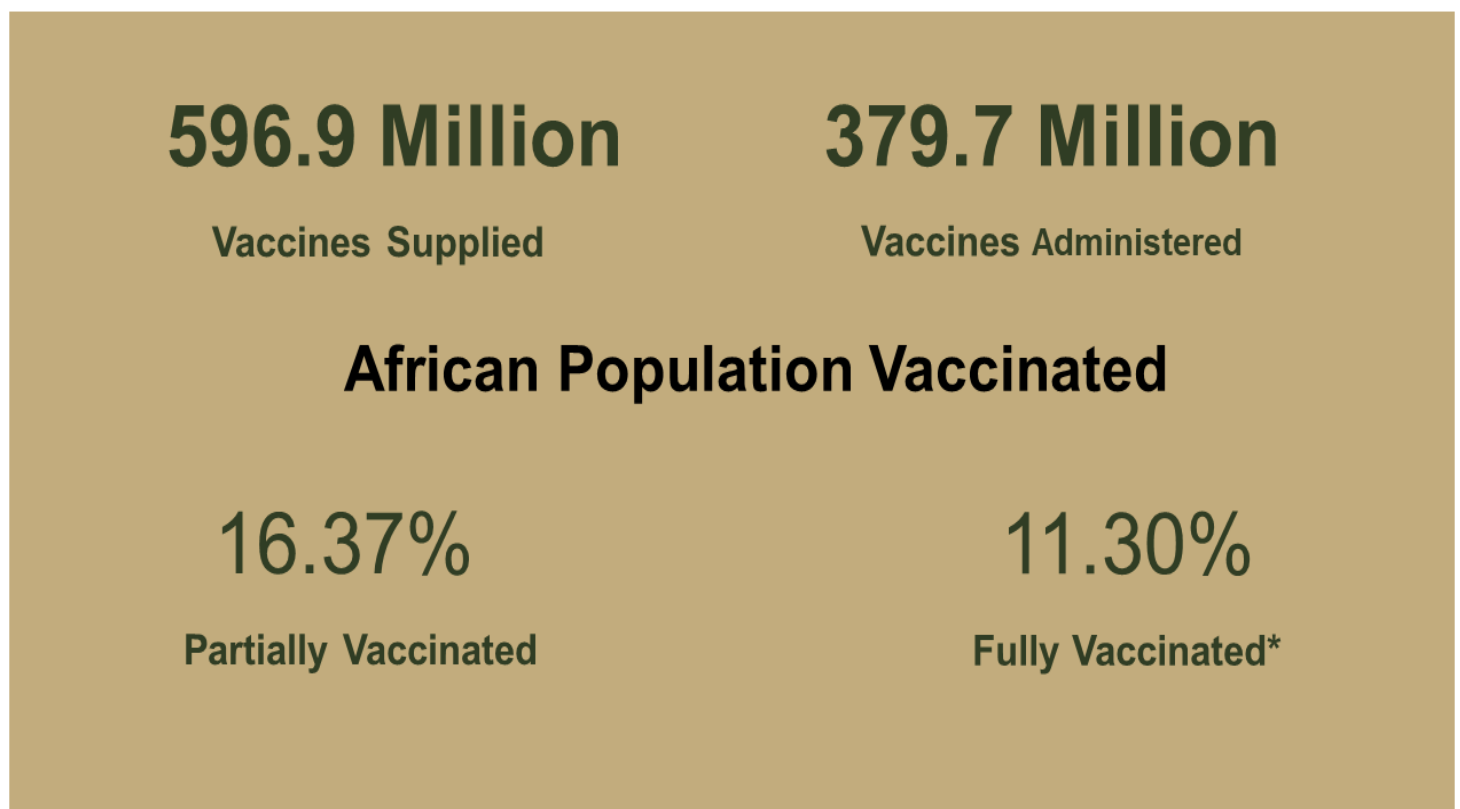


# COVID-19 Scientific and Public Health Policy Update<sup>1</sup> – (2 February 2022)

*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

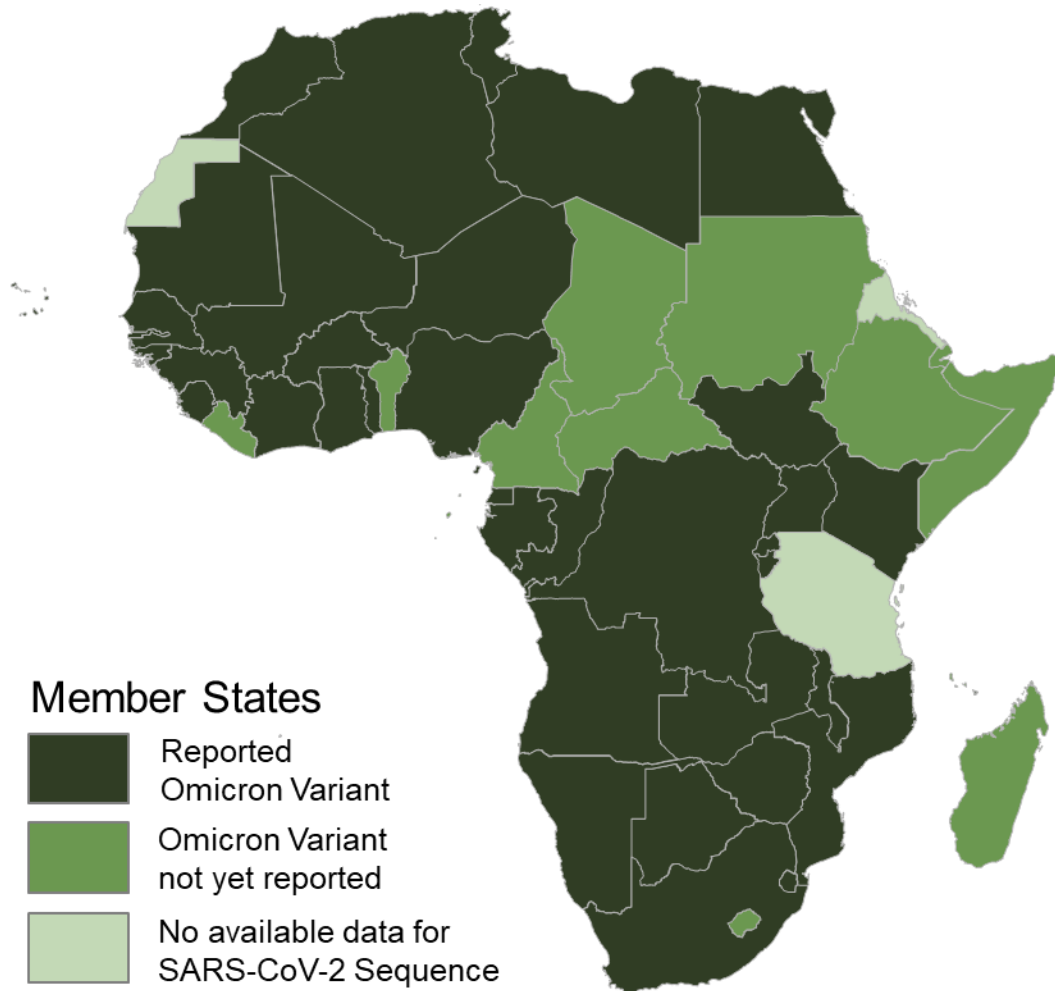


\*Received two doses/ one dose of Johnson & Johnson vaccine  
<https://africacdc.org/COVID-19-vaccination/>  
 Updated 2<sup>nd</sup> February, 2022

<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 Omicron variant (B.1.1.529), first reported in South Africa on 24<sup>th</sup> November 2021, has spread to 159 countries worldwide; 39 Member States in Africa have reported this variant. <https://africacdc.org/institutes/africa-pathogen-genomics-initiative/>



Updated 2<sup>nd</sup> February, 2022

## B. New guidelines and resources

### Since 18<sup>th</sup> January 2022,

- Africa CDC<sup>2</sup> has published new guidance and resources on:
  - [FAQs: Waste Management for COVID-19 in Healthcare Settings for Africa](#)
  - [Africa CDC – Mastercard Foundation: Saving Lives and Livelihoods Newsletter](#)
- U.S. CDC<sup>3</sup> has published new guidance and resources on:
  - [Interim Infection Prevention and Control Recommendations to Prevent SARS-cov-2 Spread in Nursing Homes](#)
  - [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the COVID-19 Pandemic](#)

<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

- [Interim Guidelines for COVID-19 Antibody Testing](#)
- [Guidance for General Laboratory Safety Practices during the COVID-19 Pandemic](#)
- [Investigating a COVID-19 Case](#)
- [Interim Guidance for Managing Healthcare Personnel with SARS-cov-2 Infection or Exposure to SARS-cov-2](#)
- [Interim Guidance for Rapid Antigen Testing for SARS-CoV-2](#)
- WHO<sup>4</sup> has published new guidance and resources on:
  - [Global analysis of health care waste in the context of COVID-19: Status, impacts and recommendations](#)
  - [End-to-end integration of SARS-CoV-2 and influenza sentinel surveillance: revised interim guidance](#)
  - [WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines](#)
  - [Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing](#)
  - [Annexes to the recommendations for use of the Pfizer–BioNTech vaccine BNT162b2 against COVID-19](#)
- U.S. FDA<sup>5</sup> has issued press releases on:
  - [FDA advisory committee meeting to discuss request for authorisation of Pfizer-BioNTech COVID-19 vaccine for children 6 months through 4 years of age](#)
  - [FDA takes key action by approving Second COVID-19 vaccine](#)
  - [FDA limits use of certain monoclonal antibodies to treat COVID-19 due to the Omicron variant](#)
  - [FDA takes actions to expand use of treatment for outpatients with mild-to-moderate COVID-19](#)
  - [As of 1<sup>st</sup> February, 421 tests and sample collection devices are authorised by the FDA under emergency use authorisations](#)
- ECDC<sup>6</sup> has issued new resources on:
  - [Overview of the implementation of COVID-19 vaccination strategies and deployment plans in the EU/EEA](#)
  - [Guidance on ending the isolation period for people with COVID-19, third update](#)
  - [Assessment of the further spread and potential impact of the SARS-CoV-2 Omicron variant of concern in the EU/EEA, 19th update](#)
  - [Interim analysis of COVID-19 vaccine effectiveness against Severe Acute Respiratory Infection due to laboratory-confirmed SARS-CoV-2 among individuals aged 50 years and older, ECDC multi-country study – first update](#)
- UKHSA<sup>7</sup> has issued new guidance and press releases on:
  - [Vaccination of workers in social care settings other than care homes: operational guidance](#)
  - [COVID-19 vaccination of people working or deployed in care homes: operational guidance](#)
  - [COVID-19: providing public health information to passengers travelling to or from England](#)
  - [Face coverings: when to wear one, exemptions and what makes a good one](#)
  - [Technical specifications for personal protective equipment \(PPE\)](#)
  - [Monitoring reports of the effectiveness of COVID-19 vaccination](#)

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

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

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

<sup>7</sup> UKHSA: United Kingdom Health Security Agency

## Scientific updates

### Basic Science

- This [study](#) in South Africa aimed to assess the ability of T cells to react with Omicron spike in participants who were vaccinated with Ad26.CoV2.S, BNT162b2, or unvaccinated convalescent COVID-19 patients. The study involved 70 participants. The authors found that 70-80% of the CD4+ and CD8+ T cell response to spike was maintained across study groups. The magnitude of Omicron cross-reactive T cells was similar to Beta and Delta variants, despite Omicron harbouring considerably more mutations. In Omicron-infected hospitalised patients (n=19), there were comparable T cell responses to ancestral spike, nucleocapsid and membrane proteins to those patients hospitalised in previous waves dominated by the ancestral, Beta or Delta variants (n=49). Thus, despite Omicron's extensive mutations and reduced susceptibility to neutralizing antibodies, the majority of T cell responses, induced by vaccination or infection, cross-recognize the variant.
- This [study](#) in the U.S aimed to understand the molecular basis for the broad evasion of humoral immunity exhibited by the SARS-CoV-2 Omicron variant. The authors determined cryo-electron microscopy and X-ray crystal structures of the spike protein and the receptor-binding domain bound to the broadly neutralizing sarbecovirus monoclonal antibody (mAb) S309 (the parent mAb of sotrovimab) and to the human ACE2 receptor. They provide a blueprint for understanding the marked reduction of binding of other therapeutic mAbs that leads to dampened neutralizing activity. Remodelling of interactions between the Omicron receptor-binding domain and human ACE2 likely explains the enhanced affinity for the host receptor relative to the ancestral virus.
- This [animal model study](#) in China showed that the Omicron variant escapes most Emergency Use Authorisation (EUA) Class I/II neutralising antibodies (Nabs), whereas the neutralisation sensitivity of Class III monoclonal antibodies (mAbs), non-ACE2-blocking antibodies, was less affected by this variant. The authors previously developed a mAb using R33. They humanized it through complementarity determining region (CDR) grafting onto human acceptor germline frameworks and named it hu33. Their in vivo results demonstrate that NAb hu33 is efficacious in treatment models against the Omicron Variant. Structural and functional analyses support the idea that hu33 is a potential treatment option for treating the SARS-CoV-2 VOCs and combating the COVID-19 pandemic.
- The authors in this [case series](#) performed a comprehensive histomorphologic analysis of autaptic visceral adipose tissue, lungs and livers of 19 subjects with COVID-19, and 23 people without COVID-19 in Italy. They also studied human adipocytes infected with SARS-CoV-2. Their study confirms the lung fat embolism in COVID-19 patients and describes for the first time novel COVID-19-related features possibly underlying the unfavourable prognosis in people with COVID-19 and obesity. They recommend for further studies to be conducted with larger sample sizes so as to confirm their findings.
- This [prospective observational minimal invasive autopsy cohort study](#) of 44 patients that died of COVID-19 in Belgium aimed to describe the clinical, radiological, histological, microbiological, and immunological characteristics at different COVID-19 disease stages including patients with post-acute COVID-19. The authors found significant differences in histopathological and immunological characteristics between patients with mild-moderate disease compared to patients with severe-critical disease, whereas differences between patients with severe-critical disease and post-acute disease were limited. Their findings show that a tailored and personal management of COVID-19 patients is necessary.
- This [prospective multicentric cohort study](#) of 215 individuals in Switzerland aimed to develop a score that can predict post-acute coronavirus disease 2019 syndrome (PACS) or long COVID. The authors studied COVID-19 patients during primary infection and up to one year later, and compared them to healthy subjects. They discovered an immunoglobulin (Ig) signature, based on total IgM and IgG3 levels, which – combined with age, history of bronchial asthma, and five symptoms during primary infection – is able to predict the risk of PACS independently of timepoint of blood sampling. They validated the score in an independent cohort of 395 individuals with COVID-19. Their results highlight the benefit of measuring Igs for the early identification of patients at high risk for PACS, which facilitates the study of targeted treatment and pathomechanisms of PACS.

## Vaccines

- This [study](#) aimed to describe reports of myocarditis and the reporting rates to the Vaccine Adverse Event Reporting System (VAERS) that occurred after mRNA-based COVID-19 vaccine administration in the U.S between December 2020 and August 2021. The authors found 1626 cases of myocarditis reported from a total of 192,405,448 individuals who received mRNA-based COVID-19 vaccines during the study period. The risk of myocarditis was increased across multiple age and sex strata and was highest after the second vaccination dose in adolescent males aged 12 to 15 years (70.7 per million doses of the BNT162b2 vaccine), in adolescent males aged 16 to 17 years (105.9 per million doses of the BNT162b2 vaccine), and in young men aged 18 to 24 years (52.4 and 56.3 per million doses of the BNT162b2 vaccine and the mRNA-1273 vaccine, respectively). This risk should be considered in the context of the benefits of COVID-19 vaccination.
- This [single-centre, randomised, controlled, observer-blinded phase 4 trial](#) in China aimed to assess the safety and immunogenicity of heterologous prime–boost immunization with CoronaVac and Convidecia. The authors found that adverse reactions after vaccination were significantly more frequent in Convidecia recipients but were generally mild to moderate in all treatment groups. Heterologous boosting with Convidecia elicited significantly increased geometric mean titres of neutralizing antibody against SARS-CoV-2 than homologous boosting with CoronaVac in participants who had previously received one or two doses of CoronaVac. Their data suggests that heterologous boosting with Convidecia following initial vaccination with CoronaVac is safe and more immunogenic than homologous boosting.
- This [matched-cohort study](#) aimed to investigate the differences in RT-qPCR cycle threshold (Ct) values across Qatar's national cohorts of primary infections, reinfections, BNT162b2 breakthrough infections, and mRNA-1273 breakthrough infections. The authors found higher mean Ct values in all cohorts of breakthrough infections compared to the cohort of primary infections in unvaccinated individuals. The Ct value was 1.3 (95% CI: 0.9–1.8) cycles higher for BNT162b2 breakthrough infections, 3.2 (95% CI: 1.9–4.5) cycles higher for mRNA-1273 breakthrough infections, and 4.0 (95% CI: 3.5–4.5) cycles higher for reinfections in unvaccinated individuals. These differences imply that vaccine breakthrough infections and reinfections are less infectious than primary infections in unvaccinated individuals. Their findings justify optimism and stress the urgency to scale-up vaccination globally in order to robustly control infection transmission and the extent of the pandemic.
- This [modelling study](#) aimed to estimate the effectiveness of vaccination with BNT162b2 against household transmission of SARS-CoV-2 in Israel before and after the Delta variant emerged. The authors employed a chain binomial model to estimate how the probability of infection per day depended on the characteristics of susceptible individuals and their household contacts. They found that vaccination reduced susceptibility to infection by 89.4% [95% CI: 88.7%, 90.0%], whereas vaccine effectiveness against infectiousness given infection was 23.0% (95% CI: –11.3%, 46.7%) during days 10 to 90 after the second dose before June 1, 2021. Total vaccine effectiveness was 91.8% (95% CI: 88.1%, 94.3%). Their results show evidence of a slight reduction in the infectiousness of vaccinated individuals who become infected in addition to protection against susceptibility to infection, leading to an overall reduction in the risk of transmission. However, vaccine effectiveness is reduced over time as a result of the combined effect of waning of immunity and the emergence of the Delta variant.
- This [study](#) in Israel aimed to estimate the protection provided to children through parental vaccination with the BNT162b2 vaccine. The authors studied households without prior infection, consisting of two parents and unvaccinated children, estimating the effect of parental vaccination on the risk of infection for unvaccinated children. They studied two periods separately– an early period (January – March 2021, Alpha variant, two doses vs. no vaccination) and a late period (July – September 2021, Delta variant, booster dose vs. two-vaccine doses). They found that having a single vaccinated parent was associated with a 26.0% and 20.8% decreased risk, and having two vaccinated parents was associated with a 71.7% and 58.1% decreased risk, in the early and late periods, respectively. Their results reinforce the importance of increasing vaccine uptake among the vaccine-eligible population to curb the spread of the SARS-CoV-2 pandemic and protect those who cannot be vaccinated.

## Diagnostics

- This [study](#) aimed to assess whether a smartphone-based assay is suitable for SARS-CoV-2 and influenza virus testing without requiring specialised equipment, accessory devices, or custom reagents. The authors enrolled 2 subgroups of 50 community-based & 50 hospitalised patients in California, U.S. They obtained saliva samples and performed assays using the smartphone-based real-time loop-mediated isothermal amplification (smaRT-LAMP) & compared them to results from a standard RT-qPCR assay. The smartphone-based LAMP assay detected SARS-CoV-2 infection and exhibited concordance with RT-qPCR tests. The smartphone-based LAMP assay was rapid (25 minutes), sensitive (1000 copies/mL), low-cost (<\$7/test), and scalable (96 samples/phone). Their findings suggest that this tool could be adapted in response to novel CoV-2 variants and other pathogens with pandemic potential including influenza and may be useful in settings with limited resources.
- This [prospective study](#) aimed to evaluate the clinical performance of the Panbio COVID-19 Ag Rapid Test Device (RADT) in nasopharyngeal specimens (NP) carried out at the point of care. The authors enrolled 244 patients with clinical suspicion of COVID-19 from primary health centres in Spain. Patients were tested by RT-PCR and RADT within 5 days since symptoms onset. The authors found that 126 patients (51.6%) tested positive by both RT-PCR and RADT, 90 patients (36.8%) returned negative results by both assays and 28 patients (11.4%) yielded discordant results (RT-PCR+/RADT-). No patients tested RT-PCR-/RADT+. Overall specificity and sensitivity of RADT was 100% (95% CI, 95.9-100%) and 81.8% (95% CI, 75-87.1%) respectively. The sensitivity of the assay increased from 79.6% when considering specimens collected at days 0-1 after symptoms onset, to 86.4% when grouping the specimens obtained on days 4-5. Their findings suggest that the RADT performs well (>=80% sensitivity) as a point-of-care test for early diagnosis of COVID-19 due to the Omicron variant. [*not peer reviewed*]

## Care and Treatment

- This [case series](#) aimed to report the clinical characteristics and outcomes of patients who had COVID-19–associated acute respiratory distress syndrome (ARDS) and underwent a lung transplant at a single US Hospital. The case series involved 102 consecutive patients who underwent a lung transplant between January 2020 and September 2021 at North-Western University Medical Centre in Chicago. Among the 102 lung transplant recipients, 30 patients (median age, 53 years [range, 27 to 62]; 13 women [43%]) had COVID-19–associated ARDS. Patient survival was 100% for the 30 patients who had COVID-19–associated ARDS and 83% for the 72 patients without COVID-19, as of 15<sup>th</sup> November 2021.
- This [parallel group, adaptive, randomised clinical trial](#) aimed to determine whether either continuous positive airway pressure (CPAP) or high-flow nasal oxygen (HFNO), compared with conventional oxygen therapy, improves clinical outcomes in hospitalised patients with COVID-19–related acute hypoxemic respiratory failure. The study included 1273 adult patients across 48 acute care hospitals in the UK and Jersey. The authors found that the composite primary outcome of tracheal intubation or mortality within 30 days occurred in 36% of the patients in the CPAP group compared with 44% in the conventional oxygen therapy group, a difference that was statistically significant, and occurred in 44% in the HFNO group compared with 45% in the conventional oxygen therapy group, a difference that was not significantly different.
- This [prognostic study](#) aimed to develop an index for predicting the expected relative treatment benefit from COVID-19 convalescent plasma (CCP) compared with treatment without CCP for patients hospitalised for COVID-19 using patients' baseline characteristics. The authors used data from a meta-analysis of 8 randomised clinical trials which enrolled a total 2287 patients. They developed a combination of baseline characteristics, termed the treatment benefit index (TBI) that predict a gradation of benefit from CCP compared with treatment without CCP. They found that pre-existing health conditions (diabetes, cardiovascular and pulmonary diseases), blood type A or AB, and earlier stage of COVID-19 were associated with a larger treatment benefit. Their findings suggest that simple patient information collected at hospitalisation can be used to guide CCP treatment decisions for patients with COVID-19.

- This [meta-analysis](#) aimed to compile individual patient data from randomised clinical trials of COVID-19 convalescent plasma (CCP) and to monitor the data until completion or until accumulated evidence enables reliable conclusions regarding the clinical outcomes associated with CCP. The meta-analysis included 8 randomised clinical trials enrolling 2341 participants. The authors monitored individual patient data in real time and analysed data using a robust Bayesian framework and advanced statistical modelling. They found no association of CCP with better clinical outcomes for the typical patient. These findings suggest that real-time individual patient data pooling and meta-analysis during a pandemic are feasible, offering a model for future research and providing a rich data resource.

### Epidemiology

- This [case report](#) from South Africa describes a 22-year-old female with uncontrolled advanced HIV infection with persistent SARS-CoV-2 beta variant infection, lasting for a minimum of 9 months. The patient had challenges with adherence to antiretroviral therapy. The authors found that the virus was able to accumulate >20 additional mutations. Antiretroviral therapy suppressed HIV and cleared SARS-CoV-2 within 6-9 weeks. This case highlights the value of well-coordinated and thoroughly established genomic surveillance efforts.
- This [retrospective cohort study](#) aimed to assess the association between type of apolipoprotein L1 (*APOL1*) variant and risk of COVID-19-associated acute kidney injury (AKI) and death in individuals with African ancestry. The study enrolled a cohort of 990 U.S veterans with African ancestry who were hospitalised with COVID-19. The authors found that 1 in 8 participants had *APOL1* high-risk genotypes. Of those with high-risk genotypes, 51.2% had AKI, and 19.2% died, suggesting that high-risk genotype may be associated with a 2-fold increase in the odds of severe AKI and death; this increased risk was observed even in patients with normal kidney function prior to COVID-19.
- This [exploratory multicentre prospective cohort study](#) aimed to assess the occurrence of physical, mental, and cognitive symptoms among patients with COVID-19 at 1 year after intensive care unit (ICU) treatment. The study was conducted in ICUs of 11 Dutch hospitals and included 246 patients. The authors found that 74.3% reported physical symptoms, 26.2% reported mental symptoms, and 16.2% reported cognitive symptoms. The most frequently reported new physical problems were weakened condition (95/244 patients [38.9%]), joint stiffness (64/243 patients [26.3%]) joint pain (62/243 patients [25.5%]), muscle weakness (60/242 patients [24.8%]) and myalgia (52/244 patients [21.3%]). Their findings indicate that physical, mental, and cognitive symptoms were frequent 1 year after ICU treatment for COVID-19.

### Infection prevention & control

- The authors in this [review](#) present a position statement and practical guide to the use of particulate filtering facepiece respirators (N95, FFP2, or equivalent) for South African health workers exposed to respiratory pathogens including Mycobacterium tuberculosis and SARS-CoV-2. They recommend firstly the use of respirators by all staff (clinical and non-clinical) during activities that involve contact or sharing air in indoor spaces with individuals who: (i) have not yet been clinically evaluated; or (ii) are thought or known to have TB and/or COVID-19 or other potentially harmful respiratory infections. Secondly, they recommend the use of respirators that meet national and international manufacturing standards; evaluation of all respirators, at the least, by qualitative fit testing; and the use of respirators as part of a 'package of care' in line with international IPC recommendations.
- This [article](#) presents concisely information on tixagevimab plus cilgavimab (Evusheld) for pre-exposure prophylaxis of COVID-19. The FDA has authorised concomitant use of the monoclonal antibodies tixagevimab and cilgavimab (Evusheld) for pre-exposure prophylaxis of COVID-19 in patients who cannot be vaccinated against COVID-19 because of severe allergy or may not benefit fully from vaccination because of immune compromise. In a double-blind trial, one-time intramuscular administration of the antibodies decreased the incidence of symptomatic COVID-19 compared to placebo in at-risk adults for 6 months. Tixagevimab and cilgavimab can be administered to eligible patients every 6 months while SARS-CoV-2 is in circulation.
- This [study](#) aimed to investigate whether wearing the face masks, filtering facepiece class 3 respirators with personal protective equipment (FPP3/PPE) during work in the intensive care unit (ICU) affects the

blood saturation (SpO<sub>2</sub>), the heart rate (HR), and the well-being of health care workers (HCWs). The study involved 21 HCWs in a university teaching hospital in Poland. Each worker served as his/her own control and performed the test two times: they wore the FFP3/PPE and did not wear it for a three-hour shift in the ICU. They found that working with an FFP3/PPE compared to not working with an FFP3/PPE caused a significant, but within normal ranges, influence on the level of SpO<sub>2</sub> with a mean decrease of – 1.43%. The highest reduction in the SpO<sub>2</sub> was – 2.29% and occurred after 150 min of work. All of the score scales of the well-being markers increased consecutively but moderately during the shift while wearing the FFP3/PPE. The authors assume that a 3-h shift rhythm is a safe and reliable solution, i.e., three hours of working in the FFP3/PPE in the ICU, followed by rest or working without an FFP3/PPE.

#### Non-pharmaceutical interventions, social distancing

- This [prospective, longitudinal study of childcare professionals](#) aimed to assess the association between masking children 2 years and older and subsequent childcare closure because of COVID-19. The study included 6654 childcare professionals from all 50 states in the U.S. The authors found that child masking at baseline (22 May – 8 June, 2020) was associated with a 13% reduction in program closure within the following year, and continued child masking throughout the 1-year study period was associated with a 14% reduction in program closure. Their results suggest that masking of children in childcare programs is associated with reduced program closures, enabling in-person education. This finding has important public health policy implications for families that rely on childcare to sustain employment.
- The authors in this [article](#) tested whether mask-wearing was negatively associated with social distancing compliance. They conducted two studies, they combined video-observational records of public mask-wearing in two Dutch cities with a natural-experimental approach to evaluate the effect of an area-based mask mandate. They found no observational evidence of an association between mask-wearing and social distancing but found a positive link between crowding and social distancing violations. Their natural-experimental analysis showed that an area-based mask mandate did not significantly affect social distancing or crowding levels. Their results alleviate the concern that mask use reduces social distancing compliance or increases crowding levels

## D. Clinical Trials Updates

### Key updates:

#### Vaccine trials:

- On 31<sup>st</sup> January 2022, [Daiichi Sankyo announced that it has initiated a trial in Japan to investigate a booster dose of DS-5670, an mRNA vaccine against the novel coronavirus infectious disease \(COVID-19\)](#). The trial is being conducted as a phase 1/2/3 study to evaluate the safety and efficacy of DS-5670 in healthy Japanese adults, including an elderly population, who completed initial vaccination (1st and 2nd shots) against COVID-19 with vaccines approved in Japan after at least 6 months following last vaccination. The first part of the study will determine the recommended booster dose of DS-5670 followed by a controlled study in 4,500 adults comparing DS-5670 to other vaccines approved in Japan. Clinical trial registration #: (NCT04821674).
- On 31<sup>st</sup> January 2022, [Moderna announced that the U.S. Food and Drug Administration \(FDA\) has approved the Biologics License Application \(BLA\) for SPIKEVAX \(COVID-19 Vaccine, mRNA\) to prevent COVID-19 in individuals 18 years of age and older](#). SPIKEVAX (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent COVID-19. The FDA based its decision on the totality of scientific evidence which included follow-up data from the Phase 3 COVE study showing high efficacy and favourable safety approximately six months after the second dose. Clinical trial registration #: (NCT04894435).



- On 26<sup>th</sup> January 2022, [Moderna announced the first participant has been dosed in the Phase 2 study of the Omicron-specific booster candidate \(mRNA-1273.529\)](#). This extension of an earlier study will evaluate the immunogenicity, safety, and reactogenicity of mRNA-1273.529 as a single booster dose in adults aged 18 years and older in two cohorts: individuals who previously received the two-dose primary series of mRNA-1273 with the second dose being at least six months ago (cohort 1), or who have received the two-dose primary series and a 50 µg booster dose of mRNA-1273 with the booster dose being at least three months ago (cohort 2). Participants in both cohorts will receive a single booster dose of mRNA-1273.529. The study is expected to recruit about 300 participants into each cohort, which will be conducted to 24 sites in the U.S. Clinical trial registration #: (NCT04405076).
- On 25<sup>th</sup> January 2022, [Pfizer and BioNTech announced the initiation of a clinical study to evaluate the safety, tolerability and immunogenicity of an Omicron-based vaccine candidate in healthy adults 18 through 55 years of age](#). The study will have three cohorts examining different regimens of the current Pfizer-BioNTech COVID-19 vaccine or an Omicron-based vaccine. The study will evaluate up to 1,420 participants across the three cohorts: First Cohort (n = 615) and second cohort (n = 600) will receive two doses and three doses respectively of the current Pfizer-BioNTech COVID-19 vaccine 90-180 days prior to enrolment. The third cohort (n=205) Vaccine-naïve participants will receive three doses of the Omicron-based vaccine.

#### Therapeutics trials:

- On 27<sup>th</sup> January 2022, [Pfizer announced that the Committee for Medicinal Products for Human Use \(CHMP\) of the European Medicines Agency \(EMA\) issued a positive opinion recommending the conditional marketing authorisation \(CMA\) of Pfizer's PAXLOVID \(nirmatrelvir \[PF-07321332\] tablets and ritonavir tablets\) for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19](#). This followed a positive opinion on the scientific evidence supporting PAXLOVID, including data from the Phase 2/3 EPIC-HR trial. The trial enrolled non-hospitalised adults aged 18 and older with confirmed COVID-19 who are at increased risk of progressing to severe illness. The data showed that PAXLOVID reduced the risk of hospitalisation or death by 89% (within three days of symptom onset) and 88% (within five days of symptom onset) compared to placebo, with no deaths observed in the treatment group. Treatment-emergent adverse events were comparable between PAXLOVID (23%) and placebo (24%), most of which were mild in intensity. Clinical trial registration #: (NCT04960202).
- On 27<sup>th</sup> January 2022, [Cocrystal Pharma reported to select two investigational novel antiviral drug candidates for further development as oral treatments for SARS-CoV-2](#). CDI-988 and CDI-873 target a highly conserved region in the active site of SARS-CoV-2 main (3CL) protease required for viral RNA replication. Although CDI-988 and CDI-873 are chemically differentiated, both exhibited superior in vitro potency against SARS-CoV-2 with activity maintained against current variants of concern including Omicron. Both candidates demonstrated a favourable safety profile and pharmacokinetic properties supportive of daily oral dosing. The first-in-human trial with one selected candidate will be initiated as soon as possible this year.
- On 27<sup>th</sup> January 2022, [BerGenBio announced their study on BerGenBio AXL inhibitor bemcentinib, in hospitalised COVID-19 patients](#). The EU-SolidAct trial is a multi-centre, randomised, adaptive Phase 2 and 3 platform trial, the master protocol of which has been developed to evaluate potential treatments in hospitalised patients with COVID-19. Under the trial, bemcentinib will be studied in up to 500 hospitalised COVID-19 patients. Clinical trial registration #: (NCT04891133).
- On 27<sup>th</sup> January 2022, [TFF Pharmaceuticals announced that it has completed enrolment of 40 healthy subjects in its Phase 1 clinical trial of a dry powder formulation of niclosamide to treat COVID-19 and other respiratory viral diseases](#). Niclosamide, originally approved as an oral anthelmintic drug by the U.S. Food and Drug Administration in 1982. Recently, it has shown to exhibit potent antiviral activity against SARS-CoV-2 but has limited water solubility as well as low absorption and bioavailability when

administered orally. The developed inhaled formulation targets the lungs directly where SARS-CoV-2 infection occurs. It avoids gastrointestinal side effects and overcoming the bioavailability limitations of systemic administration of Niclosamide. This safety trial comprised of two phases: single ascending dose (SAD) and multiple ascending dose (MAD). In the SAD, healthy subjects in three arms were given single inhalation doses of 0.5, 2, and 6mg. Six subjects will be given active drug while two will receive a placebo. In the previously completed preclinical in vivo efficacy study showed a seven-fold reduction in lung viral load in a hamster model when dry powder niclosamide was administered 24 hours after inoculation with SARS-CoV-2 when the disease was already severe. Clinical trial registration #: (NCT05168644).

- On 27<sup>th</sup> January 2022, [Todos Medical announced positive interim data for its Tollovir oral antiviral Phase 2 clinical trial for the treatment of hospitalised \(severe and critical\) COVID-19 patients.](#) Tollovir is an oral antiviral inhibitor of 3CL protease. It is also an anti-cytokine therapy candidate to treat nidovirus subcategory of coronaviruses comprising SARS-CoV-2, Covid-19, SARS-CoV-1, MERS and 229E. Tollovir met its primary endpoint of reducing time to clinical improvement as measured by the National Emergency Warning System 2 (NEWS2) and met several key secondary clinical endpoints, including complete reduction in COVID-19 deaths. The study NLC-V-01 was a double blinded randomised placebo-controlled study designed to evaluate the safety and efficacy of NLC-V (Tollovir) in hospitalised adult patients with a confirmed diagnosis of SARS-CoV-2 infection. About 78 patients were set to be randomised using a 1:1 ratio (approximately 39 per arm) and stratified by weight group (<70 kg, 70-100kg, and >100kg) to receive Tollovir or placebo, in addition to standard of care. Patients who need mechanical ventilation received the randomised treatment using Liquid Syrup. No cases of deaths linked to COVID-19 were reported in the Tollovir arm as against 22% in the placebo arm.
- On 21<sup>st</sup> January 2022, [Gilead announced that the U.S. Food and Drug Administration \(FDA\) has granted expedited approval of a supplemental new drug application \(sNDA\) for Veklury \(remdesivir\) for the treatment of COVID 19.](#) The drug targets non-hospitalised adult and adolescent patients who are at high risk of progression to severe COVID-19, including hospitalisation or death. This comes amidst a surge in COVID-19 cases and the reduced susceptibility to several anti-SARS-CoV-2 monoclonal antibodies (mAbs) due to the Omicron variant. Veklury targets the highly conserved viral RNA polymerase, thereby retaining activity against existing SARS-CoV-2 variants of concern. In vitro laboratory testing shows that Veklury retains activity against the Omicron variant. To date, no major genetic changes have been identified in any of the known variants of concern that would significantly alter the viral RNA polymerase targeted by Veklury. Clinical trial registration #: (NCT04501952).

#### Immunotherapies trials:

- On 24<sup>th</sup> January 2022, [the U.S. Food and Drug Administration revised the authorisations for two monoclonal antibody treatments – bamlanivimab and etesevimab \(administered together\) and REGEN-COV \(casirivimab and imdevimab\) – to limit their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments.](#) This comes after data showed that these therapies are very unlikely to be active against the omicron variant of the SARS-CoV-2 virus. Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses, like SARS-CoV-2. Like other infectious organisms, SARS-CoV-2 can mutate over time, resulting in certain treatments not working against certain variants such as omicron.

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

### Contributors

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