

Member States Information Session **- Update on global COVID-19** **vaccine and immunization**

Dr. Kate O'Brien, Director, IVB / WHO

Monday, November 7



**World Health
Organization**

Agenda

Update on global COVID-19 vaccine and immunization

7 November 2022: Member State Briefing: 10h30-12h00 (CET)

- | | | |
|---|-------------------------------------|--|
| 1 | Opening Remarks (5 mins) | Director Kate O'Brien |
| 2 | Presentation (30 mins) | Director Kate O'Brien |
| 3 | Q&A Discussion (50 mins) | Tania Cernuschi, Unit Head,
Agenda, Policy & Strategy,
IVB |
| 4 | Closing (5 mins) | Director Kate O'Brien |

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- 1 Context of **Global COVID-19 Vaccine Strategy**
- 2 Update on protecting **high-priority groups** and on **boosters**
- 3 Development of **Variant-containing vaccines (VcV)**
- 4 **Triggers for updates** to the COVID-19 Global Strategy
- 5 Update on **COVAX Facility country product portfolio** and country planning for **product optimization**

Recap of Global Strategy: Update summary – health, social & economic security drive strategy

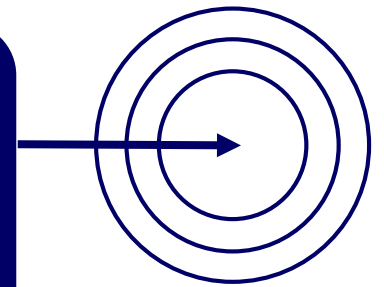
AS OF 21 JULY 2022

Goals

1 Sustain and enhance momentum to reduce mortality & morbidity, protect health systems, and resume socio-economic activity with existing vaccines



2 Accelerate development & access to improved vaccines to achieve durable, broadly protective immunity, and reduce transmission



Full recovery

Tactics

Step 1
Highest and high-priority use groups

Step 2
Medium priority use groups

Step 3
Low priority use groups



Objective 1
Increased investment in innovation

Objective 2
Distributed manufacturing & access for all countries



Key enablers

Vaccination delivery approaches across the life course

Sustained political engagement and investments

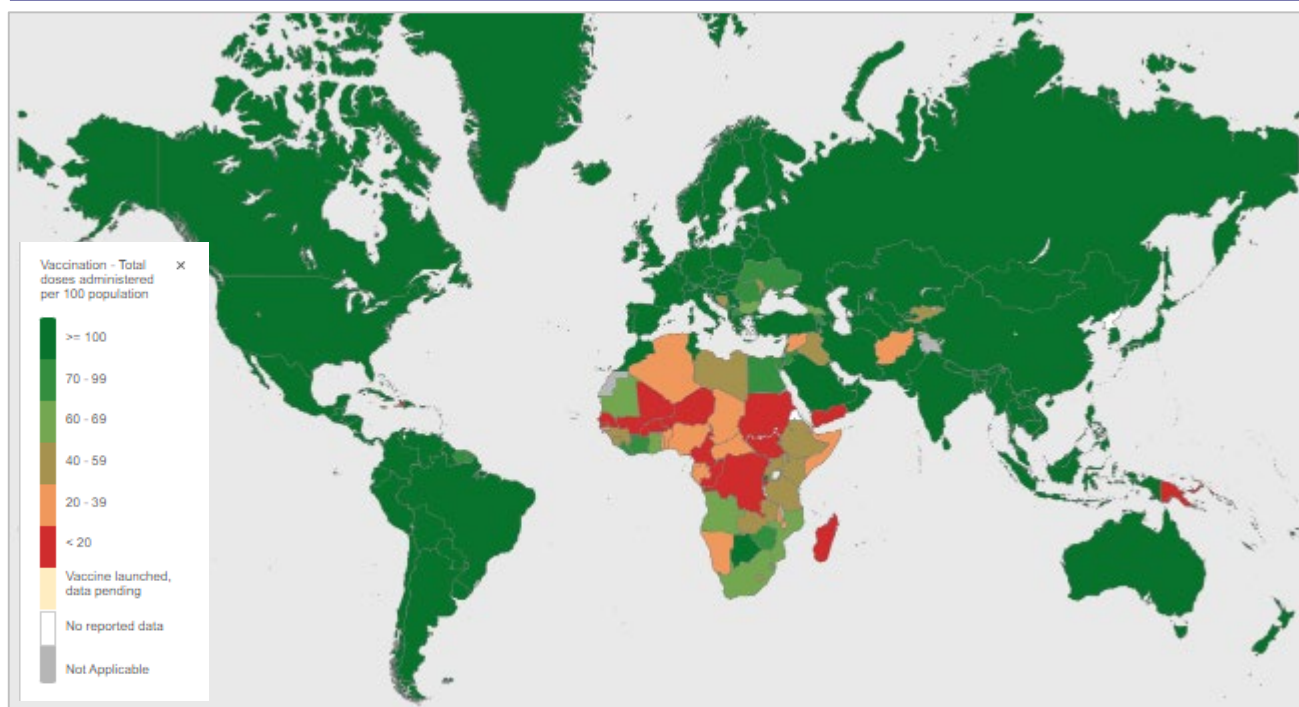
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12.8 billion doses of COVID-19 vaccine have been administered globally, yet coverage of high-priority groups stagnating & in LICs remains behind

DATA AS OF OCTOBER 24, 2022

Persons vaccinated with at least one dose per 100 population



COVID-19 primary series vaccination

Income group	% of total population	% of 60+ population	% of HCWs population
Total	64 / 36	77 / 23	76 / 24
HIC	75 / 25	80 / 20	70 / 30
UMIC	76 / 24	81 / 19	79 / 21
LMIC	58 / 42	72 / 28	87 / 13
LIC	19 / 81	40 / 60	42 / 58

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.

High total population coverage will not deliver on protecting all priority populations: it requires intentional focus

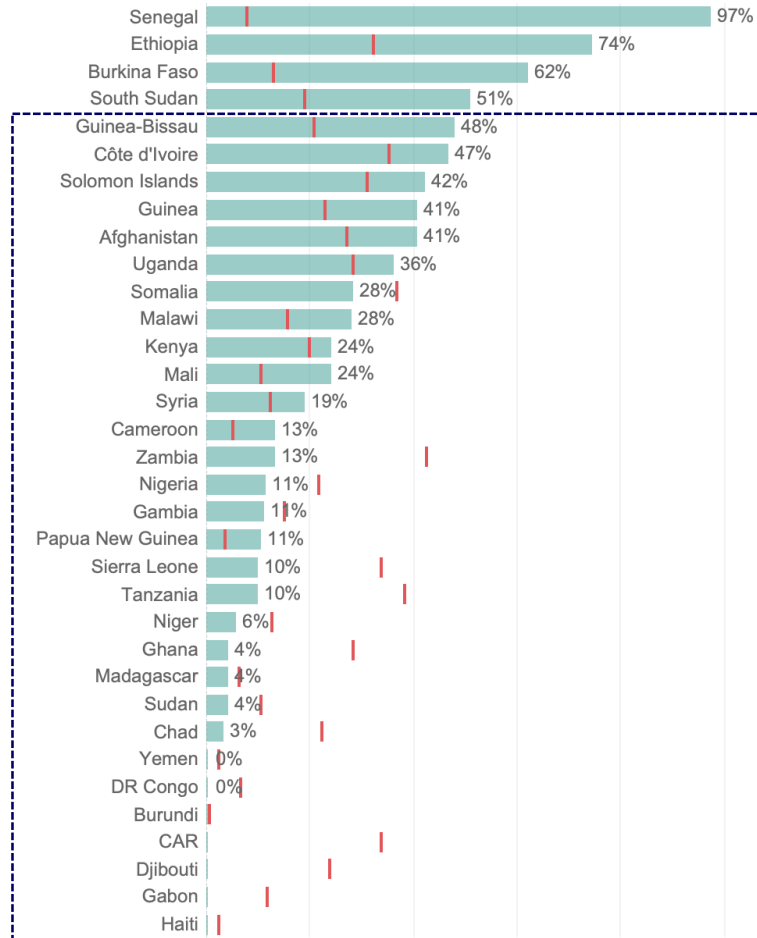
DATA AS OF OCTOBER 27, 2022



60+

Coverage 60+, compared to total population

Complete primary series of adults, 34 countries for concerted support



30 of 34 countries reporting below 50%; 16 reporting coverage higher than total population

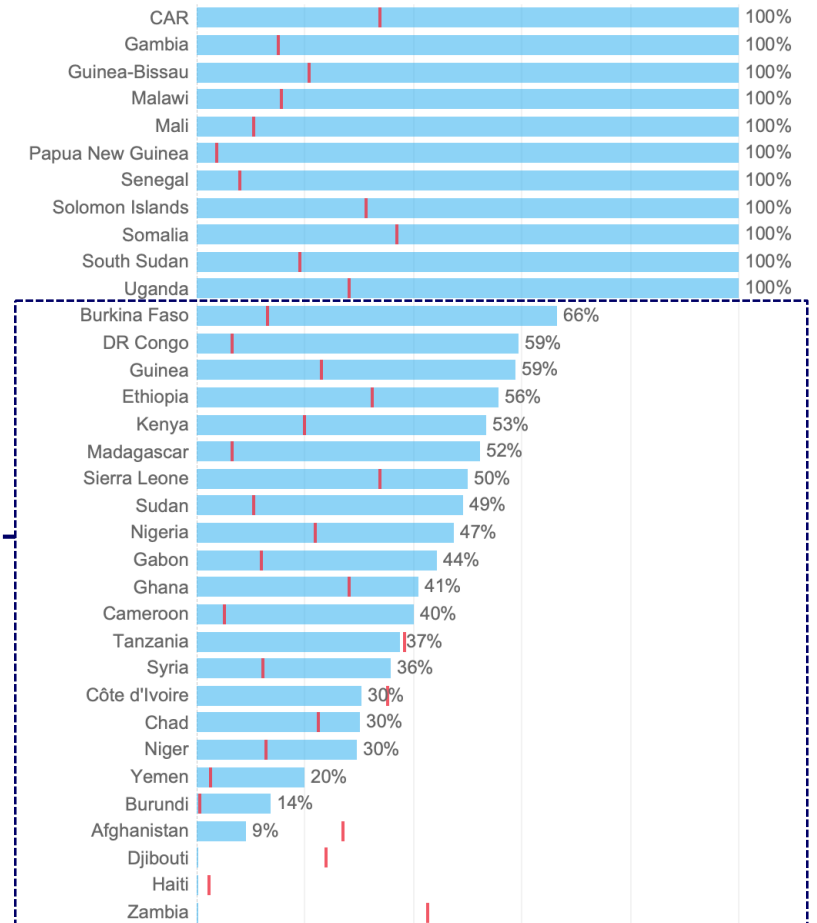
HCW coverage higher than 60+, although coverage needs improvement

Overall population coverage, complete primary series
Complete primary series coverage



Coverage of healthcare workers compared to total population

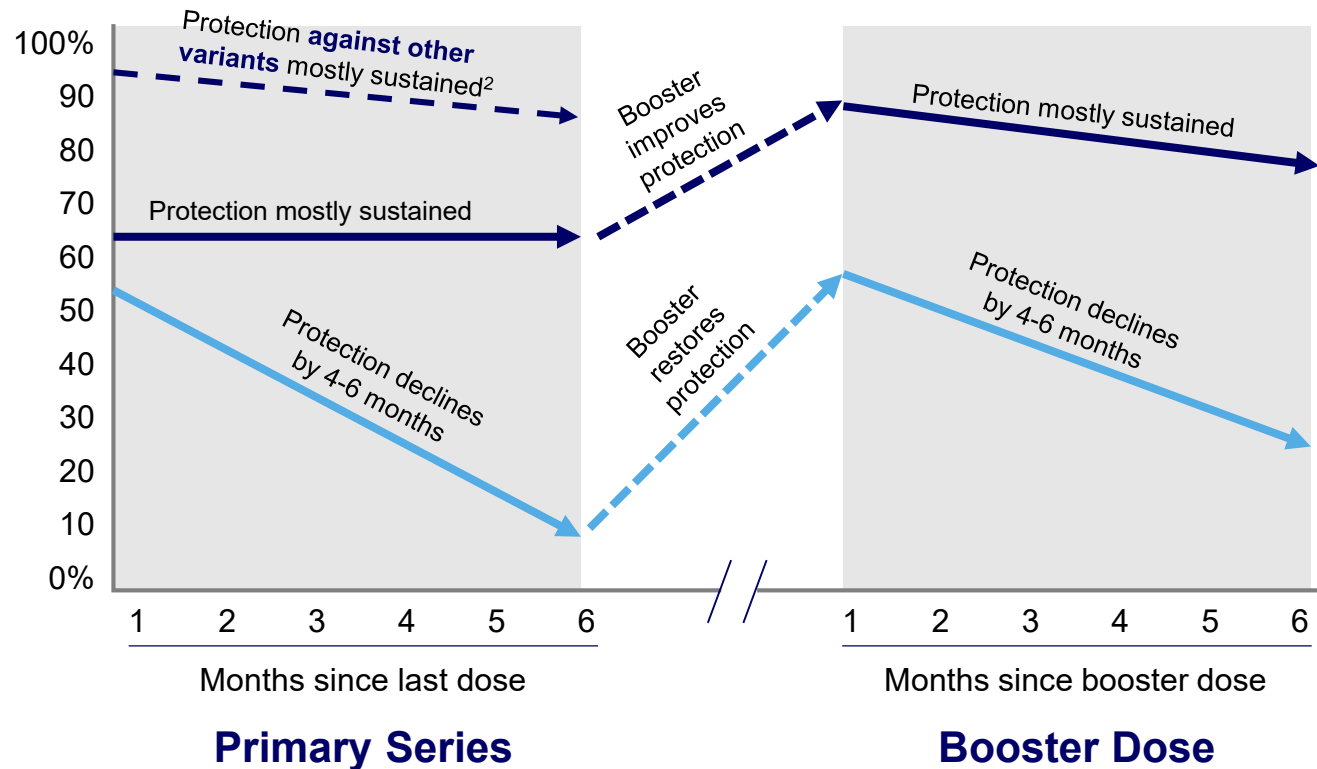
Complete primary series of HCWs, 34 countries for concerted support



Boosters are important: they restore protection against symptomatic disease and improve protection against severe disease

→ Severe disease → Symptomatic disease

Average vaccine effectiveness¹



Key messages

- While VE is lower than for pre-Omicron variants, **vaccines continue to protect individuals from symptomatic and severe disease**
- **Booster doses** are important as they help **enhance protection against severe disease** – and restores protection against symptomatic disease
- There is **some waning of boosters' protection** over time, particularly for symptomatic disease
- A **second booster** dose increases protection against symptomatic and severe disease compared to 3rd dose, but with **modest marginal benefits**



Good practice statement on the use of second booster doses for C19 vaccines can be [found here](#); **SAGE Roadmap for prioritizing uses of C19 vaccines** can be [found here](#)

1. Based on 81 studies in 20 countries

2. Approximation based on results for Pfizer-BioNTech vaccine from Duration of effectiveness of vaccines against SARS-CoV-2 infection and COVID-19 disease by Feiken D et al. ([https://doi.org/10.1016/S0140-6736\(22\)00152-0](https://doi.org/10.1016/S0140-6736(22)00152-0)), in which all studies were carried out before the omicron variant began circulating.

WHO SAGE guidance on booster doses

DATA AS OF OCTOBER 7, 2022

WHO recommends that any¹ WHO EUL COVID-19 vaccines or authorized mRNA bivalent variant-containing vaccines can be used for booster vaccination

First booster

- **All persons aged 12 years and above**, with an interval of **4-6 months after completion of the primary series**
- **Prioritizing resources to higher-priority use groups**
- **Any of the WHO EUL vaccines** can be used for first booster dose, **or any of the authorized bivalent variant-containing vaccines**

Key reference: WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines

<https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccines-SAGE-Prioritization-2022.1>

Additional boosters

- Second boosters for **all older persons**, all persons with moderately and severely **immunocompromising conditions**, adults with **comorbidities** that put them at higher risk of severe disease; **pregnant women**; and **health workers**
- **Recommended 4-6 months after the previous dose**
- **Any of the WHO EUL vaccines or any of the authorized bivalent variant-containing vaccines** can be used

Key reference: Good practice statement on the use of second booster doses for COVID-19 vaccines

<https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-good-practice-statement-second-booster>

1. see also good practice statement on heterologous schedules: <https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-heterologous-schedules>

WHO recommended schedules for primary series and booster doses¹

Heterologous schedules (“mix and match”): There is increasing evidence that subsequent doses/boosters using different COVID-19 vaccine platform may provide superior immune response compared to homologous schedules

Initial dose or second dose of primary series

Monovalent mRNA vaccine³
(Pfizer, Moderna)

Viral vector vaccine
(AstraZeneca/SII, Janssen, CanSinoBIO)

Protein subunit vaccine
(Novavax/SII)

Inactivated vaccine³
(Sinopharm BBIP, Sinovac)

Options for subsequent doses (to complete primary series² or booster doses)

Monovalent mRNA vaccines³ / viral vector vaccines/ protein subunit vaccines can be considered, as heterologous or homologous schedule, to complete primary series and/or booster doses. **VCV mRNA vaccines** are not yet authorized for completion of the primary series, only for booster doses.

Inactivated vaccines may be only considered to complete primary series and/or booster doses if they were administered as a first dose/primary series

1. WHO SAGE. [Interim recommendations for heterologous COVID-19 vaccine schedules](#), and [Highlights from the Meeting of the Strategic Advisory Group of Experts \(SAGE\) on Immunization – 3-6 October 2022](#). 2. The subsequent doses to finalize primary series could be the second dose or the third dose in immunocompromised persons and adults ≥60 years who received 2 doses of Sinovac or Sinopharm. 3. **Monovalent mRNA vaccines can be used for primary series and booster doses. To date mRNA Variant-containing Vaccines (VCVs) are only for use as booster doses**, not for primary series. 4. Refers only to inactivated BIBP/Sinopharm and Coronavac COVID-19 vaccines.

Booster coverage well below primary coverage in 60+ & strategic action from global level challenging with data reporting and quality limitations

DATA AS OF OCTOBER 11, 2022

LOW DATA QUALITY AND COMPLETENESS

■ Completed booster vaccination

■ Not completed booster vaccination

X Less than half of countries reporting

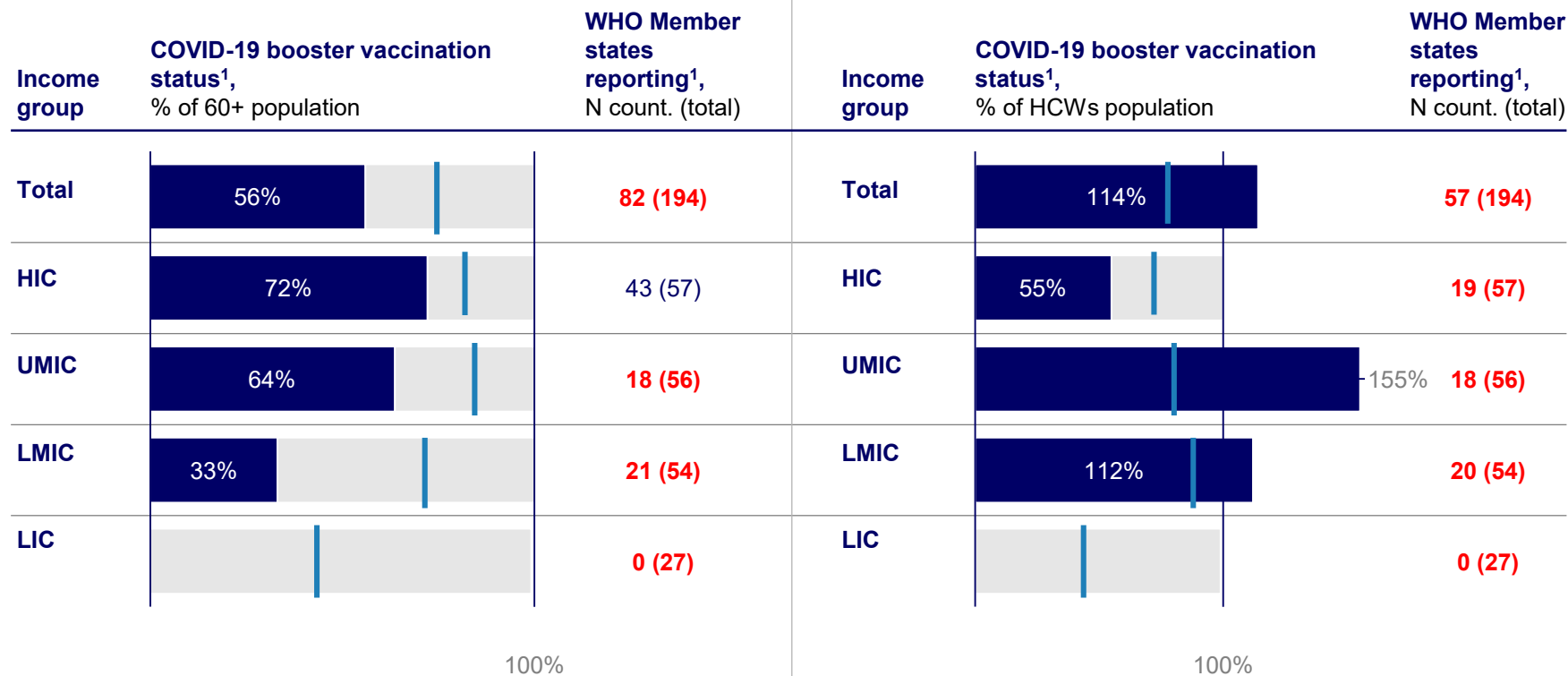
| Primary vaccination coverage



Elderly population (60+)



Healthcare workers



Of note

- The missing data is severe and hard to interpret, although seems that most countries have started booster programmes
- Booster coverage is well below primary coverage for high risk groups
- Importance for MS to continue focus on protecting high risk groups
- MS sharing of quality data helps WHO trigger support to specific country/districts

1. Based on countries that report >0% booster coverage and have reported recent data, i.e., August 2022 or more recent

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Limited clinical data available on variant-containing COVID-19 vaccines




DATA AS OF NOVEMBER 02, 2022

PRELIMINARY

✔ Data publicly available¹

☐ Product authorized by at least one SRA or NRA or product with a WHO EUL

☐ Product not authorized

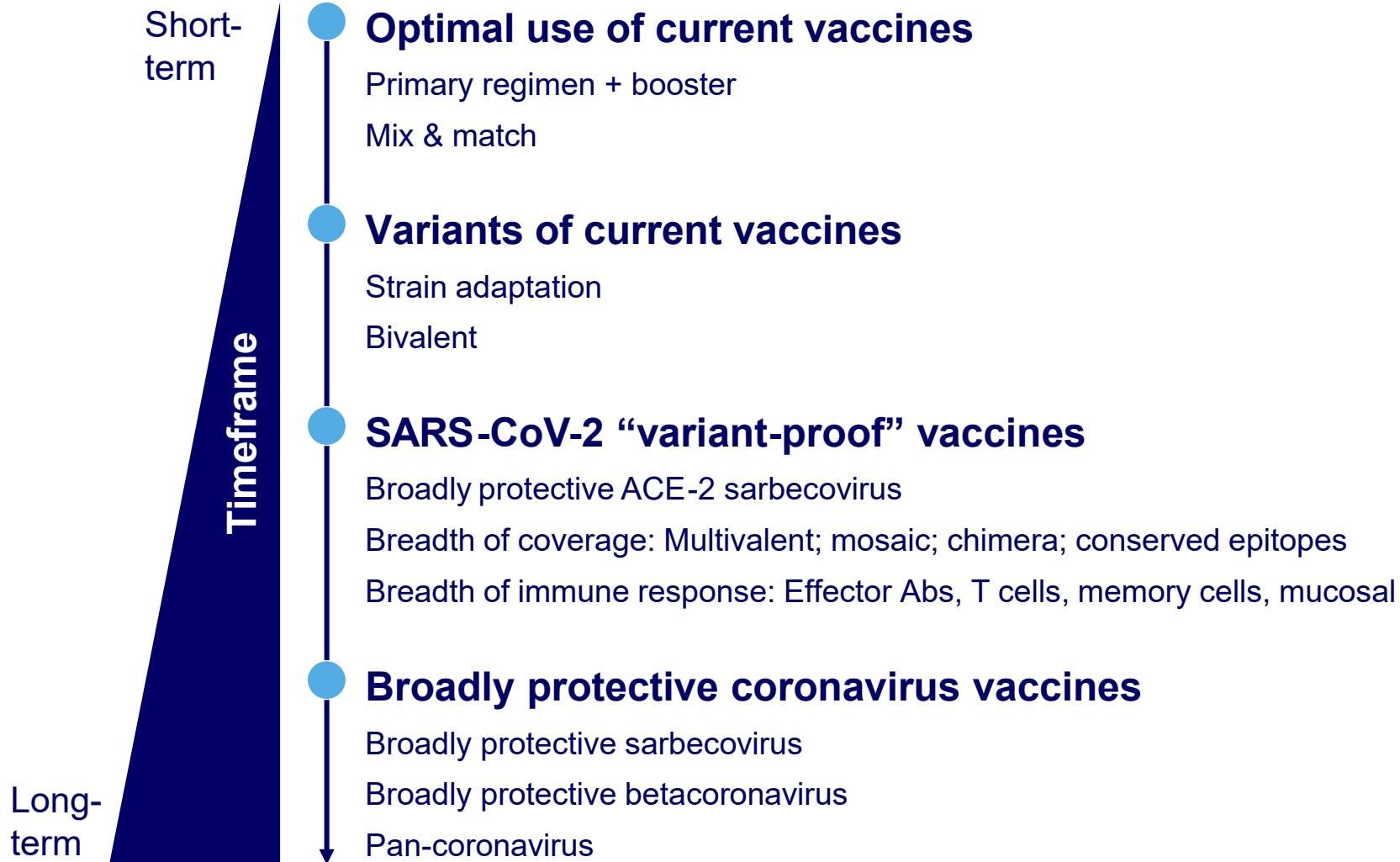
Manufacturer	Beta		Omicron BA.1		Omicron BA.4/5	
	Monovalent	Bivalent	Monovalent	Bivalent	Monovalent	Bivalent
	☐✔	☐✔	☐	☐✔	☐	☐✔
			☐✔	☐✔		☐✔
	☐✔	☐✔ D614				

Novavax and Sinopharm: Omicron-containing products under development

1. Includes immunogenicity data in primed individuals for monovalent and bivalent BA.1 products for Pfizer, and bivalent beta and BA.1 products from Moderna, and immunogenicity data in a small number of unprimed individuals for the Pfizer monovalent BA.1. No immunogenicity data for any of the bivalent products in unprimed individuals.

Short- and Long-term approach to broad protection

AS OF SEPTEMBER 1, 2022



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Global Covid-19 vaccination strategy: context & next steps

Context



Next steps

In July 2022, WHO published an update to the **Global COVID-19 Vaccination Strategy** ([link](#)).

This strategy has **two goals**:

- 1. Sustain and enhance momentum to reduce mortality & morbidity**, protect health systems, and resume socio-economic activity with existing vaccines
- 2. Accelerate development & access to improved vaccines** to achieve durable, broadly protective immunity, and reduce transmission

3 main conditions could trigger a new COVID-19 strategy in the coming months:

- **A key change in epidemiology** (i.e., significant surge in disease or deaths)
- **New scientific evidence** (e.g., on duration of protection of vaccines & performance against infection and transmission)
- **PHEIC or pandemic status is resolved** (i.e., COVID-19 virus considered endemic)








If none of these conditions are met, the July 2022 strategy remains valid

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12 COVID-19 vaccines with WHO SAGE recommendations; most of them have been included in the COVAX portfolio

AS OF NOVEMBER 02, 2022

Platform	Vaccine	Manufacturer	WHO EUL Date ¹	Latest WHO SAGE recommendations	Links	COVAX Portfolio
Messenger Ribonucleic Acid (mRNA)	1 COMIRNATY ^{®2}		31-Dec-20	18-Aug-22	WHO SAGE Interim Recommendation;	
	2 SPIKEVAX [®]		30-Apr-21	18-Aug-22	WHO SAGE Interim Recommendation;	
Viral vector	3 COVISHIELD ^{®3}		15-Feb-21	15-Mar-22	WHO SAGE Interim Recommendation;	
	4 VAXZEVRIA ^{®2,3}		16-Apr-21			
	5 Ad26.COVS-2 ^{®2}		12-Mar-21	06-Jun-22	WHO SAGE Interim Recommendation;	
Inactivated virus ⁴	6 CONVIDECIA [®]		19-May-22	19-May-22	WHO SAGE Interim Recommendation	-
	7 Inactivated SARS-CoV-2 vaccine BIBP [®]		07-May-21	15-Mar-22	WHO SAGE Interim Recommendation;	
	8 CORONAVAC [®]		01-Jun-21	15-Mar-22	WHO SAGE Interim Recommendation;	
	9 COVAXIN ^{®5}		03-Nov-21	15-Mar-22	WHO SAGE Interim Recommendation;	-
	10 VALNEVA [®]		No EUL	18-Aug-22	WHO SAGE Interim recommendation	-
Recombinant spike protein nanoparticle	11 COVOVAX ^{®6}		17-Dec-21	27-Sep-22	WHO SAGE Interim Recommendation;	
	12 NUVAXOVID ^{®6}		20-Dec-21			

1. <https://extranet.who.int/pqweb/vaccines/vaccines-covid-19-vaccine-eul-issued>

2. EUL recommended also for booster https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_21September2022.pdf

3. Same vaccine products produced in different manufacturing sites or having different registered names can be used interchangeably

4. SAGE reviewed in October 2022 another inactivated vaccine: Biological E BECOV-2 COVID-19 vaccine (Corbevax[™]) and will issue recommendations once the product is listed by WHO EUL

5. For COVAXIN international supply is suspended.

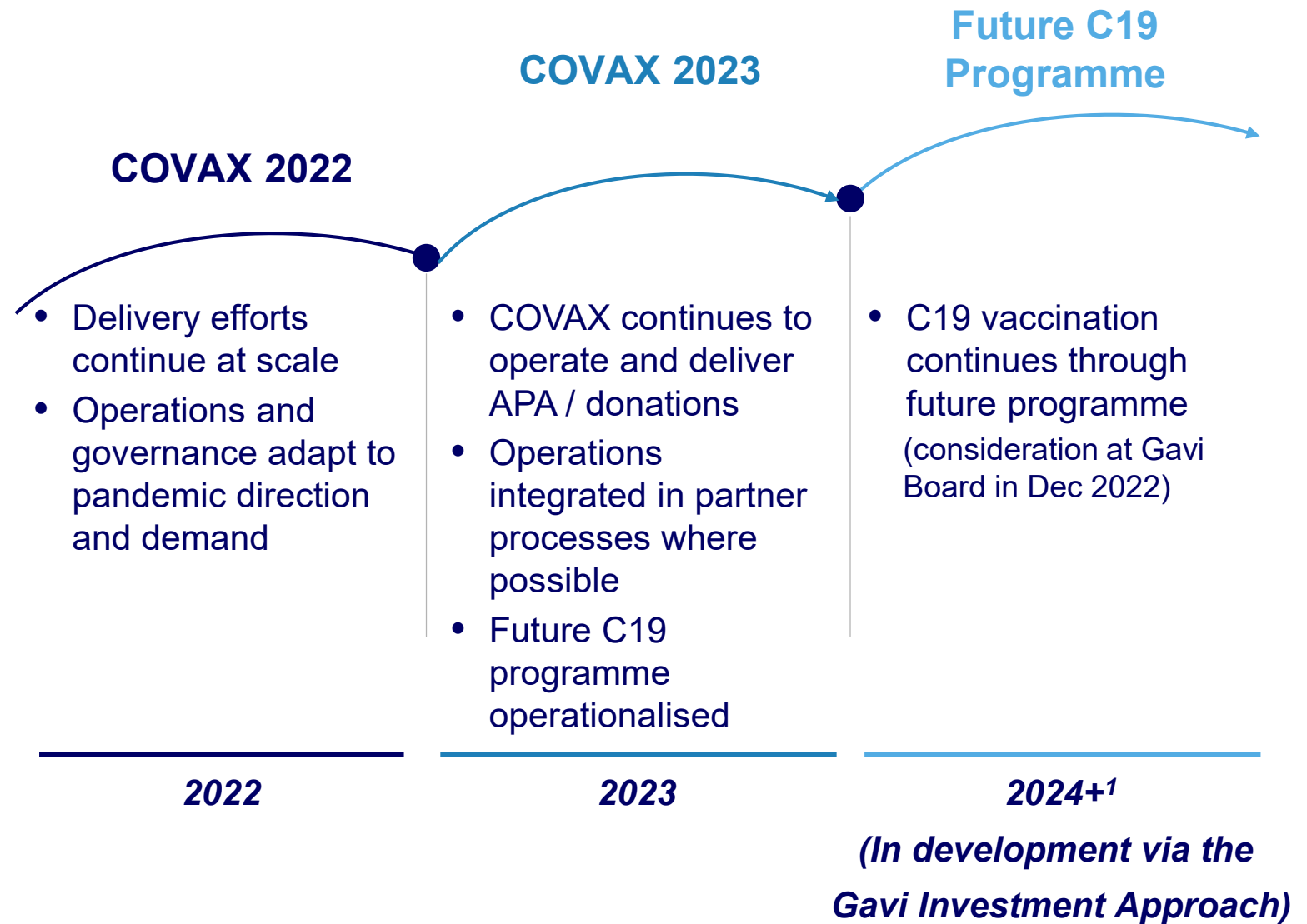
6. Same vaccine products produced in different manufacturing sites or having different registered names can be used interchangeably Due to the interchangeability, the rest of the presentation refers to these vaccine products as Novavax. In COVAX, these two vaccine products are referred as "Novavax, NVX-2373"

COVAX 2023 – Introduction

COVAX has followed direction of **WHO Global Vaccination Strategy and related SAGE guidance**: strategy has evolved, so has COVAX approach

COVAX established **set of objectives, an approach and plan for remainder of 2022**

Mindful that pandemic direction is not certain, a **range of scenarios have been developed to aid the 2023 planning**



1. Under discussion in Gavi through Gavi/COVAX governance processes

COVAX 2022: Snapshot of currently available supply - Purpose

AS OF OCTOBER 24, 2022

- The **COVAX supply snapshot is updated monthly** to show products that are currently available for allocation to Participants, including variant-containing vaccines (VCVs) for the first time this month
- The snapshot is **intended to help inform Participant requests**: Participants can **request any product even if not currently listed in the snapshot**
- Note that **typical timelines for delivery** to country is **3-4 weeks after a Purchase Order (PO) has been issued.**
- **Prior to PO issuance, the allocation must be accepted**, and necessary preparedness documents completed.

COVAX 2022: Snapshot of currently available supply – November 2022

AS OF OCTOBER 24, 2022

Manufacturer	Product name	Formulation/presentation ¹	Population ²	Primary/Booster	Indicative Shelf Life/Expiry Date	
Pfizer/BioNTech	Comirnaty	Original vaccine	PBS	Adults and adolescents	Primary/Booster	31 Oct 2022 labelled, 30 April 2023 if SL extension is applied by country's NRA
			RTU ³	Adults and adolescents	Primary/Booster	<u>Immediately available</u> : 30 Nov 2022 labelled, 28 Feb 2023 if SL extension is applied by country's NRA <u>Available as of mid-Dec</u> : 30 Sep 2023 labelled shelf life (no extension)
			Pediatric	Pediatric	Primary only	Minimum 30 Apr 2023 labelled shelf life (no extension)
		Variant-containing vaccine (VCV)	Adults and adolescents	Booster only	Mid-2023	
Moderna	Spikevax	Original vaccine ³	Adults, adolescents, and pediatric	Primary/Booster for Adults and adolescents Primary only for pediatric	Dec 2022 and Jan 2023. Availability of fresher supply subject to confirmed country demand.	
		Variant-containing vaccine (VCV)	Adults and adolescents	Booster only	Up to 9 months	
J&J	Ad26.COV2.S (Janssen COVID-19 Vaccine)	Original vaccine	Adults	Primary/Booster	Minimum Jul 2023	
SII	ChAdOx1 nCoV-19 ("Covishield")	Original vaccine	Adults	COVAX supply limited to completion of primary series only, i.e., not available for 1st dose of primary series or booster ⁴	Jan 2023	
	NVX-CoV2373 ("Covovax")	Original vaccine	Adults and adolescents	Primary/Booster	TBD upon request	
Novavax	NVX-CoV2373 ("Nuvaxovid")	Original vaccine	Adults and adolescents	Primary/Booster	TBD upon request	

[1] Original vaccines also known as monovalent (ancestral strain) vaccines. VCVs also known as bivalent (ancestral and omicron strains) vaccines; [2] Pediatric: ages 5-11 (Pfizer) or ages 6-11 (Moderna); Adolescents: ages 12-17; Adults: ages 18+. For Pfizer, pediatric doses for children aged 6 months to 4 years may be available on case-by-case basis; [3] Limited quantities available; [4] Available in limited quantities on case-by-case basis for administration of second (and third for eligible population) dose only to complete primary series

Potential composition of COVAX 2023 portfolio – Base Case

AS OF OCTOBER 2022



Vaccination use-cases

1. Complete existing programs to reach participant-specific coverage targets for all adults

2. Additional boosters (4th dose) for highest/high priority risk groups who completed primary vaccination

3. Limited pediatric program



Product

Primary

- Prototype Vx

Booster (3rd dose)

- Prototype Vx or VCVs

Prototype Vx or potentially VCVs

Pediatric Vx

The supply strategy for 2023 is a combination of using the existing portfolio/supply, soliciting fresh donations and procuring new supply

The **2023 portfolio is still in flux**, as new products will be secured based on the demand-planning exercise. **As of now, COVAX envisions to have the following products:**

- Janssen
- Novavax
- Pfizer and Moderna VCVs
- Pfizer and Moderna original strain (potential)

BACK UP

There remains unsettled science on C-19 vaccine approach, considering population immunity, variants, and more....

What we know



Hybrid (infection- and vaccine-induced) immunity **is better than either alone**

Older adults tend to have lower seroprevalence than other groups in low coverage settings

Groups at risk for severe outcomes (esp. 60+) have had excess mortality, even in less affected geographies; **communications and targeted infrastructure** important to increase **vaccination uptake**

Variant-containing vaccines have been authorized, but only mRNA products, and only for **booster**, without clinical impact data as yet (**SAGE Good Practice Guidance on VcV, 5 Oct 2022**)

What remains unknown



How many doses are required to **maintain immunity**? What is the vaccine effectiveness in light of **herd immunity**?

What is the evidence on **vaccine durability** and protection against **Post COVID-19 condition (Long COVID)**?

What is the **optimum interval** between doses?

Can seroprevalence be used, and how, to **modify the vaccine dosing regimen** while maintaining individual and population benefit ?

How **effective will variant containing vaccines** be on various outcomes, particularly infection and transmission? What are the **differences in immunogenicity** between the different products available?

How will vaccines/immunization perform against **yet to emerge variants**? Do **multiple infections** in combination with immunization give better protection?

Overview of the current COVID-19 vaccines under EUL and the process behind

Main features

11 vaccines with different manufacturing platforms

- mRNA (2)
- Viral vector (4)
- Inactivated (3)
- Protein subunit (2)

- Expanding regulatory oversight and manufacturing sites
- 19 NRAs of reference (mainly EMA)
- over 70 manufacturing sites

A range of age indications, shelf life and storage conditions

Covid 19 vaccines developed

Approval by authority of reference

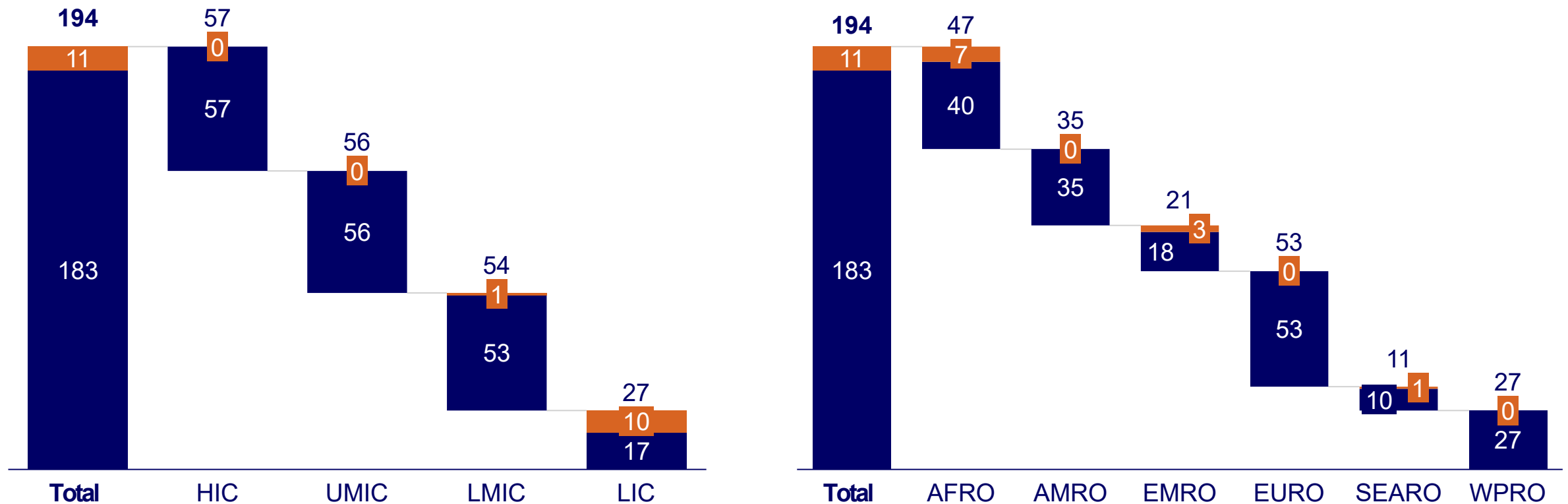
WHO EUL recommendation

183¹ WHO Member States are rolling out COVID-19 vaccine booster/additional doses, but still lacking in lower income countries

DATA AS OF OCTOBER 17, 2022

■ Did not start any booster/ additional dose programme²
■ Started a booster/ additional doses programme

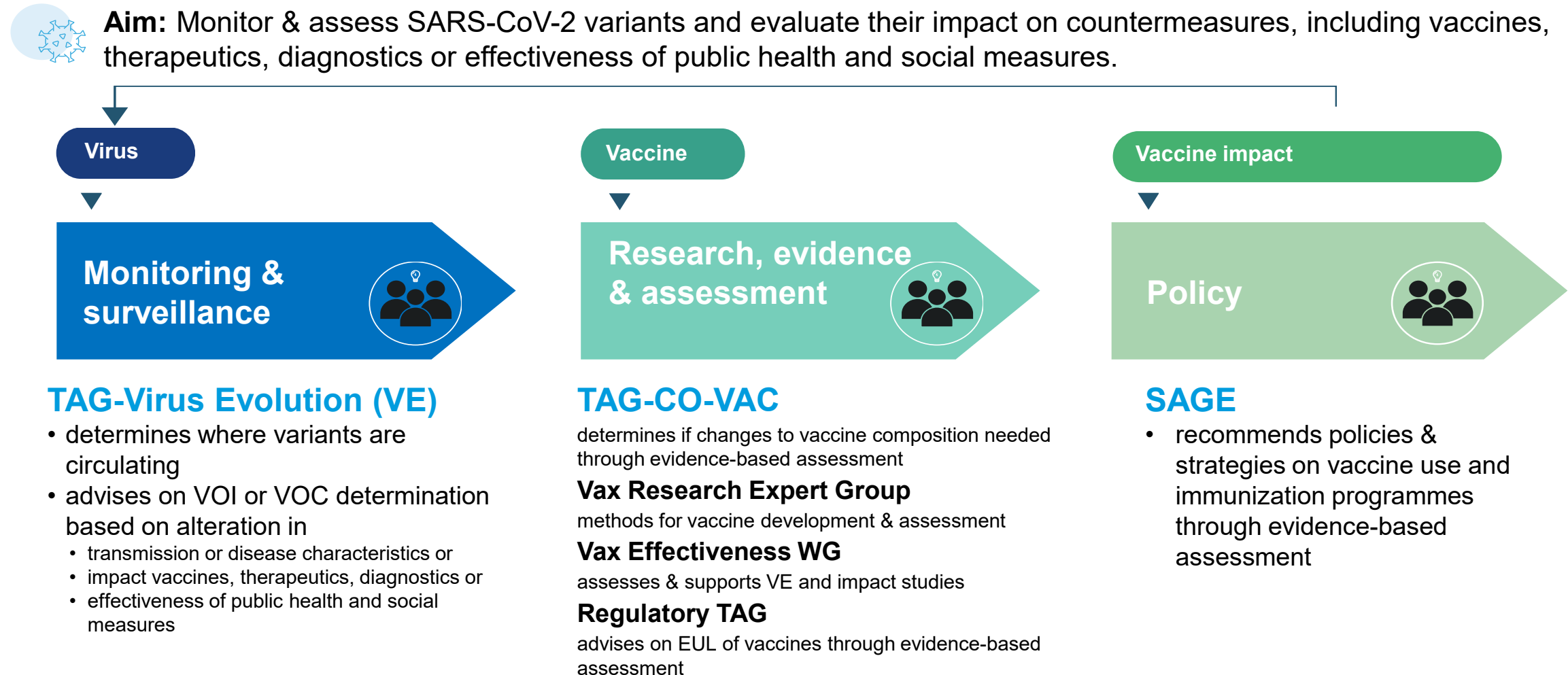
Status of COVID-19 boosters/additional dose programmes, # of WHO Member States
 Per income group Per WHO region



Source: WHO COVID-19 Dashboard, Our World in Data, WHO Regional Offices

- Five countries (Benin, Congo, Comoros, Haiti, and Nicaragua) do offer booster doses but do not report data on them
- Burkina Faso, DRC, Eretria, Mali, Niger, South Sudan, Chad, Afghanistan, Djibouti, Somalia, and DPRK

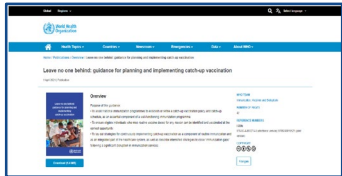
WHO COVID-19 advisory groups develop recommendations on variants and variant vaccines along a comprehensive pathway



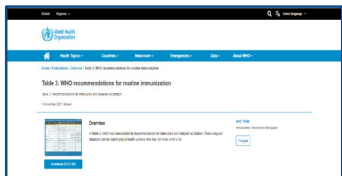
Resources on catch-up and immunization recovery



Catch-up vaccination landing page
<https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/implementation/catch-up-vaccination>

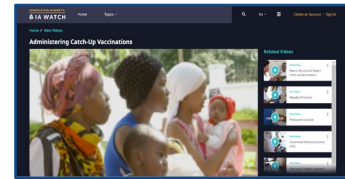


Leave No One Behind: Guidance for planning and implementing catch-up vaccination (EN,FR,PT)
<https://www.who.int/publications/i/item/9789240016514>

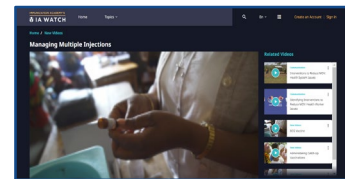


WHO Recommendations for interrupted or delayed vaccination (EN,FR)
<https://www.who.int/publications/m/item/table-3-who-recommendations-for-routine-immunization>

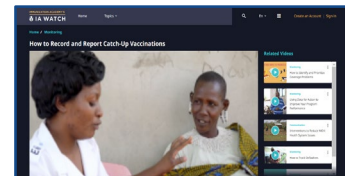
Catch-up vaccination videos (EN,FR coming soon):



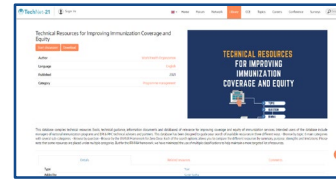
Administering catch-up vaccination
<https://watch.immunizationacademy.com/en/videos/807>



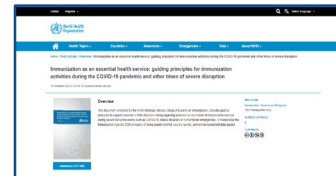
Managing multiple injections
<https://watch.immunizationacademy.com/en/videos/805>



How to record and report catch-up vaccination
<https://watch.immunizationacademy.com/en/videos/806>



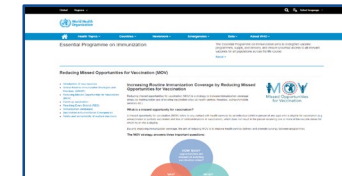
Technical Resources for Improving Immunization Coverage and Equity
<https://www.technet-21.org/en/library/main/7095-technical-resources-for-improving-immunization-coverage-and-equity>



Immunization as an essential health service: guiding principles for immunization activities during the COVID-19 pandemic and other times of severe disruption (EN)
www.who.int/publications/i/item/immunization-as-an-essential-health-service-guiding-principles-for-immunization-activities-during-the-covid-19-pandemic-and-other-times-of-severe-disruption



Guiding principles for recovering, building resiliency, and strengthening of immunization in 2022 and beyond (FR)
www.technet-21.org/en/library/main/7946-principes-directeurs-de-la-reprise-de-la-promotion-de-la-resilience-et-du-renforcement-de-la-vaccination-en-2022-et-au-delà



Missed Opportunities for Vaccination resource guides (EN,FR)
[www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/implementation/reducing-missed-opportunities-for-vaccination-\(mov\)](https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/implementation/reducing-missed-opportunities-for-vaccination-(mov))



Vaccination in the second year of life (2YL) guides and resources (EN,FR,PT)
[www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/integration/vaccination-in-the-second-year-of-life-\(2yl\)](https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/integration/vaccination-in-the-second-year-of-life-(2yl))

WHO SAGE recommendations on co-administration of COVID-19 vaccines with other vaccines

Adults and adolescents

COVID-19 vaccines may be given concomitantly, or any time before or after, other vaccines including live-attenuated, inactivated, adjuvanted, or non-adjuvanted vaccines.

- *WHO recommends that countries consider co-administration of COVID-19 vaccines with seasonal influenza vaccines.*

Children

Evidence from co-administration studies is **currently insufficient to make a recommendation** for concomitant administration with COVID-19 vaccines

- A minimum interval of 14 days between administration of COVID-19 vaccines and other vaccines is recommended