U.S. FOOD & DRUG ADMINISTRATION

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

- 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

- 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

- 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

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 4th 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…

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…

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

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

- Pfizer-BioNTech COVID-19 Vaccine
  - 2-dose primary series (3rd 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 (3rd 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