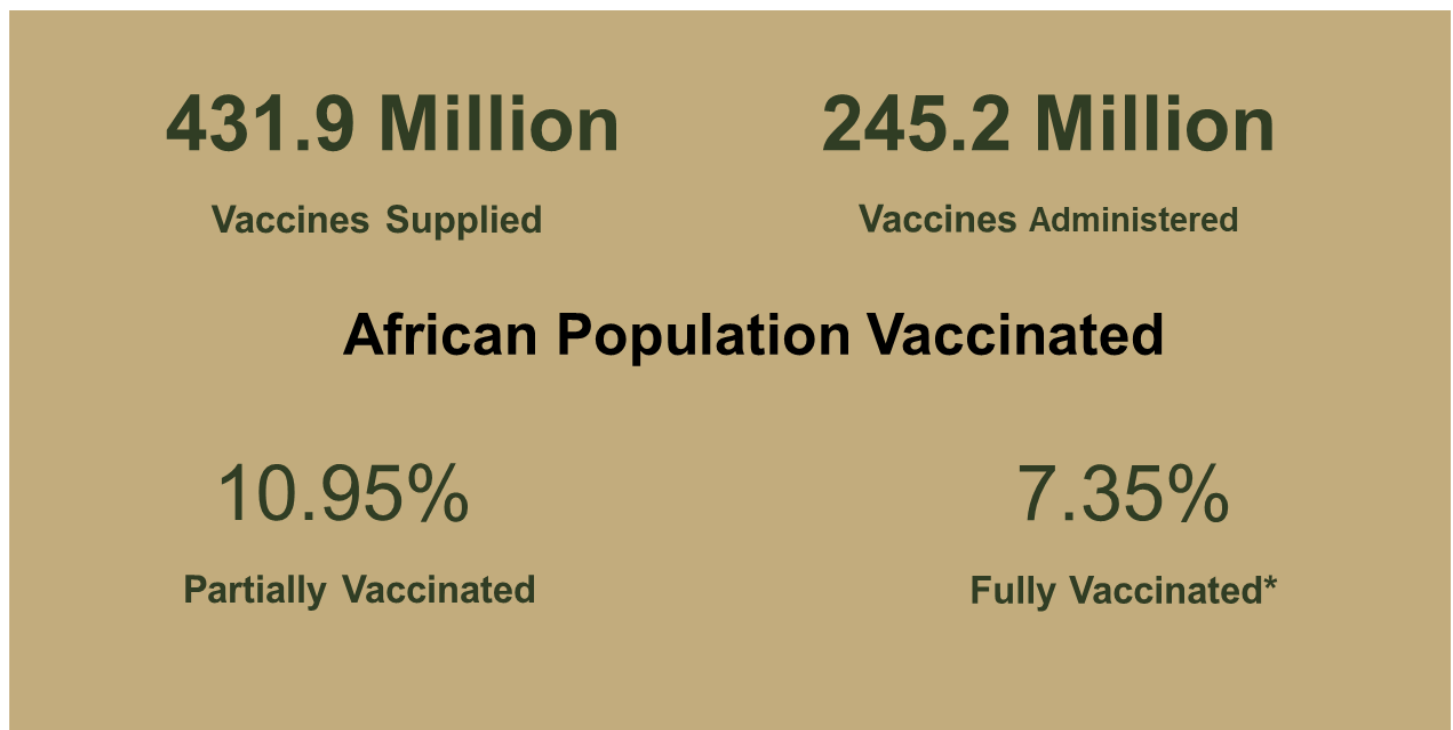


COVID-19 Scientific and Public Health Policy Update¹ – (8 December 2021)

*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



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

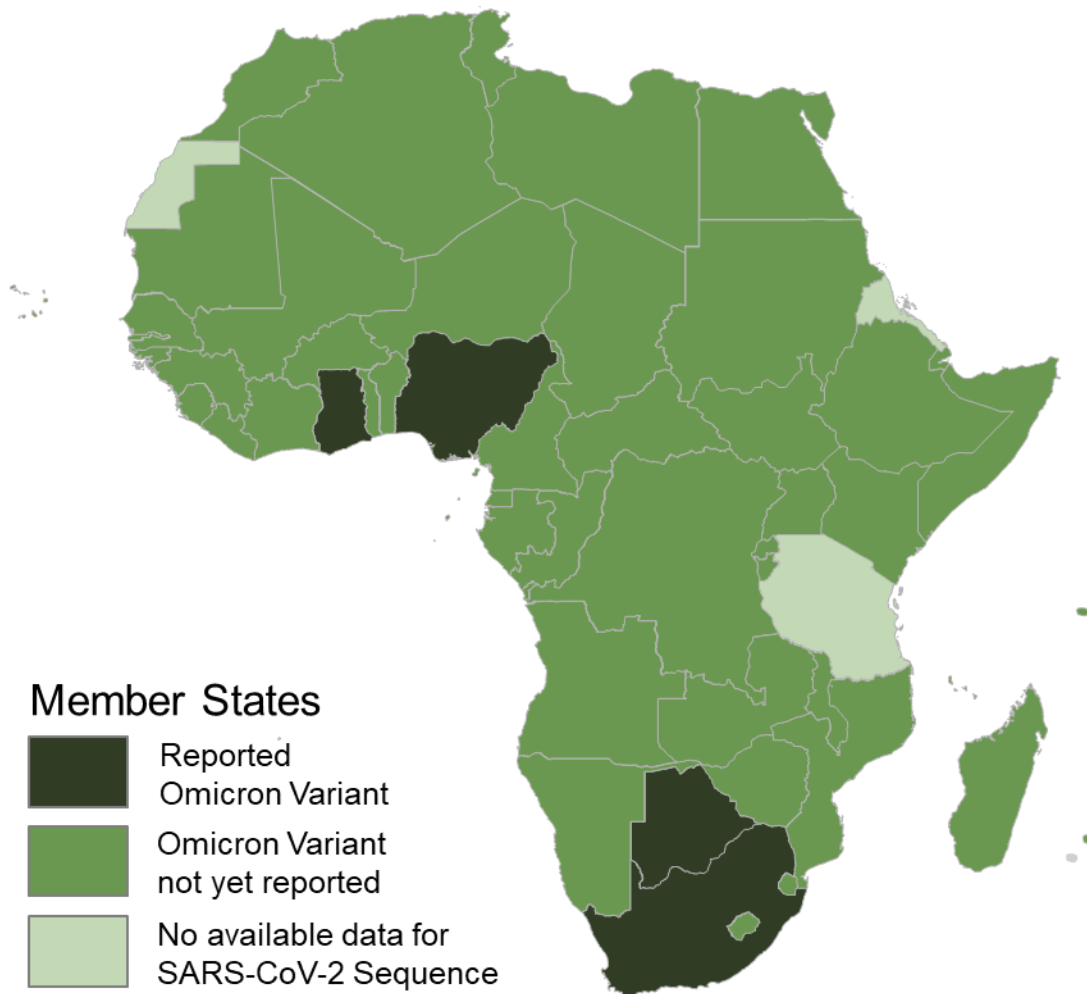
<https://africacdc.org/COVID-19-vaccination/>

Updated 8th 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, has spread to 57 countries worldwide; 4 Member States in Africa have reported this variant. <https://africacdc.org/institutes/africa-pathogen-genomics-initiative/>



Updated 8th December, 2021

B. New guidelines and resources

Since 23rd November 2021,

- Africa CDC² has published new guidance and resources on:
 - [Strategies for Managing Acute Shortages of PPE during the COVID-19 Pandemic](#)
 - [Africa CDC Policy Recommendation for African Union Meetings and Travel During COVID-19 Outbreak](#)
- U.S. CDC³ has published new guidance and resources on:
 - [Public Health Guidance for Potential COVID-19 Exposure Associated with Travel](#)
 - [Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination](#)

² Africa CDC: Africa Centres for Disease Control and Prevention

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

- [Interim Public Health Recommendations for Fully Vaccinated People](#)
- [Use of Masks to Control the Spread of SARS-CoV-2](#)
- WHO⁴ has published new guidance and resources on:
 - [Therapeutics and COVID-19](#)
 - [Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19](#)
 - [Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing](#)
 - [COVID-19 and the social determinants of health and health equity: evidence brief](#)
 - [COVID-19 vaccine trial designs in the context of authorized COVID-19 vaccines and expanding global access: ethical considerations](#)
 - [Global vaccine safety blueprint 2.0 2021-2023](#)
 - [Living guidance for clinical management of COVID-19](#)
 - [WHO third global infodemic management conference: whole-of-society challenges and approaches to respond to infodemics](#)
- U.S. FDA⁵ has issued press releases on:
 - [FDA Authorizes New Long-Acting Monoclonal Antibodies for Pre-exposure Prevention of COVID-19 in Certain Individuals](#)
 - [FDA updated the SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests web page](#)
 - [FDA expands authorization of bamlanivimab and etesevimab for treatment and Post-Exposure Prevention of COVID-19 to younger paediatric patients, including newborns](#)
 - [As of 7th December, 425 tests and sample collection devices are authorized by the FDA under emergency use authorizations \(EUAs\)](#)
- ECDC⁶ has issued new resources on:
 - [Threat Assessment Brief: Implications of the further emergence and spread of the SARS-CoV-2 B.1.1.529 variant of concern \(Omicron\) for the EU/EEA first update](#)
 - [Interim public health considerations for COVID-19 vaccination of children aged 5-11 years](#)
 - [Surveillance of COVID-19 in long-term care facilities in the EU/EEA](#)
 - [Assessment of the current SARS-CoV-2 epidemiological situation in the EU/EEA, projections for the end-of-year festive season and strategies for response, 17th update](#)
- PHE⁷ has issued new guidance and press releases on:
 - [SARS-CoV-2 Omicron VOC: investigating and managing suspected or confirmed cases](#)
 - [COVID-19: management of staff and exposed patients and residents in health and social care settings](#)
 - [COVID-19 vaccination: booster dose resources](#)

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

C. Scientific updates

Basic Science

- This study aimed to perform a comprehensive analysis of the S glycoprotein mutations of the Omicron variant and also classified them into different groups based on different combination of coexisting S glycoprotein mutations. The authors retrieved a total of 309 SARS-CoV-2 genome sequences of the Omicron variant from the Global Initiative on Sharing All Influenza Data (GISAID) on 2nd December

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

2021. The 309 sequences were submitted from 21 different nations across six continents. Majority of the sequences were submitted from 4 African countries; South Africa (N=170), Ghana (N=33), Botswana (N=19) and Reunion (N=1). [The authors found more than 35 mutations in the S glycoprotein. They discuss the probable effects of observed mutations on several aspects of virus biology based on known available knowledge of mutational effects on S glycoprotein structure, function, and immune evasion characteristics.](#) [not peer reviewed]

- This in vitro study aimed to assess the main protease (M^{PRO}) mutants of emerging SARS-CoV-2 lineages. The authors analysed the most widespread amino acid substitutions in SARS-CoV-2 M^{PRO}, characterized them by enzyme kinetics and assessed their susceptibility to inhibition by PF-07321332 (Paxlovid). They identified the currently most prevalent M^{PRO} variants (G15S, T21I, L89F, K90R, L205V) in different lineages of SARS-CoV-2 (C.37 Lambda, B.1.1.318, B.1.2, B.1.351 Beta, P.2 Zeta) and experimentally confirmed that they are equally potent as the wildtype. [They show that PF-07321332 has similar potency against the variants as against the wildtype. Their data suggest that the efficacy of specific M^{PRO} inhibitors such as PF-07321332 is not compromised in current COVID-19 variants.](#) [not peer reviewed]
- This study compared serological responses to coronaviruses in Sierra Leoneans and Americans. The authors tested blood samples collected before the reports of the first COVID-19 cases in Wuhan, China. Their results demonstrate that the percentage of Sierra Leonians with cross-reactive antibodies to SARS-CoV-2, MERS-CoV, and seasonal coronaviruses was higher than in United States blood donors. Serological responses to coronaviruses by Sierra Leoneans did not differ by age or sex. Approximately a quarter of Sierra Leonian pre-pandemic blood samples had neutralising antibodies against SARS-CoV-2 pseudo virus, while about a third neutralised MERS-CoV pseudo virus. [They recommend further studies on the pre-existing immunity to coronavirus antigens as a potential factor contributing to reduced caseloads and deaths from COVID-19 in Sierra Leone.](#)
- This study presents high-dimensional profiling of blood and respiratory samples in severe COVID-19 patients to examine the association between cell-linked molecular features and mortality outcomes. The authors found that, peripheral transcriptional profiles by single-cell RNAseq based deconvolution of immune states are associated with COVID-19 mortality. They also found that persistently high levels of an interferon signalling module in monocytes over time leads to subsequent concerted upregulation of inflammatory cytokines. SARS-CoV-2 infected myeloid cells in the lower respiratory tract upregulate CXCL10, leading to a higher risk of death. [Their analysis suggests a pivotal role for viral infected myeloid cells and protracted interferon signalling in severe COVID-19.](#)

Vaccines

- This study aimed to investigate whether the Omicron variant escapes neutralisation triggered by the mRNA-based vaccine, BNT162b2. They also explored whether Omicron neutralises the ACE2 receptor to infect host cells. The authors conducted a live virus neutralisation assay using sera from 12 participants who had received BNT162b2; out of which 6 people had also previously had COVID-19 during South Africa's 1st wave (ancestral D614G virus). They found that the Omicron variant requires the ACE2 receptor for cell entry. There was a 41-fold reduction in neutralisation against Omicron compared to D614G (Geometric Mean Titre of 32 vs 1321 respectively). Five participants, all of whom were previously infected maintained relatively high neutralisation levels. Their findings suggest that [Omicron variant shows escape from BNT162b2, however the escape is incomplete in participants with history of previous infection. Previous infection, followed by vaccination or booster is likely to increase the neutralisation level and likely confer protection from severe disease in Omicron infection.](#) [not peer reviewed]
- This pseudovirus neutralisation assay aimed to quantify the neutralisation sensitivity of the Omicron Variant of Concern. The authors analysed 2 cohorts of 17 serum samples each in Sweden. One of the cohorts was of blood donors with detectable neutralisation against WuHu1 founder variant. The other cohort was from hospital workers at the Karolinska University Hospital. The neutralisation was assessed in HEK293T-ACE2 cells. The authors found that almost all serum samples evaluated retained some neutralisation activity against the Omicron variant. The First WHO International Standard

(20/136) showed a ± 40 -fold reduction in the neutralisation of Omicron (IC₅₀ from 0.6 IU/ml to 23.4 IU/ml). [Their findings require both internal and independent confirmation. They recommend further urgent investigation on the clinical impact of natural and vaccine-induced immunity with respect to protection from infection and severe disease by the Omicron Variant.](#) [not peer reviewed]

- This cohort study among paramedics in Canada aimed to investigate the immunogenicity of extended mRNA (BNT162b2 and mRNA-1273) vaccine dosing intervals. The authors performed 2 separate investigations; the 1st compared antibody levels at comparable time intervals after the second dose (short [≤ 28 days] vs medium [42-49 days] vaccine dosing intervals), the 2nd compared antibody levels sampled at a standardized interval (170-190 days) after the first dose (short [≤ 36 days] vs long [100-120 days] comparison). [They found that longer mRNA vaccine dosing intervals demonstrated improved immunogenicity, which was consistent when responses were measured based on timing of the first or second dose. Their results suggest that extending dosing intervals may be particularly advantageous against the Delta variant.](#)
- This test-negative, case-control study aimed to assess the effectiveness of the ChAdOx1 nCoV-19 vaccine against the delta (B.1.617.2) variant, in addition to the cellular immune response to vaccination. The study was conducted at 2 medical research centres in India. Their results showed that two doses of the vaccine provided 63.1% (95% CI 51.5–72.1) protection against infection, attributed predominantly to the delta variant during the surge in India. Protection against moderate-to-severe disease was higher than protection against infection. The effectiveness of single-dose vaccine was 46.2% (31.6–57.7) against infection. The authors also found that protective humoral immune response against the delta variant was significantly reduced when compared with wild-type SARS-CoV-2, but T-cell-mediated immunity was maintained. [They recommend that COVID-19 vaccination policies should encourage complete vaccination in addition to other epidemiological public health measures to overcome the threat posed by the delta variant and other emerging SARS-CoV-2 variants.](#)
- This case-control study which used 2 approaches (test-negative and matched case-control designs) aimed to evaluate the initial short-term additional benefit of a 3-dose vs a 2-dose regimen of the BNT162b2 vaccine against infection of SARS-CoV-2. The study included 306,710 Israeli adults 40 years and older who were members of Maccabi Healthcare Services. Comparing those who received a booster and those who received 2 doses, the authors found that there was an [86% reduction in the odds of testing SARS-CoV-2 positive 28 to 65 days following receipt of the booster \(OR 0.14 \[95% CI, 0.13-0.15\]\). They recommend further monitoring of data from the population to determine the duration of immunity following the booster.](#)
- This retrospective cohort study aimed to evaluate the incidence of myocarditis after the receipt of the BNT162b2 mRNA vaccine in Israel. The authors evaluated patients who were enrolled in Clalit Health Services. These are patients who had been vaccinated during the period from 20th December 2020 through 24th May 2021. [They estimate the incidence of myocarditis being 2.13 cases per 100,000 persons; the highest incidence was among male patients between the ages of 16 and 29 years. They also report that most cases of myocarditis were mild or moderate in severity.](#)
- This study aimed to present the clinical and epidemiologic characteristics and follow-up findings of cases of myocarditis that were diagnosed after receiving BNT162b2 mRNA vaccine against COVID-19 in Israel. The authors reviewed data from the Israeli national database from 20th December 2020, to 31st May 2021, regarding all cases of myocarditis. They report that, [the incidence of myocarditis, although low, increased after the receipt of the BNT162b2 vaccine, particularly after the second dose among young male recipients. The clinical presentation of myocarditis after vaccination was usually mild.](#)
- This retrospective, multicentre, nationwide cohort study aimed to determine the association between SARS-CoV-2 vaccination and COVID-19 among a population of Veterans Affairs patients with cancer in the U.S. The authors found that the overall vaccine effectiveness (VE) in the matched cohort was 58% starting 14 days after the second dose. Patients who received chemotherapy within 3 months prior to the first vaccination dose were estimated to have a VE of 57% starting 14 days after the second dose vs 76% for those receiving endocrine therapy and 85% for those who had not received systemic therapy for at least 6 months prior. They recommend [additional risk reduction strategies, such as](#)

[serologic testing for vaccine response and a third vaccine dose to optimize outcomes in some of the immunosuppressed subgroups that may remain at early risk for COVID-19 despite vaccination.](#)

- This cohort study aimed to evaluate whether passive exposure to live attenuated poliovirus in the oral polio vaccine (OPV) is associated with diminished symptomatic infection with SARS-CoV-2. The study involved 4190 women in Iran. The authors found that none of the women indirectly exposed to OPV developed COVID-19 during the 9 months of the study, while 0.74% of age-matched women who had no exposure to OPV developed COVID-19. They recommend for [further studies to be conducted on the potential protective effect of OPV especially in countries where it is in use for polio prevention and specific COVID-19 vaccines are delayed, less affordable, or fail to meet demand.](#)
- This open-label two-arm non-randomised trial aimed to investigate the immunogenicity of inactivated COVID-19 vaccine (BIBP-CorV) in people living with HIV (PLWH). The study involved 42 HIV-1 infected individuals who were stable on combination antiretroviral therapy (cART) and 28 healthy individuals in Hubei, China. Their results demonstrate that the [inactivated SARS-CoV-2 vaccine was safe and immunogenic in PLWH who are stable on cART with suppressed viral load and CD4⁺ T cell count > 200 cells/μL. The CD3⁺, CD4⁺ and CD8⁺ T cell counts of PLWH decreased significantly after vaccination \(P<0.0001\), but it did not lead to any adverse clinical manifestation. They recommend further studies to investigate the persistence of the vaccine-induced immunities in PLWH.](#)
- This multicentre, randomised, controlled, phase 2 trial aimed to investigate the reactogenicity and immunogenicity of seven different COVID-19 vaccines as a third dose after two doses of ChAdOx1 nCov-19 or BNT162b2. The study involved 2878 adults in the UK. Their results showed that all vaccines tested (ChAd, BNT, m1273, NVX, Ad26, CVn, and VAL) boosted immunity after ChAd/ChAd as measured by anti-spike IgG and neutralising assays. They also showed that six vaccines (ChAd, BNT, m1273, NVX, Ad26, CVn) boosted immunity after BNT/BNT. Fatigue and pain were the most common solicited local and systemic adverse events. There were no safety concerns. The authors recommend that policy makers and national immunisation advisory committees should establish criteria for choosing which booster vaccines to use in their populations. [Their decision should be based on immunological considerations, known side-effect profiles, in-country availability, and ultimately a decision on what level of boost is sufficient in the context of national strategic disease control objectives.](#)

Diagnosics

- This study describes four RT-qPCR assays that enable rapid identification of the newly emerging SARS-COV-2 Omicron (B.1.1.529) variant of concern. The assays were developed by the Israel Ministry of Health Central Virology Laboratory (CVL) and the Israel Institute for Biological Research (IIBR). The assays target Omicron characteristic mutations in the nsp6 (Orf1a), spike and nucleocapsid genes. The authors demonstrate that the [assays can be implemented in any molecular diagnostic laboratory and do not require the use of specific brand instruments, or unique reagents, are amendable for multiplexing, and may be used as a reliable first-line tool to identify B.1.1.529 suspected samples.](#) [not peer reviewed]
- The authors in this study developed a lateral flow point of care test that can measure levels of RBD-ACE2 neutralising antibody (NAb) from whole blood, with a result that can be determined by eye or quantitatively on a small instrument. They then compared the lateral flow test with the gold-standard microneutralisation assay, using samples from convalescent and vaccinated donors in Australia, as well as immunised macaques. They found that their test correlates closely with microneutralisation assay data (specificity 100% and sensitivity 96% at a microneutralisation cut-off of 1:40) and that fingerprick whole blood samples are sufficient for the test. [Their test can improve immunity testing access in areas with limited access to laboratories and equipment for more conventional virus neutralisation tests or ELISA-based inhibition assays.](#)

Care and Treatment

- This phase 3 portion of an adaptive, multicentre, double-blind, randomised, placebo-controlled trial aimed to assess the safety and efficacy of REGEN-COV (casirivimab and imdevimab) in preventing

hospitalization or death among high-risk outpatients. The study involved 2696 patients (1355 REGEN-COV, 1341 Placebo groups) from U.S & Mexico. Their findings showed that [the 1200-mg dose of REGEN-COV, like the 2400-mg dose, reduced the risk of COVID-19–related hospitalisation or death, reduced the SARS-CoV-2 viral load more rapidly than placebo and sped the time to recovery.](#)

- This prospective, open-label, randomised clinical trial aimed to evaluate the efficacy of convalescent plasma (CP) in preventing worsening respiratory failure or death in patients with COVID-19 pneumonia. The study involved 487 hospitalized patients (241 to receive CP plus standard therapy (ST); 246 to ST alone) at 27 clinical sites in Italy. The authors found that high-titre anti–SARS-CoV-2 CP [did not reduce the progression to severe respiratory failure or death within 30 days in patients with moderate to severe COVID-19 pneumonia. They also found that adverse events occurred more frequently in the CP group compared with the control group \(5.0% vs 1.6%; P= 0.04\).](#)
- This cohort study aimed to quantify the rate of post discharge arterial and venous thromboembolism in patients with COVID-19 and identify the factors associated with the risk of post discharge venous thromboembolism. The study involved 2832 patients admitted in 5 U.S hospitals. The authors found that patients with a history of venous thromboembolism (OR, 3.24; 95% CI, 1.34-7.86), peak dimerized plasmin fragment D (D-dimer) level greater than 3 µg/mL (OR, 3.76; 95% CI, 1.86-7.57), and pre-discharge C-reactive protein level greater than 10 mg/dL (OR, 3.02; 95% CI, 1.45-6.29) were more likely to experience venous thromboembolism after discharge. Patients who received post discharge anticoagulation therapy had fewer events (OR, 0.18; 95% CI, 0.04-0.75; P= .02). [Their findings suggest that post discharge anticoagulation therapy may be considered for high-risk patients with COVID-19.](#)
- This phase 3, randomised, double-blind, placebo-controlled trial aimed to assess the efficacy and safety of Lenzilumab, a Granulocyte-macrophage colony-stimulating factor (GM-CSF) neutralising monoclonal antibody, in treating hospitalised COVID-19 patients. The study involved 520 participants from 29 sites in the USA and Brazil. The authors found that Lenzilumab significantly improved survival without invasive mechanical ventilation (IMV) in hospitalised patients with COVID-19 (hazard ratio 1.54; 95% CI 1.02–2.32; p=0.040), with a safety profile similar to that of placebo. [A reduction in the risk of IMV was also observed, this was greater than that provided by standard background care including remdesivir and corticosteroids.](#)

Epidemiology

- This systematic review and meta-analysis aimed to determine the overall prevalence of COVID-19 infection in developing countries, assess age specific patterns of seroprevalence in these locations and estimate age specific infection fatality ratios (IFRs) and compare them to values for high income countries. The authors included 62 IFR estimates from studies from 25 countries. They found that the seroprevalence in many developing country locations was markedly higher than in high-income countries. In most locations, seroprevalence among older adults was similar to that of younger age cohorts, underscoring the limited capacity that these nations have to protect older age groups. Age-specific IFRs were roughly 2x higher than in high-income countries. [The median value of the population IFR was about 0.5%, similar to that of high-income countries, because disparities in healthcare access were roughly offset by differences in population age structure. They advocate for the accelerated provision of vaccine doses to vulnerable populations in developing countries.](#) [not peer reviewed]
- This prospective study aimed to assess the seroprevalence of SARS-CoV-2 in 2 household cohorts in a rural and an urban community at 5 timepoints from July 2020 to March 2021, during 2 epidemic waves in South Africa. The authors compared seroprevalence to reported laboratory-confirmed infections, hospitalizations, and deaths to calculate infection–case, infection–hospitalization, and infection–fatality ratios. The study involved 1,211 participants. Their results show that, post–second wave seroprevalence ranged from 18% in the rural community children <5 years of age, to 59% in urban community adults 35–59 years of age. [The second wave saw a shift in age distribution of case-patients in the urban community \(from persons 35–59 years of age to persons at the extremes of age\), higher attack rates in the rural community, and a higher infection–fatality ratio in the urban community. They estimate that ≈95% of SARS-CoV-2 infections were not reported to the national surveillance.](#)

- This cross-sectional analysis of population-based public health surveillance data aimed to assess the sociodemographic, clinical, and epidemiologic characteristics of California residents who were diagnosed with TB and COVID-19. The study involved 91 participants. The authors found that TB/COVID-19 was disproportionately diagnosed among residents who were Hispanic or Latino, had diabetes, or were living in low health equity census tracts. Their results suggest that TB and COVID-19 occurring together may be associated with increases in mortality compared with either disease alone, especially among older adults. [They recommend addressing health inequities and integrating prevention efforts to avert the occurrence of concurrent COVID-19 and TB and potentially reduce deaths.](#)
- This ambidirectional cohort study in Sweden aimed to describe the somatic, functional, affective, neuropsychological status and rehabilitation needs of COVID-19 patients at five months post-discharge. The study involved 158 of the 745 previously hospitalised patients from the county of Östergötland. The authors found that most of the patients that reported concerning problems suffered a broad array of signs and symptoms attributable to COVID-19 involving respiratory, visual, auditory, motor, sensory and cognitive functions at 5 months after acute illness. [This translated into 16% \(95% CI: 12.8, 20.0\) of the survivors of the total regional cohort require further rehabilitative interventions at the time of the 5 month follow up. Their findings underscore the necessity to develop structured programs for routine screening of rehabilitation needs after COVID-19.](#)
- This prospective observational study aimed to determine whether symptom profiles can be used to differentiate individuals with systemic side-effects of vaccination alone from individuals with superimposed SARS-CoV-2 infection. The study involved 1,072,313 participants of the COVID Symptom Study (CSS) in the UK. Their results show that post-vaccination symptoms cannot be distinguished with clinical confidence from early SARS-CoV-2 infection, either using symptom profiles or machine-derived models. [Their study highlights the critical importance of testing symptomatic individuals - even if recently vaccinated – to ensure early detection of SARS-CoV-2 infection and help prevent future waves of COVID-19.](#)
- This national incident cohort study aimed to identify which children with asthma were at increased risk of serious COVID-19 outcomes. The study involved 752,867 children in Scotland aged 5-17 years. The authors found that school-aged children with asthma with previous recent hospital admission or two or more courses of oral corticosteroids are at markedly increased risk of COVID-19 hospital admission. [They recommend that school-aged children with poorly controlled asthma should be considered a priority for vaccinations.](#)

Infection Prevention and Control

- This risk modelling study in the U.S aimed to solve the airplane seating assignment problem by producing seating arrangements that minimize transmission risks between passengers aboard an aircraft. The authors analysed previous risk models and introduce two new risk models, masked and unmasked, based on previous experiments performed aboard real aircraft to test aerosol dispersion of SARS-CoV-2 sized particles. [They make recommendations on when each risk model is applicable and the types of seating arrangements that are optimal for each risk model.](#)

Non-pharmaceutical interventions, social distancing

- This study in the U.S aimed to examine the presence of trace elements after total acid digestion of face masks, as well as to examine how trace metals may transfer out of the masks. The authors studied 24 face mask samples mainly being surgical masks, as well as 3 samples of KN95 masks. They determined the total concentrations of trace elements and assessed the possibility that any detected element present could transfer into the human body, based on saliva leaching and breathing experiments using inductively coupled plasma mass spectrometry (ICP-MS). They found that although most masks analysed contained trace elements below their corresponding detection limits, [a few masks did contain detectable levels of trace elements. In particular, the maximum values that were determined in certain analysed samples were: Pb \(13.33 \$\mu\text{g g}^{-1}\$ \), Cu \(410 \$\mu\text{g g}^{-1}\$ \), Zn \(56.80 \$\mu\text{g g}^{-1}\$ \), and Sb \(90.18 \$\mu\text{g g}^{-1}\$ \). In the masks that Pb was present, it easily leached out \(58% transfer during a 6-h](#)

[exposure\) during the saliva simulation experiments. They recommend that masks should pass strict quality control and quality assurance tests before being made available in the marketplace.](#)

- This study aimed at investigating the release of synthetic and natural microfibers from reusable and disposable face masks of different fabrics after the laundering in a domestic washing machine. The study was conducted in Italy. The authors found that, after a single wash, face masks released an average (\pm SE) of 284.94 ± 73.66 microfibers, independently of the fabrics. Polyurethane (541.33 ± 51.84 microfibers) and cotton-based (823.00 ± 112.53 microfibers) face masks released the highest amount of synthetic and natural microfibers, respectively. They recommend further studies testing different laundering conditions (i.e., testing the effect of different temperatures, detergents and softeners, and repeated washing) [so as to estimate the contribution of face mask-derived microfibers to freshwater contamination, as well as to explore their potential hazard towards aquatic organisms.](#)

D. Clinical Trials Updates

Key updates:

Vaccine trials:

- On 7th December 2021, Medicago and GlaxoSmithKline (GSK) announced [positive efficacy and safety results from the global phase 3 clinical trial for their adjuvanted plant-based COVID-19 vaccine candidate](#). This randomised, observer-blinded, crossover placebo-controlled phase III trial assessed the efficacy and safety of the vaccine candidate formulation, compared to placebo, in > 24,000 subjects aged >18 years. The study was conducted in Canada, United States, United Kingdom, Mexico, Argentina, and Brazil. According to the data, the overall vaccine efficacy rate against all variants of SARS-CoV-2 was 71% (Confidence Interval: CI 58.7, 80.0%); vs 75.3% (95% CI: 52.8, 87.9) against Delta variant; and 88.6% (95% CI: 74.6, 95.6) against the Gamma variant. The vaccine candidate was well-tolerated, with no related serious adverse events reported in the vaccine group. Based on these results, Medicago will imminently seek regulatory approval from Health Canada as part of its rolling submission.
- On 5th December 2021, Johnson & Johnson announced preliminary results from [a phase II COV2008 clinical trial which demonstrated that a booster shot of the Johnson & Johnson COVID-19 vaccine \(Ad26.COV2. S\) increased both antibody and T-cell responses](#) when administered six months after a two-dose primary regimen of Pfizer-BioNTech COVID-19 vaccine, BNT162b2. Data shows that after a heterologous mix-and-match booster dose of the Johnson & Johnson COVID-19 vaccine, antibodies continued to increase for at least four weeks, concurrently with a strong increase in CD8+ T-cell responses, whereas in individuals who received a homologous booster with the BNT162b2 vaccine, antibodies waned from week two to week four post-boost. These results demonstrate the potential benefits of heterologous boosting (mix-and-match). Clinical trial registration #: (VAC31518COV2008).
- On 30th November 2021, GreenLight Biosciences and International AIDS Vaccine Initiative (IAVI) [announced their plans to partner to advance messenger RNA \(mRNA\) COVID-19 vaccine candidate in Africa](#). This partnership aims to broaden and accelerate timely manufacturing and deployment of mRNA COVID-19 vaccines in low-income countries across the world. In a phase I clinical trial, GreenLight will provide its mRNA vaccine candidate and also prepare for large-scale manufacturing of the vaccine. IAVI will be responsible for overall clinical trial management and will also ensure that the trial meets regulatory standards. The trial is planned to begin in the first quarter of next year after research sites and clinical research partners have been finalised, and ethical and regulatory approvals have been secured.
- On 26th November 2021, [Clover Biopharmaceuticals announced the initiation of phase II clinical trial to assess its COVID-19 vaccine candidate, SCB-2019 \(CpG 1018/Alum\), as a heterologous booster shot in people who received an initial vaccine regimen](#). CB-2019 is an adjuvanted recombinant SARS-CoV-2 trimeric S-protein subunit vaccine. This double-blind, controlled, randomised, two-stage phase II clinical trial will assess the safety and immunogenicity of a booster dose of SCB-2019 in approximately 520 healthy adult subjects at multiple trial centres in Brazil. Its first stage will analyse three vaccine formulations given as a booster shot almost six months after the initial vaccine regimen with AstraZeneca-Fiocruz's recombinant COVID-19 shot. In the second stage, the immunogenicity and

safety of a booster dose of the opted formulation of SCB-2019 will be analysed in people inoculated with two shots of either the CoronaVac vaccine or the AstraZeneca-Fiocruz vaccine. The preliminary results from the trial are expected to be announced in the first half of next year. Clinical trial registration #: (NCT05087368)

- On 25th November 2021, Pfizer and BioNTech announced that [the European Medicines Agency's \(EMA\) Committee for Medicinal Products for Human Use \(CHMP\) has given a positive opinion on the use of their COVID-19 vaccine, Comirnaty, in children aged five to <12 years.](#) This decision was based on scientific data submitted to EMA which included results from a randomised, controlled phase II/III clinical trial. The study enrolled approximately 4,500 children aged 5 to 11 years who were given two 10µg doses of Comirnaty 21 days apart. The results of the phase II/III trial showed a favourable safety profile, robust immune responses and a vaccine efficacy rate of 90.7%. The European Commission (EC) will review the CHMP recommendation and is anticipated to make a final decision on a variation to the Conditional Marketing Authorization for the vaccine soon. Clinical trial registration #: (NCT04816643)

Therapeutics trials:

- On 2nd December 2021, ARCA biopharma announced the [completion of subject enrolment into phase IIb ASPEN-COVID-19 clinical trial of its small recombinant protein, rNAPc2,](#) to treat hospitalised COVID-19 patients. This international, multi-centre, randomised phase IIb ASPEN-COVID-19 clinical trial has enrolled a total of 160 participants from various sites in the United States, Argentina and Brazil. The study aims to evaluate two dose regimens of rNAPc2 against heparin in hospitalised Covid-19 patients with a high D-dimer level. Further, the trial will assess safety and determine the optimal rNAPc2 dose regimen for a potential Phase III clinical trial. Change in D-dimer levels from the baseline to day 8 relative to standard of care heparin is the primary endpoint of the study. Clinical trial registration #: (NCT04655586)
- On 30th November 2021, First Wave BioPharma announced that an independent data monitoring committee (DMC) [has recommended continuation of subject enrolment for the second part of its ongoing phase II RESERVOIR clinical trial of FW-COV to treat gastrointestinal \(GI\) infections related to COVID-19.](#) This recommendation was based on the review of the safety data collected from the first 25 patients enrolled in part 2 of the RESERVOIR trial which reported no safety issue. FW-COVs is an oral, niclosamide-based small molecule tablet, developed to remove the SARS-CoV-2 (SARS2) virus from the GI tract. This two-part, two-arm, randomised, placebo-controlled phase II RESERVOIR clinical trial will assess the safety and ability of the FW-COV drug to remove SARS-CoV-2 virus from the digestive tract. Patients enrolled in Part 2 of the study are randomised. The second part of the study will enrol up to 150 patients randomised to receive either niclosamide or a placebo treatment for 14 days. Clinical trial registration #: (NCT04858425)
- On 29th November 2021, NRx Pharmaceuticals announced [that it has completed an analysis to identify clinical evidence that indicates its drug, ZYESAMI \(Aviptadil\) substantially improve survival and recovery from critical COVID-19 and respiratory failure in patients previously treated with remdesivir.](#) The analysis was conducted in the subgroup of ZYESAMI and placebo treated patients who were previously treated with remdesivir in the phase III COVID-AIV trial. Results of the 127 patients who remained in respiratory failure despite treatment with remdesivir, showed a significant increase in the likelihood of recovery and a four-fold increase in the odds of survival after being treated with aviptadil compared to placebo. The analysis was conducted in response to US Food and Drug Administration (FDA) request for additional clinical data on effect of ZYESAMI compared to currently-approved therapy including remdesivir. NRx plans to submit new analysis and safety data to the FDA in support of Emergency Use Authorization and Breakthrough Therapy Designation Requests. Clinical trial registration #: (NCT04311697).
- On 29th November 2021, BetterLife Pharma announced that its subsidiary Altum Pharmaceuticals and Pontificia Universidad Católica de Chile [have initiated phase II segment of the phase I/II IN2COVID clinical trial of the inhaled product, AP-003, to treat Covid-19.](#) This comes after phase I portion of the IN2COVID clinical trial which enrolled eighteen subjects was concluded. AP-003 demonstrated an

excellent safety and tolerability profile with no recorded serious adverse events in phase I. AP-003 is an antiviral recombinant human interferon alpha-2b (rhIFN- α 2b) therapy. This phase II portion of the randomised, double-blind, placebo-controlled IN2COVID clinical trial will enrol up to 150 participants aged ≥ 18 years with mild or moderate COVID-19. Participants will be randomised into a 1:1 ratio to receive either nebulised AP-003 or a placebo two times a day for ten days. Clinical trial registration #: (NCT04988217)

- On 29th November 2021, AB Science reported that [it has begun dosing the first subject in its phase II trial, which will assess the antiviral activity of masitinib in COVID-19 patients](#). Masitinib is an orally administered tyrosine kinase inhibitor that targets mast cells and macrophages, mainly cells for immunity. The study expects to enrol up to 78 non-hospitalized mild or moderate COVID patients or hospitalized COVID-19 patients who require no non-invasive ventilation. The double-blind, randomised, placebo-controlled Phase II clinical trial aims to assess the efficacy of masitinib in symptomatic mild to moderate patients diagnosed with COVID-19. The primary efficacy goal will be to demonstrate that the therapy can reduce the SARS-CoV-2 viral load faster compared to a placebo control group which will receive best supportive care (BSC). Clinical trial registration #: (NCT05047783)
- On 26 November 2021, Merck and Ridgeback Biotherapeutics provided an update of their phase III MOVE-OUT clinical trial for [their investigational oral antiviral drug, molnupiravir \(MK-4482, EIDD-2801\), that showed reduction of effectiveness of the drug against the virus than previously thought](#). According to data from 1433 participants, hospitalisation or mortality risk was 9.7% in the placebo arm against 6.8% in subjects who received molnupiravir, indicating an absolute risk of 3% and relative risk reduction of 30%. The drug's efficacy is considerably lower than what was reported in the interim analysis in October when molnupiravir was said to reduce the risk of hospitalisation and death by around 50%. The adverse event profile for molnupiravir remained consistent with the profile reported at the planned interim analysis (9 deaths in the placebo group vs 1 death in the molnupiravir group). Clinical trial registration #: (NCT04575597)
- On 20th November 2021, Akston Biosciences [reported that it has begun dosing the first of 100 subjects in an open-label bridging clinical study of the COVID-19 vaccine candidate, AKS-452, in India](#). AKS-452 is a protein sub-unit vaccine designed to induce a Th1/Th2 mixed immune response against the Receptor Binding Domain (RBD) of the SARS-CoV-2 spike protein. The open-label bridging trial will enrol a total of 100 healthy adult subjects aged ≥ 18 years with results anticipated in January 2022. Thereafter, a double-blind phase II/III study will be initiated and anticipated to enrol up to 1,500 healthy adults at 12 trial centres sites in five states in India. In both studies, healthy volunteers will receive two 90 μ g doses administered 28 days apart. AKS-452 is shelf stable for at least six months at room temperature (25 $^{\circ}$ C or 77 $^{\circ}$ F). Clinical trial registration #: (NCT04681092)

Immunotherapies trials:

- On 7th December 2021, GlaxoSmithKline and Vir Biotechnology announced [an update to the preclinical data released earlier confirming that Sotrovimab, an investigational monoclonal antibody, retains in vitro activity against the full known Omicron \(B.1.1.529\) spike protein](#). The preclinical data was generated through pseudo-virus testing of the 37 combined known mutations of the Omicron variant, identified to date in the spike protein. These data builds on the promising signals released earlier and underscoring the importance of Sotrovimab for early treatment of COVID-19. Sotrovimab is an investigational SARS-CoV-2 neutralising monoclonal antibody which binds to an epitope on SARS-CoV-2 shared with SARS-CoV-1 thus preventing resistance to develop.
- On 3rd December 2021, the U.S. Food and Drug Administration (FDA) [announced the expansion of the emergency use authorisation \(EUA\) of bamlanivimab and etesevimab, neutralising antibody combination treatment, to treat COVID-19 in paediatric patients](#). The combination therapy is recommended for prevention and treatment of mild-to-moderate COVID-19 in paediatric patients including new-borns aged < 12 years who are at increased risk of disease progression such as death or hospital admission. This decision was based on safety and efficacy results from phase II/III BLAZE-1 clinical trial of the combination therapy enrolling paediatric and infant subjects to treat mild to

moderate COVID-19 at increased risk for severe disease development. Clinical trial registration #: (NCT04427501)

- On 2nd December 2021, GlaxoSmithKline and Vir Biotechnology announced that United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) has [granted conditional marketing authorisation for their investigational COVID-19 therapy, Xevudy \(sotrovimab\), for the treatment of COVID-19](#). This decision was based on the safety and efficacy data obtained from the phase III COMET-ICE trial conducted on 1,057 participants. It was observed that sotrovimab reduced risk of hospitalisation and death in mild to moderate COVID-19 adult patients by 79%. The neutralising monoclonal antibody has been authorised to treat symptomatic mild-to-moderate COVID-19 adults and adolescents aged ≥ 12 years who are at high risk of developing severe disease. MHRA has recommended administering sotrovimab within five days of COVID-19 symptoms onset. Clinical trial registration #: (NCT04913675)

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

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