doses of mRNA vaccines

Summary

Safety and immunogenicity for a 3rd dose of BNT162b2 (Pfizer-BioNTech presentation)

- 23 individuals from the Phase 1 study boosted ~8 months after 2nd dose
- 312 individuals from the Phase 3 study boosted ~7 months after 2nd dose
- 1 month after the booster dose, geometric mean titers **3-fold higher** than 1 month after the 2nd dose
  - When evaluating proportion with a seroresponse: **99.5**% responded after the booster dose, compared to **98**% after the 2nd dose
- Reactogenicity similar after the booster dose and after 2nd dose

Work Group Interpretation

Safety and immunogenicity for a third dose of BNT162b2 (Pfizer-BioNTech presentation)

- Limited number of individuals included in evaluations of safety and immunogenicity of a booster dose
- Immunogenicity data are reassuring; unknowns remain:
  - Unknown impact of lower antibody levels pre-booster
  - Unknown kinetics of antibodies over 1 month post-boost
  - Unknown how boost in antibodies translate to clinical protection
- Safety data is also reassuring; limited size:
  - 306 individuals included in safety population
  - Unable to determine risks of rare side effects (such as myocarditis) after booster dose
- Anticipate ability to review additional data from ongoing trial with ~10,000 individuals in upcoming weeks/months

Summary and Work Group Interpretation

Immunity and SARS-CoV-2

- Immune response generated by COVID-19 vaccines broad, includes cellular and humoral immune response
- Waning of antibodies likely do not represent the entire picture
  - Memory B cells maintained out to 6 months after primary series
- Immune response may be impacted by aging and variants
- Transmission possible with infections after vaccination
  - Unknown how booster doses of COVID-19 vaccines may impact transmission

Summary and Work Group Interpretation

Vaccine effectiveness

- Significant declines in VE against **infection** in individuals ≥65 years of age for mRNA products in the Delta period
- Smaller declines in VE against **hospitalization** in individuals ≥65 years of age, but more substantial than younger populations
- Among adults <65 years of age, vaccines **remain effective** in preventing hospitalization and severe disease
- Vaccines may be less effective in preventing infection or milder symptomatic illness due to waning over time and predominance of the Delta variant

Summary and Work Group Interpretation

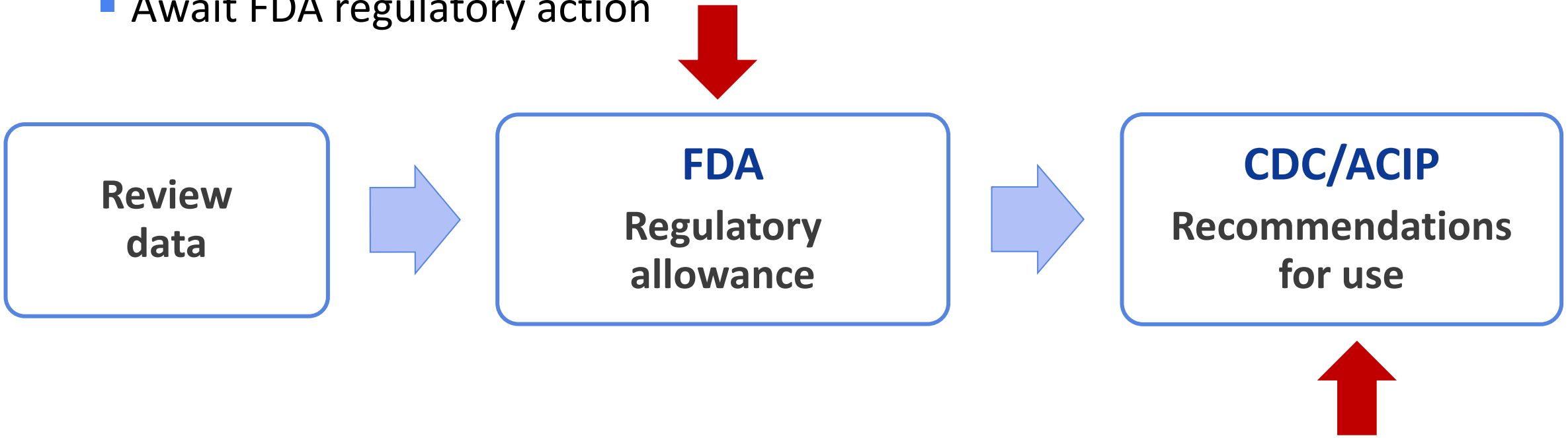
Modeling the potential impact of booster doses in nursing home residents

- Both increasing vaccination coverage of staff and increasing VE in residents can impact cases among LTCF residents
- Community levels of transmission substantially impact cases in LTCFs
- To protect our vulnerable LTCF population:
  - Improve vaccine effectiveness in LTCF residents (which could include use of booster doses of COVID-19 vaccines)
  - Increase vaccination coverage of LTCF staff
  - Lower rates of community transmission

Next Steps

Next Steps

- Await FDA regulatory action



After FDA regulatory action, ACIP will have additional discussions around recommendations for use

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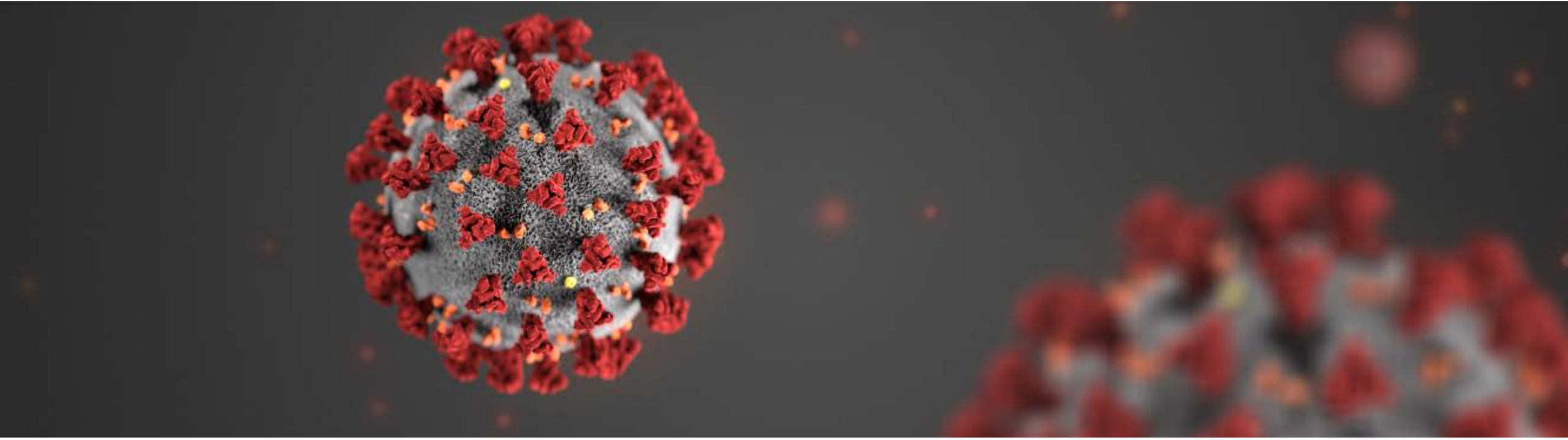
- Vaccine Task Force
- Epi Task Force
- Respiratory Viruses Branch

Questions for ACIP

1. Is there additional data ACIP would need to review before discussions around COVID-19 vaccine policy?



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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