



Dialogue with civil society: ACT-A and COVID-19 vaccines

9 March 2021

Housekeeping

- Please use mute and turn video off while not speaking to preserve livestream quality
- We will have time for Q&A after the initial presentation
- To ask for the floor, please indicate your name and organization in the chat

Agenda

1. Welcome and introductions	COVAX	10 mins
2. Updates from civil society representatives	CSOs	10 mins
3. COVID-19 vaccine data and first introductions	WHO	20 mins
4. Updates on the vaccine pipeline	CEPI	10 mins
5. COVAX Facility update and supply forecast	Gavi	10 mins
6. Q&A/Discussion	All	30 mins

Update from civil
society representatives

CSO representatives

Civil Society Representation in COVAX

- Following a nomination process (coordinated by the lead agencies and led by civil society in October 2020), representatives were nominated to 10 working groups across COVAX.
- Co-chairs of CSO
Coordination: Mike Podmore, STOP AIDS and Lisa Hilmi, CORE Group, representing GAVI CSO

Vaccines Pillar			
Working Group	Name	Affiliated CBO/ NGO	Country
CCM	Mesfin Teklu Tessema	IRC	US/Ethiopia
Access/Allocation	Karrar Karrar	Save the Children	UK
Vaccine Strategy	Jane Barratt	International Federation on Aging	Canada
Technical Review Group	Rebecca Grais	MSF	France
Country Readiness & Delivery (Coordination Group)	Katy Clark	American Red Cross	Switzerland
Country Readiness & Delivery (Communication, Advocacy, Training)	Carla Toko	Village Reach	Democratic Republic of the Congo
Country Readiness & Delivery (Demand)	Robert Kanwagi	World Vision	Kenya
Manufacturing SWAT	Alain Alsalhani	MSF	France/Syria
Enabling Science SWAT	Sheetal Sharma	Safari Doctors	Kenya
Clinical Development and Operations SWAT	Farah Qamar	Aga Khan Foundation	Pakistan

Civil Society Coordination in COVAX and across ACT-A

■ **Regular methods of communication:**

- Listserv and bi-weekly calls for COVAX representatives (co-facilitated by Platform for ACT-A Civil Society and Community Representatives & Gavi CSO Constituency)
- Broader ACT-A calls for all civil society representatives (coordinated by the Platform for ACT-A Civil Society and Community Representatives)

■ **Recent steps for improved coordination:**

- Call(s) between civil society representatives and the COVAX lead agencies
- Letter sent to all lead agencies in ACT-A

■ **Next steps:**

- Broader consultation with civil society and communities, particularly at the national and regional level
- Monthly Covax-CS Dialogue calls co-created and hosted by COVAX lead agencies and COVAX CS reps

COVAX CS Representatives: Key Priorities

- **Equity** → Allocation (global & sub-national), vaccine nationalism, Humanitarian Buffer
- **Operationalizing COVAX**: delivery funding, reaching the most vulnerable, including migrants, IDPs, asylum seekers
- **Vaccine supply constraints**: Increase global manufacturing capacity, dose sharing
- **Transparency and accountability**

COVID-19 vaccine data and first introductions

Kate O'Brien, WHO

COVID-19 vaccines: overview of key numbers (data at 8 March)

- **90 days** since first countries started vaccinating¹, **71 days** since all EU countries received vaccines, and **7 days** since first use of COVAX doses²
- **304 million vaccine doses** have been administered:
 - 78% of these doses have been administered in 10 countries
 - At least 9 different vaccines (3 platforms) have been administered³
- Campaigns **have started in 124 economies**:
 - incl. 65 HICs, 33 UMICs, 23 LMICs and 3 LICs
 - The vaccines used by the highest number of economies are: Pfizer-BioNTech (67 economies using it), followed by Oxford/AZ (58), Moderna (30), Gamaleya (20) and Sinopharm (16)
- **COVAX has shipped doses to 26 countries**⁴:
 - 4 LMICs & 1 LIC have started campaigns thanks to COVAX doses
 - In total, **15.6 M mn COVAX doses shipped**⁴

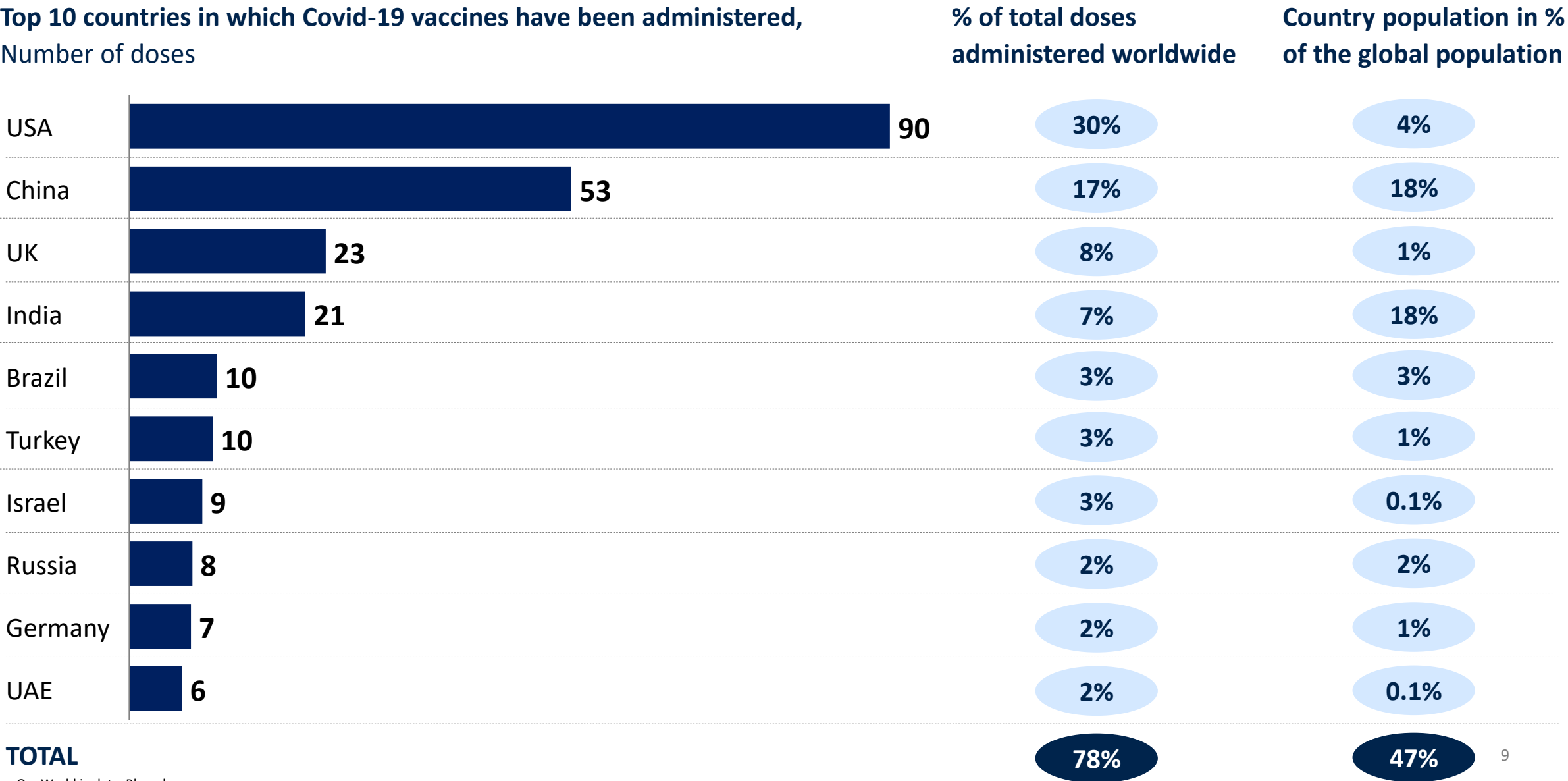
1. Dec. 8, 2020 in the UK (Pfizer)

2. March 1 in Ghana and Côte d'Ivoire

3. Pfizer, Moderna, Gamaleya, Sinovac, Sinopharm, SII, Bharat Biotech, AZ, Johnson & Johnson

4. On Jan 17, India received an additional 10 mn doses through COVAX from India-based supplier SII (excluded from this figure)

78% of vaccine doses have been administered in 10 countries (data at 8 March)

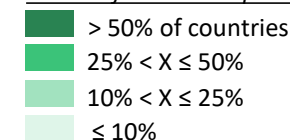


Source: Our World in data; Bloomberg

Covid-19 vaccination rollout has started in 124 economies

(data at 8 March)

Status of Vx roll out per income group



Green text: COVAX doses only

Economies classified by income level ¹	# of economies per income group	# economies where vaccination has started	% of income group where vaccination has started
High income economies (HICs)	83	65	78%
Upper-middle income economies (UMICs)	56	33	59%
Lower-middle income economies (LMICs)	50	23	46%
Low income economies (LICs)	29	3	10%
Total	218	124	57%

List of economies where vaccination has started

Andorra, Austria, Australia, Bahrain, Barbados, Belgium, Bermuda, Canada, Cayman Islands, Channel Islands, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Greenland, Gibraltar, Hungary, Hong Kong SAR, Iceland, Ireland, Isle of Man, Israel, Italy, Japan, Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Macao, Malta, Mauritius, Monaco, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Saudi Arabia, San Marino, Seychelles, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Trinidad and Tobago, Turks and Caicos, UAE, UK, Uruguay, USA

Albania, Argentina, Azerbaijan, Belarus, Belize, Brazil, Bulgaria, China, Colombia, Costa Rica, Dominican Republic, Ecuador, Gabon, Guatemala, Guyana, Indonesia, Iran, Jordan, Kazakhstan, Lebanon, Malaysia, Maldives, Mexico, Montenegro, Paraguay, Peru, Russia, Serbia, South Africa, Suriname, Thailand, Turkey, Venezuela

Algeria, **Angola**, Bangladesh, Bolivia, Cambodia, **Côte d'Ivoire**, El Salvador, Egypt, **Ghana**, Honduras, India, **Kenya**, Laos, Mongolia, Morocco, Myanmar, Nepal, Pakistan, Philippines, Senegal, Sri Lanka, Ukraine, Zimbabwe

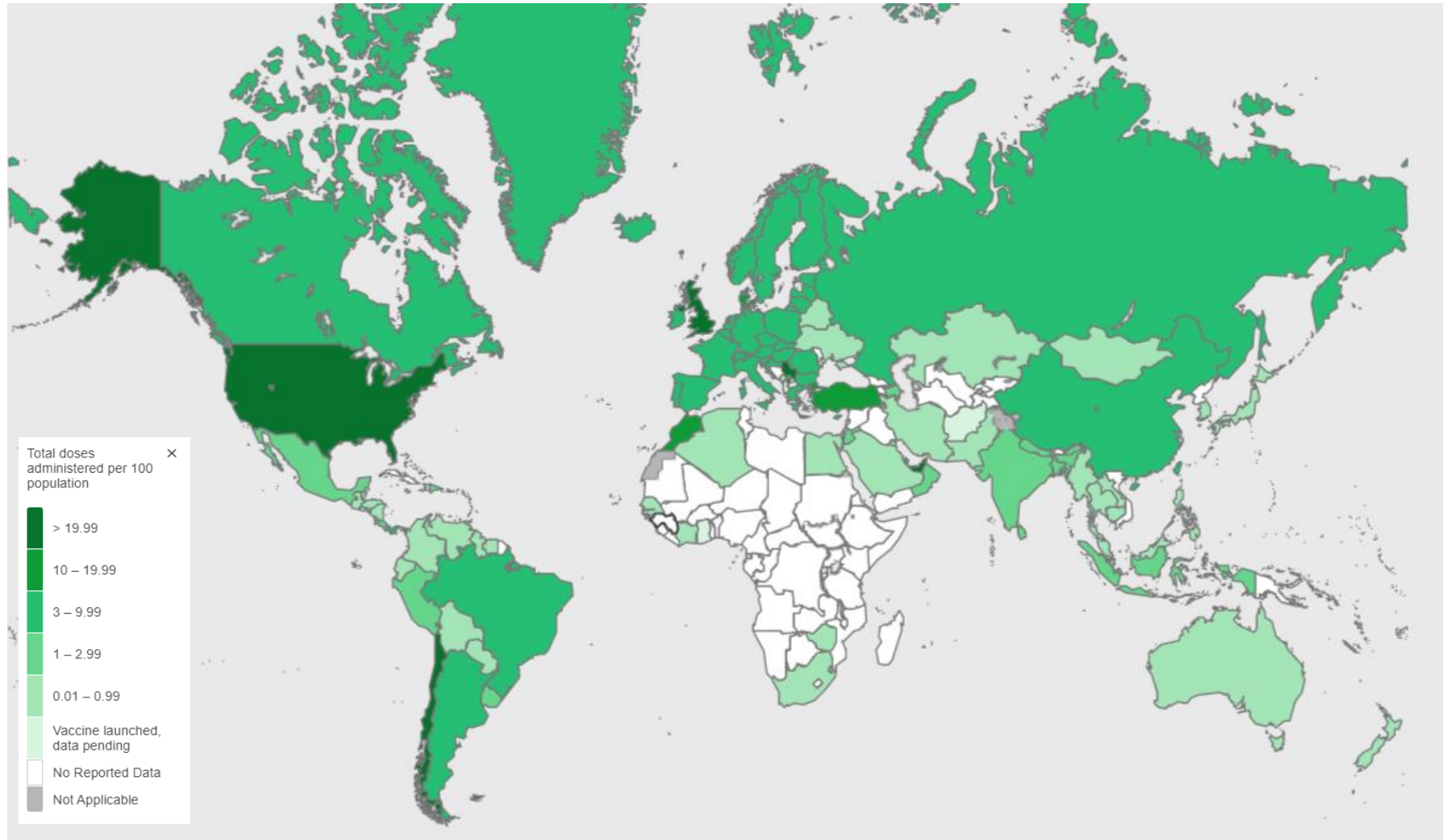
Afghanistan, Guinea, **Rwanda**

1. World Bank classification (2021)

Source: World Bank; WHO COVID-19 dashboard; Our World in data; Bloomberg; Reuters

Accelerating the equitable rollout of COVID-19 vaccines is more important than ever

COVID-19 vaccine doses administered per 100 people, March 8, 2021



SOURCE: WHO COVID-19 Dashboard

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.

The wave of COVAX deliveries kicked off on February 24th

24 February

The first batch of COVAX doses has arrived in Ghana (600,000 doses)



26 February

South Korea receives 117,000 COVAX doses



2 March

3.94 million doses of COVAX vaccines arrive in Nigeria



26 February

504,000 doses have landed in Côte d'Ivoire



1 March

Côte d'Ivoire and Ghana start their first COVID-19 COVAX vaccinations



...

In total, > 10 million COVAX doses have been delivered in just over a week

2 March

First COVAX doses also arrived in Angola, Cambodia, DRC and Gambia



4 March

Philippines receives first doses from AstraZeneca



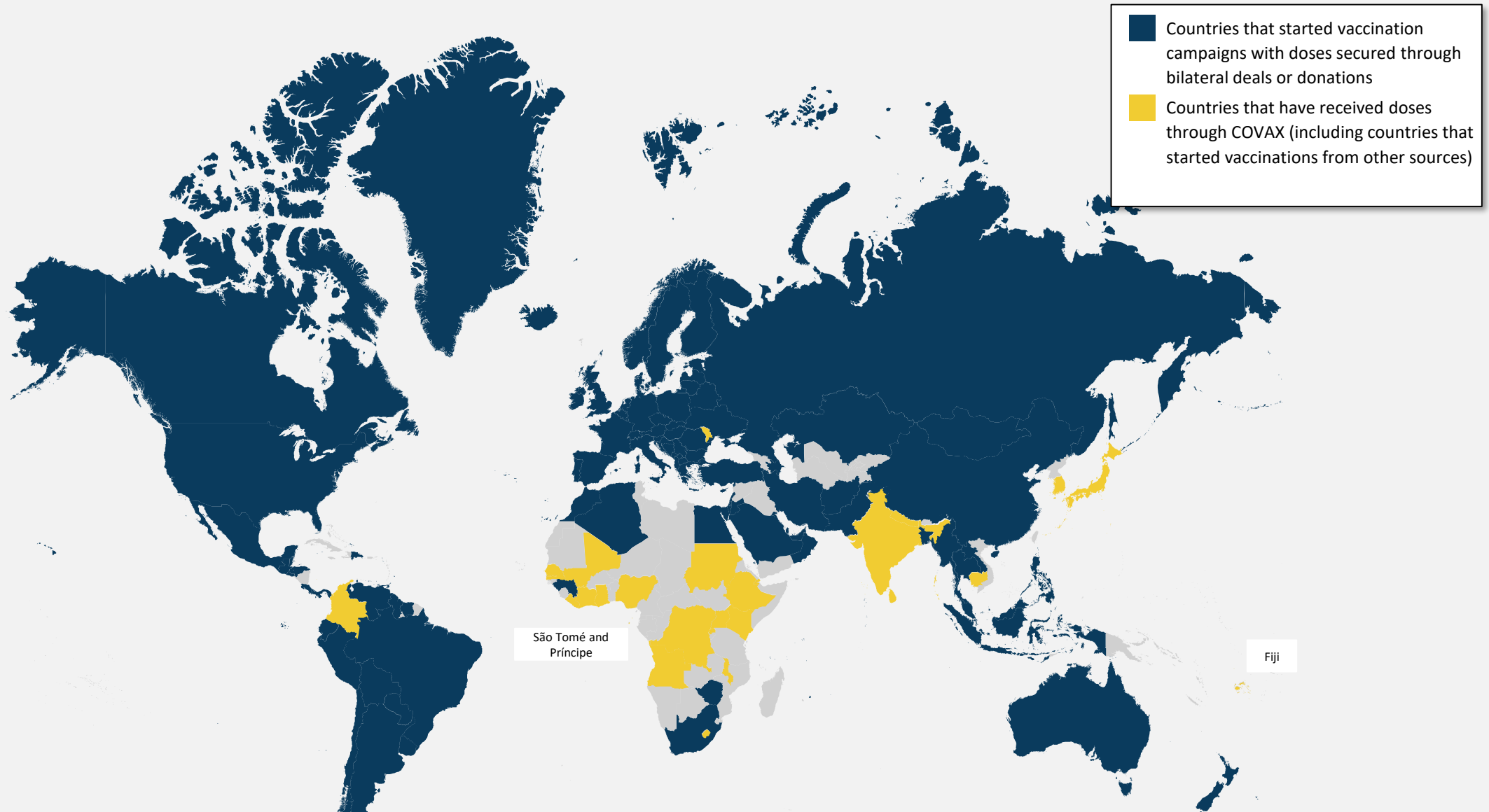
3 March

First COVAX doses arrived in Rwanda, Kenya and Sudan



- More shipments to come in the coming days and weeks
- Planned shipments for the next 7 days are available on the [UNICEF Vaccine market dashboard](#) (see tab “Delivery”)

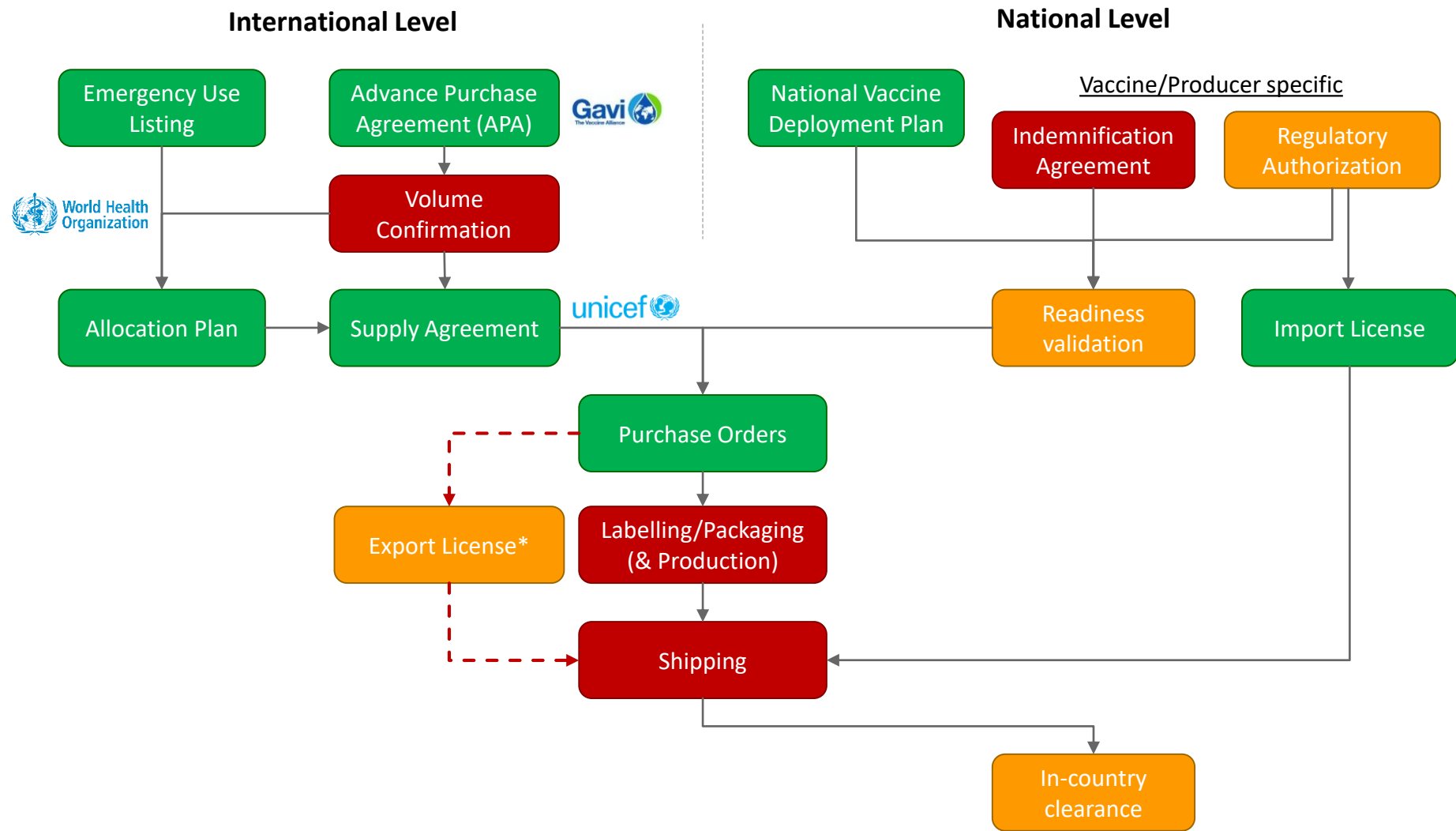
Countries that have received doses through COVAX (8 March)



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, Our World in Data; Press research

Deliveries of COVAX doses is a complex process – key bottlenecks at 8 Mar



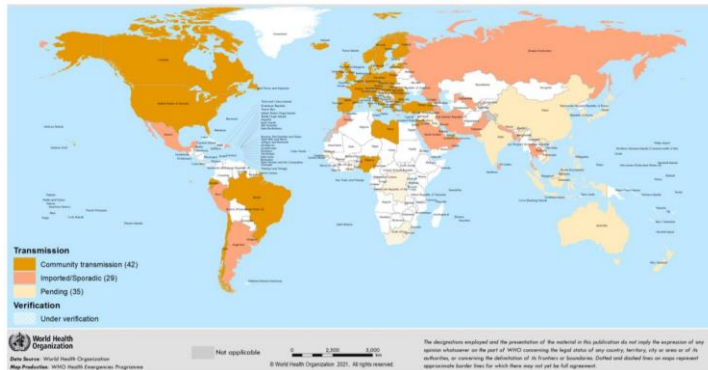
Addressing the challenges to further accelerate roll-out of COVAX Facility vaccines require several actions from countries

1. Each country needs to submit for each product a **signed I&L agreement** and a **Regulatory Authorization**
2. Ensure timely **export licenses for COVAX** (ideally waivers)
3. Prepare in-country use of vaccines by **costing¹, securing resources and preparing / launching Vx campaigns**
4. Encourage manufacturers to **rapidly provide data for EUL/PQ & SAGE²**
5. All Member States allow manufacturers to **prioritize COVAX commitments**

1. Using available tools such as the [CVIC tool](#); 2. [WHO PQ/EUL pipeline](#)

There are three main variants of concern

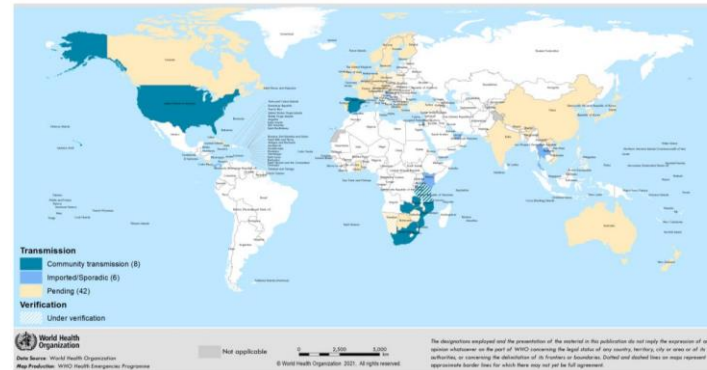
Figure 4. Countries, territories and areas reporting VOC 202012/01, as of 2 March 2021



VOC 202012/01
(first identified in the UK)

Variants of concerns are defined by WHO by their transmission, disease severity or impact on Covid counter measures

Figure 5. Countries, territories and areas reporting 501Y.V2, as of 2 March 2021



501Y.V2 or B.1.351
(first identified in South Africa)

Evidence supports ongoing use of existing vaccines – with some concerns about B.1.351 vs. some vaccines (available data still limited)

Figure 6. Countries, territories and areas reporting P.1, as of 2 March 2021



P.1 (first identified in Brazil)

COVID-19 Vaccine and SARS-CoV2 variants

Data are limited, early, and incomplete

Availability of Evidence (9 March 2021)

	B 1.1.7 (original report SSA)		B 1.351 (original report AZ)		P 1 (original report Brazil)	
	Clinical	Lab	Clinical	Lab	Clinical	Lab
AstraZeneca	✓	pending	limited	✓		prelim
J & J			prelim	pending		
Moderna		✓		✓		
Novavax	prelim		prelim	pending		
Pfizer		✓		✓		
Sinopharm				pending		
Sinovac						✓

Evidence on protection against severe disease, hospitalization and deaths are especially limited

Performance against B.1.351 or 501Y.V2 (variant first identified in South Africa)

PRELIMINARY



Reduction of neutralizing activity in laboratory assays	Clinical efficacy in South Africa	Clinical efficacy in global studies	Clinical efficacy criteria
3x	-	95%	-
6x	-	94.1%	-
2.5-31x / eliminated ³	22% (NS) ²	62-90%	Mild & moderate
-	-	91.6%	-
pending	57%	72%	Moderate to severe
pending	49% ¹ 60% ²	89%	Mild, moderate & severe
1.6x	-	79 - 86%	-
-	-	50.4%	-

1. Including HIV positive subjects (6% of the study population); 2. Excluding HIV positive subjects; 3. previously infected placebo participants showed similar results

Sources South Africa: [J&J](#); [Novavax](#); [Moderna](#); [Pfizer](#) 1 & [Pfizer](#) 2; [AstraZeneca/Oxford](#); [Sinopharm](#) Sources global: 1. [The Lancet on AZ/Oxford](#), [The Lancet on Sputnik V](#), [Bloomberg on Sinovac](#), [Bloomberg on Sinopharm](#), [Novavax website](#), [J&J website](#)












Regulatory timeline of key Vx candidates

<https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-vaccines-within-who-eulpq-evaluation-process>

Legend (timing of approval)

- Approval / Emergency use
- Expected March 2021
- From April 2021
- No info
- COVAX Facility product

Estimated dates of approval / Emergency use

Vx candidates	FDA	MHRA	EMA	WHO EUL/PQ	Country reliance on PQ
 Pfizer BIONTECH  AZ with EMA as authority of reference  AZ South Korea w/ MFDS Korea as authority of record SII / AZ vaccine (Covishield) with DCGI India as authority of record	Dec. 12, 2020 Emergency Use	Dec. 2, 2020 Emergency Use	Dec. 21, 2020 Cond. Authorization ¹	Dec. 31, 2020 Emergency use	Since Jan
	April 2021 ²	Dec. 30, 2020 Emergency Use ³	Jan. 29, 2021 Cond. Auth. ¹ (non-Covax)	Between March and April 21 (Covax sites)	Between April and July 21 onwards
	Not applicable	Not applicable	Not applicable	Feb. 15, 2021 Emergency use	Since Feb
	-	-	-	Feb. 15, 2021 Emergency use	Since Feb
 Sinopharm / BIBP⁵				March 2021 (Earliest)	April 2021 onwards
 sinovac	No FDA approval		No EMA approval	March 2021 (Earliest)	April 2021 onwards
 moderna	Dec. 18, 2020 Emergency Use	Jan. 8, 2021 Emergency Use	Jan. 6, 2021 Cond. Authorization ¹	March 2021	April 2021 onwards
 Janssen Infectious Diseases & Vaccines	Feb. 27, 2021 Emergency Use		March 2021	March 2021	April 2021 onwards
 THE GAMALEYA NATIONAL CENTER				Rolling submission started from Gamaleya. CMC data awaited	
 康希诺生物 CanSinoBIO				Rolling submission of data from April 2021	April 2021 onwards
 Sinopharm / WIBP⁴					
 NOVAVAX *				Novavax submitted EOI on 23 Feb	

Key messages

- Pfizer:** WHO EUL on Dec. 31st with EMA as authority of record; ongoing country reliance on PQ
- AZ:** WHO EUL confirmed 15 Feb with MFDS (South Korea) as authority of record
- SII/AZ:** WHO EUL confirmed on 15 Feb with DCGI (India) as authority of record
- Focus on assessment of J&J, SinoPharm and Moderna.
- Gamaleya: only partial submission. CMC data awaited. Sinovac: additional data awaited.

*. SII/Novavax needs to be specified

1. Conditional marketing authorization 2. According to the chief adviser for the U.S. COVID-19 vaccine program (Dec. 30, 2020; [Source](#)) 3. Temporary authorisation of supply of the vaccine in the emergency use setting (which is distinct from a marketing authorisation) 4. Wuhan Institute of Biological Products Co Ltd 5. Beijing Bio-Institute of Biological Products Co-Ltd

SOURCE: https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_08Feb2021.pdf; <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/>

COVAX delivered vaccine doses to low- and middle-income countries faster than the H1N1 vaccine deployment initiative in 2010 and aims at delivering 25 times more doses

HIGHLY PRELIMINARY NUMBERS

Focus of discussion

Dimensions	Indicators		COVAX (March 2021)	H1N1 vaccine deployment Initiative	Difference
Breadth of participation	# of letter of intent		190	94	>2x
	# of recipients of doses		To be determined	77	To be determined
Funding	Total pledges, in mn USD		5,900	56	>100x
Time to 1 st dose	# of days after 1 st vaccination in HICs	First country	38 (India)	94	~2 months faster
		First country in Africa	78 (Ghana)	145	
		First 10 countries reached	Est. 90	149	
Vaccine doses ²	# of countries that received doses after	1 month ¹	>20	~4	4-5x
		2 months	Est. 50	13	
		3 months	142	29	
	Cumulative doses delivered after... (in Mn)	1 month	15.6 (at 12 days) 30+ (expected)	<1	>25x
		3 months	Est. 250	10	
		12 months	Est. 2,000	78	

2. Does not include the exceptional delivery of COVAX vaccines to India in January 2021 (10mn doses)

SOURCE: Report of the WHO Pandemic Influenza A (H1N1) Vaccine Deployment Initiative ([Link](#)); COVAX Facility supply forecast as of Jan 22, 2021 [Link](#)

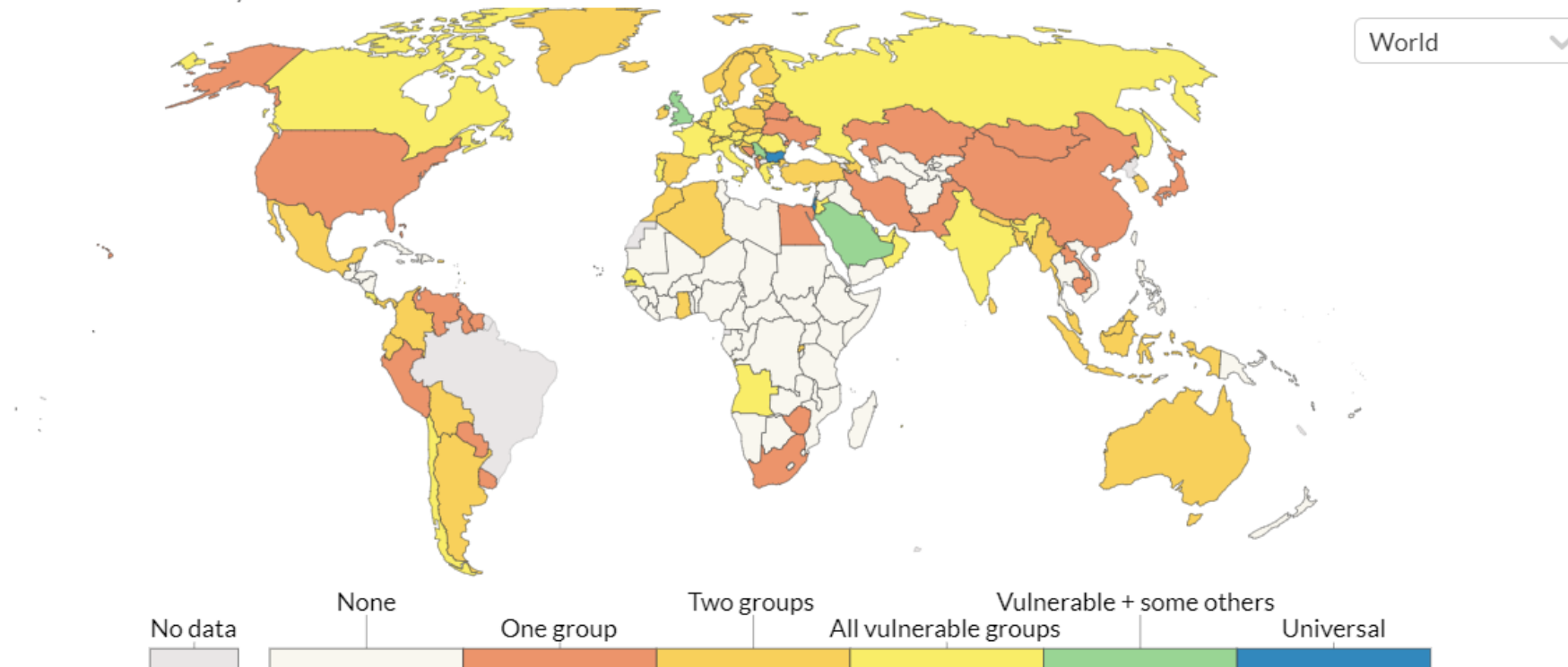
Overview of Covid-19 vaccination policies worldwide

COVID-19 Vaccination Policy, Mar 7, 2021

This metric records policies for vaccine delivery for different groups.

- Availability for ONE of following: key workers/ clinically vulnerable groups / elderly groups
- Availability for TWO of following: key workers/ clinically vulnerable groups / elderly groups
- Availability for ALL of following: key workers/ clinically vulnerable groups / elderly groups
- Availability for all three plus partial additional availability (select broad groups/ages)
- Universal availability

Our World
in Data



Source: Hale, Webster, Petherick, Phillips, and Kira (2020). Oxford COVID-19 Government Response Tracker – Last updated 8 March, 02:00 (London time)

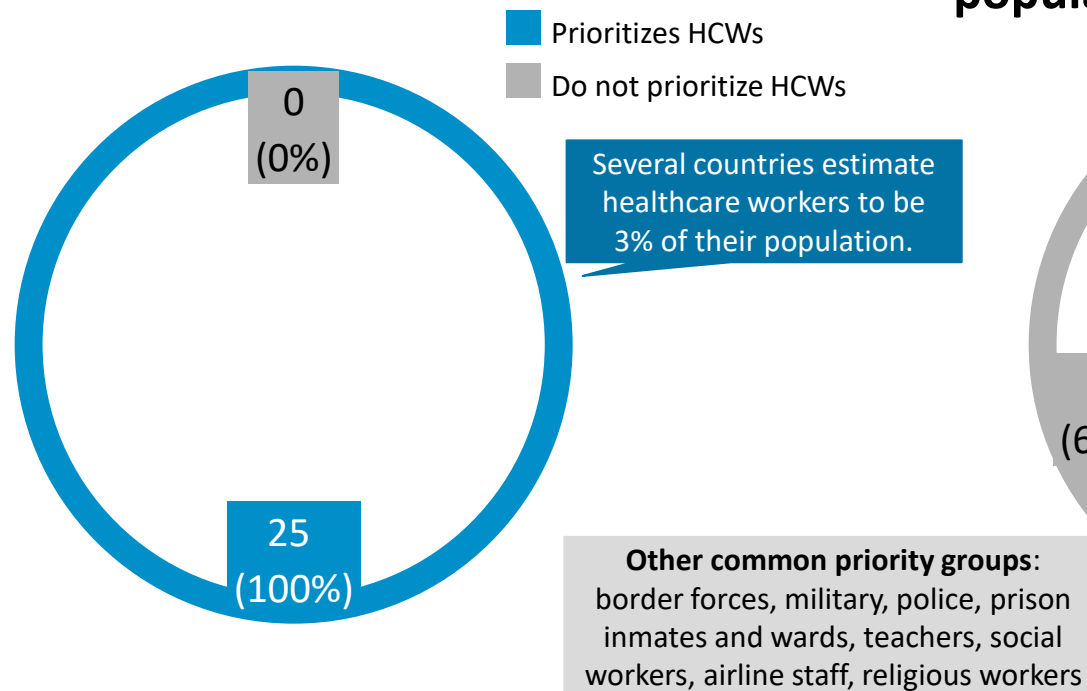
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SOURCE: Our World in Data

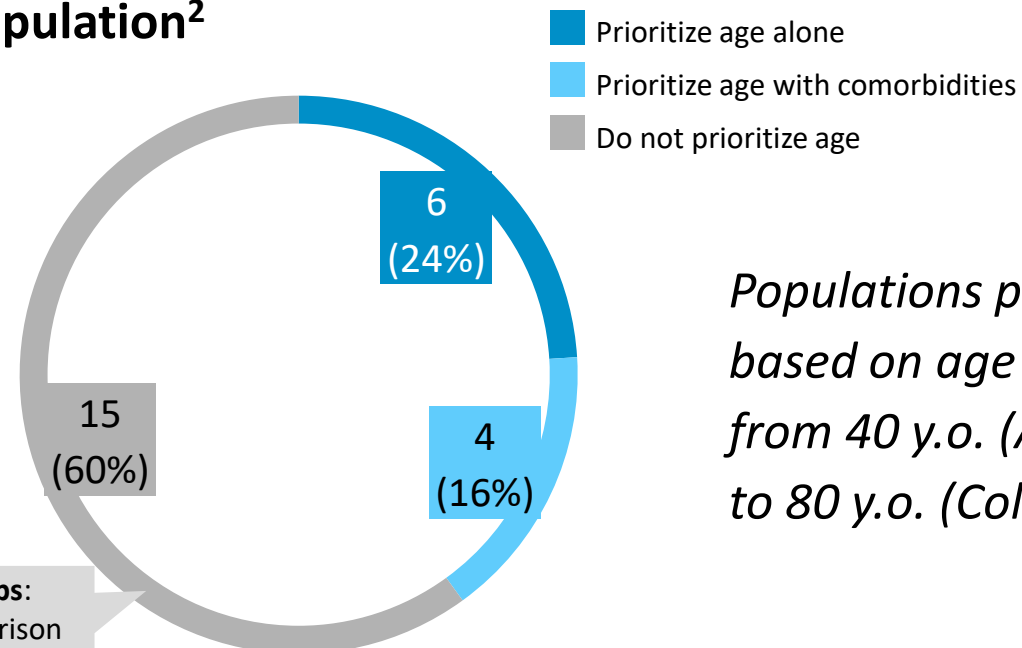
Zoom on prioritized populations in countries that already received COVAX doses (data at March 8)

Out of 25 countries with an NDVP that have received COVAX doses¹...

... 25 prioritize health care workers



... 10 prioritize based on age in the first 3% of population²



Populations prioritized based on age range from 40 y.o. (Angola) to 80 y.o. (Colombia)

1. At the time of writing, COVAX had shipped to 26 countries (excluding India). The figure shown here includes 25 countries due to no NDVP available for Republic of Korea; 2. 100% prioritize based on age in the first 20% of the prioritized population

WHO calls for urgent action to ramp up production of COVID-19 vaccines for all

*“One of our main priorities now is to increase the ambition of COVAX to help all countries end the pandemic. **This means urgent action to ramp up production.**”*

Dr Tedros Adhanom Ghebreyesus, DG of the WHO on March 5



WHO is working on 3 approaches :

1. **Connecting companies that produce vaccines with others that have excess capacity** to fill and finish them (e.g., partnership between Johnson & Johnson and Merck announced last week)
2. **Advocating bilateral technology transfers**, so that companies that own vaccine patents can license them to another company.
3. **Implementing a coordinated technology transfer** - whereby universities and manufacturers would license their vaccines and Knowhow to other companies through a global mechanism coordinated by WHO through Technology Transfer Hubs

How CSOs can continue helping COVAX

- **Contribute to aspects of programme delivery, where feasible**
 - **Support the vaccination of prioritized populations within countries**
 - **Support acceptance and uptake of vaccination:**
 - By supporting community leaders and their voices
 - By discussing the benefits and safety of vaccination with local communities
 - By promoting accurate information about vaccines
 - By advocating for fair and equitable access to vaccines
 - ... and any other locally tailored assistance
 - **Help to raise funds for COVAX**
- ... and other areas where CSOs and community representatives may support



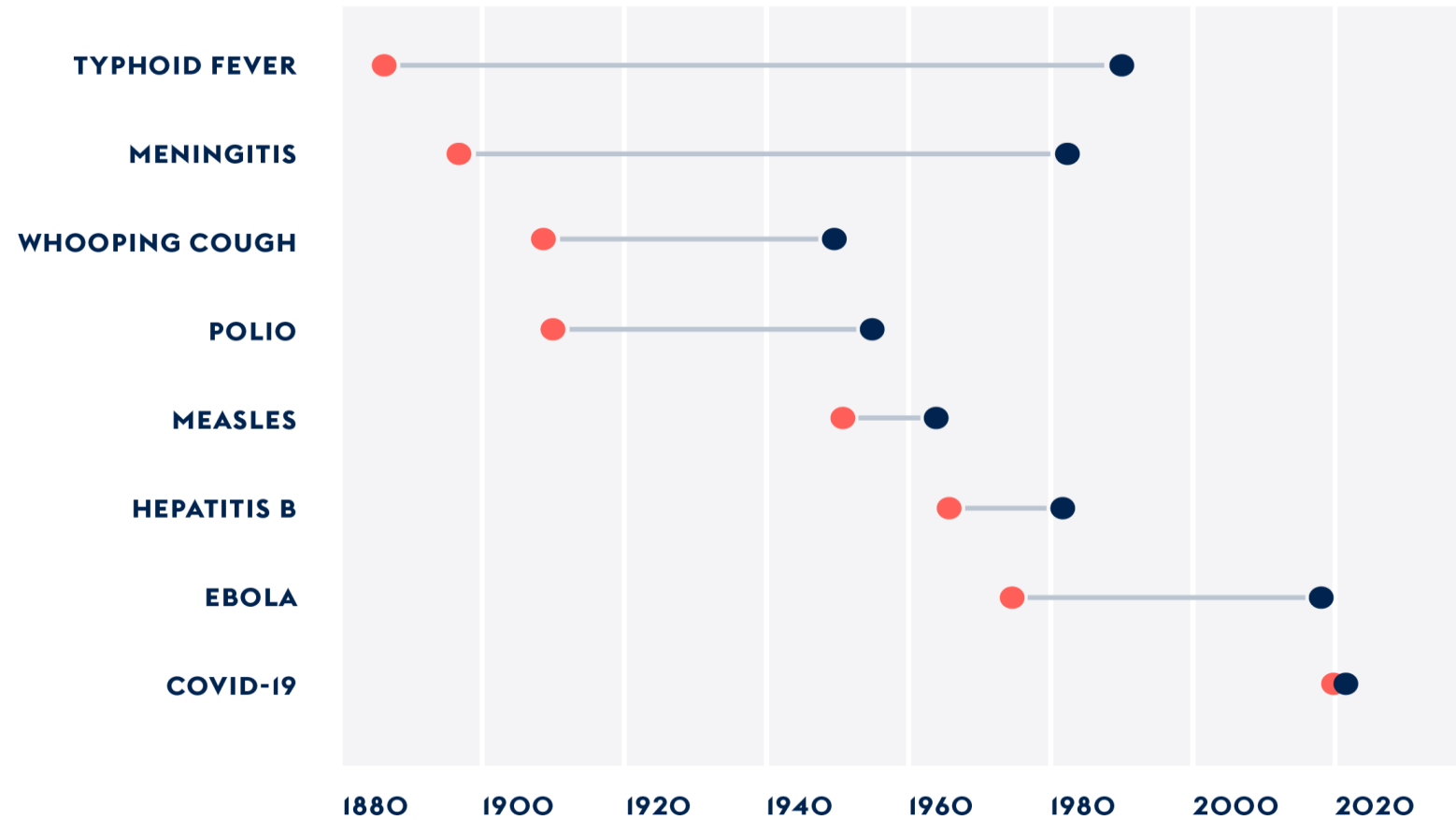
Vaccine pipeline: latest developments

Kristine Rose, Richard Wilder

CEPI

Rapid progress in vaccine innovation

● Year in which pathogen was linked to disease ● Year in which US vaccine was licensed



Data source: Our World in Data

CEPI's response to COVID-19

CEPI has moved quickly and collaboratively to rapidly develop vaccines against the COVID-19 virus.

We have so far invested ~1.2 USD Bn in the search for a COVID-19 vaccines, through **11 partnerships** where of 9 is still active.

Our ultimate goal is to develop vaccines against COVID-19 as quickly as possible, making **2bn** doses available by the end of 2021 through COVAX.

CEPI



COVAX R&D Wave 1 portfolio



COVID-19

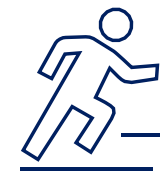
Adjuvants:



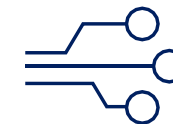
DYN/VAX

	Moderna	CureVac	Inovio	Novavax	Clover	Biological E	AZ/University of Oxford
Location	USA	Tubingen, Germany	Plymouth Meeting, USA	Maryland, USA	China	India	Cambridge, UK
Platform	mRNA (modified)	mRNA (unmodified)	DNA	Protein	Protein	Protein	Viral Vector
Antigen / Adjuvant	Full-length S protein /	Full-length S protein /	Full-length S protein /	Full-length S protein / Matrix-M (saponin-based)	Full-length S protein / AS03 and CpG	Monomer RBD / CpG-alum	Full-length S protein /
Current clinical phase	Phase III	Phase II/III	Phase II/III	Phase III	Phase I	Phase I	Phase III
Clinical trial sites	USA, JPN	DEU, BEL, PER, PAN, ARG, COL, DOM, FRA, MEX, NLD, ESP	USA, KOR, CHN	AUS, USA, MEX, PRI, ZAF, GBR	AUS, Phase II/III in multiple countries	IND	GBR, USA, BRA, ZAF, IND, BGD, RUS, TUR, PER, DEU, FRA, CZE, ITA, NLD, ESP
Expected 1 st efficacy data	Nov-20	Q1 21	Q1 21	Jan-21 (UK) Q2 21 (US)	Q3 21	Q3 21	Nov-20
Signed budget to date (\$ M)	0.90	15.28	21.95	414.53	327.78	4.96	205.15

+ CEPI has also supported SK Bioscience and Hong Kong University COVID-19 vaccine candidate as part of '**Wave 2**' investments



Speed



Scale



To deliver 2 billion doses by
the end of 2021, 2-3
successful programmes are
needed to:

- ① Produce early doses to support clinical studies
- ② Scale up processes to industrial scale before clinical trials begin
- ③ Scale-out products in different countries to expand capacity
- ④ Stockpile vaccines in bulk in anticipation of dose level definition
- ⑤ Anticipate projects failing during clinical development
- ⑥ Repurpose facilities for successful products, if needed

A world map illustrating global distribution points for COVID-19 vaccine manufacturing. The map features several orange circular icons containing black silhouettes of factories or pharmaceutical plants. These icons are distributed across six continents:

- North America:** One icon located in Mexico.
- South America:** One icon located in Brazil.
- Europe & Western Asia:** Multiple icons scattered throughout Spain, France, Germany, Italy, Turkey, and Russia.
- Middle East & Northern Africa:** Icons located in Egypt, Saudi Arabia, Iraq, Iran, India, China, and Japan.
- Southern Regions:** Two icons located in South Africa and one in Australia.

The background shows landmasses in light grey against a dark blue/black ocean background.

- Produce early doses to support clinical studies
- Scale up processes to industrial scale before clinical trials begin
- Scale-out products in different countries to expand capacity
- Stockpile vaccines in bulk in anticipation of dose level definition
- Anticipate projects failing during clinical development
- Repurpose facilities for successful products, if needed



CEPI is committed to enabling equitable access

CEPI's partnerships are supporting scale-out to different geographical sites and provides the COVAX Facility with the right of first refusal to procure potentially up to 1bn doses in 2021:

- AstraZeneca UK Limited (AZ), manufacture in Europe and Asia
- BioE, manufacture in India
- Clover, manufacture in China + potential tech transfer
- Novavax, manufacture in Europe and Asia
- SK BioSciences, manufacture in South Korea

CEPI has signed agreements with Biofabri (Spain) and GC farma (Republic of Korea) to reserve drug product manufacturing capacity for up to 1bn doses of CEPI-supported candidates

CEPI has also signed agreements with Dynavax to secure adjuvant in support of CEPI-supported candidates.

Source: https://cepi.net/wp-content/uploads/2020/12/Enabling-equitable-access-to-COVID19-vaccines_26Jan-2021.pdf

Emergence of new COVID-19 variants with increased transmission rates

❖ *At least five new variants of concern are spreading rapidly*

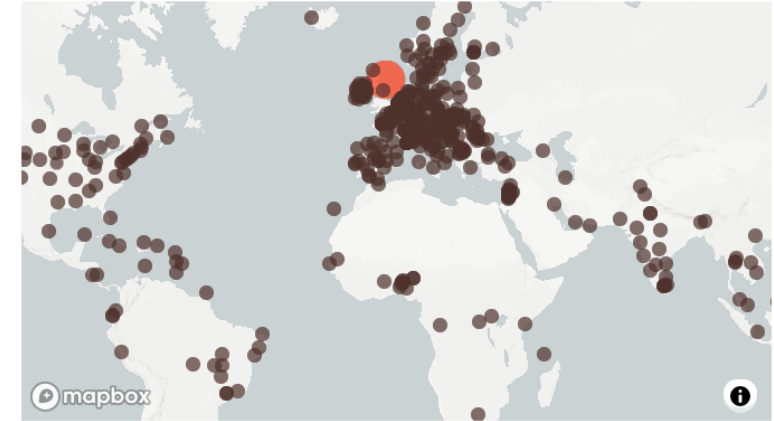
- By country of first identification: B.1.1.7 (United Kingdom); B.1.351 (South Africa); B.1.1.28.1 (Brazil); B.1.526 (U.S. – NY); B.1.427/B.1429 (US - CA)
- Resulting in increased stress on healthcare systems and need for more stringent nonpharmaceutical interventions to maintain control
- B.1.1.7 variant may result in more severe disease

❖ *Evidence suggests current vaccines may be highly effective in preventing death and hospitalization from all variants*

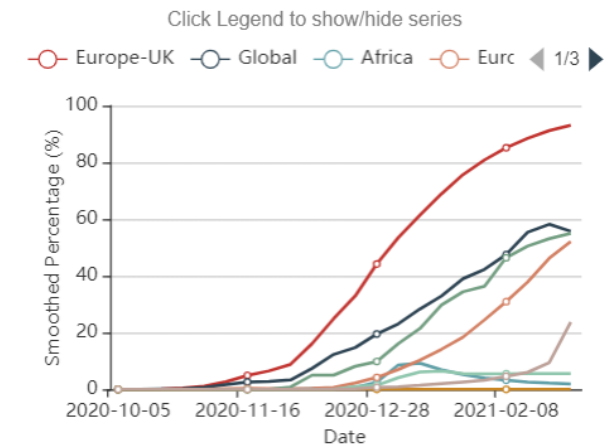
❖ *Some new variants can reduce effectiveness of vaccines and natural immunity's protection against symptomatic disease*

❖ There is an urgent need to develop vaccines for new variants (at risk), so sufficient doses are ready before a decision to introduce new vaccines is taken.

Map of tracked variant occurrence



Relative Variant Genome Frequency per Region (exponentially smoothed alpha=0.3)



Source: <https://www.gisaid.org/hcov19-variants/>

New variants are making future vaccine planning more complex

Options	Details	Considerations
Linear increase in coverage	<ul style="list-style-type: none">• Focus on maximizing production, distribution and coverage of existing vaccines• Clinical trials to expand the use of current vaccines (i.e. broaden immune response, special populations)	<ul style="list-style-type: none">• Viable option if one or more current vaccines is highly effective in preventing death and hospitalization from all variants• May not stop SARS-CoV-2 transmission long-term
Variant specific boosters & reformulation	<ul style="list-style-type: none">• Current vaccines may be reformulated to better address variants	<ul style="list-style-type: none">• Reformulated vaccine could be given as 1st dose or as boosters to already vaccinated• Similar to influenza vaccines, SARS-CoV-2 vaccines may need to be reformulated regularly
Boosters for waning immunity	<ul style="list-style-type: none">• Regardless of protection against variants, boosters may be needed for durable protection against infection or severe disease	<ul style="list-style-type: none">• Similar to booster doses against tetanus

COVAX R&D strategies to address challenges of SARS-CoV-2 evolution

Short term

❖ **Assessing new variants**

Agility project – partnership with GISAID, PHE and NIBSC to evaluate whether new variants compromise the effectiveness of current vaccines

Expanding CEPI central laboratory network to include variant neutralization assays

Refining animal models in CEPI Animal Model Network to assess vaccines designed to address variants

❖ **Optimizing current vaccines**

Extending protection afforded by current vaccines (adjuvants; HPB)

Clinical trials to support expanded use of current vaccines- ongoing call for proposals

❖ **Developing new vaccines**

Goal: Strain change, if needed, in 100 days from decision to proceed

Stepwise approach to funding developers to prepare, test, and manufacture vaccines against new strains

Work with Regulators to determine a strain change mechanism

Medium term

❖ **Fund candidates with additional antigen targets to be available by 2022 if needed**

❖ **Evaluate limitations in manufacturing capacity that pose a threat to delivery of vaccines for new variants; including raw materials**

Long term

❖ **Develop broadly protective beta coronavirus vaccines to better protect against existing and potential future coronavirus threats – Call for proposal by end of March**

COVAX Facility update and supply forecast

Sanne Wendes

Overview

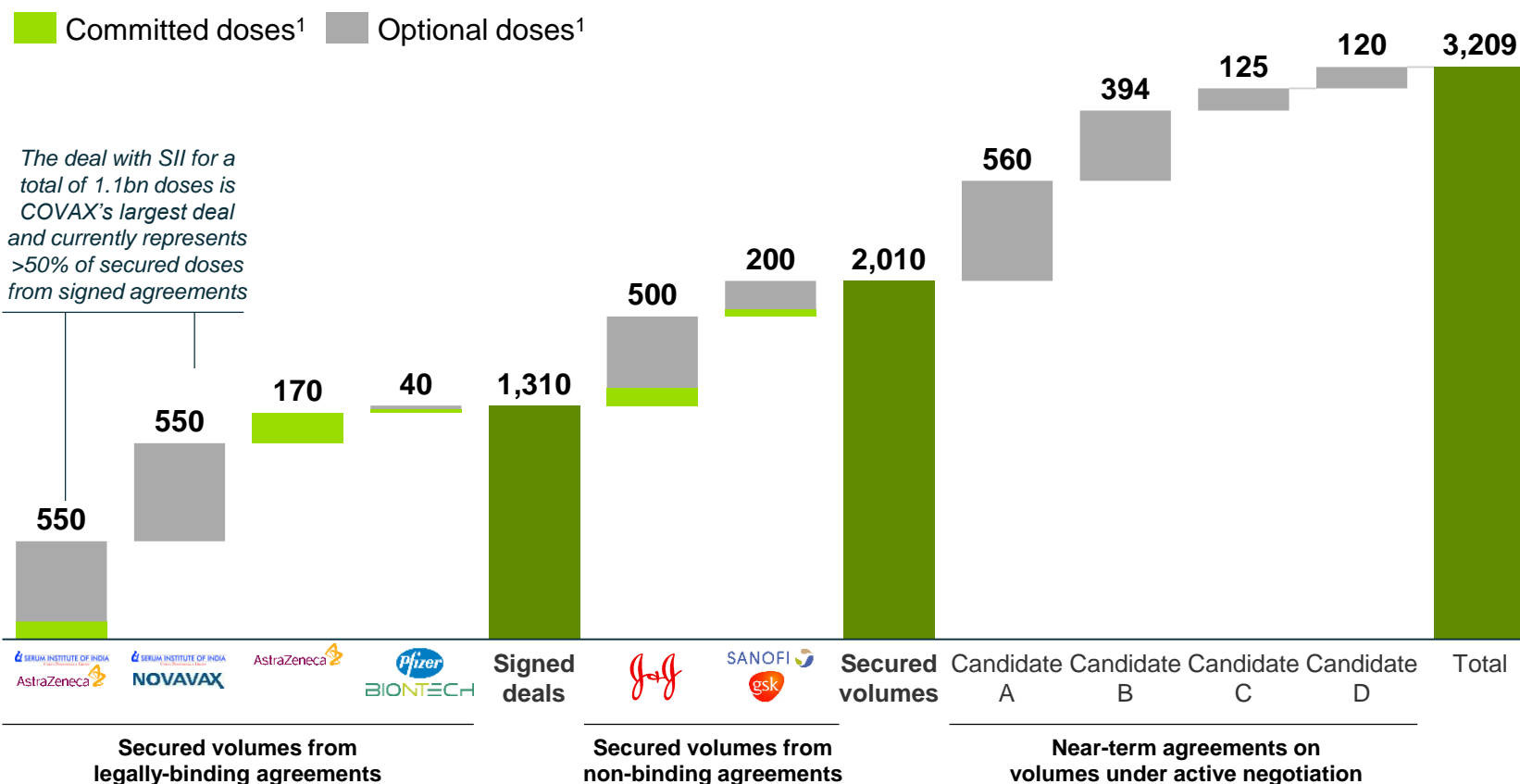
- ① COVAX Facility Updates
 - Supply & Deals
 - Delivery & Shipment
- ② COVAX Facility Design
 - Dose Sharing
 - Exchange
 - COVAX Buffer
- ③ Vaccine Candidate Decision Making
- ④ Country Readiness

COVAX Facility candidate-specific supply

2021 and 2022

PRELIMINARY

COVAX Available Supply, Mn doses, 2021 and 2022



There are 7 vaccines in the COVAX portfolio:

1. AstraZeneca: ChAdOx1-S [recombinant] ("AZD1222")
2. Novavax²: NVX-CoV2373
3. SII: Covishield ("AZD1222")
4. SII: Covovax ("NVX-CoV2373")
5. Pfizer: BNT162b2
6. Janssen J&J: Ad26COV2.S
7. Sanofi-GSK: Recombinant Protein

1 "Committed doses" are doses that the COVAX Facility is required to purchase once a legally-binding agreement has been signed. "Optional doses" are doses that the COVAX Facility has the option to make a firm order commitment for in the future, but is not required to purchase.

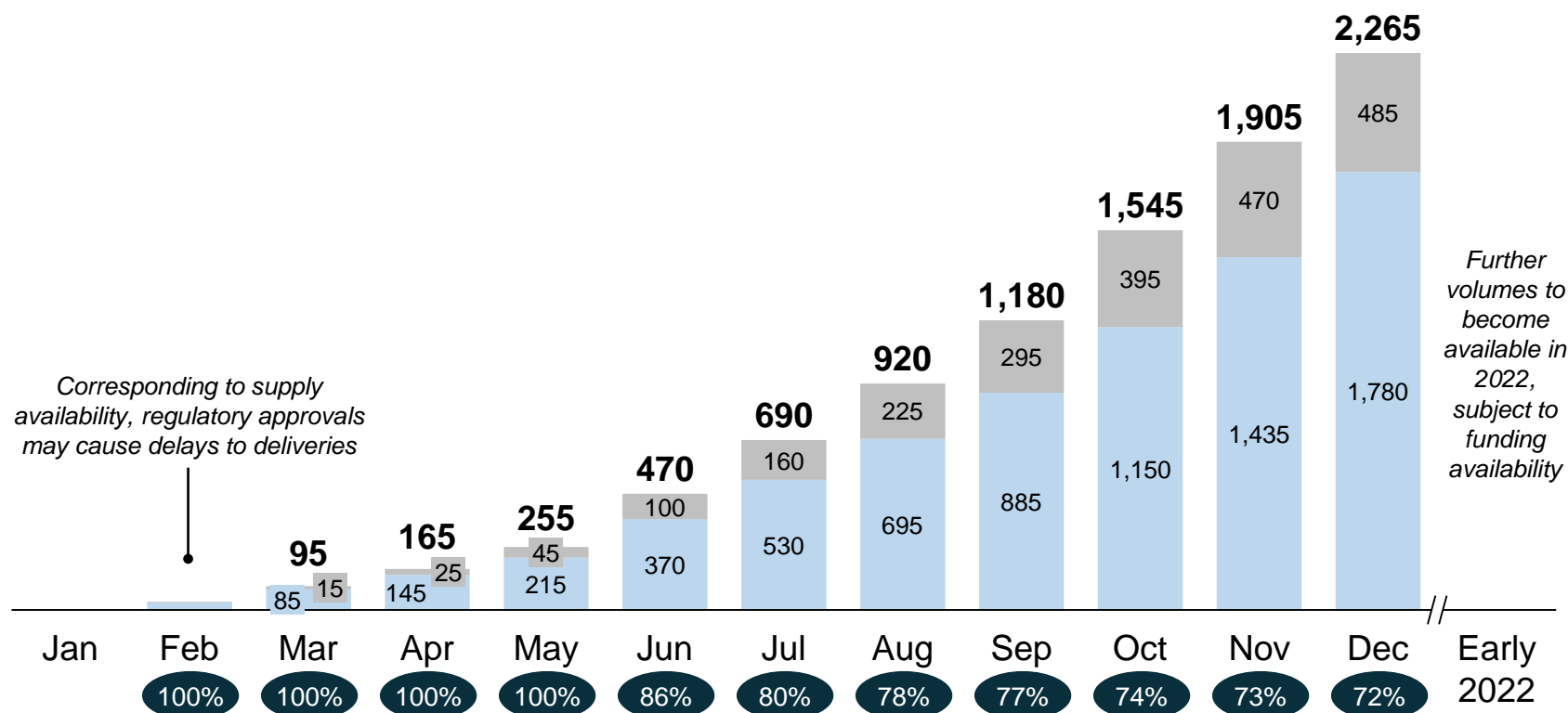
2 Building on the recently announced memorandum of understanding with Novavax, negotiations on the final terms of the agreement and the distribution of volumes between Novavax and the Serum Institute of India are ongoing; updates will be published in due course.

COVAX Facility global supply forecast (AMC/SFP)

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

COVAX Available Supply, Cumulative, Mn doses, 2021¹

AMC SFP X% % Secured volumes from signed agreements²



¹ Supply refers to volumes of vaccine available from the manufacturer. Timing of forecasts is based on anticipated release of doses from manufacturers. Volumes for expected single-dose regimen vaccine candidates doubled to ensure comparability across vaccine candidates. Volumes have been rounded to the nearest 5M, and so totals may not equal sum of segments.

² Signed agreements include legally-binding agreements, memoranda of understanding, and statements of intent.

CAVEATS

Contracts: Some of the supply included in the projections are linked to deals that are already concluded and some are currently being negotiated. Terms are subject to change.

Candidate attrition: Some candidates are still in clinical development. If they do not achieve positive clinical trial outcomes (safety and efficacy) and regulatory approval, these volumes will not be procured by COVAX.

Regulatory approval: Supply timing will depend on regulatory success and timelines, including reviews of individual batches ("batch release").

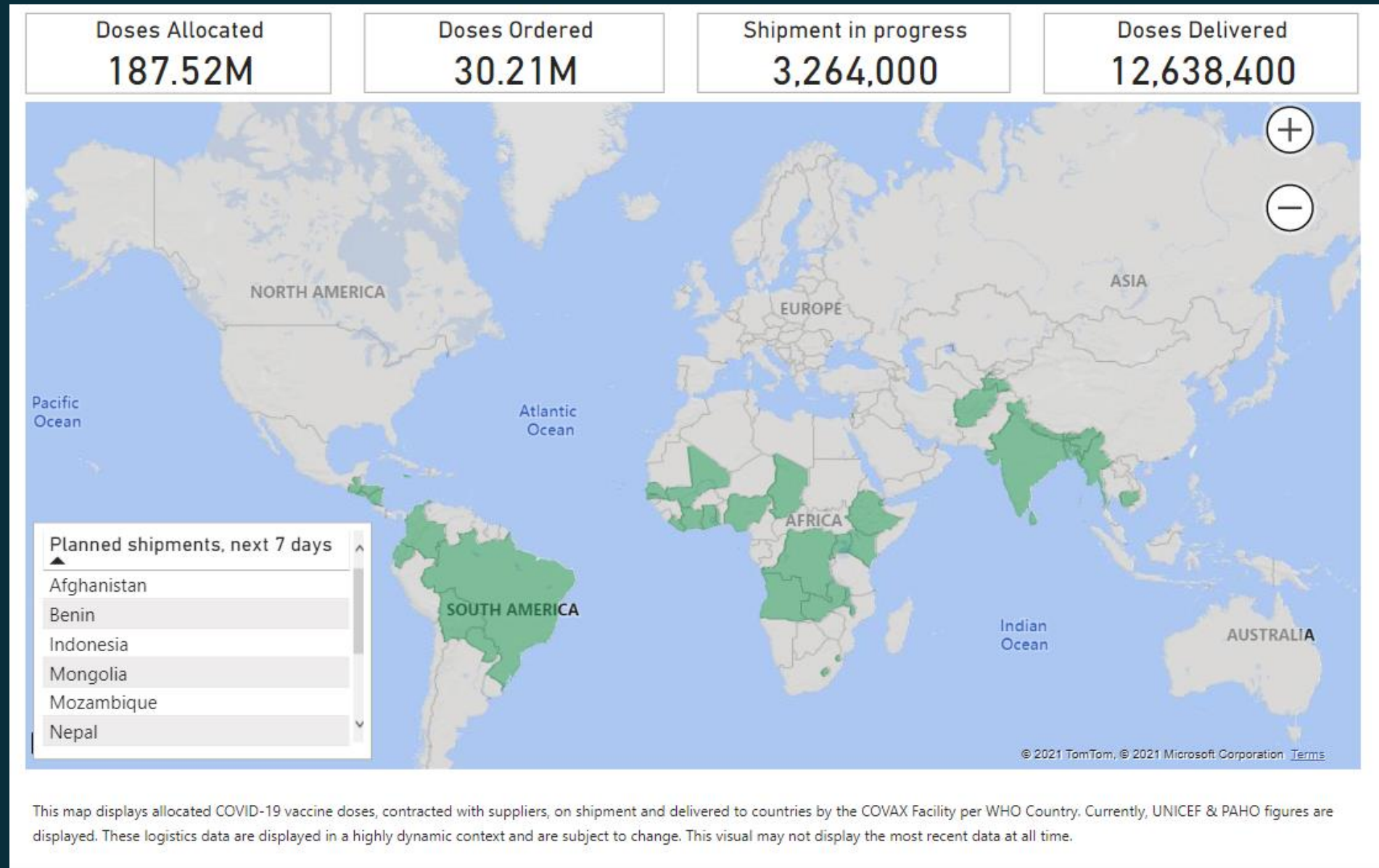
Manufacturing: In many cases, manufacturing is yet to reach full scale. Manufacturing productivity will be influenced by multiple factors, which will in turn influence volume and timing of supply.

Delivery: Timing of delivery will depend on various factors, including local regulatory approval, country readiness, logistics, indemnification and liability in place, in-country distribution etc.

Funding availability: Total potential supply is shown; procurement of these doses will depend on COVAX AMC fundraising, AMC92 cost-sharing beyond donor-funded doses, and the final prices and volumes of doses allocated to AMC92.

Allocation: These supply forecasts reflect a preliminary distribution of doses based on each participant's share of available supply pro rata by demand and are to be treated as indicative. Final timing and volumes will be determined by the WHO Allocation Mechanism.

12.6mn Doses Have Been Delivered and Another 30.2m Ordered



COVAX Exchange



Mechanism under development to:

provide participants with a platform through which to trade their allocated doses with each other

Through the Exchange, participants will be able to potentially improve upon their allocation

Product consistency: a participant trades to minimize the number of different vaccines and improve the performance of its vaccine programs.

Optimize preferences: a participant trades to increase access to a vaccine that it prefers.

(tbd) Temporal trade: a participant could trade current doses for future doses (to a time when they plan to expand their program)

Principles for the Exchange include:

- **Mutual Benefit**
- **Fairness**
- **Speed**
- **Validity**
- **Financial Neutrality**
- **Simplicity**

Dose sharing mechanism under development to bring additional doses to AMC Participants to supplement funded doses

Mechanism under development, and conversations with donors underway to share excess doses via COVAX

Dose sharing via COVAX will help to:

- **Accelerate coverage:** Shared doses enable COVAX to reach high-risk populations faster
- **Deepen coverage:** Shared doses expand coverage rates for recipients
- **Promote equity:** Shared doses leverage allocation mechanism for distribution to advance equity goals
- **Ensure efficiency and maximize benefits to countries:** Streamlined processes and preferential terms for, e.g., indemnity and liability; access to no fault compensation scheme

All shared doses will meet COVAX standards for safety and effectiveness, and will be channeled through relevant COVAX processes

Under development: A COVAX Buffer to act as last resort

Pending Gavi Board approval, 5% of COVAX Facility doses and COVAX AMC funding is proposed to:

1 Ensure access to COVID-19 vaccines for high-risk populations in humanitarian settings

National plans are the first resort for covering all high-risk groups



if unavoidable gaps in vaccination plans

Humanitarian Agencies to show **demonstrable gap** in coverage, **competence and experience** in delivering vaccination campaigns in humanitarian contexts, and ability to **reach target populations**

Humanitarian Buffer doses available only as a last resort



e.g. non-government controlled territories

2 Provide a contingency provision to enable an emergency release of doses to meet public health needs where normal vaccine allocation timelines may not be sufficient

- This mechanism is only considered relevant and appropriate once all COVAX Facility participants have been allocated an initial number of doses to ensure that all participating economies have established a **basic, equal level of coverage**

Indicative candidate pathway



IPG: Independent Product Group

PRG: Procurement Reference Group

MSDC: Market-Sensitive Decisions Committee

Criteria of country readiness



Ongoing and throughout: Countries work on preparing for vaccine, refining their NDVPs (including conducting pre-assessment checks), securing funding for vaccine delivery programme

104 Total NDVPs submitted for review through PP

86 AMC92 submitted

Discussion/Q&A

All

Thank you

FOR FURTHER INFORMATION...

COVAX Facility:

<https://www.gavi.org/covax-facility> and <https://www.gavi.org/vaccineswork>

COVID-19 vaccines:

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines>

Country readiness and delivery:

<https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery>

To sign up for our mailing list: CSO_COVAX@who.int