



# Current recommendations from SAGE regarding COVID-19 vaccines

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25 October 2021

Critical Evidence Questions For COVID-19 Vaccines Policy Making  
14 October 2020 (Publication)

**Overview**

This document lists areas of evidence that would assist SAGE in formulating policy recommendations for consideration by WHO regarding the use of COVID-19 vaccines as they become available. It is not intended as alternative to the lists of requirements for licensure as formulated by regulatory bodies nor does it replace or provide an alternative to the WHO Target Product Profile. Rather, it reflects the evidence needs for COVID-19 vaccine policy making, based on the current scientific thinking, to assist SAGE in deciding upon the optimal use given the limited vaccine supply in order to maximize impact on the pandemic in different epidemiologic and epidemiologic settings.

**Compendium of Critical Questions**

Background paper with COVID-19 generic considerations

WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination  
14 September 2020



**Values Framework**

Background paper with vaccine-specific considerations

WHO SAGE ROADMAP FOR PRIORITIZING USES OF COVID-19 VACCINES IN THE CONTEXT OF LIMITED SUPPLY  
An approach to inform planning and subsequent recommendations based upon epidemiologic setting and vaccine supply scenarios  
Version 1  
20 October 2020



**Prioritization Roadmap**

**Interim recommendations for use (product/platform specific)**

EVIDENCE TO RECOMMENDATIONS: COVID-19 VACCINES  
A framework to inform the assessment of evidence and formulation of subsequent COVID-19 vaccine recommendations

**Vaccine-specific recommendations based on Evidence Framework**

WHO Strategic Advisory Group of Experts (SAGE) on Immunization Working Group on COVID-19 Vaccines: Prioritized Infectious Disease and Economic Modelling Questions

**Request for Information**

- As part of its scoping of the landscape of modelling groups and initiatives related to COVID-19 vaccines, we invite modellers and economists to provide information about their work on COVID-19 vaccination that addresses prioritized modelling questions to contribute to informing deliberations around policy recommendations from the WHO SAGE on Immunization.

**Modeling**

Evidence to Recommendations & grading tables

**Additional considerations (e.g. current epidemiology)**

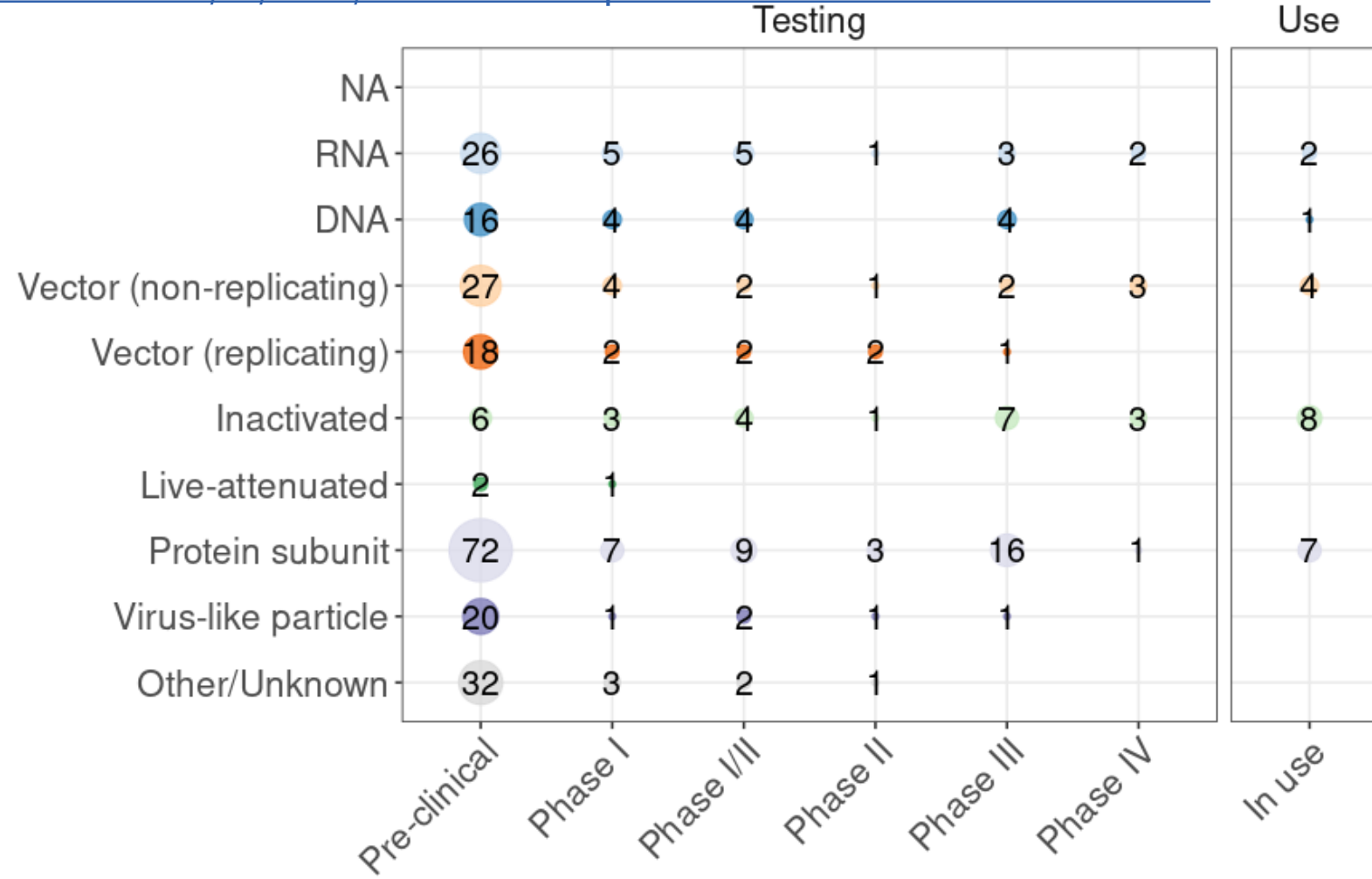


**The outputs from the SAGE on COVID-19 vaccinations**

# COVID-19 vaccine development landscape

As of 14 October 2021, **a total 332 candidate vaccines** of which **113 in clinical trials**, **22 in large scale use**

<https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>









# Overview of WHO EULs and SAGE recommendations

**At least 17 vaccines\*  
deployed to date...**

- Adbala
- Anhui ZL - Recombinant
- AstraZeneca - Vaxzevria
- Beijing CNBG - BBIBP-CorV
- Bharat - Covaxin
- CanSino - Convidecia
- Chumakov - Covi-Vac
- Gamaleya - Gam-Covid-Vac
- Janssen - Ad26.COV 2-S
- Moderna - mRNA-1273
- Pfizer BioNTech - Comirnaty
- RIBSP - QazVac
- SII - Covishield
- Sinovac - CoronaVac
- Soberana02
- SRCVB - EpiVacCorona
- Wuhan CNBG - Inactivated



**...out of which 6 have WHO EUL authorization and SAGE recommendations**

	WHO EUL	SAGE Interim Recs	
		Initial	Updates
	Dec 31 (2020)	Jan 5	Jun 14
	Feb 15 <sup>1</sup>	Feb 8	Apr 21/ July 30
	Mar 12	Mar 17	Jun 14
	Apr 30	Jan 25	June 14
	May 7	May 7	Oct 5
	June 1	May 24	Oct 5

**Additional vaccines under evaluation; Bharat Covaxin most advanced in process**

\* Authorized by National Regulatory authorities for use outside research

1. MFDS Korea EUL finalized Feb 15. EMA SK-Catalent followed Apr 16 and Wuxi (DS) Apr 30

# Three interim statements from SAGE on 10 August 2021 and 4 October 2021



<https://www.who.int/news/item/10-08-2021-interim-statement-on-covid-19-vaccine-booster-doses>

[https://www.who.int/news/item/10-08-2021-interim-statement-on-dose-sparing-strategies-for-covid-19-vaccines-\(fractionated-vaccine-doses\)](https://www.who.int/news/item/10-08-2021-interim-statement-on-dose-sparing-strategies-for-covid-19-vaccines-(fractionated-vaccine-doses)); <https://www.who.int/news/item/10-08-2021-interim-statement-on-heterologous-priming-for-covid-19-vaccines>

## Heterologous priming for COVID-19 vaccines

The same vaccine product should be used for both doses.

If different COVID-19 vaccine products are inadvertently administered in the two doses, no additional doses of either vaccine are recommended.

**At present, mix and match schedules constitute off-label use of respective vaccines and as such should only be used if benefits outweigh the risks such as in situations of interrupted vaccine supply.**

## Dose-sparing strategies for COVID-19 vaccines (fractionated vaccine doses)

While SAGE acknowledges the potential public health benefits of dose-sparing strategies to increase vaccine supply and accelerate population-level vaccination coverage, and possibly also a reduction in reactogenicity, **SAGE considers there is currently insufficient evidence to recommend the use of fractional doses.** Any use of a fractional dose at this point in time constitutes an off-label use of the vaccine. **SAGE encourages research in the area**, with a particular emphasis on research into using fractionated doses as potential boosters and fractional doses in children and adolescents. Programmatic and operational considerations should be considered from the start.

## COVID-19 vaccine booster doses

**Introducing booster doses should be firmly evidence-driven and targeted to the population groups in greatest need.**

The rationale for implementing booster doses should be guided by evidence on waning vaccine effectiveness, in particular a decline in protection against severe disease in the general population or in high risk populations, or due to a circulating VOC.

To date, the evidence remains limited and inconclusive on any widespread need for booster doses following a primary vaccination series.

WHO is carefully monitoring the situation and will continue to work closely with countries to obtain the data required for policy recommendations.

# 4-7 October SAGE meeting

## COVID-19 vaccination additional doses recommendations

### COVID-19 Vaccination in Immunocompromised Persons

- Extending primary series with additional dose to enhance reduced performance of standard primary series and mitigate the risk of COVID-19 in these individuals.
- Deliver at 1-3 mo following last dose of standard primary series, or earliest opportunity thereafter.
- Homologous product, in standard practice. A heterologous dose acceptable if required by vaccine supply and access considerations.

### Inactivated COVID-19 vaccines (Sinovac-Coronavac, BIBP-CorV Sinopharm)

- Additional dose recommended for those  $\geq 60$  years as part of an extended primary series.
- Deliver at 3-6 months following second dose, or earliest opportunity thereafter.
- Homologous product, in standard practice. A heterologous dose acceptable if required by vaccine supply and access considerations.

August 5, 2021  
12:13 AM EEST  
Last Updated a month ago

Healthcare & Pharmaceuticals

# WHO calls for halting COVID-19 vaccine boosters in favor of unvaccinated

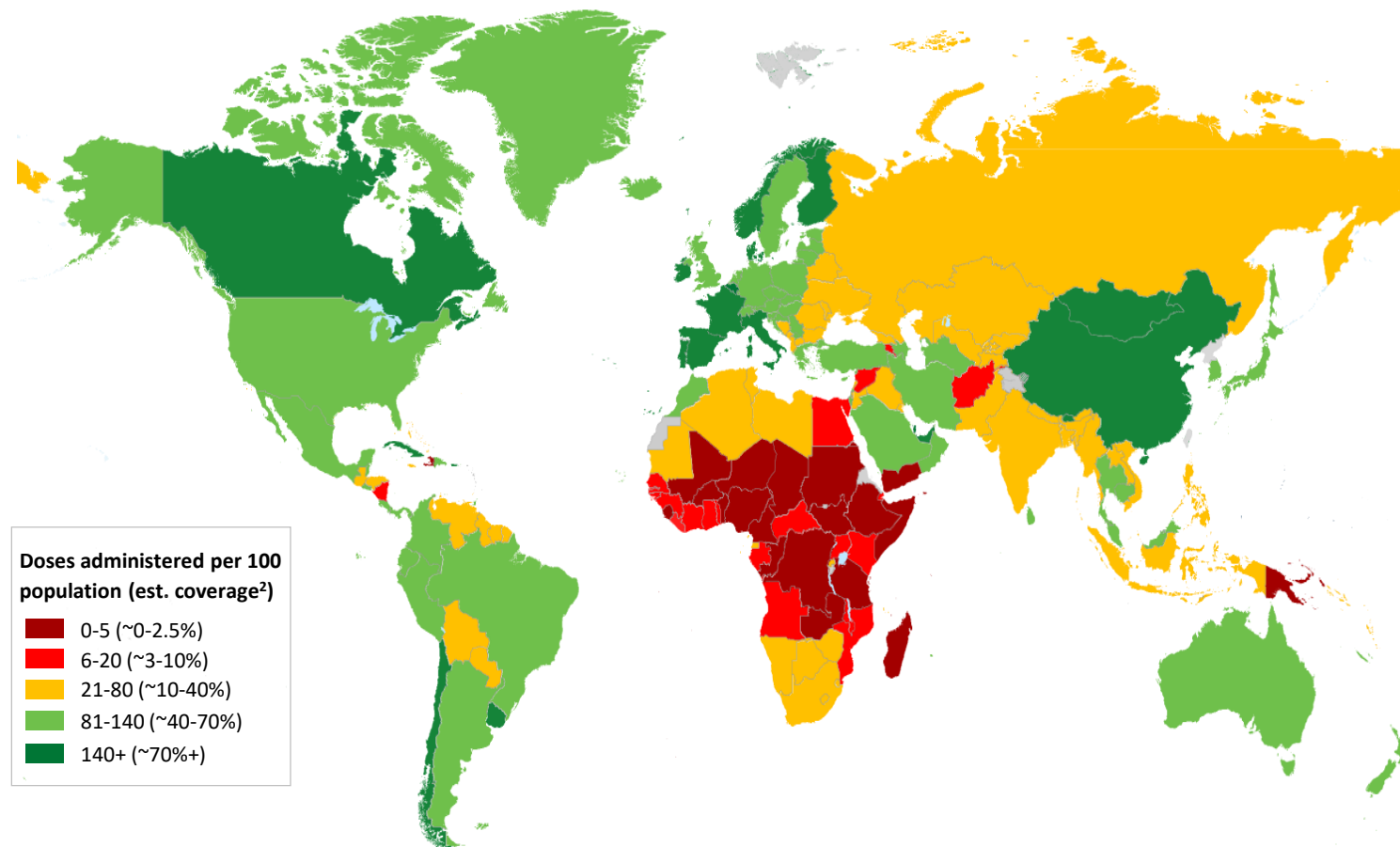
By Manas Mishra and Dania Nadeem



Dr Tedros Adhanom Ghebreyesus  
Director-General

# Vaccine equity is the ‘challenge of our time’

## Covid-19 vaccine doses administered per 100 population (est. coverage<sup>1</sup>)



- >6.6 billion vaccine doses have been administered worldwide
- Less than 3% of people in LICs have received at least 1 dose

1. Assuming 2 doses per fully vaccinated inhabitant

Note: The designations employed and the presentation of these materials do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Source: WHO COVID-19 Dashboard (map creation), Bloomberg (total # of doses administered), COVAX SCO tracker (UNICEF data) (COVAX shipments)



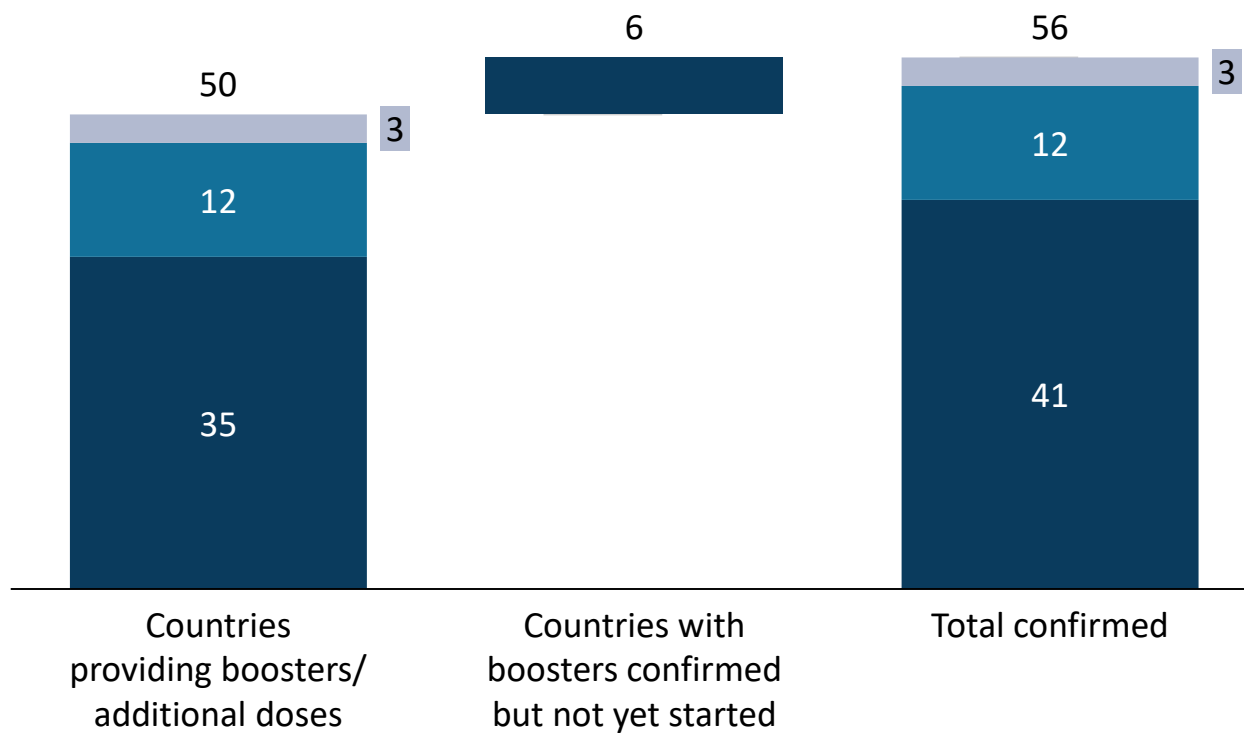
# At least 56 countries have confirmed COVID-19 vaccine boosters/additional doses

**PLEASE NOTE: WHO DOES NOT RECOMMEND BOOSTER DOSES, AND HAS CALLED FOR A VACCINE BOOSTER MORATORIUM UNTIL END OF 2021**

INDICATIVE // NON-EXHAUSTIVE

Status of COVID-19 booster administration, # of countries

LIC LMIC UMIC HIC



## Key takeaways

**50 countries (70% are HICs) started administering boosters/additional doses as of Oct 5<sup>th</sup>:**

**6 HICs confirmed a booster program but yet to start**

**At least 12 other countries are considering a booster program**

**At least 3x as many booster doses are administered daily as there are primary doses in LICs**

## Rationale for boosters/additional doses

*Outcome of primary interest - severe disease/hospitalization*

1. **Decline over time** in performance of vaccine primary series
2. **Variants** have evolved to a degree that protection by original vaccines becomes inadequate (original or variant vaccine boost).
3. **Inadequate protection with primary series** for some risk groups (for example, immunocompromised) (“**Additional dose**”, not a booster)

*The need for booster doses may differ by vaccine product, epidemiological setting, risk group, and other factors*

*SAGE is reviewing data on each of these elements –  
next SAGE meeting tentatively on 18 November 2021*