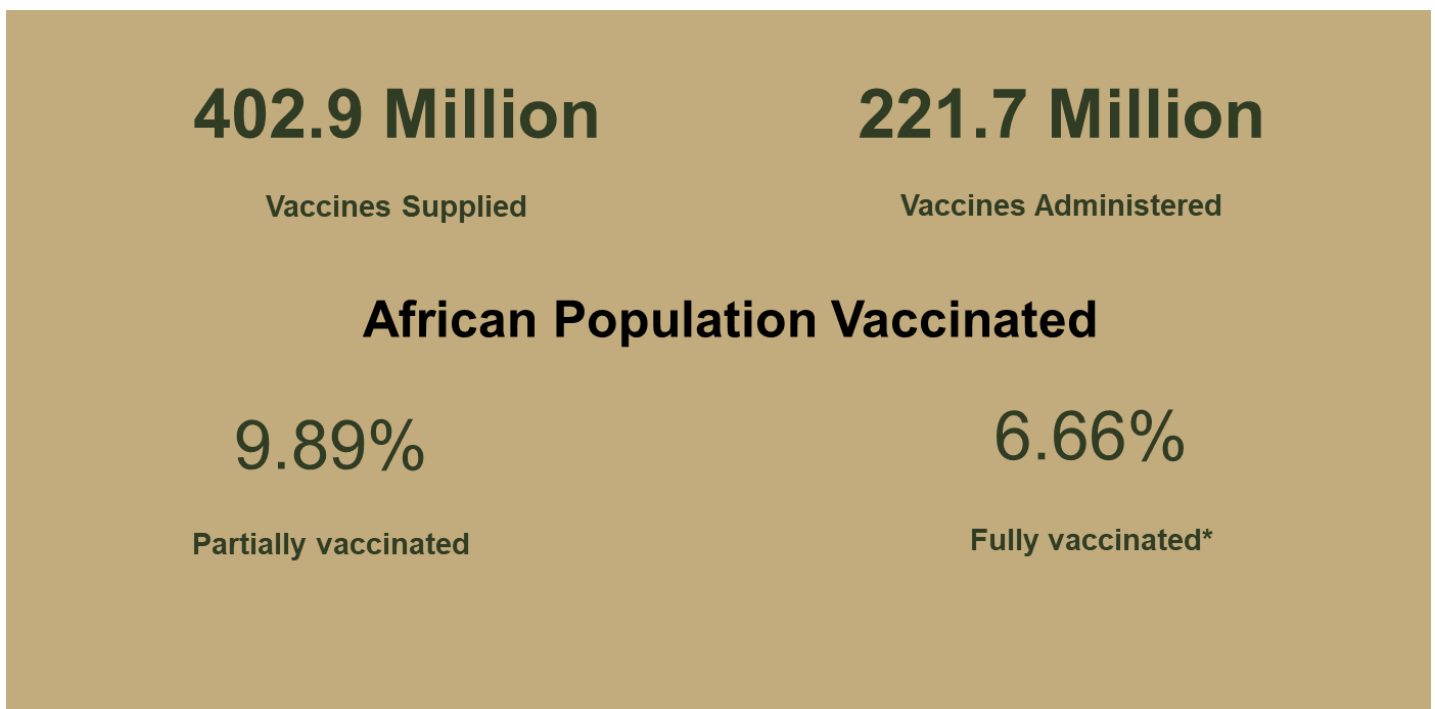


# COVID-19 Scientific and Public Health Policy Update<sup>1</sup> – (24 November 2021)

*In addition to the Weekly Outbreak Brief and other documents on the spread of COVID-19 and the actions that the African Union/Africa CDC and WHO/AFRO are taking to help African Union Member States, we share a biweekly brief detailing the latest developments in scientific knowledge and public health policy from around the world, as well as updates to the latest guidance from Africa CDC, WHO and other public health agencies. Contents of this document are **not intended to serve as recommendations** from the African Union-Africa CDC or WHO/AFRO; rather, it is a summary of the scientific information available in the public space to Member States. It is important to note that the outbreak is evolving rapidly and that the nature of this information will continue to change. We will provide regular updates to ensure Member States are informed of the most critical developments in these areas.*

## A. Trending Topics

### Status of Vaccines in Africa

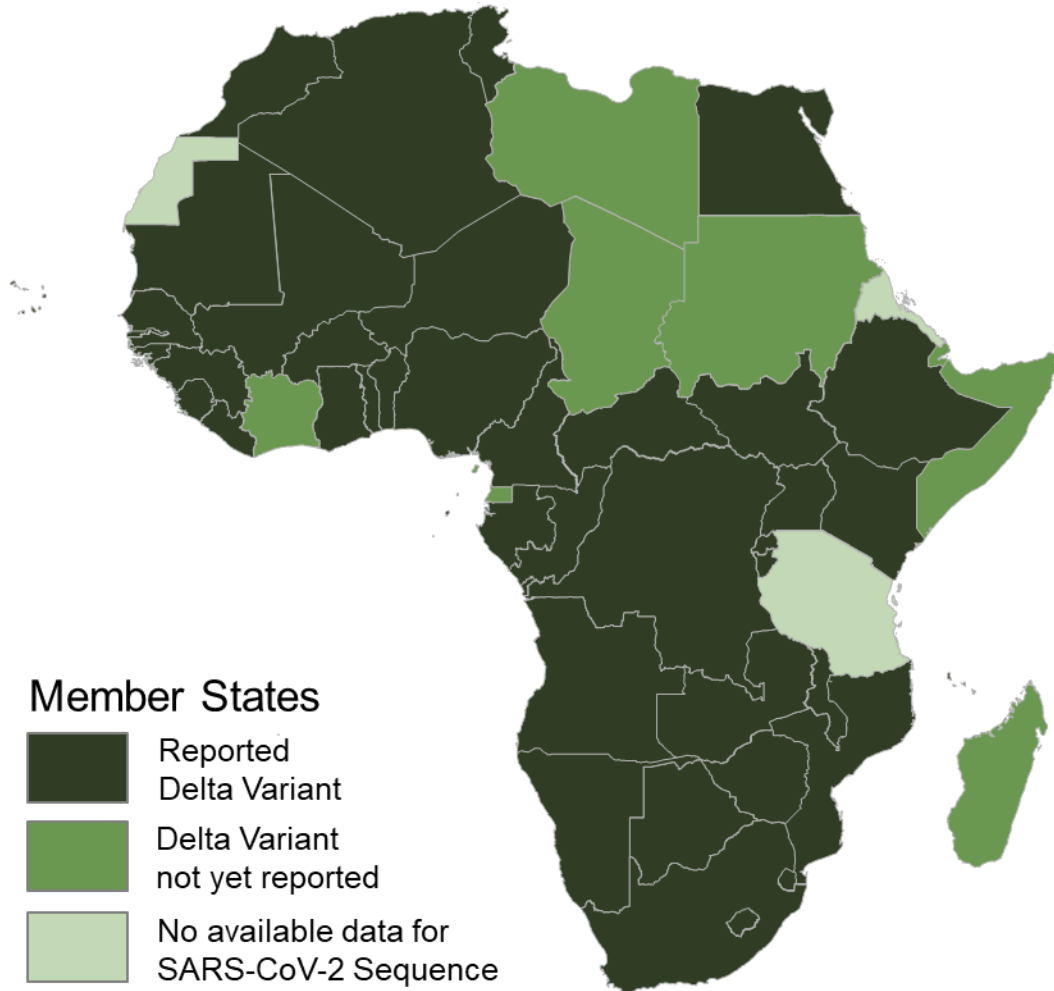


\*Received two doses/ one dose of Johnson & Johnson vaccine  
<https://africacdc.org/COVID-19-vaccination/>  
 Updated 24<sup>th</sup> November, 2021

<sup>1</sup> This update compiled for use by African Union Member States and is developed collaboratively by the African Union-Africa CDC and World Health Organization - Regional Office for Africa. **This is a preliminary summary of information and not considered policy, guidance, or final conclusions of the African Union- Africa CDC or WHO/AFRO.**

**Variants of Concern**

- The Delta variant (B.1.617.2), first reported in India, has spread to more than 193 countries worldwide; 42 Member States in Africa have reported this variant. <https://africacdc.org/institutes/africa-pathogen-genomics-initiative/>



Updated 24<sup>th</sup> November, 2021

**COVID-19 booster doses and vaccination in children in Africa**

**Table 1: COVID-19 Booster doses:**

Date of the commencement of booster doses	Country	Type of booster dose vaccine
9 November 2021	South Africa	<b>Homologous booster doses:</b> Janssen (J&J)
4 October 2021	Morocco	<b>Heterologous booster doses:</b> AstraZeneca, Sinopharm, J&J

**Table 2: COVID-19 Vaccination among adolescents in Africa**

Date of the commencement of vaccination	Country	Description
31 August 2021	Morocco	<b>Age group:</b> 12 -17 years old <b>Vaccine:</b> Pfizer and Sinopharm
16 October 2021	South Africa	<b>Age group:</b> 12 -17 years old <b>Vaccine:</b> Pfizer
10 November 2021	Guinea Conakry	<b>Age group:</b> 12 – 17 years old <b>Vaccine:</b> Pfizer and Moderna
12 November 2021	Seychelles	<b>Age group:</b> 12 -17 years old <b>Vaccine:</b> Pfizer

**B. New guidelines and resources**

Since 9<sup>th</sup> November 2021,

- Africa CDC<sup>2</sup> has published new guidance and resources on:
  - [Policy Recommendation for African Union Meetings and Travel During COVID-19 Outbreak](#)
  - [Outbreak Brief 96: Coronavirus Disease 2019 \(COVID-19\) Pandemic](#)
- U.S. CDC<sup>3</sup> has published new guidance and resources on:
  - [Interim Public Health Recommendations for Fully Vaccinated People](#)
  - [Considerations for Inpatient Obstetric Healthcare Settings](#)
  - [COVID-19 Guidance for Operating Early Care and Education/Child Care Programs](#)
  - [Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination](#)
  - [Public Health Guidance for Potential COVID-19 Exposure Associated with Travel](#)
  - [Operational Considerations for Personal Protective Equipment in the Context of Global Supply Shortages for Coronavirus Disease 2019 \(COVID-19\) Pandemic: non-US Healthcare Settings](#)
- WHO<sup>4</sup> has published new guidance and resources on:
  - [Living guidance for clinical management of COVID-19](#)
  - [Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19](#)
  - [Annexes to the recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19](#)
  - [Annexes to the recommendations for use of the Pfizer–BioNTech vaccine BNT162b2 against COVID-19](#)
  - [Guidance on operational microplanning for COVID-19 vaccination](#)
  - [Injection safety in the context of coronavirus disease vaccination](#)
- U.S. FDA<sup>5</sup> has issued press releases on:
  - [On 15<sup>th</sup> November: FDA updates test policies to help to ensure accuracy and reliability of tests and increase access to at-home tests](#)

<sup>2</sup> Africa CDC: Africa Centres for Disease Control and Prevention

<sup>3</sup> U.S. CDC: United States Centers for Disease Control and Prevention

<sup>4</sup> WHO: World Health Organization

<sup>5</sup> U.S. FDA: United States Food and Drug Administration

- [FDA expands eligibility for COVID-19 vaccine boosters](#)
- [On 22<sup>nd</sup> November: FDA authorised three over-the-counter COVID-19 antigen diagnostic tests](#)
- [as of 23<sup>rd</sup> November: 423 tests and sample collection devices are authorised by the FDA under emergency use authorisations](#)
- ECDC<sup>6</sup> has issued new resources on:
  - [Assessment of the current SARS-CoV-2 epidemiological situation in the EU/EEA, projections for the end-of-year festive season and strategies for response, 17th update](#)
  - [Overview of the implementation of COVID-19 vaccination strategies and deployment plans in the EU/EEA](#)
- PHE<sup>7</sup> has issued new guidance and press releases on:
  - [UK COVID-19 alert level methodology: an overview](#)
  - [COVID-19: infection prevention and control \(IPC\)](#)
  - [COVID-19 vaccination: booster dose resources](#)
  - [Safer public places - managing public outdoor settings](#)

The full list of latest guidance and resources from WHO and other public health institutions can be found in this [link](#).

## C. Scientific updates

### Basic Science

- This in-depth immune response profiling study compared the immune signature from hospitalized SARS-CoV-2–infected patients to patients hospitalized pre-pandemic with influenza or respiratory syncytial virus (RSV) in the U.S. Their results indicate that the immune landscape in SARS-CoV-2 patients is largely similar to flu or RSV patients. Unique to patients infected with SARS-CoV-2 who had the most critical clinical disease were changes in the regulatory T cell (T<sub>reg</sub>) compartment. A T<sub>reg</sub> signature including increased frequency, activation status, and migration markers was correlated COVID-19 severity. [Their findings are relevant as T<sub>regs</sub> are considered for therapy to combat the severe inflammation seen in COVID-19 patients. Existing knowledge of flu and RSV infections could be leveraged to identify common treatment strategies with SARS-CoV-1 as the overlapping immune landscapes have been defined.](#)
- This study in the U.S shows that the Delta and Kappa variants dampen the in vitro potency of vaccine-elicited serum neutralising antibodies and provide a structural framework for describing their immune evasion. Mutations in the B.1.617.1 (Kappa) and B.1.617.2 (Delta) spike glycoproteins abrogate recognition by several monoclonal antibodies via alteration of key antigenic sites, including remodelling of the B.1.617.2 N-terminal domain. [The ACE2 binding affinities of the B.1.617.1 and B.1.617.2 receptor-binding domains are comparable to the Wuhan-Hu-1 isolate whereas B.1.617.2+ \(Delta+\) exhibits markedly reduced affinity.](#)
- The authors in this cross-sectional study in the UAE conducted a trans-ancestry genome wide association study (GWAS) meta-analysis of COVID-19 severity. They discovered eight highly plausible genetic associations with hospitalized cases. The genes are expressed in the lung, associated to tumour progression, emphysema, airway obstruction, and surface tension within the lung, as well as an association to T-cell-mediated inflammation and the production of inflammatory cytokines. [They recommend further genetic studies to facilitate the development of population specific therapeutics to mitigate COVID-19.](#)

<sup>6</sup> ECDC: European Centre for Disease Prevention and Control

<sup>7</sup> PHE: Public Health England

- The authors in this meta-analysis analysed 24 studies of neutralisation against SARS-CoV-2 variants, with the aim of predicting the efficacy of existing vaccines against variants of concern, new vaccines, and vaccines after waning and boosting. Their findings suggest that good protection against the current variants of concern can be achieved by vaccination with existing vaccines (using ancestral spike targets) and that boosting with these vaccines is probably an effective strategy to combat waning of immunity and the current variants of concern. [In the future, vaccines targeting novel variants of concern might be required if highly escaped variants arise, but existing vaccines provide an effective method for boosting immunity against the current variants of concern.](#)
- This cohort study in the U.S aimed to compare temporal IgA and IgG response in human milk and microneutralization activity against SARS-CoV-2 between lactating parents with infection and vaccinated lactating parents up to 90 days after infection or vaccination. The authors recruited 47 lactating parents with infection and 30 lactating parents who were vaccinated. They found that antibody response in milk after infection was IgA dominant and highly variable while vaccination was associated with a robust IgG response, which began to decline by 90 days after the second vaccine dose. [Milk from both groups showed neutralization activity against live SARS-CoV-2 virus, which can be attributed to IgA and IgG SARS-CoV-2 antibodies.](#)

## Vaccines

- This cross-sectional study examined authorization and delivery of 6 unique COVID-19 vaccines recommended by the World Health Organization in 25 countries where they were tested. Their results show that across manufacturers, high-income countries received more doses to vaccinate larger median proportions of countries' populations 15 years and older. COVAX delivered a median 15.4%, 48.8%, and 78.8% of procured doses of tested vaccines in low-, lower middle-, and upper middle-income countries that have hosted ongoing and completed trials, respectively. [They recommend a corresponding fair access to benefits when low- and middle-income countries are included in research, to help avoid exploitation.](#)
- This retrospective cohort study aimed to assess the COVID-19 vaccine effectiveness (VE) after 6-9 months from vaccine administration. The authors utilised Swedish nationwide registries and enrolled 842,974 pairs (N=1,684,958), including individuals vaccinated with 2 doses of ChAdOx1 nCoV-19, mRNA-1273, or BNT162b2, and matched unvaccinated individuals. Their results show that [VE against symptomatic COVID-19 infection wanes progressively over time across all subgroups, but at different rates according to type of vaccine, and faster for men and older frail individuals. Their results strengthen the evidence-based rationale for administration of a third booster dose.](#) [not peer reviewed]
- This prospective cohort study aimed to evaluate the long-term humoral immune response in naïve and previously infected volunteers who received SPUTNIK V. The study involved 602 healthcare personnel in Tucuman, Argentina. Their findings revealed that seroconversion was detected in 97% of individuals after 28 days post-vaccination (dpv). Anti-RBD titres began to decrease after 60 dpv, but remained detectable in 94% at 90 dpv. At 180 dpv, anti-RBD titres persisted in 31%. Previous infection triggered an increased immune response to the first dose and increased neutralization activity against variants of concern. Second doses in previously infected individuals further increased titres, even 90 dpv. Basal antibody titres had more influence on post-vaccination anti-RBD responses than the time elapsed between diagnosis and vaccination. Their [findings suggest that when considering one-dose vaccination policies for individuals with previous SARS-CoV-2 infection, serological studies to determine basal titres may be important, independent of when diagnosis occurred.](#)
- This exploratory sub-study of a randomised, observer-blinded, placebo-controlled, phase 3 trial aimed to evaluate the safety, immunogenicity, and efficacy of NVX-CoV2373 when co-administered with licensed seasonal influenza vaccines. The study was conducted at four hospitals in the UK. Their study revealed that reactogenicity events were more common in the co-administration group than in the NVX-CoV2373 alone group. Co-administration resulted in no change to influenza vaccine immune response although a reduction in antibody responses to the NVX-CoV2373 vaccine was noted. NVX-CoV2373 vaccine efficacy in the sub study was 87.5% (95% CI -0.2 to 98.4) and in the main study was 89.8%



(95% CI 79.7–95.5). [Their results suggest that concomitant vaccination might be a viable immunisation strategy.](#)

- This multicentre, randomised, controlled, phase 4 trial aimed to assess the safety of concomitant administration of ChAdOx1 or BNT162b2 plus an age-appropriate influenza vaccine. The study enrolled 679 adult participants at 12 UK sites. Their results support the concomitant administration of second doses of the ChAdOx1 and BNT162b2 COVID-19 vaccines with age-appropriate inactivated influenza vaccines. [They show that concomitant vaccination is possible as it raises no safety concerns, most systemic reactions were mild or moderate, and immune responses were not adversely affected.](#)
- This randomised, double-blind, placebo-controlled, multicentre, phase 3 clinical trial in 25 Indian hospitals or medical clinics aimed to evaluate the efficacy, safety, and immunological lot consistency of BBV152, a whole virion inactivated SARS-CoV-2 vaccine. The study involved 24,419 adult participants with no serological evidence of previous exposure to SARS-CoV-2. Participants received two doses of BBV152 vaccine or placebo, 4 weeks apart. Efficacy against any severity of COVID-19 with onset 14 days after the second vaccination was 77.8% (95% CI 65.2–86.4), and efficacy against severe COVID-19 was 93.4% (57.1–99.8). Efficacy against asymptomatic COVID-19 was 63.6% (29.0–82.4). [Their preliminary analysis found an efficacy of 65.2% \(95% CI 33.1–83.0\) against the delta variant, but further investigations are necessary to confirm clinical efficacy against this variant and others. Safety monitoring and reactogenicity assessments of BBV152 did not raise concerns about the vaccine.](#)
- This phase 3 clinical trial in the U.S assessed vaccine recipients for neutralizing and binding antibodies as correlates of risk for COVID-19 disease and as correlates of protection. The authors measured the immune markers at second vaccination and 4 weeks later. Their results showed that all markers were inversely associated with COVID-19 risk and directly associated with vaccine efficacy. Vaccine recipients with post-vaccination 50% neutralisation titres 10, 100, and 1000 had estimated vaccine efficacy of 78% (95% CI 54, 89%), 91% (87, 94%), and 96% (94, 98%), respectively. [Their results help define immune marker correlates of protection and may guide approval decisions for mRNA COVID-19 vaccines and other COVID-19 vaccines.](#)

### Diagnostics

- The authors in this study developed an algorithm based upon the mass spectrometric analysis of 1000+ breath samples from different sources with different ambient backgrounds in the U.S. Their algorithm has been shown to predict fairly well the status of patients in regard to being identified as COVID-19 positive with PCR or not. Specific biomarkers have been identified to be correlated to the infection with SARS-CoV-2, and it has been identified that these biomarkers are age related. The results show that [their method for identification of COVID-19 infection is a promising tool, which can give fast and accurate results in areas where large crowds are anticipated or in areas of concentrated continuous presence, such as airplanes.](#)
- This cross-sectional study in Ethiopia aimed to assess the diagnostic value of saliva samples for diagnosis of SARS-COV-2 infection in comparison to nasopharyngeal samples (NPS). The authors obtained pairs of NPS-saliva samples from 152 symptomatic confirmed COVID-19 patients, and compared their positivity rate, viral load, and duration of viral shedding. [Their results show that saliva has higher yield in detecting SARS-CoV2, and COVID-19 patients show higher viral load and prolonged period of viral shedding in saliva. They recommend saliva as a better alternative sample to NPS to diagnose COVID-19 patients.](#)

### Care and Treatment

- This ongoing, double-blind, phase 3 trial at 37 sites in four countries (the United States, Canada, Brazil, and Spain) aimed to evaluate the efficacy and safety of sotrovimab in high-risk, ambulatory patients with mild-to-moderate COVID-19. Their findings showed that the relative risk reduction in hospitalisation (for >24 hours) or death between patients who received a single 500-mg dose of sotrovimab and those who received placebo was 85%. The authors did not identify any safety signals.

Their findings indicate that [sotrovimab can be a therapeutic agent for outpatients with COVID-19, they speculate that it has the potential to remain therapeutically active even as SARS-CoV-2 continues to evolve.](#)

- This single-centre prospective cohort study in the U.S aimed to characterise associations of pulmonary radiographic and physiologic sequela of severe COVID-19, and to identify independent risk factors for the development of post-COVID fibrosis. Their results show that at 4 months after hospitalisation, fibrotic-like patterns were more common in those who underwent mechanical ventilation (72%) than in those who did not (20%). They demonstrate that severity of initial illness, duration of mechanical ventilation, lactate dehydrogenase on admission and leucocyte telomere length are independent risk factors for fibrotic-like radiographic abnormalities. These fibrotic-like changes correlate with lung function, cough and measures of frailty, but not with dyspnoea. [They recommend additional prospective studies to characterise temporal changes of post-COVID-19 fibrotic abnormalities, and clinical trials to investigate therapeutic options to promote its resolution.](#)

## Epidemiology

- This prospective observational study aimed to describe the long-term functional impairment of respiratory, motor, psychological and cognitive function 12 months after SARS-CoV-2 infection. The authors compared them to the symptomatic burden at 4 months follow-up, in an attempt to clarify reversibility of symptomatology. The study involved 238 patients aged 18 years or older who were discharged from a university hospital in Northern Italy. Their results show that [in the time elapsed from 4 to 12 months after hospital discharge, motor function improves, while respiratory function does not, being accompanied by evidence of lung structural damage. Symptoms remain highly prevalent one year after acute illness.](#)
- This modelling study aimed to assess the usefulness of SARS-CoV-2 RT-PCR cycle thresholds (Ct) values trends produced by the “Laboratoire Hospitalier Universitaire de Bruxelles - Universitair Laboratorium Brussel” (LHUB-ULB) in Belgium for monitoring the epidemic's dynamics at local and national levels and for improving forecasting models. Their study established a correlation between the trends in the SARS-CoV-2 RT-PCR Ct values and the trends of the COVID-19 incidence a few days later. [Their findings underline that consolidated microbiology laboratories can act as epidemic sensors as they gather data that are representative of the geographical area they serve.](#)
- This systematic review, which was conducted in Iran, gathers information from 64 reports of de novo movement disorders developing after/during infection with SARS-CoV-2. The authors also describe 3 cases presenting with myoclonus occurring shortly after COVID-19. They found that myoclonus and ataxia were the most frequent movement disorders occurring in COVID-19 patients. Other movement disorders were not common after COVID-19, [implying that SARS-CoV-2 mainly affects the brain through immune-mediated pathways rather than a direct invasion of the central nervous system. Nonetheless, COVID-19 can affect the outcome of patients with established movement disorders.](#)
- This study used a stochastic evolutionary modelling framework to explore the emergence of fitter variants of SARS-CoV-2 during long-term infections. The authors found that mutations that increased the rate of viral replication increased in frequency within hosts during the course of a typical SARS-CoV-2 infection. This expansion led to more frequent transmission of the new variant and faster emergence of the variant on a population level. [Targeting these low-probability stochastic events that lead to the establishment of novel advantageous viral variants might allow us to slow the rate at which they emerge in the patient population, and prevent them from spreading deterministically due to natural selection. Their work suggests practical ways to achieve control of long-term SARS-CoV-2 infections.](#)
- This systematic review and meta-analysis aimed at investigating associations between COVID-19 mortality and SARS-COV-2 variants spread during the second wave of COVID-19 pandemic in Europe. The authors analysed data from 38 European countries. They found that [an increase of 0.1 in the proportion of B.1.1.7 variant, considering the pre-peak period, was associated with 35.8% increase in the height of the second wave peak. During the period from 1<sup>st</sup> January to 25<sup>th</sup> February 2021, an increase of 0.1 in the proportion of the same VOC was related with a 15.3% increase in the cumulative](#)

[number of deaths during that period. Their results also suggest that the higher proportion of EU2 variant \(mutation S:447 N\) was associated with increased cumulative mortality in the European region.](#)

### Infection Prevention and Control

- The authors in this study developed an in-house ray-tracing (RT) simulator based on Ultraviolet-C (UV-C) LEDs to inactivate SARS-CoV-2 in public environments. The authors investigated a realistic case of public space, i.e., a food court in Singapore, to demonstrate the relative impact of environmental UV-C attenuation on the SARS-CoV-2 inactivation. They optimised a specific UV-C LED germicidal system and its corresponding exposure time according to the simulation results. [These ray-tracing-based simulations provide a useful guideline for safe deployment and efficient design for germicidal UV-C LED technology.](#)

### Non-pharmaceutical interventions, social distancing

- This cross-sectional study aimed to estimate the seroprevalence of unidentified SARS-CoV-2 infection in the general population after 3 major pandemic waves in Hong Kong, a city without complete lockdown. The study enrolled 4198 participants. The authors identified 6 participants to be positive for anti-SARS-CoV-2 IgG; the adjusted prevalence of unidentified infection was 0.15% (95% CI, 0.06%-0.32%). [Their findings suggest that stringent isolation and quarantine policies even without complete city lockdown are successful in minimising SARS-CoV-2 transmission.](#)
- This modelling study aimed to quantify the impact of COVID-19 confinement measures on access to inpatient services using data from 204 Kenyan hospitals. The authors found significant drops in monthly volumes of live births (11%), over-fives admissions for medical (29%) and surgical care (25%) with especially high declines in admissions in the under 5 age group (59%) in public hospitals. Similarly, substantial declines were apparent in private hospitals, where significant reductions in admissions to the medical (34%), surgical (28%) and paediatrics (62%) wards were observed. [The declines have been sustained and recent data suggests a reversal in trends with services appearing to be going back to the historical levels starting March 2021.](#)
- This systematic review and meta-analysis conducted in Australia aimed to review the evidence on the effectiveness of public health measures in reducing the incidence of COVID-19, SARS-CoV-2 transmission, and COVID-19 mortality. The authors included 8 studies in the meta-analysis. Their results indicated a reduction in incidence of COVID-19 associated with handwashing (relative risk 0.47, 95% confidence interval 0.19 to 1.12,  $I^2=12%$ ), mask wearing (0.47, 0.29 to 0.75,  $I^2=84%$ ), and physical distancing (0.75, 0.59 to 0.95,  $I^2=87%$ ). [Efforts to implement public health measures should consider community health and sociocultural needs. They recommend further research to better understand the effectiveness of public health measures in the context of vaccination.](#)
- This cluster randomised trial evaluated the effect of an intervention designed using the theory of normative social behaviour (TNSB), using disgust as opposed to health as a motive, along with provision of a handwashing station on handwashing with soap (HWWS) practices after toilet use. The study was undertaken in Abidjan, Côte d'Ivoire. The provision of handwashing stations alone was also assessed. The authors found that TNSB intervention led to a substantial increase in HWWS after toilet use, which was sustained for at least 5 months. The provision of handwashing stations alone had only a small, short-term effect on HWWS after toilet use. [The COVID-19 pandemic highlights the importance of identifying effective ways of promoting HWWS in epidemic and non-epidemic circumstances. The authors recommend further trials to evaluate the effects of non-health-based behaviour change interventions on HWWS practices in different settings.](#)
- This modelling study analysed data from 93 countries implementing lockdowns to investigate their immediate impact on mobility and the subsequent evolution of mobility. The authors found that at the start of a lockdown, median mobility is reduced to 36% below the baseline, and by another 18% in the subsequent 2 weeks. Most countries observed a significant rebound in mobility during the lockdown period. [Although lockdowns significantly reduce mobility, their impact is also subject to fatigue as the](#)



[lockdown period extends longer. The magnitude of mobility reductions achieved and fatigues reported in this research can help policy makers anticipate the likely impact of their lockdown policies.](#)

## D. Clinical Trials Updates

### Key updates:

- This paper summarises [key findings about the pandemic vaccine trials in Low- and Middle-Income Countries and Global Health Security](#). The authors highlight the different forms of COVID-19 vaccine inequity experienced by low-income countries (LICs) and middle-income countries (MICs) including: (1) Inadequate accessibility to COVID-19 vaccines due to high price charges and inadequate resources by the countries to purchase the vaccines; (2) Lack of access to the tested vaccines even when the LICs and MICs conduct vaccine trials which is contrary to the Universal Declaration of Human Rights that states, “everyone has the right to share in scientific advancement and its benefits”; and (3) Preferential access to vaccines is given to nations that conduct trials of which very few LICs and MICs conduct these trials. Furthermore, one challenge observed in globally rolling out COVID-19 vaccines tested in HICs is that there may be important epidemiological differences between countries, such as comorbidities, that could potentially influence vaccine effectiveness and adverse reactions. In this regard, LICs and MICs should ensure that they test product candidates in their own populations, use locally generated data, and ensure local access to the products. They should increase their own investments in designing and conducting trials, regulatory capacity, and manufacturing, thus becoming self-sufficient in making their own medical products. Greater sovereignty over trials in LICs and MICs would help ensure that everyone is made safer from pandemics.

### Vaccine trials:

- On 19<sup>th</sup> November 2021, Pfizer and BioNTech [announced that the U.S. Food and Drug Administration \(FDA\) has expanded emergency use authorisation of a booster dose of the Pfizer-BioNTech COVID-19 vaccine to include individuals aged >18 years](#). The booster dose is to be administered at least six months after completion of the primary series, and is the same dosage strength as the doses in the primary series. The decision is based on the positive top line results from the phase 3 COVID-19 booster trial that indicated a booster dose confers a relative 95% vaccine efficacy against the COVID-19 infection to individuals who previously received Pfizer-BioNTech primary two-dose series when compared to those who did not receive a booster (Clinical trial #: NCT04955626). In addition, the adverse event profile was generally consistent with other clinical safety data for the vaccine, with no new safety concerns identified.
- On 17<sup>th</sup> November 2021, Novavax and Serum Institute of India(SII) [announced that the Philippine Food and Drug Administration \(FDA\) has granted emergency use authorisation to the Novavax COVID-19 vaccine, NVX-CoV2373, for active immunisation of people aged >18 years. In addition, the company has also submitted a Biologics License Application \(BLA\) for NVX-CoV2373 to the South Korea's Ministry of Food and Drug Safety \(MFDS\)](#). The vaccine can be stored with standard refrigeration, at 2° to 8° Celsius, thus, can be transported and stored using the current vaccine supply chain, potentially increasing access in hard-to-reach areas. In two Phase III trials conducted in the United States and Mexico, the vaccine offered 100% protection against moderate and severe COVID-19 with an overall efficacy of 90.4%. The vaccine was generally well-tolerated and elicited a robust antibody response.
- On 16<sup>th</sup> November 2021, Pfizer [announced that it is seeking emergency use authorisation from US Food and Drug Authority \(FDA\) for its investigational oral antiviral candidate, PAXLOVID \(PF-07321332; ritonavir\)](#), for the treatment of mild to moderate COVID-19 in patients at increased risk of hospitalizations or death. This submission is based on positive results from the Evaluation of Protease Inhibition for COVID-19 in High-Risk Patients (EPIC-HR) interim analysis, (clinical trial no: NCT04960202), which enrolled non-hospitalized adults aged  $\geq 18$  with confirmed COVID-19. Data demonstrated an 89% reduction in risk of COVID-19-related hospitalization or death from any cause in patients treated with PAXLOVID compared to placebo within three days of symptom onset. No case of

death was reported in the treatment group within five days of symptom development. Treatment-emergent adverse events were comparable between PAXLOVID (19%) and placebo (21%), most of which were mild in intensity. PAXLOVID is an investigational SARS-CoV-2 protease inhibitor antiviral that hinders SARS-CoV-2-3CL protease activity, which is an enzyme needed for viral replication.

- On 29<sup>th</sup> October 2021, the South African Medical Research Council and National Department of Health of South Africa announced that in partnership with Jansen & Jansen company, [they will start providing booster doses to health workers under the Sisonke 2 Booster study from 9<sup>th</sup> November 2021](#). Participants will be administered with a homologous Janssen (J&J) booster vaccine dose six months after the prime dose. A total of 496,424 healthcare workers including breastfeeding and pregnant women who received a first dose of the J&J vaccine under Sisonke vaccine effectiveness study will be eligible to receive the booster dose. This decision was based on the positive results from the phase III ENSEMBLE study that indicated that J&J booster dose vaccine efficacy after six months antibody titres increased 4-7 folds (Clinical trial #: NCT04614948). The study has already been approved by SAHPRA, the National Department of Health and SAMRC Ethics Committee.

#### Therapeutics trials:

- On 19<sup>th</sup> November 2021, [the Committee for Medicinal Products for Human Use \(CHMP\) of the European Medicines Agency \(EMA\) issued advice on the usage of Merck Lagevrio \(molnupiravir/ MK 4482\) to treat COVID-19](#) recommending that the drug be used to treat adults with COVID-19 who do not require supplemental oxygen and are at increased risk of disease progression. The drug should be administered immediately after diagnosis of COVID-19 and within 5 days of the start of symptoms and 800 mg should be taken twice a day for 5 days. Furthermore, Lagevrio is not recommended during pregnancy or in women who can become pregnant (not using effective contraception). The advice is based on the outcome of a data review from concluded and ongoing trials.
- On 19<sup>th</sup> November 2021, Todos Medical and its partner NLC Pharma [announced the completion of subject recruitment for preliminary assessment of the phase II clinical trial of oral antiviral drug, Tollovir, for treatment of severe and critical COVID-19 patients admitted in the hospitals](#). Tollovir is a 3CL protease inhibitor and anti-cytokine therapeutic candidate for the treatment of the nidovirus subcategory of coronaviruses that includes SARS-CoV-2, COVID-19, SARS-CoV-1, MERS and 229E. This phase II, randomised, double-blind, placebo controlled clinical trial aims to enrol up to 77 subjects hospitalized with COVID-19. The Data Safety and Monitoring Board (DSMB) will conduct an interim analysis of 31 patients enrolled in the study so far. Reduction in the duration of hospitalization and time to clinical improvement will be the primary endpoints. The secondary endpoints will include deaths, incidence and duration of time on supplemental oxygen as well as incidence of deterioration and need for mechanical ventilation.
- On 16<sup>th</sup> November 2021, Tevogen announced it has [concluded dosing of the first cohort of participants in the proof of concept clinical trial of its investigational immunotherapy, TVGN-489, for treatment of COVID-19 in high-risk patients](#). TVGN-489 is a product comprised of highly purified SARS-CoV-2 specific cytotoxic CD8+ T lymphocytes (CTLs) which can potentially identify targets spread across the complete viral genome. This single centre, open-label clinical trial, conducted in Philadelphia, is designed to study the safety, optimal dosage and efficacy of TVGN-489 when given to adult patients aged  $\geq 18$  years with a SARS-CoV-2 infection. The trial is enrolling participants at high risk of severe COVID-19 progression due to advanced age or other underlying health conditions. The outcomes of participants receiving the investigational therapy will be compared to patients receiving standard of care (Clinical trial registration #: NCT04765449).
- On 11<sup>th</sup> November 2021, Synairgen announced that [it has achieved its recruitment target of 610 randomised subjects for its global phase 3 SPRINTER trial \(SG018\) of inhaled interferon beta, SNG001, for the treatment of hospitalised COVID-19 patients](#). Interferon beta is a naturally-occurring protein which orchestrates the body's antiviral responses. This randomised, double-blind, placebo-controlled phase 3 SPRINTER trial is being conducted in 17 countries. Statistical analysis will be concluded once the last subjects complete the initial trial follow up period of 35 days. After successful completion of the phase 3 trial, the company anticipates to file an Emergency Use Authorisation (EUA)

with the United States for patients requiring hospitalisation due to COVID-19 (Clinical trial registration #: NCT04732949).

#### Immunotherapies trials:

- On 18<sup>th</sup> November 2021, AstraZeneca reported [new data from two Phase III randomised, placebo controlled clinical trials \(PROVENT and TACKLE\) demonstrating robust efficacy for its long-acting antibody \(LAAB\) combination, AZD7442, for COVID-19 treatment and prevention.](#) AZD7442 is a cocktail of tixagevimab (AZD8895) and cilgavimab (AZD1061) LAABs derived from B-cells donated by convalescent patients after SARS-CoV-2 virus infection. According to the data from the PROVENT trial, one 300mg IM dose of AZD7442 reduced the risk of symptomatic COVID-19 by 83%. In the separate TACKLE outpatient treatment trial, data analysis showed that one 600mg IM dose of AZD7442 reduced the risk of severe COVID-19 or death from any cause by 88% in patients with mild-to-moderate COVID-19 compared to placebo when treated within three days of symptom onset. In both PROVENT and TACKLE studies, AZD7442 was generally well tolerated (Clinical trial registration #: NCT04625725 & NCT04723394).
- On 12<sup>th</sup> November 2021, Regeneron Pharmaceuticals [announced that the European Commission \(EC\) has approved REGEN-COV, a cocktail of two monoclonal antibodies, casirivimab and imdevimab for use in the United states and Ronapreve for use in the European Union \(EU\) and other countries.](#) The EC granted marketing authorization for Ronapreve for the treatment of COVID-19 in individuals aged >12 years who do not require oxygen supplementation and are at increased risk of disease progression. The decision follows the positive opinion about the monoclonal antibodies by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency's (EMA) and favourable results from two Phase 3 trials involving > 6,000 individuals that evaluated the efficacy and safety of the antibody cocktail to treat non-hospitalized patients already infected with SARS-CoV-2, and to prevent symptomatic infection in asymptomatic household contacts of SARS-CoV-2 infected individuals.
- On 12<sup>th</sup> November 2021, GlaxoSmithKline and Vir Biotechnology announced [that the intramuscular \(IM\) dose of its experimental therapy, sotrovimab, met the primary goal of the Phase III COMET-TAIL clinical trial in at-risk patients with mild-to-moderate COVID-19.](#) Sotrovimab is an investigational SARS-CoV-2 neutralising monoclonal antibody which binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 thus making it difficult to develop resistance. This randomised, multi-centre, open-label COMET-TAIL Phase III trial was designed to evaluate the efficacy, safety, and tolerability of sotrovimab delivered via intramuscular (IM) administration versus intravenous (IV) administration in high-risk patients up to seven days after symptom onset. Data from the trials demonstrated that intramuscular (IM) administration of sotrovimab was non-inferior to intravenous (IV) administration for the early treatment of mild-to-moderate COVID-19 in high-risk, non-hospitalised adults and adolescents ( $\geq 12$  years). GSK and Vir Biotechnology plans to seek regulatory approvals from various agencies worldwide including the US Food and Drug Administration on the current Emergency Use Authorization for sotrovimab (Clinical trial registration #: NCT04913675).
- On 11<sup>th</sup> November 2021, Human Medicines Committee (CHMP) of the [European Medicines Agency \(EMA\) recommended authorizing two monoclonal antibody \(mAb\) drugs, Ronapreve \(casirivimab/imdevimab\) and Regkirona \(regdanvimab\), for treatment of COVID-19 patients.](#) The Regeneron-Roche cocktail of monoclonal antibodies, Ronapreve (casirivimab/imdevimab), and Celltrion's antibody therapy, (regdanvimab) are being recommended for adults and adolescents ( $\geq 12$  years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and are at increased risk of disease progression. CHMP reached this conclusion after they had evaluated data from studies showing that treatment with Ronapreve or Regkirona significantly reduces hospitalisation and deaths in COVID-19 patients at risk of severe COVID-19. Monoclonal antibodies are proteins designed to attach to the spike protein of SARS-CoV-2 to block the virus from attaching into the human cells.

#### Diagnostic approvals:

- On 18<sup>th</sup> November 2021, the U.S. Food and Drug Administration [issued an emergency use authorisation for the first COVID-19 self-testing kit for home use that provides results within 30 minutes](#). The single-use test, Lucira, is a molecular (real-time loop mediated amplification reaction) test that is intended to detect the novel coronavirus SARS-CoV-2. The Lucira COVID-19 All-In-One Test Kit has been approved for home use with self-collected nasal swab samples in individuals aged  $\geq 14$  years suspected of COVID-19 and also in point-of-care (POC) settings for all ages but samples must be collected by a healthcare provider when for children ( $< 14$  years). The test is currently authorized for prescription use only.

**For further detailed information for each country, refer to the full table [here](#)**

#### Contributors

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