

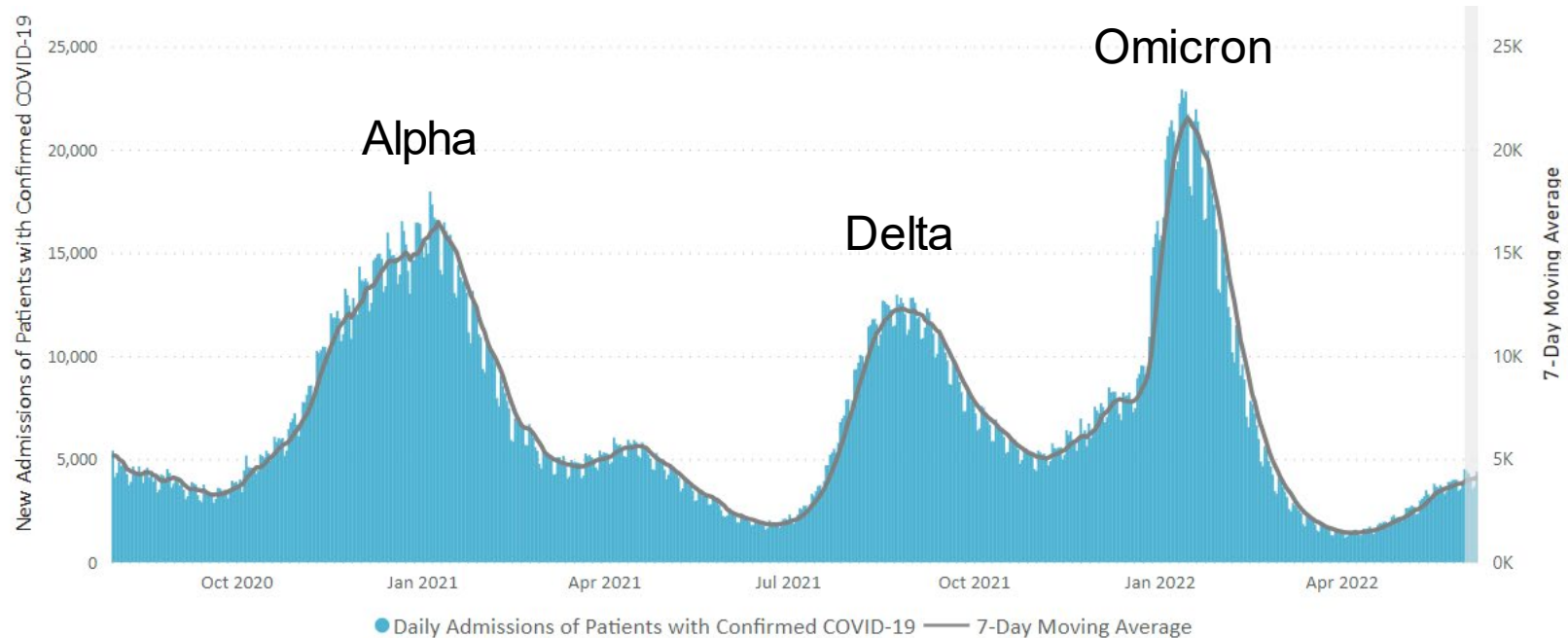
## **Vaccines and Related Biological Products Advisory Committee Meeting**

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# Considerations for Whether and How the COVID-19 Strain Composition Should be Modified

Peter Marks, MD, PhD  
June 28, 2022

# Evolution of COVID-19 Pandemic



<https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions>

# Selected Vaccines – June 2022

- **mRNA**

- BNT162b2 (Pfizer-BioNTech) – EUA granted Dec 11, 2020
  - Licensure for individuals 16 years of age and up granted to COMIRNATY on August 23, 2021
- mRNA-1273 (Moderna) – EUA granted Dec 18, 2020
  - Licensure for individuals 18 years of age and up granted to SPIKEVAX on January 31, 2022

- **Non-Replicating Viral Vector**

- Ad26.COVS.S (Janssen) – EUA granted Feb 27, 2021

- **Protein Subunit**

- NVX-CoV2373 (Novavax) – Under consideration for EUA

# Global impact of the first year of COVID-19 vaccination: a mathematical modelling study

Oliver J Watson\*, Gregory Barnsley\*, Jaspreet Toor, Alexandra B Hogan, Peter Winskill, Azra C Ghani

## Summary

**Background** The first COVID-19 vaccine outside a clinical trial setting was administered on Dec 8, 2020. To ensure global vaccine equity, vaccine targets were set by the COVID-19 Vaccines Global Access (COVAX) Facility and WHO. However, due to vaccine shortfalls, these targets were not achieved by the end of 2021. We aimed to quantify the global impact of the first year of COVID-19 vaccination programmes.

**Methods** A mathematical model of COVID-19 transmission and vaccination was separately fit to reported COVID-19 mortality and all-cause excess mortality in 185 countries and territories. The impact of COVID-19 vaccination programmes was determined by estimating the additional lives lost if no vaccines had been distributed. We also estimated the additional deaths that would have been averted had the vaccination coverage targets of 20% set by COVAX and 40% set by WHO been achieved by the end of 2021.

**Findings** Based on official reported COVID-19 deaths, we estimated that vaccinations prevented 14.4 million (95% credible interval [CrI] 13.7–15.9) deaths from COVID-19 in 185 countries and territories between Dec 8, 2020, and Dec 8, 2021. This estimate rose to 19.8 million (95% CrI 19.1–20.4) deaths from COVID-19 averted when we used excess deaths as an estimate of the true extent of the pandemic, representing a global reduction of 63% in total deaths (19.8 million of 31.4 million) during the first year of COVID-19 vaccination. In COVAX Advance Market Commitment countries, we estimated that 41% of excess mortality (7.4 million [95% CrI 6.8–7.7] of 17.9 million deaths) was averted. In low-income countries, we estimated that an additional 45% (95% CrI 42–49) of deaths could have been averted had the 20% vaccination coverage target set by COVAX been met by each country, and that an additional 111% (105–118) of deaths could have been averted had the 40% target set by WHO been met by each country by the end of 2021.

**Interpretation** COVID-19 vaccination has substantially altered the course of the pandemic, saving tens of millions of lives globally. However, inadequate access to vaccines in low-income countries has limited the impact in these settings, reinforcing the need for global vaccine equity and coverage.



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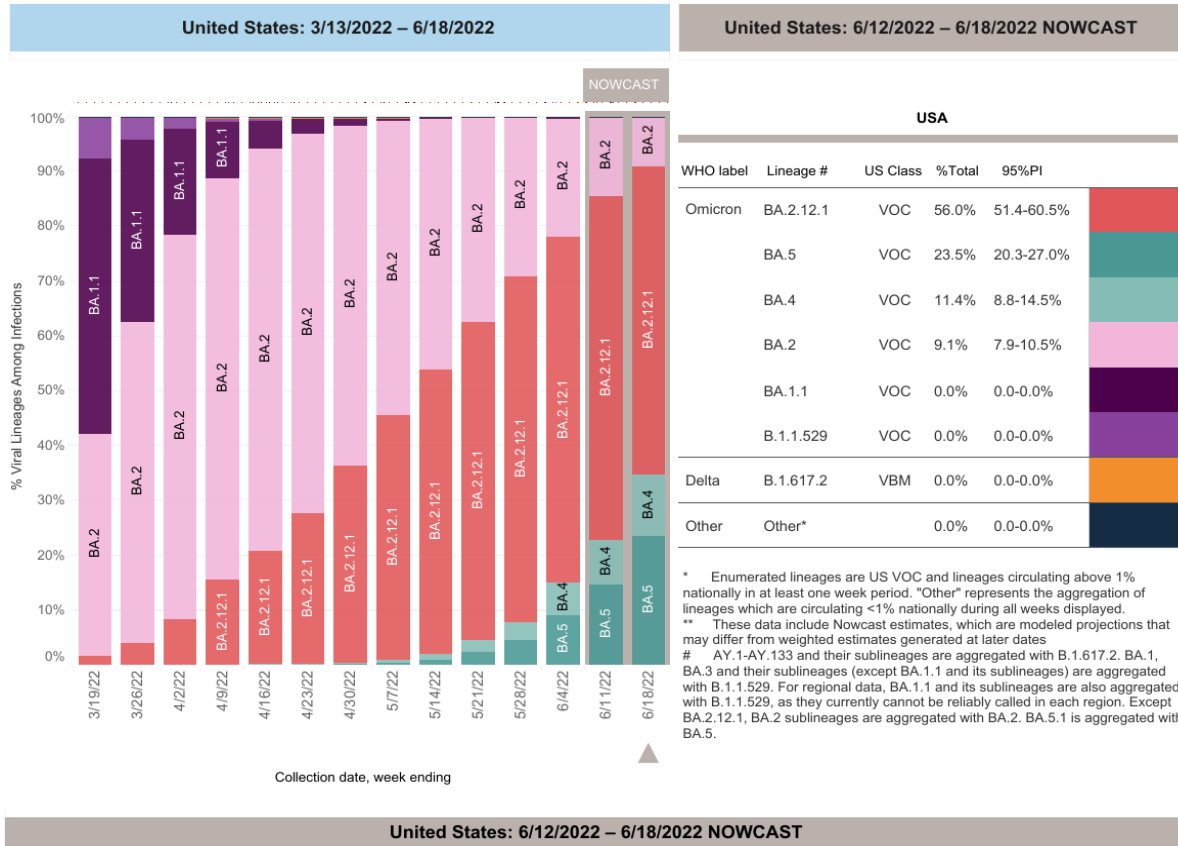
# Boosters for the General Population

- Evidence from the United States and elsewhere indicates that immunity from current vaccines wanes with time, notably in the setting of the Omicron variants
- An additional vaccine dose may provide more durable immunity, particularly for certain populations, preventing
  - Hospitalization
  - Death
  - Serious complications of COVID-19 such as long COVID-19

# Boosters for New Variants

- FDA has issued guidance to address the development of vaccines to address new SARS-CoV-2 variants
  - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>
- Move to a variant vaccine based upon an authorized or approved vaccine will be based on immunobridging
- Need to fully consider the ramifications of a switch to a new variant vaccine (or a multivalent vaccine)

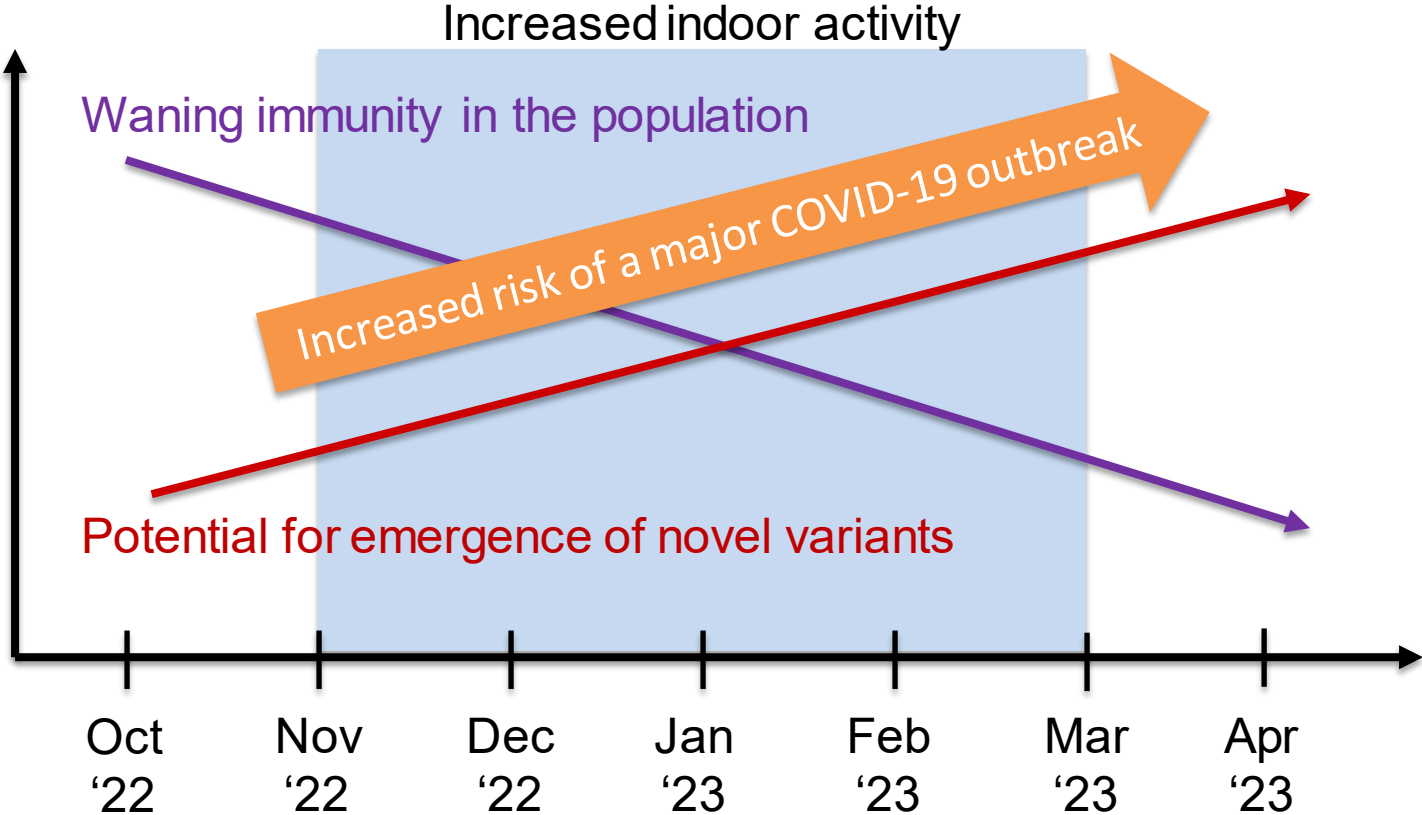
# Recent Evolution of SARS-CoV-2



<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>



# Potential Evolution of COVID-19

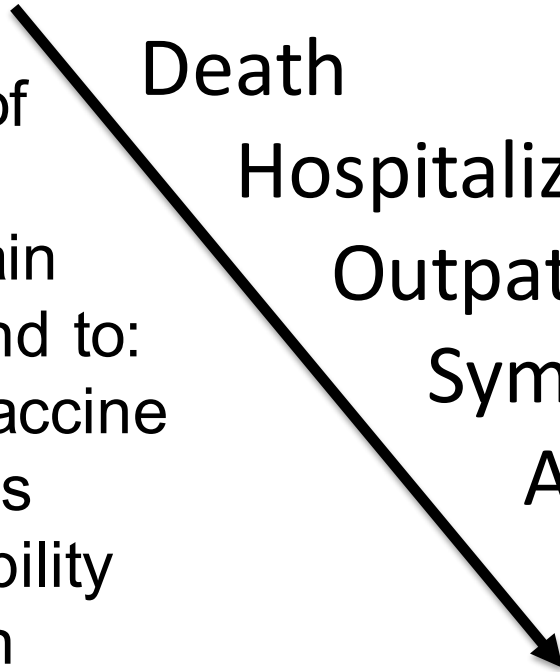


# Vaccine Prevention

Lower vaccine effectiveness

Better match of vaccine to circulating strain may correspond to:

- Improved vaccine effectiveness
- Better durability of protection



Death

Hospitalization

Outpatient emergency care

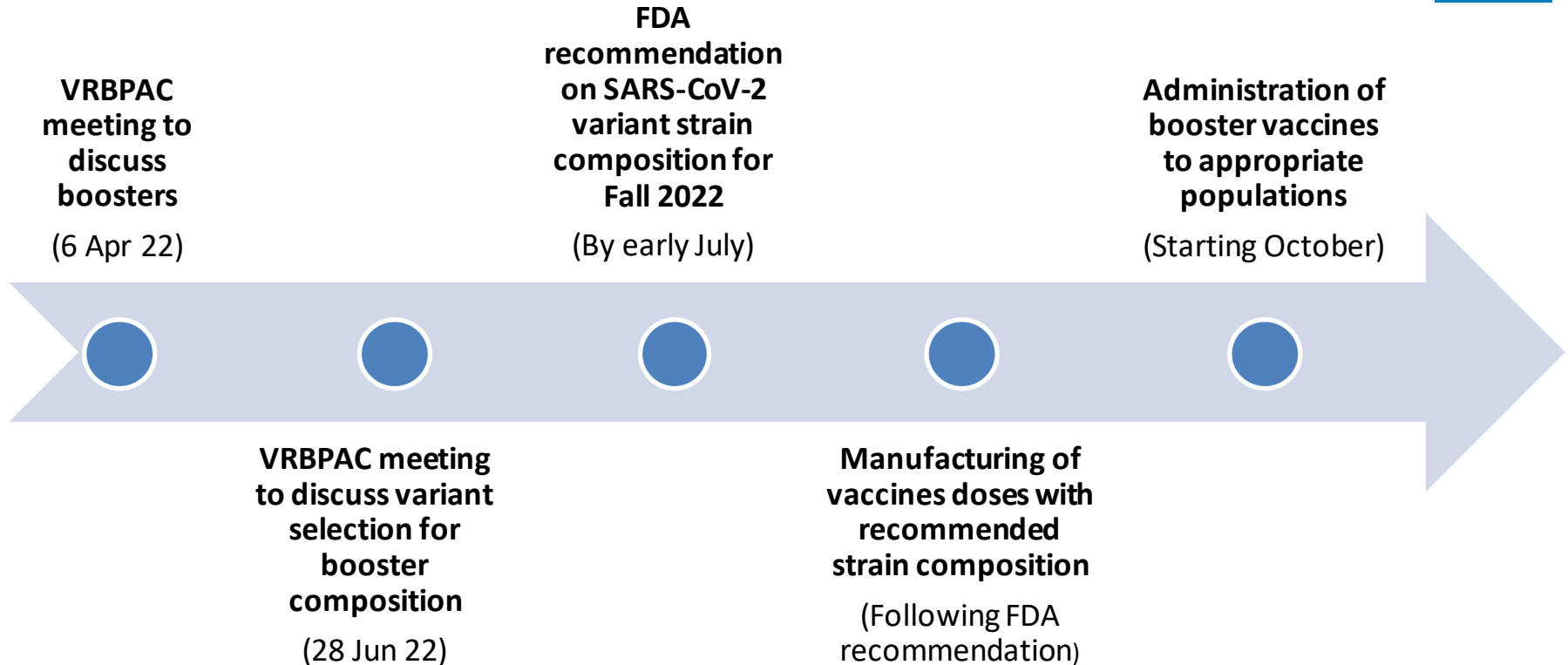
Symptomatic infection

Asymptomatic infection

Transmission

Higher vaccine effectiveness

# Variant Strain Selection Timeline



# Summary

- New variants of SARS-CoV-2 continue to emerge relatively rapidly
- Protection against existing variants from prototype vaccines is less robust and wanes over time
- Omicron is the latest and most transmissible variant to date
- BA.1 is no longer circulating the US and BA.4/5 is poised to become the dominant variant; BA.4/5 likely to cover BA.1
- Small trials showed that vaccines to Beta, Delta, and Omicron BA.1 are immunogenic with no new safety concerns identified
- Decision is now needed on the variant(s) to include for Fall 2022



# VRBPAC Discussion Questions

Please discuss the various considerations involved in updating the strain composition for COVID-19 vaccines in the U.S. Please provide input on the following and discuss whether any additional data are needed to facilitate a recommendation:

- Is a change to the current COVID-19 vaccine strain composition necessary at this time?
- Please discuss the evidence supporting:
  - 1) the selection of a specific Omicron sub-lineage (e.g., BA.1 vs. BA.4/BA.5)
  - 2) a monovalent (Omicron) or bivalent vaccine (prototype + Omicron)
  - 3) extrapolating the available clinical data for modified vaccines to different age ranges

# VRBPAC Discussion Questions

- What additional data, if any, would be needed to recommend an updated composition of the primary series vaccine? If the booster vaccine composition changes, would continuing use of the prototype primary series vaccine this fall still be acceptable?



# VRBPAC Voting Question

- Does the committee recommend inclusion of a SARS-CoV-2 Omicron component for COVID-19 booster vaccines in the United States?



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