Re: Vaccines in Africa Memo Vol.1 no.1
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Memo: This memo is a product of the VacSafe Working Group, a group of leading scientists, vaccine and public health experts, and policymakers. Its purpose is to provide an informed overview on the state of SARS-CoV-2 vaccines in Africa (54 countries and 2 disputed territories) for use and reference by legislators. Data and information sourced for this briefing are drawn from reputable public sources.

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VacSafe Working Group

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Africa (54 countries 1 disputed territory)

1. SARS-CoV-2 Vaccination Status in Africa

- As of May 3, 2021, the Our World in Data vaccine tracker has reported that approximately 18 million doses of COVID-19 vaccines have been administered in Africa.

- The editorial team is in the process of creating an interactive map that cross-references several datasets to produce meaningful indices about vaccine manufacturing, acquisition, distribution, and take-up in Africa. Please see the Appendix (Fig. 1) below to find a static picture of what this will look like, with South Africa as an example. The Appendix also includes an annotated list of referenced data sets.

2. Emerging Variants

- Multiple variants of the virus that causes COVID-19 are circulating globally. In collaboration with a SARS-CoV-2 Interagency Group (SIG), US CDC established three classifications for the SARS-CoV-2 variants being monitored: Variant of Interest (VOI), Variant of Concern (VOC), and Variant of High Consequence (VOHC).

- There are currently five VOCs in the United States

- B.1.1.7: initially detected in the UK.
- B.1.351: initially detected in South Africa in December 2020.
- P.1: initially identified in travelers from Brazil, in early January 2021.
- B.1.427 and B.1.429: first identified in California in February 2021 and classified as VOCs in March 2021.

- As of April 28th, 2021 there were two VOCs known to be circulating in Africa – B.1.1.7 and B.1.351.

3. Vaccine Efficacy, Safety, and Approval

- Moderna - WHO Emergency Use Listing.
- Oxford-AstraZeneca (Covishield) - Africa Regulatory Taskforce (ART) approved, WHO Emergency Use Listing – approved in 25 African countries.
- Pfizer-BioNTech - WHO Emergency Use Listing – approved in Rwanda, Tunisia and South Africa.
- Sinopharm - BBIBP-CorV - approved in 15 African countries.
- Sinovac (CoronaVac) - approved in Egypt, Tunisia and Zimbabwe.
- Bharat Biotech (Covaxin) - approved in Botswana and Zimbabwe.
- Gamaleya Institute (Sputnik V) - approved in 10 African countries.
- Janssen/Johnson & Johnson (Ad26.COV2.S) - WHO Emergency Use Listing and approval in Tunisia, South Africa, and Zambia.

4. Continental Vaccine Acquisition

- With a population of 1.24B, Africa is dependent on three vaccine sources: (1) the WHO's COVAX scheme (co-led with the Global Alliance for Vaccines and Immunization (GAVI) and Coalition for Epidemic Preparedness Innovations (CEPI)); (2) the African Union (AU) via the African Vaccine Acquisition Trust (AVAT); and (3) bilateral agreements with pharmaceutical companies and/or vaccine producing countries and donation agreements.

- COVAX:
    - 600M doses have been secured for 36 African countries. The timeline for delivery of these vaccines remains uncertain. Bans on the export of the Oxford-AstraZeneca vaccine, delays in production at the Serum Institute in India, and cold-chain storage challenges have already contributed to delays.
- African Union via AVAT:
    - Oxford-AstraZeneca: procurement paused as of April 8th, 2021.
    - Johnson & Johnson: 220M doses with option of extending to purchase a further 180M (~$10 per dose).
    - Oxford-AstraZeneca, Johnson & Johnson, Pfizer-BioNTech: in January AU agreed to purchase a combined total of 270M doses of these three vaccines.
    - Gamaleya Institute (Sputnik V): 300M doses at $9.75 price per dose.
- Significant Bilateral Vaccine Purchases & Vaccine Diplomacy:
    - Egypt: 50M doses of Sputnik V.
    - South Africa: 31M J&J and 30M Pfizer-BioNTech.
    - China Vaccine Donations to African States (to date): ~1M doses to ~8 African countries.
    - Russia Vaccine Donations: >1M doses of Sputnik V to 3 African countries (Algeria, Guinea, and Zimbabwe).

5. Vaccine Fill & Manufacturing

- Current vaccine manufacturing capacity in Africa is limited and focused on internal markets; there is an absence of large-scale production at present and limited export of vaccine products.
- The continent uses roughly 25% of the annual global vaccine supply (representing approximately 1.3B doses). 99% of those doses are imported.

- The African Union and Africa CDC launched the *Partnership for African Manufacturing Framework*. This framework, which includes a partnership with CEPI, could see Africa's manufacturing increase from meeting the vaccine needs of less than 1% of the continent's population to 60% by 2040.

- According to a recent UK AID report, there are currently only 10 players in vaccine manufacturing on the continent. These manufacturers collectively produce about 12M doses per annum. Appendix Figure 2 gives more detail on the vaccine profile covered as well as actual and planned activities in key areas of the vaccine value chain, based on the information contained in the report.

- The majority of Africa's vaccine manufacturing capacity is concentrated on fill-finish and packaging and labeling. South Africa's Biovac is currently developing its manufacturing capacity. However, at the current rate, Biovac's vaccine production will not begin for 12-24 months and will be limited to approximately 30M doses per year.

- At present, there are no facilities in Africa that have capacity to produce RNA or vector-based vaccines.

6. Vaccine Distribution

- COVAX has initiated three rounds of vaccine allocation to participant countries (See Appendix Table 1 for country-level allocation in AFRO region).

    - The first round of allocation was announced in early February and outlined an exceptional distribution of 1.2M doses of the Pfizer-BioNTech vaccine; distribution of these doses took place during Q1 of 2021.

    - The second round of allocation covered 237M doses of the Oxford-AstraZeneca (COVISHIELD) vaccine. Many of these doses are being manufactured by the Serum Institute in India. Distribution was intended to be completed in May, but rising COVID-19 cases in India and bans on the export of the Oxford-AstraZeneca vaccine have caused significant delays.

    - The third round of allocation covered 14.1M doses of the Pfizer-BioNTech vaccine. Distribution will take place between April and June 2021.

- Cold-chain storage requirements remain a significant challenge in distributing the Pfizer-BioNTech vaccine.

- Distribution of 220 million single-dose Johnson & Johnson vaccines secured by the AU through the African Vaccine Acquisition Task Team (AVATT) will take place across 18 months. Distribution will be facilitated by the African Medical Supplies Platform (AMSP) The contract includes an option to purchase an additional 180M doses (see section 4).

- UNICEF is partnered with GAVI to aid in vaccine distribution and procurement. As the single largest buyer of vaccines in the world, UNICEF is leveraging its experience and partnerships to help with procurement, shipping, and storage of COVID-19 vaccines.

- GAVI, partnered with UNICEF, leads the procurement and delivery arm of COVAX.

- CEPI works on the R&D front of COVID-19 vaccines. CEPI has made significant investments in vaccine manufacturing capacity and is investing in the next generation of COVID-19 vaccines, which have the potential to minimize reliance on cold-chain storage. Reducing reliance on cold-chain storage will make delivery and distribution of future vaccine candidates in Africa significantly easier.

7. Vaccination Licensing Issues/IP/tech transfer

- Vaccine Intellectual Property

    - As of June 2020, AstraZeneca, CEPI, and GAVI have entered into a voluntary licensing agreement with the Serum Institute of India (SII) facilitating IP transfers and the production of a not-for-profit vaccine.

    - On October 16, 2020, South Africa and India launched proceedings with the World Trade Organization's Trade-Related Aspects of Intellectual Property to temporarily suspend IP rights for COVID-19 vaccinations. Europe, Britain and Japan oppose the petition. Proceedings are ongoing.

    - The newly appointed Director-General of the WTO, Dr Ngozi Okonjo-Iweala, endorsed voluntary pharmaceutical licensing in April. "There is some capacity in developing countries unused now. Let's have the same kind of arrangement that AstraZeneca has with the Serum Institute of India … Novavax, J&J and all the others should follow suit" she said to the BBC.

- Technological Transfer

    - There are currently nine technology platforms for designing and making COVID 19 vaccines: (1) live attenuated virus; (2) inactivated virus; (3) non-replicating viral vector; (4) replicating viral vector; (5) recombinant protein; (6) peptide based; (7) virus-like particle; (8) DNA; and (9) RNA. The COVID-19 vaccines currently approved for use are based on technologies 2, 3, 6 and 9 as listed previously.

    - South Africa's Aspen Pharmacare signed an agreement to transfer J&J vaccine technology for the final stage of production, fill and finish, at their Nelson Mandela Bay plant in the Eastern Cape. The J&J vaccine is made using a non-replicating adenovirus vector.

    - Algeria announced that the country will be producing the Russian vaccine Sputnik V as of September 2021. Sputnik V uses a method very similar to J&J where genetic information is ferried to its destination by a non-replicating adenovirus. It is not clear what the extent of technology transfer is.

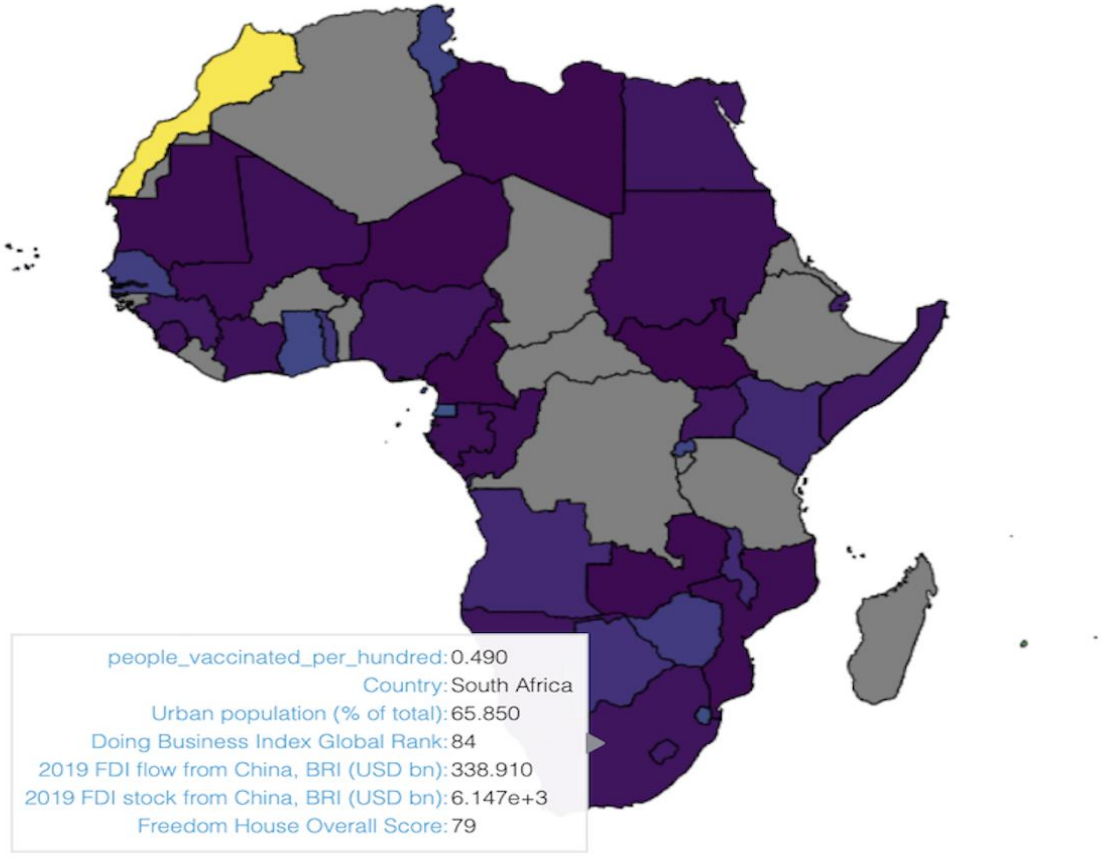
    - No African country is yet producing RNA vaccines. The leap in technology required to scale Africa's vaccine manufacturing capacity to accommodate RNA-based technologies will require significant investment in technology and expertise.

    - At the recent *Partnership for African Manufacturing Framework* meeting, the Africa CDC laid out plans to establish vaccine manufacturing hubs in each of its five regions. In each instance, major barriers to technology transfer - particularly investment, technical skills, and infrastructure - must be overcome.

    - In a recent Foreign Affairs article, the authors argue that major international organizations like GAVI and CEPI, national governments, and private companies must work collectively to take advantage of the "medical miracle" RNA vaccines provide.

Appendix – Data Tables and Referenced Datasets

Figure 1: Static Image of Interactive Map Currently Under Development by Editorial Team



Datasets Referenced in Map

- Our World In Data COVID vaccine tracker aggregates a number of different sources of data on the vaccination situation across the world, and is a starting point for understanding the vaccine situation globally, including in Africa.
- Johns Hopkins SAIS China Africa Research Initiative provides a breakdown of Chinese foreign direct investment into the African continent. This is a proxy for where China's interests in the continent lie, and where there may be opportunities for further vaccine diplomacy.
- Our World In Data urbanization report aggregates estimates from the UN World Urbanization Prospects group on the proportion of population living in urban areas. This

is a proxy for centralization of infrastructure and thus the relative challenge of vaccine distribution.

- Freedom House Freedom in the World report measures the condition of political rights and civil liberties across the world. This may help policymakers identify relationships between oppressiveness of governments and vaccine uptake.
- World Bank Group's Doing Business index provides objective measures of business regulations for local firms in 190 economies. This helps inform both the local level of economic development and also the potential for local firms to participate in the distribution effort.

Figure 2: Africa's Vaccine Value Chain Entities and Status

Africa's vaccine value chain players by value chain step[5] ✓ Current ✓ Planned
2020, total = ~10

Manufacturer	Products	R&D	Drug substance mfg	Fill & finish	Pack & label	Import for distribution
Institut Pasteur Dakar	Yellow Fever		✓	✓	✓	
Egy Vac (Vacsera)	BCG-T, Tuberculin, Tetanus, DTP, Typhoid, Cholera			✓	✓	
Institut Pasteur Tunis[2]	BCG		✓	✓		
Biovac	BCG[6], Measles[6], Pneumococcal conj.[3], Hepatitis B[3], Hexavalent Vaccine[7]		✓	✓	✓	✓
Aspen Pharmacare	Covid-19 candidate			✓	✓	
Institut Pasteur Morocco	BCG, DT, Yellow Fever, Typhoid Fever, Influenza, Rabies					✓
EPHI: Eth Public Health Institute	Plan to produce vaccines[4]		✓		✓	✓
Biovaccines	Plan to produce Hep-B Plan to produce Tetanus Plan to produce DTP+Hep-B Plan to produce Yellow Fever Plan to produce Measles		✓		✓	
Innovative Biotech	HIV	✓				
Institut Pasteur Algeria	Rabies		✓			✓

Source: *Expanding vaccine manufacturing in Africa* (February 2021), Great for Growth: UKAID

Table 1: To-date COVAX Allocation of Vaccine Doses in WHO AFRO Region by Country and Manufacturer

Participant	Region	SFP/AMC	Round 1: Pfizer/BioNTech (Exceptional Distribution, Q1 2021)	Round 2: AZ & SII/AZ (Feb - May 2021)		Round 3: Pfizer/BioNTech (April - June 2021)
Algeria	**AFRO**	AMC	-	1,881,600	AZ	-
Angola	**AFRO**	AMC	-	2,172,000	SII/AZ	100,620
Benin	**AFRO**	AMC	-	792,000	SII/AZ	-
Botswana	**AFRO**	SFP	-	100,800	AZ	19,890
Burkina Faso	**AFRO**	AMC	-	1,380,000	SII/AZ	-
Cabo Verde	**AFRO**	AMC	5,850	108,000	SII/AZ	-
Cameroon	**AFRO**	AMC	-	1,752,000	SII/AZ	-
Central African Republic	**AFRO**	AMC	-	312,000	SII/AZ	-
Chad	**AFRO**	AMC	-	1,080,000	SII/AZ	100,620
Comoros	**AFRO**	AMC	-	108,000	SII/AZ	-
Congo, Dem. Rep.	**AFRO**	AMC	-	5,928,000	SII/AZ	-
Congo, Rep.	**AFRO**	AMC	-	360,000	SII/AZ	-
Cote d'Ivoire	**AFRO**	AMC	-	1,740,000	SII/AZ	100,620
Eswatini	**AFRO**	AMC	-	108,000	SII/AZ	-
Ethiopia	**AFRO**	AMC	-	7,620,000	SII/AZ	-
Gambia, The	**AFRO**	AMC	-	156,000	SII/AZ	-
Ghana	**AFRO**	AMC	-	2,052,000	SII/AZ	-
Guinea	**AFRO**	AMC	-	864,000	SII/AZ	-
Guinea-Bissau	**AFRO**	AMC	-	120,000	SII/AZ	-
Kenya	**AFRO**	AMC	-	3,564,000	SII/AZ	-
Lesotho	**AFRO**	AMC	-	132,000	SII/AZ	-
Liberia	**AFRO**	AMC	-	324,000	SII/AZ	-
Malawi	**AFRO**	AMC	-	1,260,000	SII/AZ	-
Mali	**AFRO**	AMC	-	1,332,000	SII/AZ	-
Mauritania	**AFRO**	AMC	-	300,000	SII/AZ	-
Mauritius	**AFRO**	SFP	-	100,800	AZ	-
Mozambique	**AFRO**	AMC	-	2,064,000	SII/AZ	-
Namibia	**AFRO**	SFP	-	108,000	AZ	-
Niger	**AFRO**	AMC	-	1,596,000	SII/AZ	-
Nigeria	**AFRO**	AMC	-	13,656,000	SII/AZ	-
Rwanda	**AFRO**	AMC	102,960	744,000	SII/AZ	100,620
Sao Tome and Principe	**AFRO**	AMC	-	96,000	SII/AZ	-
Senegal	**AFRO**	AMC	-	1,104,000	SII/AZ	-
Sierra Leone	**AFRO**	AMC	-	528,000	SII/AZ	-
South Africa	**AFRO**	SFP	117,000	2,426,400	AZ	1,275,300
South Sudan	**AFRO**	AMC	-	732,000	SII/AZ	-
Togo	**AFRO**	AMC	-	540,000	SII/AZ	100,620
Uganda	**AFRO**	AMC	-	3,024,000	SII/AZ	-
Zambia	**AFRO**	AMC	-	1,212,000	SII/AZ	-
Zimbabwe	**AFRO**	AMC	-	984,000	SII/AZ	-
non-UN Member Sates	-	-	-	1,125,600	AZ	-

Source: COVAX -- 'Allocation Round 3: Pfizer-BioNTech Vaccine, April - June 2021' (12 Apr 2021)

KEY:

SFP - Self-Financing Participant | AMC - Advance Market Commitment | AZ - AstraZeneca | SII - Serum Institute of India

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