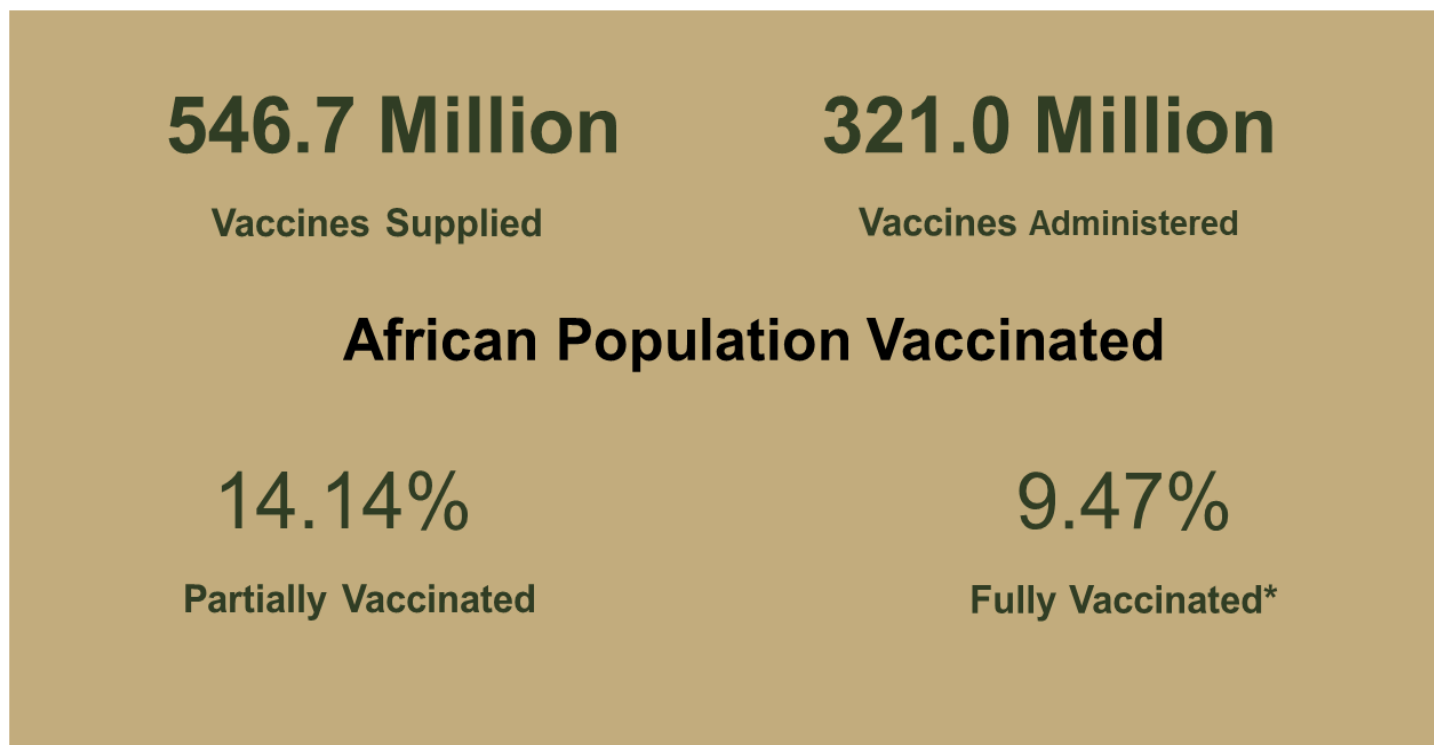


COVID-19 Scientific and Public Health Policy Update¹ – (5 January 2022)

*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

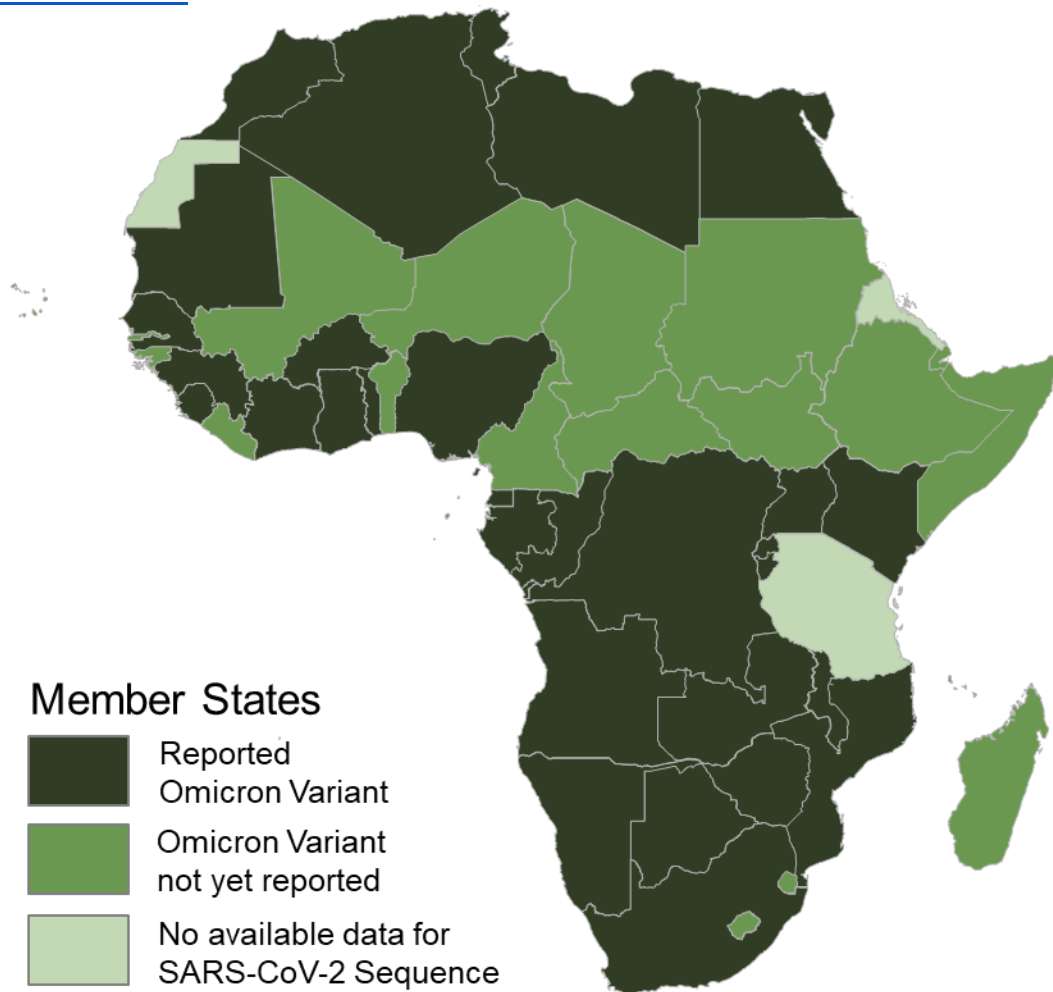


*Received two doses/ one dose of Johnson & Johnson vaccine
<https://africacdc.org/COVID-19-vaccination/>
 Updated 5th January, 2022

¹ 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 Omicron variant (B.1.1.529), first reported in South Africa, has spread to 111 countries worldwide; 29 Member States in Africa have reported this variant. <https://africacdc.org/institutes/africa-pathogen-genomics-initiative/>



Updated 5th January, 2022

B. New guidelines and resources

Since 21st December 2021,

- Africa CDC² has published new guidance and resources on:
 - [Outbreak Brief 103: Coronavirus Disease 2019 \(COVID-19\) Pandemic](#)
- U.S. CDC³ has published new guidance and resources on:
 - [CDC Expands Booster Shot Eligibility and Strengthens Recommendations for 12-17 Year Olds](#)
 - [Operational Considerations for the Identification of Healthcare Workers and Inpatients with Suspected COVID-19 in non-US Healthcare Settings](#)
 - [Contact Tracing for COVID-19](#)
 - [Testing Strategies for SARS-CoV-2](#)
 - [Duration of Isolation and Precautions for Adults with COVID-19](#)
 - [Strategies to Mitigate Healthcare Personnel Staffing Shortages](#)

² Africa CDC: Africa Centres for Disease Control and Prevention

³ U.S. CDC: United States Centers for Disease Control and Prevention

- [Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2](#)
- WHO⁴ has published new guidance and resources on:
 - [An implementation guide for the management of COVID-19 on board cargo ships and fishing vessels](#)
 - [COVID-19 infection prevention and control living guideline: mask use in community settings, 22 December 2021](#)
 - [WHO recommendations on mask use by health workers, in light of the Omicron variant of concern](#)
- U.S. FDA⁵ has issued press releases on:
 - [On 3rd January 2022, FDA Takes Multiple Actions to Expand Use of Pfizer-BioNTech COVID-19 Vaccine](#)
 - [On 28th December 2021, FDA updated the emergency use authorisation \(EUA\) for COVID-19 convalescent plasma](#)
 - [On 23rd December 2021, FDA Authorises Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults](#)
 - [As of 28th December, 419 tests and sample collection devices are authorised by the FDA under emergency use authorisations](#)
- PHE⁶ has issued new guidance and press releases on:
 - [PCR home testing for people eligible for new COVID-19 treatments](#)
 - [Travel to England from another country during coronavirus \(COVID-19\)](#)

Scientific updates

Basic Science

- The authors in this study performed complete autopsies on 44 patients with COVID-19 in the U.S. The study aimed to map and quantify SARS-CoV-2 distribution, replication, and cell-type specificity across the human body, including brain, from acute infection through over seven months following symptom onset. The authors show that SARS-CoV-2 is widely distributed, even among patients who died with asymptomatic to mild COVID-19, and that virus replication is present in multiple pulmonary and extrapulmonary tissues early in infection. They also detected persistent SARS-CoV-2 RNA in multiple anatomic sites, including regions throughout the brain, for up to 230 days following symptom onset. Despite extensive distribution of SARS-CoV-2 in the body, they observed a paucity of inflammation or direct viral cytopathology outside of the lungs. Their [findings prove that SARS-CoV-2 causes systemic infection and can persist in the body for months](#). [not peer reviewed]
- This neutralisation assay in South Africa aimed to characterise developing immunity to Omicron. The authors also investigated whether neutralising immunity elicited by Omicron also enhances neutralising immunity of the Delta variant. They enrolled both previously vaccinated and unvaccinated individuals who were infected with SARS-CoV-2 in the Omicron infection wave in South Africa soon after symptom onset. They then measured their ability to neutralise both Omicron and Delta virus at enrolment versus a median of 14 days after enrolment. They found that neutralisation of Omicron increased 14.4-fold (95% CI 5.5-37.4) over this time, showing a developing antibody response to the variant. Importantly, there was an enhancement of Delta virus neutralisation, which increased 4.4-fold (95% CI 2.1-9.2). The increase in Delta variant neutralisation in individuals infected with Omicron may result in decreased ability of Delta to re-infect those individuals. [Along with emerging data indicating that Omicron, at this time in the pandemic, is less pathogenic than Delta, such an outcome may have positive implications in terms of decreasing the COVID-19 burden of severe disease](#). [not peer reviewed]

⁴ WHO: World Health Organization

⁵ U.S. FDA: United States Food and Drug Administration

⁶ PHE: Public Health England

- This U.S animal model study involving African green monkeys found that delivery of remdesivir (RDV) by inhalation achieves effective antiviral activity in the respiratory tract following SARS-CoV-2 infection. Inhaled RDV resulted in lower systemic exposures than IV administration and was well tolerated as a repeat-dose regimen during SARS-CoV-2 infection. Inhaled RDV is therefore a safe and effective therapeutic approach for controlling viral load during early SARS-CoV-2 infection. [Inhaled RDV represents a promising treatment strategy for reducing the COVID-19 public health burden.](#)

Vaccines

- This vaccine effectiveness (VE) study presents the preliminary findings from the Sisonke 2 study in South Africa. The authors enrolled 227310 Healthcare workers who had received an initial single dose of the Ad26.COVS vaccine to receive a homologous booster given 6-9 months after the initial vaccination in HCW. The authors compared VE against COVID19 admission for omicron during the period 15th November to 20th December 2021. They observed that VE for hospitalisation increased over time since booster dose, from 63% (95%CI 31-81%); to 84% (95% CI 67-92%) and then 85% (95% CI: 54-95%), 0-13 days, 14-27 days, and 1-2 months post-booster. [Their findings are important given the increased reliance on the Ad26.COVS vaccine in Africa.](#) [not peer reviewed]
- This cohort study in the Dominican Republic aimed to evaluate the effects of a heterologous BNT162b2 mRNA vaccine booster on the humoral immunity of participants that had received a two-dose regimen of CoronaVac. The authors found that the regimen induces elevated virus-specific antibody levels and potent neutralisation activity against the ancestral virus and Delta variant, resembling the titres obtained after 2 doses of mRNA vaccines. Neutralisation of Omicron was undetectable in participants that had received a two-dose regimen of CoronaVac vaccine. A BNT162b2 booster resulted in a 1.4-fold increase in neutralisation activity against Omicron, compared to two-dose mRNA vaccine. Despite this increase, neutralising antibody titres were reduced by 6.3-fold and 2.7-fold for Omicron compared to ancestral and Delta variant, respectively. Previous SARS-CoV-2 infection did not affect the neutralising titres for Omicron in participants that received the heterologous regimen. [Their findings highlight the global need for vaccine boosters to combat the impact of emerging variants.](#) [not peer reviewed]
- This retrospective cohort study in the U.S aimed to identify the incidence rate and incidence rate ratio (IRR) for COVID-19 breakthrough infection after SARS-CoV-2 vaccination among persons with or without immune dysfunction. The authors analysed data from 664,722 patients who received at least 1 dose of a SARS-CoV-2 vaccine. They found that those with immune dysfunction, such as people with HIV infection (adjusted IRR [AIRR], 1.33; 95% CI, 1.18-1.49), rheumatoid arthritis (AIRR, 1.20; 95% CI, 1.09-1.32), and solid organ transplant (AIRR, 2.16; 95% CI, 1.96-2.38) had a higher rate of breakthrough infection. Compared with partial vaccination, full vaccination was associated with a 28% reduced risk for breakthrough infection (AIRR, 0.72; 95% CI, 0.68-0.76). [They recommend continued use of nonpharmaceutical interventions and alternative vaccine strategies \(e.g., additional doses or immunogenicity testing\) in persons with immune dysfunction.](#)
- This single-blind, randomised, non-inferiority trial aimed to examine safety, reactogenicity, and immunogenicity of heterologous COVID-19 regimens including m1273 and NVX as boost vaccines for people who received a first dose of ChAd or BNT in the community COVID-19 vaccination programme in the UK, given after the prime at 8–12 weeks. Their findings show that heterologous second dosing with m1273, but not NVX, increased transient systemic reactogenicity compared with homologous schedules. Their findings confirm previous evidence of mixed adenoviral and mRNA schedules as being safe, tolerable, and immunogenic alternatives to homologous schedules when given at an 8–12 weeks interval. [Their results provide reassurance that there are multiple appropriate options to complete primary immunisation in individuals primed with BNT or ChAd, which will facilitate rapid vaccine deployment globally.](#)
- This neutralising activity evaluation in China aimed to explore the immunogenicity of COVID-19 breakthrough infection patients, a third heterologous booster of protein subunit vaccine (ZF2001) primed with two doses of inactivated vaccines (BBIBP-CorV), and a third homologous booster of an inactivated vaccine against SARS-CoV-2 pseudo types corresponding to the prototype, Beta, Delta, and the emergent Omicron variant. The authors enrolled 37 participants in the study. Their findings

demonstrate that [vaccine-induced immune protection might more likely be escaped by Omicron compared to prototypes and other VOCs. After two doses of inactivated whole-virion vaccines as the “priming” shot, a third heterologous protein subunit vaccine and a homologous inactivated vaccine booster could improve neutralisation against Omicron.](#)

- This prospective cohort study aimed to assess the immunogenicity of the mRNA-1273 vaccine among people living with HIV (PLWHIV). The authors enrolled 71 PLWHIV in Italy on suppressive combination antiretroviral therapy, majority had good CD4+ T cell counts. The participants were given a two-dose regimen of mRNA-1273, 28 days apart. The authors assessed anti-spike (anti-S) antibody titres and neutralising antibody activity 28 days after completing the vaccination schedule. They found that the vaccine schedule produced detectable humoral immune response, similar to individuals without HIV infection, supporting vaccination in PLWHIV. They recommend further studies to [test vaccine effectiveness, durability of the humoral response, assess the cellular immune response, and confirm their results also in those who are viraemic or display very low CD4+ T cell counts.](#)
- This double-blind, randomised, international, placebo-controlled, endpoint-case driven, phase 3 clinical trial investigated the efficacy, safety, and immunogenicity of one dose of 5×10^{10} vp/mL Ad5-nCoV vaccine in healthy adults. Participants were enrolled from 66 sites in Pakistan, Mexico, Russia, Chile, and Argentina. The vaccine was found to be 57.5% efficacious against symptomatic infection beginning 28 days postvaccination and 63.7% efficacious against symptomatic infection beginning 14 days postvaccination. Against severe disease, the Ad5-nCoV vaccine was 91.7% effective against severe disease beginning 28 days and 96.0% effective 14 days post vaccination. The vaccine was well-tolerated and immunogenic. Serious adverse events were reported in 14 (0.1%) participants in the vaccine group and 10 (0.1%) participants in the placebo group. Medically attended adverse events were reported by 40 (0.2%) Ad5-nCoV recipients and 43 (0.2%) placebo recipients. [Their findings indicate that the Ad5-nCoV adenovirus-vectored vaccine can play an important part in the public health response to COVID-19, particularly in resource-limited areas of the world.](#)

Diagnosics

- This study aimed to evaluate the diagnostic performance of saliva and mid-turbinate swabs as RT-PCR samples for the Delta and Omicron variants. The authors recruited 382 acutely symptomatic, non-hospitalised patients who presented for SARS-CoV-2 testing in a hospital in South Africa. They collected paired mid-turbinate (MT) and saliva (SA) swabs for testing. They found that the positive percent agreement (PPA) of saliva swabs and mid-turbinate swabs to a composite standard was 71% (95% CI: 53-84%) and 100% (95% CI: 89-100%), respectively, for the Delta variant. However, for the Omicron variant saliva and mid-turbinate swabs had a 100% (95% CI: 90-100%) and 86% (95% CI: 71-94%) PPA, respectively. [Their findings suggest that the pattern of viral shedding during the course of infection is altered for Omicron with higher viral shedding in saliva relative to nasal samples resulting in improved diagnostic performance of saliva swabs.](#) [not peer reviewed]
- This modelling study in the U.S aimed to compare SARS-CoV-2 viral dynamics among 36 participants who were infected with the B.1.1.7 (alpha) variant, 36 participants with the B.1.617.2 (delta) variant, and 41 participants with a variant that was not of current interest or concern, along with 37 vaccinated and 136 unvaccinated participants. The authors found no meaningful difference in the mean peak viral load, proliferation duration, clearance duration, or duration of acute infection of either the alpha or the delta variant as compared with variants not of interest or concern. They also found no meaningful difference in the mean peak viral load or proliferation duration between vaccinated and unvaccinated participants. [They recommend further studies among diverse cohorts to better understand differences in SARS-CoV-2 viral trajectories and inform interventions to mitigate the effects of COVID-19.](#)
- This study presents a comparative analysis of seven Antigen-detecting rapid diagnostic tests (Ag-RDTs), evaluated in a multi-centre, clinical accuracy study with over 7000 participants in Germany and Brazil. The authors assessed accuracy overall and in predefined subgroups (according to viral load, presence of symptoms and symptoms duration). They found that three tests meet the requirements formulated for WHO EUL (> 80% sensitivity, > 97% specificity) and a fourth test came very close. All tests showed high sensitivity in the first three days after symptom onset ($\geq 87.1\%$) and in individuals

with viral loads $\geq 6 \log_{10}$ SARS-CoV2 RNA copies/mL ($\geq 88.7\%$). [A comparative system usability and ease-of-use assessment was also conducted, the results complement the accuracy assessment of the tests and highlight critical factors to facilitate widespread use of Ag-RDTs in point-of-care settings.](#)

Care and Treatment

- This randomised, double-blind, and placebo-controlled clinical trial in China aimed to evaluate the long-term safety and efficacy of intravenous infusions of human umbilical cord-derived mesenchymal stem cells (UC-MSCs) in severe COVID-19 patients. The authors had enrolled 100 patients in their phase 2 trial. They found that MSC medication showed numerically improvement in lung lesion volume compared with the placebo. MSC also contributed to higher proportion of normal CT images, lower incidence of symptoms in the 1-year follow-up. MSC treatment did not affect the production and maintenance of neutralising antibodies in COVID-19 patients after 1 year. The incidence of adverse events was similar in the two groups. Their findings indicate [that UC-MSC administration achieves a long-term benefit in the recovery of lung lesions and symptoms in COVID-19 patients with good tolerance.](#)
- This phase 2a randomised, double-blind, placebo-controlled clinical trial aimed to evaluate the safety, tolerability, and antiviral activity of molnupiravir dosed twice daily for 5 days in patients with mild to moderate COVID-19. The authors enrolled 202 unvaccinated participants with confirmed SARS-CoV-2 infection and with symptom duration < 7 days. The authors found that the time to viral RNA clearance was decreased in the 800 mg molnupiravir group (median 14 days) compared to the placebo group (median 15 days) (log rank p-value=0.013). 92.5% of participants receiving 800 mg molnupiravir achieved viral RNA clearance compared with 80.3% of placebo recipients by study end. Infectious virus was detected in swabs from 1.9% of the 800 mg molnupiravir group compared with 16.7% of placebo group at day 3 of treatment (p =0.016). At day 5 of treatment, infectious virus was not isolated from any participants receiving 400 or 800 mg molnupiravir compared with 11.1% of placebo recipients (p =0.034 and 0.027, respectively). [Molnupiravir was well tolerated, with a similar number of adverse events across all doses.](#)

Epidemiology

- This cohort study aimed to estimate the transmission dynamics following the spread of Omicron VOC within Danish households during December 2021. The authors used data from Danish registers to estimate the household secondary attack rate (SAR). They identified 6,397 secondary infections during a 1–7-day follow-up period among 11,937 households (2,225 with the Omicron VOC). The SAR was 31% and 21% in households with the Omicron and Delta VOC, respectively. They found an increased transmission for unvaccinated individuals, and a reduced transmission for booster-vaccinated individuals, compared to fully vaccinated individuals. Comparing households infected with the Omicron to Delta VOC, they found an Odds Ratio of 1.17 times higher SAR for unvaccinated, 2.61 times higher for fully vaccinated and 3.66 times higher for booster-vaccinated individuals, demonstrating strong evidence of immune evasiveness of the Omicron VOC. [Their findings confirm that the rapid spread of the Omicron VOC primarily can be ascribed to the immune evasiveness rather than an inherent increase in the basic transmissibility.](#) [not peer reviewed]
- This study aimed to describe the clinical severity of patients hospitalised with SARS-CoV-2 infection during the first 4 weeks of the Omicron-dominated 4th wave and compare this to the first 4 weeks of the Beta-dominated 2nd and Delta-dominated 3rd waves in Gauteng Province, South Africa. The authors found that the [proportion of cases admitted was lower and those admitted were less severe during the first four weeks of the Omicron-dominated fourth wave in Gauteng province. They warn readers from extrapolating their findings to other populations with different co-morbidity profiles, prevalence of prior infection and vaccination coverage.](#) [not peer reviewed]
- This study reports a super-spreading event where 21 of 33 healthcare workers were infected with the Omicron variant after attending a social gathering in early December 2021 in the Faroe Islands, even though all infected participants had been vaccinated three times and had a recent negative test. All

the infected cases experienced symptoms. Loss of taste and smell seem to be less common in these cases, compared with previous outbreaks. Their findings indicate that the [Omicron variant displays potent immune-escape properties and that even individuals recently boosted are at risk of getting infected. They recommend social distancing and the avoidance of larger festive gatherings during the pandemic so as to prevent possible super-spreading events.](#) [not peer reviewed]

- This study describes the experiences and lessons learned from the SARS-CoV-2 monitoring and surveillance program at the Public Health Laboratory on Bioko Island, Equatorial Guinea that was implemented as part of the national COVID-19 response and monitoring activities. The authors report how three distinct SARS-CoV-2 variants have dominated the epidemiological situation in the country since March 2020. They also present a case report of co-infection of two SARS-CoV-2 VOC, Beta and Delta, in a clinically asymptomatic and fully COVID-19 vaccinated man living in Equatorial Guinea. [Rapid identification of co-infections is relevant since these might provide an opportunity for genetic recombination resulting in emergence of novel SARS-CoV-2 lineages with enhanced transmission or immune evasion potential.](#)
- This study assessed hospitalised patients with a positive SARS-CoV-2 test result during the fourth wave compared with previous waves in South Africa. The authors analysed data from Netcare, a private health care group consisting of 49 acute care hospitals (>10 000 beds) across South Africa. They observed a [different pattern of characteristics and outcomes in patients hospitalised with COVID-19 in the early phase of the fourth wave compared with earlier waves. Younger patients were found to have fewer comorbidities, fewer hospitalisations and respiratory diagnoses, and a decrease in severity and mortality.](#)

Infection Prevention and Control

- This serological survey aimed at investigating whether SARS-CoV-2-seropositivity in healthcare workers in a public hospital in Rio de Janeiro, Brazil, was influenced by social determinants of health and the social vulnerability in subgroups of workers. The study involved 1,154 HCWs. The authors found that the serum prevalence for the virus in the healthcare workers was 30%. Non-white workers (208/561) with lower income (169/396) and schooling (150/353), as well as users of the mass transportation system (157/246) showed the highest infection rates. Importantly they mostly corresponded to hospital support workers (131/324), in particular the cleaning personnel (42/70). Accordingly, income, schooling and work modality appeared as negative predictors. [Their findings illustrate the inequality in SARS-CoV-2 infection among HCWs. They can be used to drive public policies for the protection and vaccination of the most vulnerable group, especially given situations of shortages of inputs and vaccines.](#)
- This longitudinal SARS-CoV-2 sero-epidemiological investigation aimed to assess the extent of infection among healthcare workers in a tertiary infectious disease hospital in the Philippines. The study involved ~1,200 HCWs. The authors identified the non-clinical support service staff belonging to lower income households as having the highest risk for COVID-19 infection among the healthcare workforce. Their socioeconomic background, compounded by their nature of work, makes them the easiest target for COVID-19 infection. Their findings [provide a wake-up call to realign hospital policies to extend provision of periodic screening and hazard pay to these non-clinical frontliners who play significant roles in fighting COVID-19 but may be perceived to have lesser risk in acquiring the infection.](#)
- This longitudinal study in the UK reports on the persistence of hesitancy for first and second vaccine doses among healthcare workers (HCWs), and the factors that predict persistent hesitancy. Their findings showed that HCWs in nursing/midwifery roles (aOR 2.00, 95%CI 1.20 – 3.28), allied health professionals (including pharmacists, healthcare scientists, ambulance workers and those in optical roles; 1.79, 1.15 – 2.80) and dental roles (3.02, 1.53 – 6.01) were more likely to remain hesitant than those in medical roles. Those who had taken up influenza vaccination in the previous seasons were less likely to remain SARS-CoV-2 vaccine hesitant (0.43, 0.28 – 0.66 [for one influenza vaccination in previous two seasons], 0.45, 0.32 – 0.62 [for influenza vaccine uptake in both seasons]). Older HCWs were less likely to remain hesitant. There were no significant differences in risk of persistent hesitancy

by sex or ethnic group. [Their findings can be used to inform interventions aimed at improving vaccine uptake in HCWs and the wider community.](#)

Non-pharmaceutical interventions, social distancing

- This prospective, observational study aimed to monitor dynamics of COVID-19 infections in schools and preschools and identify factors influencing the extent of outbreaks. The authors analysed routine surveillance data of Mecklenburg-Western Pomerania, Germany, from calendar week (CW) 32, 2020 to CW19, 2021 regarding SARS-CoV-2 infection events in schools and preschools considering changes in infection control measures over time. [Their findings indicate that outbreak events at schools and preschools are effectively contained by an obligation for adults and children to wear face masks.](#)
- This randomised clinical trial in the U.S aimed to examine the effectiveness of low-cost behavioural interventions (i.e. nudges) in increasing downloads of Pennsylvania's COVID Alert PA app. The authors explored the effectiveness of 2 nudges on 39,937 individuals, one nudge displaying a descriptive social norm (vs not) and another framing the benefit of downloading for others (vs self). Their findings show that [participants were significantly more likely to click on the link to download the app when a social norm was absent \(vs present\) and when the message focused on the benefits to others \(vs self\).](#) [Overall, their findings suggest that costless nudges can help reduce the spread of harmful viruses by increasing downloads of contact tracing apps.](#)

D. Clinical Trials Updates

Key updates:

Vaccine trials:

- On 4th January 2022, [Gritstone bio, Inc. shared positive results from the first cohort of Phase I CORAL-BOOST clinical trial of its CORAL self-amplifying mRNA \(samRNA\) vaccine for Covid-19.](#) Findings showed that the 10µg vaccine dose offered robust neutralising antibody responses to Spike and strong CD8+ T cell responses. The new CD8+ T cell responses across a wide range of non-spike epitopes, including several established T cell targets, were observed in the trial, which indicates the vaccine's variant-proof immunity potential. The vaccine was also found to be well-tolerated with encouraging safety profile without any grade 3/4 side effects or unexpected reactogenicity or safety issues noted. Clinical trial registration #: (NCT05148962).
- On 3rd January 2022, [Pfizer Inc. and BioNTech SE announced that the U.S. Food and Drug Administration \(FDA\) has expanded the Emergency Use Authorisation \(EUA\) of a booster dose of the Pfizer-BioNTech COVID-19 Vaccine to include individuals 12 years of age and older.](#) The booster dose is the same dosage strength (30-µg) as the dose approved in the primary series. In addition, the booster can be used in eligible adults aged 18 years and above who received primary vaccine series with a separate authorised Covid-19 shot.
- On 31st December 2021, [Novavax announced that it has completed submission of the final data package to fulfil the prerequisites for emergency use authorisation \(EUA\) application request to the U.S. Food and Drug Administration \(FDA\) for NVX-CoV2373, the recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant.](#) NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials designed as a 2:1 randomised, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity. A trial in the U.S. and Mexico, with 25,452 participants, achieved 90.4% efficacy overall. Clinical trial registration #: (NCT04611802).
- On 23rd December 2021, [Pfizer and BioNTech announced they have submitted their longer-term follow-up data from the pivotal phase 3 clinical trial which involved 2,228 individuals aged 12 through 15 years to the European Medicines Agency \(EMA\) to further support the favourable safety and efficacy profile of COMIRNATY® \(COVID-19 mRNA vaccine\) in this age group.](#) In the trial, a two-dose series of COMIRNATY (30-µg per dose) was 100% effective (95% confidence interval [CI, 87.5, 100.0]) against COVID-19, measured seven days through over four months after the second dose. Among 30 confirmed symptomatic cases of COVID-19 in the trial with and without evidence of prior infection with

SARS-CoV-2, all cases of COVID-19 were in the placebo group (n=1,129) and no cases were in the Pfizer-BioNTech vaccine group (n=1,131). The adverse event profile was generally consistent with other clinical safety data for the vaccine, with a favourable safety profile observed in individuals with at least 6 months of safety follow-up after the second dose.

- On 22nd December 2021, [Akston Biosciences announced positive data from the phase 3 clinical trial of its second-generation SARS-CoV2 vaccine candidate, AKS-452](#). The AKS-452 is a protein sub-unit vaccine, a type of vaccine used safely for decades. The interim analysis showed a robust overall 98% seroconversion response after either two 45µg doses (100%), or a single 90µg dose (96%) in healthy adults at 56 days. It showed the vaccine induced a robust Th1/Th2 mixed immune response against the Receptor Binding Domain (RBD) of the coronavirus spike protein. Two 45 µg doses and single 90 µg of protein subunit vaccine AKS-452 were generally well-tolerated and showed robust neutralising antibody titres. Primary immunogenicity endpoints were met. The vaccine is shelf stable for at least 6 months at 25° C (77° F). Clinical trial registration #: (NCT04681092).

Therapeutics trials:

- On 23rd December 2021, [Merck and Ridgeback Biotherapeutics announced that the U.S. Food and Drug Administration \(FDA\) has granted Emergency Use Authorisation \(EUA\) for molnupiravir, an investigational oral antiviral \(MK-4482, EIDD-2801\)](#). The EUA for molnupiravir was granted to treat mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalisation or death, and for whom alternative COVID-19 treatment options authorised by the FDA are not accessible or clinically appropriate. The authorisation is based on the phase 3 MOVE-OUT trial which shows molnupiravir reduced the absolute risk of hospitalisation or death by 3.0% (95% confidence interval [CI]: 0.1, 5.9). Clinical trial registration #: (NCT04405739).
- On 23rd December 2021, [OPKO Health, reported preliminary topline results from its Phase 2 trial with RAYALDEE® to treat mild-to-moderate COVID-19](#). RAYALDEE is an extended-release oral formulation of calcifediol, a prohormone of calcitriol, the active form of vitamin D3. 171 symptomatic COVID-19 outpatients were enrolled from multiple U.S. sites and randomised in a 1:1 ratio for 4 weeks of treatment with RAYALDEE or placebo and a 2-week follow-up. Five symptoms were evaluated: trouble breathing, chest congestion, dry or hacking cough, body aches and pains, and chills and shivering. The three symptoms related to respiratory function, evaluated together, resolved more quickly when serum 25D was elevated at Days 7 and 14 (Wilcoxon p<0.05), with resolution of chest congestion occurring 3.4 days sooner (Wilcoxon p<0.05). In subjects achieving increases in serum 25D of at least 25 ng/mL, chest congestion resolution occurred 4 days earlier (Wilcoxon p< 0.05). The mean time to resolution for all five symptoms considered in aggregate was not significantly different between the treatment groups since symptoms unrelated to respiratory function were unresponsive to treatment. Clinical trial registration #: (NCT04551911).
- On 22nd December 2021, [Pfizer announced that the U.S. Food and Drug Administration \(FDA\) has authorised the emergency use \(EUA\) of PAXLOVID™ \(nirmatrelvir \[PF-07321332\] tablets and ritonavir tablets\) for the treatment of mild-to-moderate COVID-19](#). The EUA was granted for the treatment of adults and paediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalisation or death. EUA based on clinical data from EPIC-HR study, showing PAXLOVID reduced risk of hospitalisation or death by 89% (within three days of symptom onset) and 88% (within five days of symptom onset) compared to placebo. Clinical trial registration #: (NCT04960202).
- On 22nd December 2021, [Ingenev Pharma announces that it has completed a double-blind placebo-controlled clinical trial designed to evaluate the benefits of hesperidin therapy in symptomatic non-vaccinated COVID-19 subjects](#). In the trial, 216 subjects were randomised to receive either Hesperidin

1000 mg once-daily or placebo for 14 days. Thirteen symptoms including fever, cough, shortness of breath and anosmia (“Group A symptoms”) were monitored. Group A symptoms in the placebo vs hesperidin groups were 88.8% vs 88.5% at day 1 and reduced to 58.5 vs 49.4 % at day 14, respectively. At that timepoint, 15 subjects in the placebo group and 28 subjects in the hesperidin group failed to report their symptoms, which may be due to symptomatic improvement and decreased willingness to cooperate for the participants that felt better. No safety issues were observed in either cohort. If missing values are assumed to represent “no symptoms”, the hesperidin group shows a statistically significant reduction of 14.5 % of Group A symptoms from 50.9% to 36.4% ($p = 0.03$). Clinical trial registration #: (NCT04715932).

- On 22nd December 2021, [The University of Alabama at Birmingham \(UAB\) and Mereo BioPharma Group plc announced top-line data from a Phase 1b/2 clinical trial evaluating alvelestat, a novel, orally active Neutrophil Elastase \(NE\) inhibitor in hospitalised COVID-19 patients.](#) No safety signals were observed in lab safety monitoring, including none in liver, renal and vital sign parameters. Treatment emergent headaches were more frequent in the alvelestat arm (4/8 - all of moderate severity) compared to placebo (1/8 of mild severity). Three patients in the alvelestat arm were noted to also have headache in the screening period. However, none were considered study-drug related by the investigator. There was no difference in frequency of other adverse events between alvelestat and placebo arms to Day 60. A single SAE of hospital readmission for acute hypoxemic respiratory failure COVID-19 was reported in the alvelestat arm and was not considered study-drug related by the investigator. There were no deaths on study (to end of study assessment at Day 90). In the alvelestat arm 62.5% (5/8) patients had a 2-point decrease in the WHO Disease Severity score by Day 5, compared to 28.5% (2/7) patients in the placebo arm. At Day 7 this improvement in WHO Severity score increased to 87.5% (7/8) in the alvelestat arm and 57% (4/7) in the placebo arm. Clinical trial registration #: (NCT04539795).

Immunotherapies trials:

- On 3rd January 2022, [Celltrion Group reported its monoclonal antibody CT-P63 maintained a robust neutralising ability against the Omicron variant of the SARS-CoV-2 virus in an experiment. CT-P63 demonstrated a well- established safety profile in the global Phase I trial.](#) It also maintained strong neutralising ability against the Omicron variant (B.1.1.529) based on structural analysis by X-ray crystallography and neutralisation data from pseudo- virus testing. Clinical trial registration #: (NCT05017168).
- On 27th December 2021, [Pluristem Therapeutics Inc. announced topline results from its Phase II dose escalation studies evaluating the safety and efficacy of intramuscular injections of PLXPAD cells for the treatment of Acute Respiratory Distress Syndrome \(ARDS\) associated with COVID-19.](#) The analysis is based on 89 patients enrolled in two Phase II studies in the U.S. (the “U.S. study”) and in Europe and Israel (collectively, the “EU study” and together with the U.S. study, the “Studies”). The primary efficacy endpoint was the number of ventilator free days (VFD) from day 1 through day 28 of the Studies. VFD at day 60 and all-cause mortality at days 28 and 60 were part of the secondary efficacy endpoints in the Studies. The Studies did not meet the primary efficacy endpoint of statistically significant improvement of VFD at 28 days. Taking into consideration the baseline risk factors of the ARDS patients, no differences in the safety profile were observed between PLX-PAD and placebo. Clinical trial registration #: (NCT04614025).
- On 23rd December 2021, [AstraZeneca reported that its long-acting antibody \(LAAB\) cocktail, Evusheld, prevent Covid-19, retained neutralisation activity against the Omicron variant of the SARS-CoV-2 virus in studies.](#) Evusheld is a combination of two LAABs, tixagevimab and cilgavimab, obtained from B-cells of convalescent Covid-19 patients. Evusheld’s Inhibitory Concentration 50 (IC50), a measure of neutralising potency of an antibody, was 273 ng/ml and 147 ng/ml in the Oxford and Washington University studies, respectively. These levels are within the range of neutralising antibody

titres found in individuals who have been previously infected with and recovered naturally from COVID-19. The data were generated from laboratory testing using actual live virus isolated from individuals who contracted the Omicron variant of COVID-19, considered a 'gold standard' for antibody neutralisation studies. Evusheld is one of only two antibody therapies authorised for use that showed neutralising activity against Omicron and against all other variants of concern in these two studies.

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

Contributors

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