Re: Vaccines in Africa Brief for Congressional Research Services (CRS)
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Brief: This report 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) with a view to inform US legislators. This briefing comes as the Omicron variant has arisen and become dominant in southern Africa, bringing the region into global attention. Africa continues to face vaccine shortages and distribution challenges. Information included in this briefing is drawn from private and public sources. For broader context, refer to earlier installments of the Vaccines in Africa Brief.

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Africa (54 countries 2 disputed territories)

1. SARS-CoV-2 Vaccination Status in Africa

The Our World in Data vaccine tracker reported that as of December 4, 2021, a total of 246.25million vaccine doses have been administered across the entire African continent. 7.48% of the population has been fully vaccinated, with 3.82% given at least one dose. This brings to a total of a total of 11.30% share of people vaccinated against COVID-19.

According to Our World in Data vaccine tracker as of December 4, 2021, the three best countries by share of people vaccinated are Seychelles (83%), Mauritius (72%) and Morocco (66%). The three lowest are Burundi (0.01%), DR Congo (0.15%) and Chad (1.1%).

The B.1.1.529 Omicron variant has raised attention as it overtakes the Delta variant in southern Africa, and is now in at least 23 countries and continues to appear in different parts of the world. The Omicron variant has more mutations than the Delta variant, leading to higher transmissibility and vaccine-induced antibody evasiveness. However, there is still more information that needs to be gathered to determine severity of illness, particularly in individuals who have developed immunity either from vaccines or past infections.

2. Vaccine Efficacy, Safety, and Approval (as of November 29, 2021)

- Moderna - WHO Emergency Use Listing and approved in Botswana, Egypt, Ghana, Kenya, Libya, Nigeria, Rwanda and Seychelles.
- Oxford-AstraZeneca (Covishield) - Africa Regulatory Taskforce approved, WHO Emergency Use Listing and approved in 35 African countries.
- Serum Institute of India (licensed to produce and sell the Oxford-Astra-Zenca Covishield vaccine) - Africa Regulatory Taskforce (ART) approved, WHO Emergency Use Listing and approved in 14 African countries.
- Pfizer-BioNTech - WHO Emergency Use Listing, FDA approval and approved in Botswana, Cabo Verde, Egypt, Gabon, Kenya, Libya, Nigeria, Rwanda, South Africa and Tunisia.
- Sinopharm - BBIBP-CorV - WHO Emergency Use Listing and approved in 24 African countries.
- Sinovac (CoronaVac) - WHO Emergency Use Listing and approved in Algeria, Benin, Egypt, South Africa, Tanzania, Togo, Tunisia and Zimbabwe.
- Bharat Biotech (Covaxin) - approved in Mauritius and Zimbabwe.
- Gamaleya Institute (Sputnik V) - approved in 19 African countries.
- Gamaleya Institute (Sputnik Light) – approved in Angola, Egypt, Mauritius, Republic of Congo, and Tanzania.
- Janssen/Johnson & Johnson (Ad26.COV2.S) - WHO Emergency Use Listing, Africa Regulatory Taskforce approved and approved in Egypt, Gabon, Ghana, Kenya, Liberia, Libya, Madagascar, Malawi, Nigeria, Senegal, South Africa, Sudan, Tanzania, Tunisia, Zambia and Zimbabwe.

3. Continental Vaccine Acquisition

Africa CDC and the Mastercard Foundation announced that 15.2 million vaccines purchased under the Saving Lives and Livelihoods initiative are being distributed across Africa. Over 3.3 millions of J&J doses arrived in Nigeria. This is the first batch of vaccines to be delivered under the initiative, and the vaccines will be distributed by UNICEF. Under this initiative and negotiated by AVAT, there was a purchase of 400 million Johnson & Johnson vaccines, and also a recent purchase of 50 million Moderna vaccines from earlier this year.

With the new emerging B.1.1.529 Omicron variant, BioNTech has said that it would be testing and tweaking the current vaccine. Candidates with three existing doses would be tested against the Omicron variant, and a new variant-specific booster would be developed as needed. Scientists are concerned if this version of the virus would be the "escape variant."

Chinese president Xi Jinping pledged to donate 1 billion vaccine doses to Africa, and encouraged Chinese companies to invest no less than $10 billion to Africa over the next three

years. In the US, President Biden made a statement saying that the US mas made more vaccine donations than every other country combined, and calls for everyone to be donating.

In light of China pledging to donate another billion doses, African countries say they no longer want "ad hoc donations with little notice and short shelf lives", demanding that donated doses should have a minimum of 10 weeks shelf life when they arrive. In a joint statement issued by the AU member states, it says that the short shelf lives of donations so far have "[...] made it extremely challenging for countries to plan vaccination campaigns and increase absorptive capacity."

These claims have not been made for the first time: In June 2021, Zimbabwe turned down three million doses of the J&J single-dose vaccine due to lacking storage capacities.

4. Vaccine Distribution

South Sudan has struggled to improve COVID-19 vaccine distribution. South Sudan's people believe that flooding, hunger and malaria are the biggest problem they face. There is acknowledgement that the pandemic exists, however, COVID-19 related deaths are simply not visible. As a result, vaccine information communicated to the population has little effect if the population does not believe that the pandemic is a major problem in their lives.

The national government of Kenya announced that residents need to bring proof of COVID-19 vaccination to access services by December 21. Although this has been welcomed by some businesses, due to the low vaccination rates, this may seem unrealistic.

As South Africa faces the fourth wave of COVID-19 with the Omicron variant, there are still struggles with the vaccine access in southern Africa, which South African president Cyril Ramaphosa says is "vaccine apartheid."

5. Vaccine Fill & Manufacturing

The African continent has been let down by the unequal international Covid-19 vaccine distribution system. The rise of the Omicron variant shows again that Africa has to take matters into their own hands. Although vastly under-reported by the media, a critical agenda has been taking shape for African countries to become independent in their vaccine development and -manufacturing abilities. On December 6th and 7th, Rwanda's President Kagame hosted the Partnership for Africa Vaccine Manufacturing meeting in Kigali. In the meeting the two key elements were pointed out: Self-reliance in development and manufacturing of life-saving technologies, and the importance of pan-African collaboration.

With their $500 million US Dollar investment plan, the Moderna factory is just one of the U.S.-backed vaccine manufacturing initiatives in Africa. In partnership with France and Germany, the U.S. government in June announced a 600 million euro investment enabling the South African firm Aspen Pharmacare Holdings Limited to produce Johnson & Johnson vaccine. The U.S. government, along with African and European development partners, also aids the Institut Pasteur de Dakar to increase production of vaccines in Senegal.

Pfizer confirmed their "fill and finish" deal with South Africa's Biovac Institute on Monday December 6th. Receiving the drug substance from Europe, production for the Pfizer-BioNTech COVID-19 vaccine is set to start in early 2022.

WHO Director-General Ghebreyesus addressed the situation at the Stakeholder Engagement Event and acknowledged the progress that had been made so far on implementing the partnerships for vaccine manufacturing in Africa. He specifically cited the following developments:

- The start of the Africa Medicines Agency treaty.
- The formal commitment of Egypt, Morocco, Rwanda, Senegal, and Algeria to COVID-19 vaccine manufacturing.
- The WHO-led establishment of an mRNA technology transfer hub in South Africa and a vaccine industry talent development program
- The coordinated development of local manufacturing capacity on the continent in partnership with the Team Europe Initiative on manufacturing and access to medicines, vaccines and health technologies.

Ghebreyesus ends his speech by pointing out the supply increase of skilled workforce with training in biomanufacturing as the biggest challenge.

On Tuesday October 22nd, BioNTech signed an agreement with the Rwandan government and Institut Pasteur de Dakar in Senegal on the construction of the first mRNA vaccine manufacturing facility in Africa starting in mid-2022. That timing sets the Pfizer partner up to potentially beat Moderna in building the first mRNA vaccine manufacturing site on the continent. Although information on the location have not been revealed, experts expect the plant to be located in either Rwanda or Senegal.

6. Vaccination Licensing Issues/IP/tech transfer

The WHO COVID-19 Technology Access Pool (C-TAP) and the Medicines Patent Pool (MPP) announced the first global, non-exclusive and transparent voluntary license for a COVID-19 diagnostic test. The technology, offered by the Spanish National Research Council (CSIC), is

an antibody test capable of quantifying three different types of antibodies, and can differentiate vaccinated people from natural COVID-19 infections for public health surveillance. This has the potential to boost testing capacity for poor countries with limited COVID-19 surveillance.

After negotiations stalled on waiving the intellectual property around Covid19 Vx ahead of a December deadline, the European Commission has now gone from threatening to veto any IP waiver to calling for a "targeted" waiver on compulsory licenses only - a move advocates call meaningless and merely a PR stunt (not that there aren't important barriers created by certain Art. 31 and especially Art. 31bis provisions, but that there are many other important barriers that must be addressed in addition).

South Africa's Aspen Pharmacare and J&J are expanding their existing manufacturing by granting Aspen the rights to manufacture finished SARS-CoV-2 Covid-19 vaccine product from drug substance supplied by J&J. Aspen will sell the finished form vaccine under its own branding to public sector markets in Africa through transactions with designated multilateral organizations and with national governments of Member States of the AU.

A federal appeals court on Wednesday dismissed two patent challenges from Moderna over key components (LNPs) involved in making its COVID-19 vaccine. The court's decision to side with Arbutus Biopharma means it could potentially sue Moderna for patent infringement and demand royalties from Moderna's COVID-19 vaccine. Even more interesting, Arbutus could also seek invalidation of Moderna's patent, to which NIH had been demanding recognition of co-inventorship.

7. 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).

The US Centers for Disease and Prevention (CDC) Global Variants Report is tracking the worldwide distribution of four variants; as of November 24, 2021, all four variants are reported to be circulating in Africa and a new fifth variant has been detected in five African countries:

- Alpha (B.1.1.7): (VOC) initially detected in the UK, December 2020
    - Verified in all African countries except: not reported in Comoros, Eritrea, Lesotho, Mali, Sierra Leone, Tanzania, and Western Sahara (a disputed territory) and unverified in Botswana and Eswatini.
- Beta (B.1.351): (VOC) initially detected in South Africa, December 2020

- Verified in all African countries except: not reported in Algeria, Burkina Faso, Cabo Verde, Chad, Egypt, Eritrea, Gambia, Mali, Niger, Western Sahara, and unverified in Congo.

- Delta (B.1.617.2): (VOC) initially detected in India, December 2020
  - Verified in all African countries except: not reported in Chad, Djibouti, Eritrea, Libya, and Sudan and unverified in Comoros, Cote d"Ivoire, Lesotho and Reunion.
- Gamma (P.1): (VOC) initially identified in travelers from Brazil, January, 2021
  - Verified in Angola, Benin, Congo, Ghana, Reunion, Sudan, and Togo
- Omicron (B.1.1.529), initially identified in Botswana and South Africa, was designated a VOC on November 26, 2021.
  - As of December 1, 2021, it had been verified in Botswana, Ghana, Nigeria, Reunion and South Africa.

The World Health Organization has currently designated two Variants of Interest (VOI).

- Lambda (C.37). initially detected in Peru, August 2020:
  - Verified in South Africa
- Mu (B.1.621), initially detected in Colombia, August 2021
  - Currently the MU variant in not verified to be circulating in Africa

The category, Variant of High Consequence, is reserved for variants that have clear evidence that prevention measures or medical countermeasures have significantly reduced effectiveness relative to previously circulating variants.

- Currently, there are no SARS-CoV-2 variants that rise to the level of high consequence.

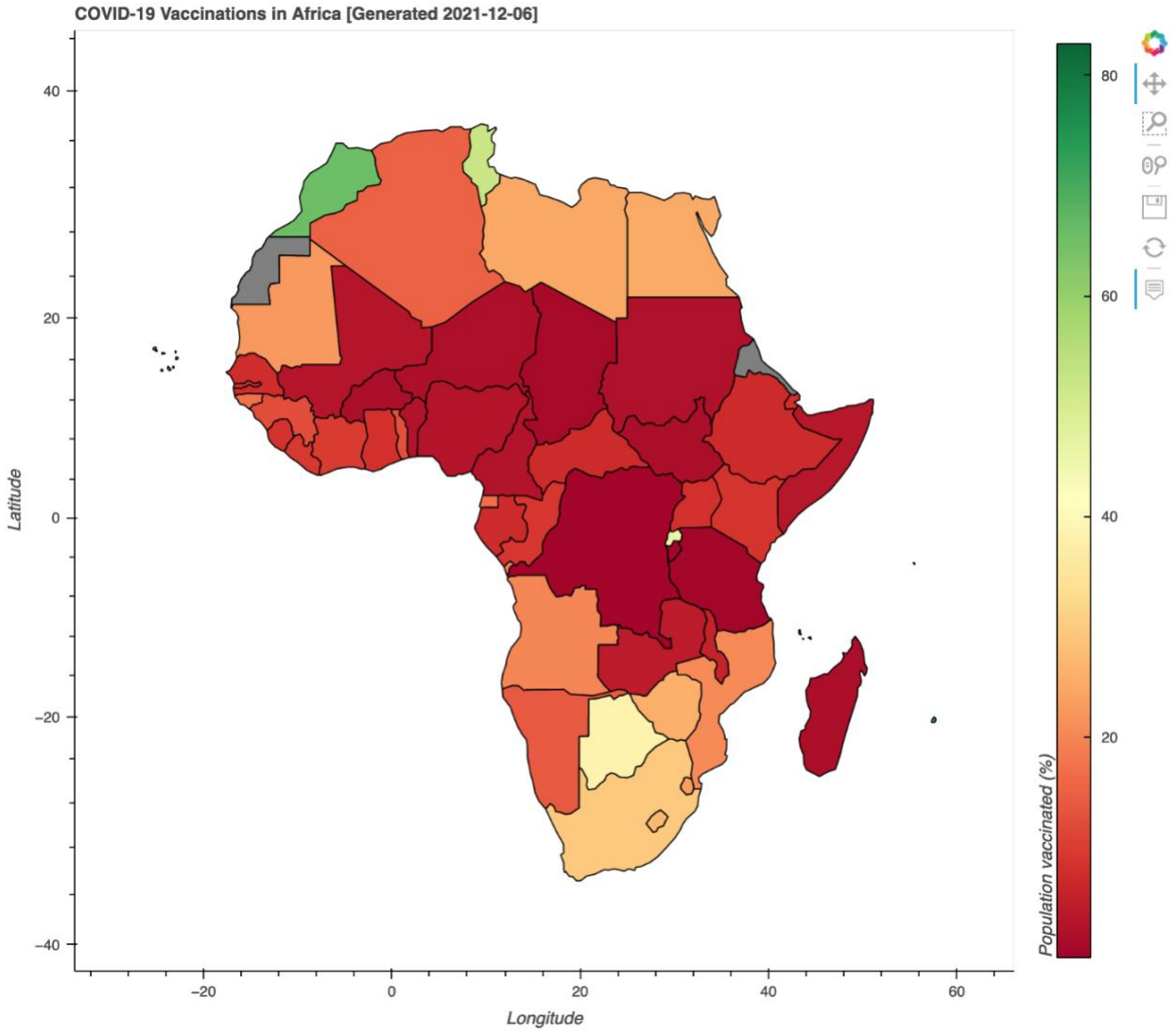
Appendix

Figures and Supplemental Information

VacSafe Working Group Website

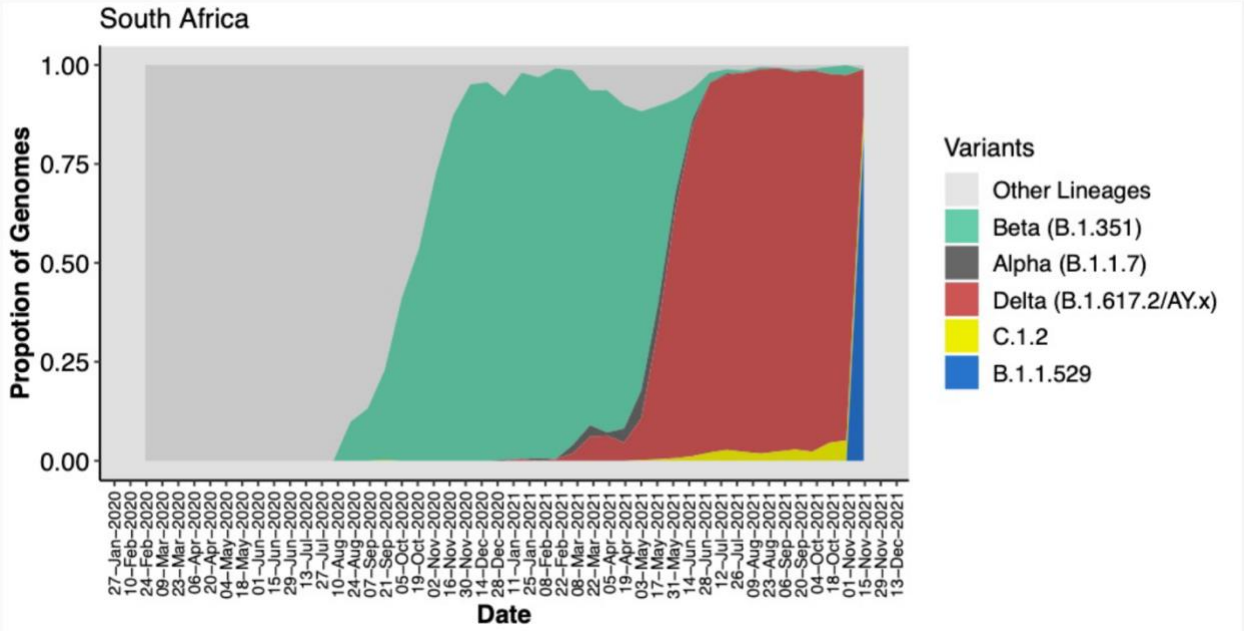
The VacSafe Working Group website houses publicly facing versions of these briefings, an interactive map that tracks COVID-19 vaccination rates and their correlates in Africa, and up-to-date information on the working group's convenings and projects. The website can be found at https://vacsafe.columbia.edu/

Figure 1: VacSafe Africa Map



The interactive map is hosted here: https://iserp.columbia.edu/vacsafe/covid-19-vaccinations-in-africa.

Figure 2: Omicron (B.1.1.529) Variant Evolution in South Africa



Source: https://www.krisp.org.za/manuscripts/25Nov2021_B.1.1.529_Media.pdf

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