

## Vaccines and Related Biological Products Advisory Committee Meeting

# COVID-19 Vaccines: Framework for Future Decisions on Strain Composition and Use of Additional Booster Doses

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# SARS-CoV-2 Pandemic

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- Since the beginning of the pandemic in early 2020, SARS-CoV-2 has caused nearly half a billion reported cases of COVID-19 and over 6 million deaths worldwide\*
- In the United States, SARS-CoV-2 has caused nearly 80 million reported COVID-19 cases and nearly 1 million deaths\*\*
- Surges in SARS-CoV-2 transmission and COVID-19 cases, hospitalizations, and deaths have been associated with:
  - Seasonal variation and variable implementation of public health control measures
  - Emergence of SARS-CoV-2 variants (e.g., Beta, Delta, Omicron) that compared to previously circulating strains are more infectious, more virulent, and/or more resistant to natural or vaccine-elicited immunity

\*[WHO COVID-19 Dashboard](#) as of 4 April 2022

\*\*[CDC COVID Data Tracker](#) as of 4 April 2022

# COVID-19 Vaccines

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- Currently, three COVID-19 vaccines have emergency use authorization (and two have FDA licensure) for use in the U.S.
- Effectiveness of available COVID-19 vaccines has been demonstrated in clinical trials and in post-authorization/post-licensure observational studies
- However, COVID-19 vaccine effectiveness has been impacted by:
  - Waning protection over time, most notably against milder disease but also to some extent (especially in more highly susceptible populations) against more severe/serious outcomes
  - Biological and antigenic characteristics of SARS-CoV-2 variants that have become dominant
- While currently available vaccines are not well-matched to the dominant circulating variant (Omicron BA.2 sublineage), vaccine effectiveness against COVID-19 and serious outcomes is improved by use of booster doses

# Planning Ahead

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- While the SARS-CoV-2 pandemic has been defined by its unpredictability, planning efforts for future utilization of COVID-19 vaccines should consider:
  - Whether vaccine strain composition should be modified to improve protection against currently circulating virus and/or to improve breadth of coverage against future emerging variants
  - Whether additional booster doses should be recommended in anticipation of the next potential COVID-19 surge (and if so, in which populations and when)
- Decisions on the planning questions above should ideally:
  - Be guided by a data-driven, formal, transparent, and coordinated process that includes all key stakeholders
  - Result in recommendations that are sensible, practical, and understandable

# VRBPAC Agenda

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Today's VRBPAC discussion will be informed by presentations addressing key questions related to future decisions on COVID-19 vaccine strain composition and utilization of additional booster doses:

1. What is the current epidemiology of COVID-19 disease and SARS-CoV-2 variants in the U.S.?  
**Update on the Epidemiology of SARS-CoV-2 Strains** - CDR Heather Scobie, CDC
2. How well are currently available COVID-19 vaccines protecting against COVID-19 and associated serious outcomes?  
**COVID-19 Vaccine Effectiveness in Children and Adults** - LCDR Ruth Link-Gelles, CDC
3. What can we learn from experience with use of a second booster dose outside of the U.S.?  
**Protection by 4<sup>th</sup> dose of BNT162b2 against Omicron in Israel** - Sharon Alroy-Pries, Israeli Ministry of Health, and Ron Milo, Weizmann Institute of Science, Israel

# VRBPAC Agenda, continued...

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Today's VRBPAC discussion will be informed by presentations addressing key questions related to future decisions on COVID-19 vaccine strain composition and utilization of additional booster doses:

4. How can data and modeling help to predict antigenic evolution of SARS-CoV-2 and effectiveness of COVID-19 vaccines going forward?

**SARS-CoV-2 Antigenic Space** - John Beigel, NIAID

**Continuing SARS-CoV-2 Evolution under Population Immune Pressure** – Trevor Bedford, Fred Hutchinson Cancer Research Center

5. How can data and modeling help to predict the trajectory of the SARS-CoV-2 pandemic going forward?

**IHME COVID-19 update** – Christopher Murray and Ali Mokdad, Institute for Health Metrics and Evaluation, University of Washington

# VRBPAC Agenda, continued...

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Today's VRBPAC discussion will be informed by presentations addressing key questions related to future decisions on COVID-19 vaccine strain composition and utilization of additional booster doses:

7. How will COVID-19 vaccine strain composition decisions be coordinated globally?

**Technical Advisory Group on COVID-19 Vaccine Composition** – Kanta Subbarao, WHO

8. What timeline is achievable for development and evaluation of modified COVID-19 vaccines?

**COVID-19 Vaccine Strain Selection: Points to Consider for Manufacturing Timelines**– Robert Johnson, BARDA

9. How should FDA approach future regulatory decisions on COVID-19 vaccine strain composition and authorization of additional booster doses (in what ways might the approach to seasonal influenza vaccines be adapted to COVID-19 vaccines)?

**Proposed Framework for Addressing Future COVID-19 Strain Composition** – Jerry Weir, FDA

# Topics for VRBPAC Discussion

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Following the scheduled presentations and open public hearing, the VRBPAC will be asked to discuss and provide input on the following topics (no voting questions):

- What considerations should inform strain composition decisions to ensure that available COVID-19 vaccines continue to meet public health needs, e.g.:
  - Role of VRBPAC and FDA in coordinating strain composition decisions
  - Timelines needed to implement strain composition updates
  - Harmonization of strain composition across available vaccines
- How often should the adequacy of strain composition for available vaccines be assessed?
- What conditions would indicate a need for updated COVID-19 vaccine strain composition, and what data would be needed to support a decision on a strain composition update?
- What considerations should guide the timing and populations for use of additional COVID-19 vaccine booster doses?





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# FDA-Authorized/Licensed COVID-19 Vaccines

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- Pfizer-BioNTech COVID-19 Vaccine
  - 2-dose primary series (3<sup>rd</sup> primary series dose in individuals with certain kinds of immunocompromise) in ages 5 years and older; COMIRNATY licensed as 2-dose primary series in ages 16 years and older
  - First booster dose (homologous or heterologous) in ages 12 years and older
  - Second booster dose (homologous or heterologous) in ages 50 years and older and in ages 12 years and older with certain kinds of immunocompromise
- Moderna COVID-19 Vaccine
  - 2-dose primary series (3<sup>rd</sup> primary series dose in individuals with certain kinds of immunocompromise) in ages 18 years and older; SPIKEVAX licensed as 2-dose primary series in ages 18 years and older
  - First booster dose (homologous or heterologous) in ages 18 years and older
  - Second booster dose (homologous or heterologous) in ages 50 years and older and in ages 18 years and older with certain kinds of immunocompromise
- Janssen COVID-19 Vaccine
  - Single dose primary vaccination in ages 18 years and older
  - First booster dose (homologous or heterologous) in ages 18 years and older