

COVID-19 Scientific and Public Health Policy Update¹ – (22 December 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

445.9 Million

Vaccines Supplied

324.7 Million

Vaccines Administered

African Population Vaccinated

13.14%

Partially Vaccinated

10.89%

Fully Vaccinated*

*Received two doses/ one dose of Johnson & Johnson vaccine

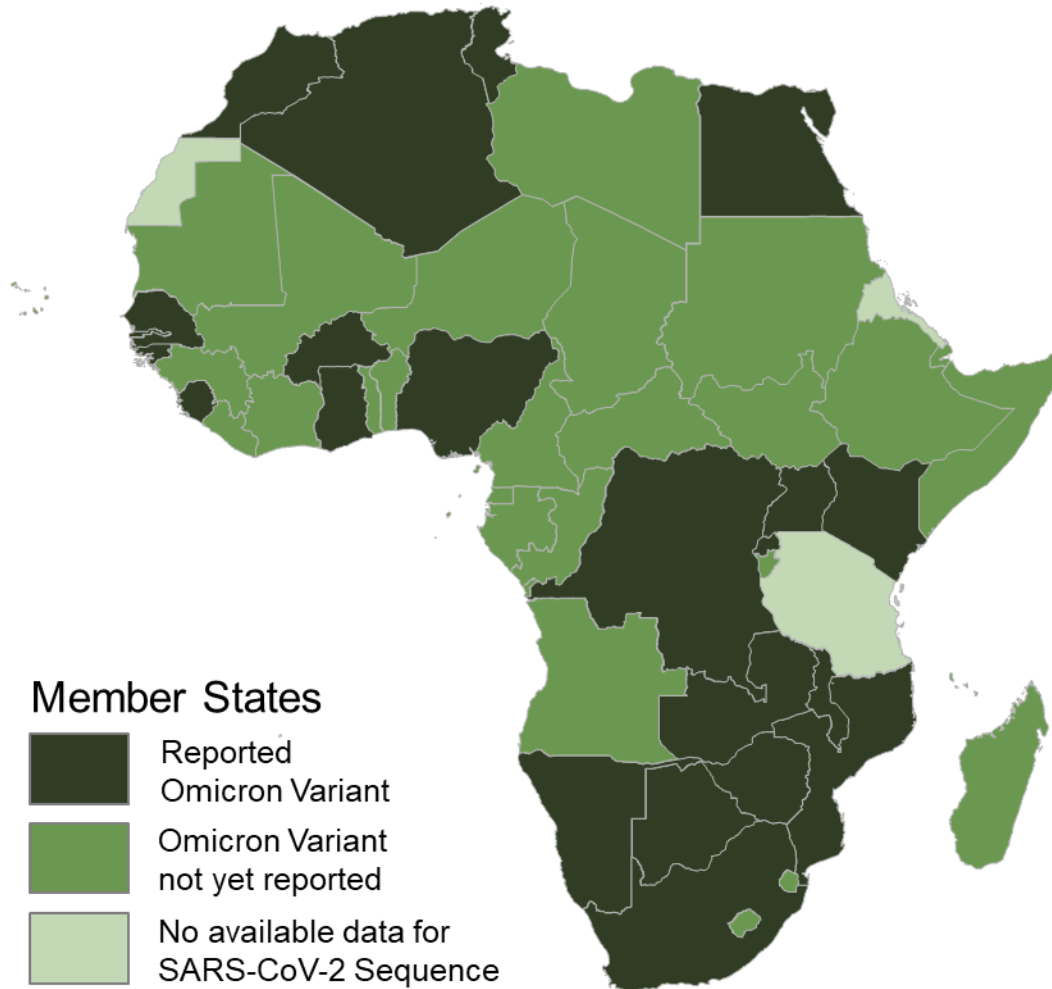
<https://africacdc.org/COVID-19-vaccination/>

Updated 22nd December, 2021

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 on 24th November 2021, has spread to 106 countries worldwide; 22 Member States in Africa have reported this variant.
<https://africacdc.org/institutes/africa-pathogen-genomics-initiative/>



Updated 22nd December, 2021

B. New guidelines and resources

Since 7th December 2021,

- Africa CDC² has published new guidance and resources on:
 - [Enhanced COVID-19 Surveillance at the Community Level in Africa](#)
 - [Responding to COVID-19 in Africa: Finding the Balance \(Part IV\) and calls to action](#)
 - [Vaccination Advocacy Infographics](#)
- U.S. CDC³ has published new guidance and resources on:
 - [Operational Considerations for the Identification of Healthcare Workers and Inpatients with Suspected COVID-19 in non-US Healthcare Settings](#)
 - [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19](#)

² Africa CDC: Africa Centres for Disease Control and Prevention

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

- [Testing Strategies for SARS-CoV-2](#)
- WHO⁴ has published new guidance and resources on:
 - [WHO recommendations on mask use by health workers, in light of the Omicron variant of concern](#)
 - [COVID-19 infection prevention and control living guideline: mask use in community settings](#)
 - [Interim recommendations for use of the Novavax NVX-CoV2373 vaccine against COVID-19](#)
 - [Infection prevention and control \(IPC\) in health-care facilities in the event of a surge or resurgence in cases of COVID-19](#)
 - [Impact of COVID-19 on human resources for health and policy response: the case of Plurinational State of Bolivia, Chile, Colombia, Ecuador and Peru](#)
 - [Interim recommendations for heterologous COVID-19 vaccine schedules](#)
 - [Framework and toolkit for infection prevention and control in outbreak preparedness, readiness and response at the national level](#)
 - [Interim recommendations for the use of the Janssen Ad26.COV2.S \(COVID-19\) vaccine](#)
- U.S. FDA⁵ has issued press releases on:
 - [On 22nd December, FDA authorised the first oral antiviral \(Paxlovid\) for treatment of COVID-19](#)
 - [On 9th December, FDA expanded the eligibility for Pfizer-BioNTech COVID-19 Booster Dose to 16- and 17-year-olds](#)
 - [As of 21st December, 418 tests and sample collection devices are authorised by the FDA under emergency use authorisations](#)
- ECDC⁶ has issued new resources on:
 - [Generic protocol for COVID-19 vaccine effectiveness studies during outbreaks in semi-closed settings in the EU/EEA](#)
 - [Assessment of the further emergence of the SARS-CoV-2 Omicron VOC in the context of the ongoing Delta VOC transmission in the EU/EEA](#)
 - [Methods for the detection and characterisation of SARS-CoV-2 variants](#)
- PHE⁷ has issued new guidance and press releases on:
 - [Management of staff and exposed patients and residents in health and social care settings](#)
 - [Guidance for care of the deceased](#)

C. Scientific updates

Basic Science

- This Australian study aimed to assess the impact of Omicron infection on the ability of: serum from vaccinated and / or previously infected individuals; concentrated human IgG from plasma donors, and licensed monoclonal antibody therapies to neutralise virus in vitro. The authors found that there was a 17 to 22-fold reduction in neutralisation titres across all donors who had a detectable neutralising antibody titre to the Omicron variant. Concentrated pooled human IgG from convalescent and vaccinated donors had greater breadth of neutralisation, although the potency was still reduced 16-fold. Of all therapeutic antibodies tested, significant neutralisation of the Omicron variant was only observed for Sotrovimab, with other monoclonal antibodies unable to neutralise Omicron in vitro. [Their results have implications for ongoing therapy of individuals infected with the Omicron variant.](#) [*not peer reviewed*]

⁴ WHO: World Health Organization

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

⁶ ECDC: European Centre for Disease Prevention and Control

⁷ PHE: Public Health England

- The authors in this study performed a neutralisation assay using Omicron Spike (S)-packaged pseudo typed viruses to evaluate whether the SARS-CoV-2 Omicron variant could escape the cross-neutralisation of convalescent sera from patients infected with the early strains or the Delta strain. The experiments were conducted in China. Their results show that the Omicron variant causes serious immune escape from the convalescent sera from COVID-19 patients. They also found that Omicron still needs angiotensin-converting enzyme 2 (ACE2) as its receptor for cell entry and exhibits a significantly increased infectivity. [They recommend urgent development of Omicron-targeted vaccines to overcome this new variant of concern.](#)
- This case series of 19 patients in Germany aimed to investigate the inflammatory cardiac phenotype associated with SARS-CoV-2 infection compared with viral myocarditis, immune-mediated myocarditis, and noninflammatory cardiomyopathy by integrating histologic, transcriptomic, and proteomic profiling. The authors report that cardiac specimens of patients with SARS-CoV-2 infection had a higher abundance of complement-associated factors and serine/threonine protein kinases, with mitogen-activated protein kinase-associated pathways having the highest abundance. [They found similarities in the cardiac immune signature among those with SARS-CoV-2 infection and viral myocarditis. Their findings have implications for the development of treatment strategies to reduce SARS-CoV-2-mediated tissue injury.](#)
- This animal model study in China aimed to investigate the role of mast cells (MCs) in SARS-CoV-2 infection. Their results showed that SARS-CoV-2-triggered MC degranulation initiated alveolar epithelial inflammation and lung injury. Administration of clinical MC stabilisers for blocking degranulation dampened SARS-CoV-2-induced production of pro-inflammatory factors and prevented lung injury. [Their findings uncover a novel mechanism for SARS-CoV-2 initiating lung inflammation, and suggest an off-label use of MC stabiliser as immunomodulators for COVID-19 treatments.](#)
- The authors in this U.S study used golden hamsters as a model to study the immune responses to SARS-CoV-2 infection. They found that SARS-CoV-2 infection induced immune responses different from influenza infection but could effectively lead to memory B and T cell responses. The generated memory T cells were able to protect against SARS-CoV-2 reinfection of animals with the same strain and a variant of concern. Despite immunity and protection to reinfection, hamsters with SARS-CoV-2 immune memory could still transmit the virus to naïve cage mates. Their findings demonstrate that, [although the establishment of immune memory does not prevent SARS-CoV-2 transmission, it is sufficient at protecting us against both the founder and the variant of concern, suggesting that, with aggressive vaccination campaigns, this pandemic can be resolved.](#)

Vaccines

- This cohort study among healthcare workers in South Africa participating in the Sisonke phase 3B Ad26.COVID.S vaccine trial aimed to assess the rate of breakthrough infections (BTIs) during periods of circulating Beta, Delta and Omicron variants of concern. The duration of each period in the study was 89 days for Beta, 180 days for Delta and 30 days for Omicron. The authors observed a total of 40,538 BTIs, with 609 during Beta, 22,279 during Delta and 17,650 during Omicron. By 15th December, daily infections during Omicron were three times that seen during the peak observed during Delta. Their findings show more BTIs but less severe COVID-19 with Omicron. [They hypothesise that re-infections and Omicron-driven primary infections were likely driven by high population SARS-CoV-2 seroprevalence, waning vaccine effectiveness over time, increased Omicron infectivity, Omicron immune evasion or a combination of these.](#) [not peer reviewed]
- This open label phase 3b implementation study aimed to assess the safety and effectiveness of the Janssen Ad26.CoV2.S vaccine among health care workers in South Africa. The study involved 477,234 participants. A total of 10,279 (2.2%) participants reported adverse events (AEs), of which 139 (1.4%) were serious. Women reported more AEs than men (2.3% vs. 1.6%). AE reports decreased with increasing age. Participants with previous COVID-19 infection reported slightly more AEs (2.6% vs. 2.1%). The commonest reactogenicity events were headache and body aches, followed by injection site pain and fever, and most occurred within 48 hours of vaccination. There were 2 cases of Thrombosis with Thrombocytopenia Syndrome and 4 cases of Guillain Barre Syndrome reported post-

vaccination. Serious AEs and AEs of special interest and deaths occurred at lower than the expected population rates. [The findings suggest that the single-dose Ad26.CoV2.S vaccine had an acceptable safety profile supporting the continued use of the vaccine in their setting.](#) [not peer reviewed]

- The authors in this U.S study developed and evaluated an adjuvanted SARS-CoV-2 spike ferritin nanoparticle (SpFN) vaccine in nonhuman primates. High-dose (50 µg) SpFN vaccine, given twice 28 days apart, induced a Th1-biased CD4 T cell helper response and elicited neutralising antibodies against SARS-CoV-2 wild-type and variants of concern, as well as against SARS-CoV-1. These potent humoral and cell-mediated immune responses translated into rapid elimination of replicating virus in the upper and lower airways and lung parenchyma of nonhuman primates following high-dose SARS-CoV-2 respiratory challenge. [The immune response elicited by SpFN vaccination and resulting efficacy in nonhuman primates supports the utility of SpFN as a vaccine candidate for SARS-causing beta coronaviruses.](#)
- This cohort study aimed to assess immune responses in ≥50-year-olds receiving a COVID-19 vaccine as part of the UK extended immunisation schedule. The authors compare serological responses after BNT162b2 and AZD1222 vaccination with varying dose intervals, and evaluate these against real-world national vaccine effectiveness (VE) estimates against COVID-19 in England. Their findings show that antibody levels 14–35 days after dose two are higher in BNT162b2 recipients with an extended vaccine interval (65–84 days) compared with those vaccinated with a standard (19–29 days) interval. Following the extended schedule, antibody levels were 6-fold higher at 14–35 days post dose 2 for BNT162b2 than AZD1222. For both vaccines, VE was higher across all age-groups from 14 days after dose two compared to one dose, but the magnitude varied with dose interval. [Higher dose two VE was observed with >6-week interval between BNT162b2 doses compared to the standard schedule. Their findings suggest higher effectiveness against infection using an extended vaccine schedule.](#)
- This case control study in the U.S aimed to assess antibody levels and variant cross-neutralisation after breakthrough infection. The study included 26 fully vaccinated health care workers who developed breakthrough infections, they were matched to 26 controls. Their results show substantial boosting of humoral immunity after breakthrough infection, despite predominantly mild disease. Boosting was most notable for IgA (median IgA EC₅₀ of 120 vs 24, 502% increase; *P* < .001). Breakthrough sera demonstrated improved variant cross-neutralisation, and Delta breakthrough infections in particular exhibited improved potency against Delta vs the original SARS-CoV-2 strain (WA1), suggesting that the [protective immune response may be broadened through development of variant boosters with antigenic inserts matching the emerging SARS-CoV-2 variants.](#)
- This cohort study aimed to assess antispikes (anti-S) IgG antibody titres before and after a third BNT162b2 dose in individuals aged 60 years and older. The study involved 97 participants at the Rabin Medical Centre in Israel. The authors found that [the median titre level increased significantly after the third dose, from a median of 440 AU/mL \(IQR, 294-923\) to 25 468 AU/mL \(IQR, 14 203-36 618\). There were no major adverse events reported.](#)
- This self-controlled case series study in England quantifies the risk of several rare cardiac adverse events associated with three COVID-19 vaccines as well as SARS-CoV-2 infection. Vaccination for SARS-CoV-2 in adults was associated with a small increase in the risk of myocarditis within a week of receiving the first dose of both adenovirus and mRNA vaccines, and after the second dose of both mRNA vaccines. [By contrast, SARS-CoV-2 infection was associated with a substantial increase in the risk of hospitalisation or death from myocarditis, pericarditis and cardiac arrhythmia.](#)

Diagnostics

- The authors in this study developed an artificial intelligence model for COVID-19 diagnosis. Their model is based on 9,573 chest computed tomography scans from 3,336 patients collected from 23 hospitals located in China and the United Kingdom. Their findings show that the model has a test sensitivity/specificity of 0.973/0.951 in China and 0.730/0.942 in the United Kingdom, achieving [comparable performance with a panel of professional radiologists. Their work advances the prospects of utilising federated learning for privacy-preserving AI in digital health.](#)

Care and Treatment

- This German study aimed to assess monoclonal antibody neutralising activity against the Omicron variant. The authors assessed 9 monoclonal antibodies previously demonstrated to effectively reduce COVID-19-associated morbidity and mortality in parallel against the Wu01 strain as well as the Alpha, Beta, Delta, and Omicron variants. They found that the neutralising activity against the Omicron variant was abolished in seven out of nine antibodies. [Their results suggest that the Omicron variant exerts substantial humoral immune escape in vitro compared to other variants, this will limit treatment options for Omicron-induced COVID-19.](#) [not peer reviewed]
- This retrospective cohort study of COVID-19 patients in China aimed to investigate the metabolic dysregulation associated with the disease. The authors found that COVID-19 induced elevated blood glucose and new-onset insulin resistance in patients without pre-existing metabolic diseases. They report on the [pathophysiology behind the hyperglycaemia and further illustrate the underlying mechanism. Their results will be of great significance in clinical treatment and follow-up studies for metabolic complications of COVID-19 patients.](#)
- This randomised, double-blind, placebo-controlled trial aimed to determine the safety and efficacy of COVID-19 convalescent plasma (CCP) compared with placebo in hospitalised patients with COVID-19 receiving non-invasive supplemental oxygen. The trial enrolled 941 participants who were hospitalised for 3 or less days or presented 7 or less days after symptom onset and required non-invasive oxygen supplementation at 21 United States hospitals. Their findings show that [CCP did not meet prespecified outcomes for efficacy, but high-titre CCP may have benefited hospitalised patients with COVID-19 early in the pandemic when other treatments \(remdesivir and corticosteroids\) were not in use, suggesting a heterogenous treatment effect over time.](#)
- This cluster randomised, crossover, noninferiority trial aimed to prospectively validate the safety of a strategy that combines the YEARS rule with the pulmonary embolism rule-out criteria (PERC) rule and an age-adjusted D-dimer threshold. The trial included 1414 patients with a suspicion of pulmonary embolism in 18 emergency departments in France and Spain. [The authors found that the 3-month risk of a missed thromboembolic event using the intervention diagnostic strategy, compared with a conventional strategy, was 0.15% vs 0.80%; the confidence interval of this difference did not cross the noninferiority margin of 1.35%.](#)
- This randomised clinical trial aimed to determine the effect of high-flow oxygen therapy through a nasal cannula compared with conventional oxygen therapy on need for endotracheal intubation and clinical recovery in severe COVID-19. The study included a total of 220 adult patients with respiratory distress in 3 hospitals in Colombia. The authors found that the rate of intubation and mechanical ventilation for those treated with high-flow oxygen therapy through a nasal cannula vs with conventional oxygen therapy was 34.3% vs 51.0% (hazard ratio, 0.62; 95% CI, 0.39-0.96; $P = .03$), respectively; the median time to clinical recovery was 11 days vs 14 days (hazard ratio, 1.39; 95% CI, 1.00-1.92; $P = .047$). [Their findings suggest that use of high-flow oxygen through a nasal cannula significantly decrease need for mechanical ventilation support and time to clinical recovery compared with conventional low-flow oxygen therapy.](#)
- The authors in this U.S study describe 4'-fluorouridine (4'-FIU, EIDD-2749), a ribonucleoside analogue that inhibits respiratory syncytial virus (RSV), related RNA viruses, and SARS-CoV-2 with high selectivity index in cells and human airway epithelia organoids. Polymerase inhibition within in vitro RNA-dependent RNA polymerase (RdRP) assays established for RSV and SARS-CoV-2 revealed transcriptional stalling after incorporation. Once-daily oral treatment was highly efficacious at 5 mg/kg in RSV-infected mice or 20 mg/kg in ferrets infected with different SARS-CoV-2 variants-of-concern, initiated 24 or 12 hours after infection, respectively. [These properties define 4'-FIU as a broad-spectrum candidate for the treatment of RSV, SARS-CoV-2, and related RNA virus infections.](#)

Epidemiology

- This study describes the genomic profile and early transmission dynamics of Omicron in South Africa and Botswana, highlighting the rapid spread in regions with high levels of population immunity. The

authors [recommend close monitoring of the spread of Omicron in countries outside southern Africa to better understand its transmissibility and capacity to evade post-infection and vaccine-elicited immunity.](#) [not peer reviewed]

- This survey aimed to determine the SARS-CoV-2 immunoglobulin G seroprevalence prior to the 4th wave of COVID-19 in Gauteng Province, South Africa. The authors evaluate the epidemiological trends in case rates and rates of severe disease from 22nd October to 15th December 2021. They obtained dry blood spot samples from 7010 individuals, of whom 1319 (18.8%) had received a COVID-19 vaccine. The overall seroprevalence ranged from 56.2% (95% CI, 52.6 to 59.7) in children aged <12 years to 79.7% (95% CI, 77.6 to 81.5) in individuals aged >50 years. Seropositivity was 6.22-fold more likely in vaccinated (93.1%) vs unvaccinated (68.4%) individuals. [Epidemiological data showed SARS-CoV-2 infection rates increased more rapidly than in previous waves but have now plateaued. Rates of hospitalisations and excess deaths did not increase proportionately, remaining relatively low.](#) [not peer reviewed]
- This study in South Africa aimed to assess the clinical severity of individuals infected with Omicron, using S Gene Target Failure (SGTF) on the Thermo Fisher Scientific TaqPath COVID-19 PCR test as a proxy. The authors performed data linkages for SARS-CoV-2 laboratory tests, COVID-19 case data, genome data, and the DATCOV national hospital surveillance system for the whole of South Africa. They then compared disease severity in SGTF-infected individuals to non-SGTF and Delta infections. Their findings suggest [a reduced risk of hospitalisation among SGTF-infected individuals when compared to non-SGTF infected individuals in the same time period, and a reduced risk of severe disease when compared to earlier Delta-infected individuals. They hypothesise that some of this reduction is likely a result of high population immunity.](#) [not peer reviewed]
- This cross-sectional aimed to describe the impact of Omicron on clinical manifestations and outcomes of hospitalised children (≤19 years) with positive SARS-CoV-2 tests in Tshwane District, South Africa from 31 October to 11 December 2021. The authors synthesised data from 5 sources. They found that during the six-week period, 6,287 paediatric COVID-19 cases were recorded, of these 462 (7.2%) were hospitalised in 42 hospitals (18% of overall admissions). The number of paediatric cases was higher than in the prior 3 waves, uncharacteristically preceding adult hospitalisations. Clinical information from 139 of 183 (76%) admitted children indicated that young children (0-4 years) were most affected (62%). [Symptoms included fever \(47%\), cough \(40%\), vomiting \(24%\), difficulty breathing \(23%\), diarrhoea \(20%\) and convulsions \(20%\). They recommend continued monitoring to understand the long-term impact of the Omicron variant on children.](#) [not peer reviewed]
- The authors in this study analysed data from all recent PCR-confirmed SARS-CoV-2 cases in England to describe the growth of the Omicron variant of concern and its immune escape characteristics. Their results suggest rapid growth of the frequency of the Omicron variant relative to Delta. They found that 18–29-year-olds, residents in the London region, and those of African ethnicity had significantly higher rates of infection with Omicron relative to Delta. They also found strong evidence of immune evasion, both from natural infection, where the risk of reinfection is 5.41 (95% CI: 4.87-6.00) fold higher for Omicron than for Delta, and from vaccine-induced protection. [Their analysis reinforces the still emerging but increasingly clear picture that Omicron poses an immediate and substantial threat to public health.](#)
- This case series reports and characterises breakthrough infections with the Omicron variant in 7 individuals who had received full primary vaccination series and booster doses with mRNA vaccines. The study was conducted in South Africa among German Visitors. The authors report that all 7 patients experienced symptomatic COVID-19 but clinical manifestations were mild to moderate. [Their findings suggest that even three doses of mRNA vaccines may not be sufficient to prevent infection and symptomatic disease with the Omicron variant. They emphasise on the need to maintain non-pharmaceutical interventions to prevent transmission.](#)
- This systematic review and meta-analysis aimed to evaluate the percentage of asymptomatic infections among individuals undergoing testing (tested population) and those with confirmed COVID-19 (confirmed population). The authors included 95 unique studies with 29 776 306 individuals undergoing testing. Their findings show that the pooled percentage of asymptomatic infections was 0.25% (95% CI, 0.23%-0.27%) among the tested population and 40.50% (95% CI, 33.50%-47.50%) among the

population with confirmed COVID-19. [The high percentage of asymptomatic infections highlights the potential transmission risk of asymptomatic infections in communities. They recommend that screening for asymptomatic infection is required, especially for countries and regions that have successfully controlled SARS-CoV-2. Asymptomatic infections should be under management similar to that for confirmed infections, including isolating and contact tracing.](#)

- This case-control study aimed to report the cumulative mortality rates at different times in cases with COVID-19-associated rhino-orbitocerebral mucormycosis (CAM) and identify risk factors for CAM-associated mortality. The study included 73 patients with CAM in a tertiary care multispeciality hospital in western India. The authors report that, of the 73 patients with CAM, 26 (36%) died; the cumulative probability of death was 26% (95% CI, 16%-41%) at day 7 and doubled to 53% (95% CI, 39%-69%) at day 21. Assisted ventilation during prior COVID-19 treatment or visual acuity of no light perception were associated with a higher risk of death. [Their findings suggest that the mortality rate after CAM is high and that a subgroup of patients with severe COVID-19 or presenting with severe orbital disease are more likely to die within 10 days of admission.](#)
- This modelling study presents a method to deduce temporal and individual variations in the basic reproduction number directly from epidemic trajectories at a community level. The authors used epidemic data that only contain the total counts of the number of infected (and tested) per day from the 98 districts in Denmark. [They estimate an overdispersion factor \$k\$ for COVID-19 to be about 0.11 \(95% CI: 0.08–0.18\), implying that 10 % of the infected cause between 70 % and 87 % of all infections.](#)

Infection Prevention and Control

- This review assesses optimal skin care during the severe acute respiratory syndrome coronavirus 2 pandemic and in the “new normal” that will follow, identifies current knowledge gaps, and [provides practical advice for the clinical setting. The review is written by a group of experienced dermatologists from across Canada.](#)
- This article explores nano-technology based alternate medicinal platforms, mediated through nanomaterials to address or mitigate viral outbreaks including SARS-CoV-2. The authors focus on the potential routes of nano-systems-assisted strategies such as antibacterial/viral coating and membranes, [lipid encapsulated drug formulations of improved efficacy, immune capture assisted sensors amongst others to combat COVID-19 infection, and a way forward to assess the limitations of nanotechnology.](#)

Non-pharmaceutical interventions, social distancing

- This cluster-randomised trial aimed to measure the effect of community-level mask distribution and promotion on symptomatic SARS-CoV-2 infections in rural Bangladesh. The trial involved 342,183 adults in 600 villages from November 2020 to April 2021. The authors cross-randomised mask type (cloth vs. surgical) and promotion strategies at the village and household level. They found that proper mask-wearing increased from 13.3% in the control group to 42.3% in the intervention arm (adjusted percentage point difference = 0.29 [0.26, 0.31]). The intervention reduced symptomatic seroprevalence (adjusted prevalence ratio = 0.91 [0.82, 1.00]), especially among adults 60+ years in villages where surgical masks were distributed (adjusted prevalence ratio = 0.65 [0.45, 0.85]). [Their results suggest that mask distribution and promotion is a scalable and effective method to reduce symptomatic SARS-CoV-2 infections.](#)
- This systematic review and meta-analysis conducted in Iran aimed to examine the effects of Non-Pharmaceutical Public Health Interventions (NPHIs) on the COVID-19 case growth rate, death growth rate, Intensive Care Unit (ICU) admission, and reproduction number in countries, where NPHIs have been implemented. The authors included 35 articles in the systematic review among which 23 studies were included in the meta-analysis, majority were from the U.S and China. Their results showed that adoption of NPHIs has resulted in a 4.68% (95% CI, -6.94 to -2.78) decrease in daily case growth rates, 4.8% (95 CI, -8.34 to -1.40) decrease in daily death growth rates, 1.90 (95% CI, -2.23 to -1.58) decrease in the COVID-19 reproduction number, and 16.5% (95% CI, -19.68 to -13.32) decrease in COVID-19 daily ICU admission. They also found that [early enforcement of lockdown, when the incidence rate is](#)

not high, contributed to a shorter duration of lockdown and a lower increase of the case growth rate in the post-lockdown era. They recommend further studies to address the impact of NPHIs on the population's other health problems than COVID-19.

D. Clinical Trials Updates

Key updates:

Vaccine trials:

- On 20th December 2021, [Moderna announced preliminary neutralising antibody data against the Omicron variant following the Moderna booster candidates at 50 µg and 100 µg dose levels](#). The data includes sera from 20 booster recipients each of mRNA-1273 at the 50 µg and 100 µg dose levels, multivalent candidate mRNA-1273.211 at the 50 µg and 100 µg dose levels, and multivalent candidate mRNA-1273.213 at the 100µg dose level. The 50-µg booster of mRNA-1273 increased neutralising antibody levels against Omicron approximately 37-fold compared to pre-boost levels and a 100-µg dose of mRNA-1273 increased neutralising antibody levels approximately 83-fold compared to pre-boost levels. Clinical trial registration #: (NCT04927065).
- On 17th December 2021, [World Health Organization granted Emergency Use Listing \(EUL\) for NVX-CoV2373, Novavax' recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant, for active immunization of individuals 18 years of age and older for the prevention of coronavirus disease 2019 caused by SARS-CoV-2](#). The grant followed the totality of preclinical, manufacturing and clinical trial data which were submitted for review. This includes two pivotal phase 3 clinical trials: PREVENT-19, which enrolled approximately 30,000 participants in the U.S. and Mexico, which resulted into efficacy of 92.6%. A trial that evaluated the vaccine in more than 14,000 participants in the U.K. and resulted into efficacy of 89.7%. In both trials, NVX-CoV2373 demonstrated high efficacy and a reassuring safety and tolerability profile. Clinical trial registration#: (2020-004123-16) and (NCT04611802).
- On 17th December 2021, [Pfizer and BioNTech announced plans to modify the phase 2/3 clinical trial of their COVID-19 vaccine in children aged six months to below five years](#). The external independent Data Monitoring Committee (DMC) conducted a routine review of the trial assessing the safety, tolerability and immunogenicity of the vaccine in this age group and found that the vaccine showed reduced efficacy in children aged two to under five years. With the amendment, the trial will now comprise a third 3µg vaccine dose administered a minimum of two months after two-dose vaccine regimen series to offer greater protection levels in these children.
- On 15th December 2021, [Committee for Medicinal Products for Human Use \(CHMP\) of the European Medicines Agency \(EMA\) issued a positive opinion for use of Johnson & Johnson COVID-19 vaccine as a booster for adults aged 18 and older at least two months after primary vaccination](#). This is supported by the data of phase 3 ENSEMBLE 2 study results which found a booster of the Johnson & Johnson COVID-19 vaccine given two months after the primary shot provided 75% protection against symptomatic (moderate to severe) COVID-19 globally (CI, 55%-87%) and 94% protection against symptomatic (moderate to severe) COVID-19 in the U.S. (CI, 59%-100%). It also demonstrated 100% protection against severe COVID-19, at least 14 days post-booster vaccination (CI, 33%-100%).
- On 15th December 2021, [GlaxoSmithKline and Sanofi announced that a single booster dose of their recombinant adjuvanted COVID-19 vaccine candidate delivered consistently strong immune responses](#). Preliminary results from the VAT0002 clinical trial investigating the safety and immunogenicity of the booster showed neutralising antibodies increased 9- to 43-fold regardless of the primary vaccine received (AstraZeneca, Johnson & Johnson, Moderna, Pfizer/BioNTech) and for all age groups tested. The booster was well tolerated, with a safety profile similar to currently approved COVID-19 vaccines. Clinical trial registration #: (NCT04537208).
- On 15th December 2021, [GeoVax Labs announced the initiation of vaccine dosing in the phase 2 portion of its Phase 1/2 clinical trial of COH04S1, a multi-antigenic SARS-CoV-2 investigational vaccine, designed to target both the spike \(S\) and nucleocapsid \(N\) proteins, to evaluate its use as a universal booster to current FDA-approved vaccines](#). COH04S1 is a synthetic, attenuated modified vaccinia Ankara (sMVA) vector expressing the SARS-CoV-2 virus' spike (S) and nucleocapsid (N) antigens. The Phase 2 booster study, for which vaccination is now underway, will include 60 healthy individuals,

18 years of age and older, who were previously vaccinated with one of the FDA-approved SARS-CoV-2 mRNA vaccines. The study is designed as a dose-escalation trial to specifically evaluate the safety profile and immunogenicity of COH04S1 as a booster shot. Clinical trial registration #: (NCT04639466).

- On 9th December 2021, [The Food Drug Authority \(FDA\) amended the emergency use authorisation \(EUA\) for the Pfizer-BioNTech COVID-19 vaccine, authorising the use of a single booster dose for administration to individuals aged between 16 and 17 years at least six months after completion of primary vaccination with the Pfizer-BioNTech COVID-19 Vaccine.](#) The extension approval is supported by the analysis of immune response data from approximately 200 participants, aged 18 to 55 years, who received a single booster dose approximately six months after their second dose. The antibody response against the SARS-CoV-2 virus one month after a booster dose of the vaccine, when compared to the response one month after the two-dose primary series in the same individuals, demonstrated a booster response.

Therapeutics trials:

- On 21st December 2021, [Gilead Sciences, announced that the European Commission \(EC\) has approved a variation to the Conditional Marketing Authorisation for Veklury \(remdesivir\) to include adults who do not require supplemental oxygen and are at an increased risk of progressing to severe COVID-19.](#) The decision is supported by results from a phase 3 clinical trial that involved 562 participants randomly assigned in a 1:1 ratio to receive Veklury or placebo. Veklury demonstrated a statistically significant 87% reduction in risk for the composite primary endpoint of COVID-19 related hospitalisation or all-cause death by Day 28 (0.7% [2/279]) compared with placebo (5.3% [15/283]) $p=0.008$. The safety profile was found to be similar between Veklury and placebo. Clinical trial registration #: (NCT04501952).
- On 17th December 2021, [the European Commission \(EC\) granted marketing authorisation to Xevudy \(sotrovimab\) for the early treatment of COVID-19.](#) The decision was based on data from the COMET-ICE phase 3 trial which demonstrated that intravenous treatment with sotrovimab resulted in a 79% reduction (adjusted relative risk reduction) ($p<0.001$) in all-cause hospitalisations for more than 24 hours or death due to any cause by Day 29 compared to placebo, meeting the primary endpoint of the trial. In absolute numbers, 30 (6%) of the 529 patients in the placebo arm progressed, compared to six (1%) of the 528 patients receiving sotrovimab. Sotrovimab has been well-tolerated. The most common adverse reactions are hypersensitivity and infusion-related reactions, seen in approximately 2% and 1% of cases, respectively. Clinical trial registration #: (NCT04545060).
- On 16th December 2021, [Committee for Medicinal Products for Human Use \(CHMP\) of the European Medicines Agency \(EMA\) issued advice on the use of PAXLOVID™ \(nirmatrelvir \[PF-07321332\] tablets and ritonavir tablets\) to treat adults with COVID-19 who do not require supplemental oxygen and who are at increased risk of progressing to severe disease.](#) The CHMP also recommend that PAXLOVID should be administered as soon as possible after diagnosis of COVID-19 and within five days of the start of symptoms.
- On 15th December 2021, [Pfizer reported positive final results from phase 2/3 EPIC-HR clinical trial where its oral antiviral candidate, Paxlovid \(nirmatrelvir and ritonavir\), decreased COVID-19-linked hospitalisation or mortality risk from any cause by 89%.](#) Data analysis from 2,246 adults enrolled in the phase 2/3 EPIC-HR trial confirmed prior results of interim analysis showing Paxlovid drug (nirmatrelvir [PF-07321332] tablets and ritonavir tablets) 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. No deaths compared to placebo in non-hospitalized, high-risk adults with COVID-19 were observed. In addition, the data has confirmed that nirmatrelvir, one of the drugs comprising Paxlovid, is a strong inhibitor of the Omicron 3CL protease. Combined with existing data on Paxlovid's efficacy against other variants of concern (VOCs), these findings indicate that the antiviral demonstrates a robust activity against VOCs and other coronaviruses. Clinical trial registration #: (NCT04960202).
- On 14th December 2021, [NRx Pharmaceuticals provided a new safety update on ZYESAMI® \(aviptadil\), which is being tested in the ACTIV-3b Critical Care Phase 3.](#) In its third scheduled analysis, the study's Independent Data Safety Monitoring Board found no new safety concerns after reviewing a

total of 348 patients and recommended continued enrolment. Clinical trial registration #: (NCT04843761).

Immunotherapies trials:

- On 21st December 2021, [Aridis Pharmaceuticals announced its fully human monoclonal antibody \(mAb\) cocktail AR-701 is broadly reactive against the Omicron and other COVID-19 \(SARS-CoV-2\) variants, SARS \(Severe Acute Respiratory Syndrome\), MERS \(Middle East Respiratory Syndrome Coronavirus\), and seasonal \('common cold'\) human coronaviruses.](#) In vitro neutralisation studies using live coronaviruses showed that AR-701 achieved broad, potent neutralisation against all SARS-CoV-2 variants tested, as well as SARS, MERS, and the seasonal 'common cold' beta coronaviruses.
- On 16th December 2021, [SAB Biotherapeutics announced data demonstrating that SAB-185 therapeutic candidate for the treatment of COVID-19 infections retains neutralisation activity against the Omicron SARS-CoV-2 variant in an in vitro pseudo virus model.](#) The results indicate that SAB-185 retains a potent ability to neutralise recombinant S protein lentiviral pseudo virus that mimics the SARS-CoV-2 Omicron (B.1.1.529) variant. SAB-185 is currently being assessed in a Phase 3 trial that has been enrolling patients since October. The antibodies within SAB-185 are directed against multiple epitopes within the full-length spike protein of the SARS-CoV-2 Wuhan strain. SAB-185 neutralises the Munich, South African, Delta, Lambda, and other circulating variant strains in nonclinical studies. Preclinical data has also indicated that SAB-185 is significantly more potent than human-derived convalescent immunoglobulin G (IgG). Clinical trial registration #: (NCT04518410)
- On 12th December 2021, [Brii Biosciences Company announced new in vitro pseudo virus neutralisation data demonstrating that amubarvimab/romlusevimab combination therapy \(previously referred to as combination BR11-196/BR11-198\) retains activity against the new Omicron SARS-CoV-2 variant \(B.1.1.529\).](#) The amubarvimab/romlusevimab combination demonstrated a statistically significant 80% reduction of hospitalisation and death and improved safety over placebo in non-hospitalized COVID-19 patients at high risk of clinical progression to severe disease. The proportion of deaths from any cause was observed to be significantly less ($p=0.0037$) on the amubarvimab/romlusevimab combination treatment ($n=0$) compared to placebo ($n=9$) from study Day 0 through Day 28. Similar efficacy rates were observed in participants initiating therapy early (0-5 days) and late (6-10 days), following symptom onset, providing critically needed therapeutic option to patients with challenges in timely access to care who may present later. Clinical trial registration #: (NCT04787211).
- On 8th December 2021, the [U.S. Food and Drug Administration issued an emergency use authorisation \(EUA\) for AstraZeneca's Evusheld \(tixagevimab co-packaged with cilgavimab and administered together\) drug for the pre-exposure prophylaxis of COVID-19 in certain adults and paediatric individuals aged >12 years.](#) This decision was supported by data from PROVENT, a randomised, double-blind, placebo-controlled clinical trial in adults greater than age 59 or with a prespecified chronic medical condition or at increased risk of SARS-CoV-2 infection for other reasons who had not received a COVID-19 vaccine and did not have a history of SARS-CoV-2 infection or test positive for SARS-CoV-2 infection at the start of the trial. A total of 3,441 people received Evusheld and 1,731 received a placebo. In the primary analysis, Evusheld recipients saw a 77% reduced risk of developing COVID-19 compared to those who received a placebo, a statistically significant difference. In additional analyses, the reduction in risk of developing COVID-19 was maintained for Evusheld recipients through six months. Clinical trial registration #: (NCT04625725).

Diagnostics:

- On 17th December 2021, [FDA made an alert to clinical laboratory and health care providers that false reactivity, or "false-positive" for Rapid Plasma Reagin \(RPR; non-treponemal\) test results, when using the Bio-Rad Laboratories BioPlex 2200 Syphilis Total & RPR kit, can occur in some people who received a COVID-19 vaccine.](#) It is not known if other RPR tests may be affected similarly. Treponemal testing for syphilis such as Treponema pallidum particle agglutination (TP-PA) and treponemal immunoassays do not appear to be impacted by this issue. Health care providers should make patients who received a reactive RPR result using the Bio-Rad BioPlex 2200 Syphilis Total & RPR test kit aware that they may need to be retested for syphilis with another test to confirm results.



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

Contributors

In alphabetical order:

Alimi, Yewande; Bouesso, Berence Ouaya; Camara, Neema; Dadji, Kwami Hoenoukpo; Hussein, Ally K; Kishimba, Rogath S; Loembé, Marguerite Massinga; Onwuekwe, Ezinne; Seydi, Aminata; Sounga, Carine Sylvie; Sy, Sokona; Tshangela, Akhona; Waya, Chimwemwe; Wangou, Monde Mambimongo.

For any queries, kindly contact: Akhona Tshangela (AkhonaT@africa-union.org)