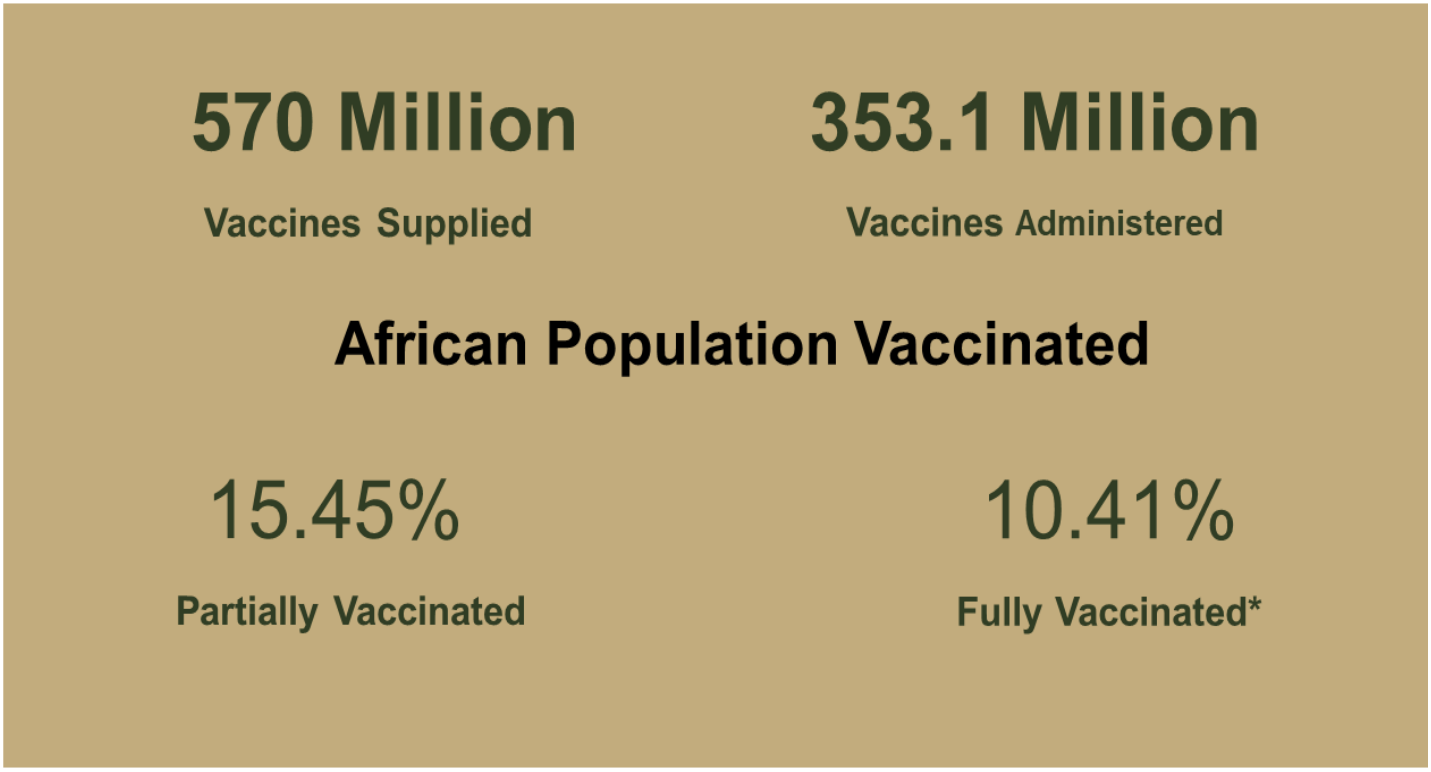
COVID-19 Scientific and Public Health Policy Update[1] – (19 January 2022)

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

A. Trending Topics

Status of Vaccines in Africa

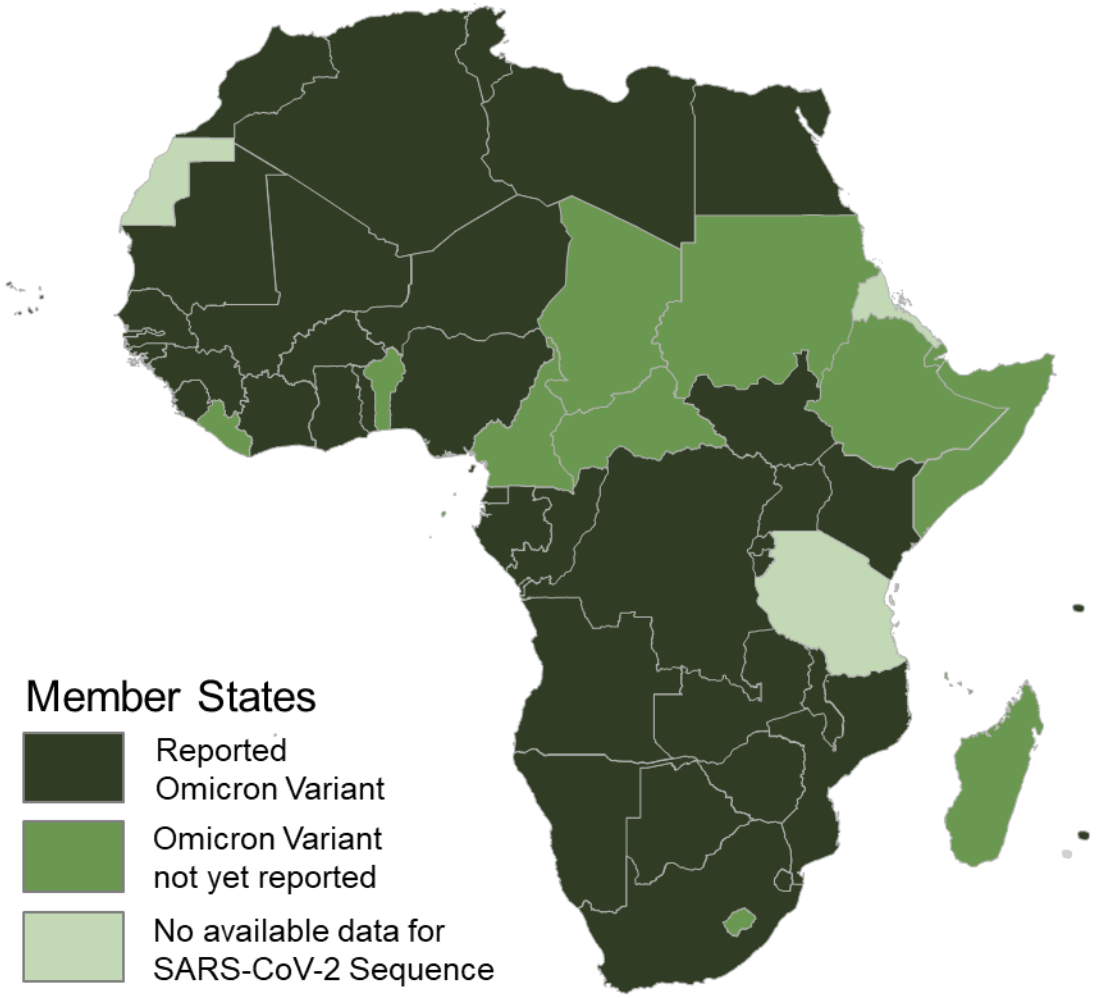


*Received two doses/ one dose of Johnson & Johnson vaccine
https://africacdc.org/COVID-19-vaccination/
Updated 19th January, 2022

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

Variants of Concern

- The Omicron variant (B.1.1.529), first reported in South Africa on 24th November 2021, has spread to 147 countries worldwide; 39 Member States in Africa have reported this variant. https://africacdc.org/institutes/africa-pathogen-genomics-initiative/



Updated 19th January, 2022

B. New guidelines and resources

Since 4th January 2022,

- Africa CDC[2] has published new guidance and resources on:
  - Outbreak Brief 104: Coronavirus Disease 2019 (COVID-19) Pandemic
- U.S. CDC[3] has published new guidance and resources on:
  - Duration of Isolation and Precautions for Adults with COVID-19
  - Contact Tracing for COVID-19
  - Operational Considerations for the Identification of Healthcare Workers and Inpatients with Suspected COVID-19 in non-US Healthcare Settings
- WHO[4] has published new guidance and resources on:
  - Therapeutics and COVID-19: living guideline

[2] Africa CDC: Africa Centres for Disease Control and Prevention
[3] U.S. CDC: United States Centers for Disease Control and Prevention
[4] WHO: World Health Organization

- WHO guidance on the ethical conduct of controlled human infection studies
- U.S. FDA[5] has issued press releases on:
  - FDA Shortens Interval for Booster Dose of Moderna COVID-19 Vaccine to Five Months
  - As of 18th January, 420 tests and sample collection devices are authorised by the FDA under emergency use authorisations

- ECDC[6] has issued new resources on:
  - Communicable diseases threats report, 9-15 January 2022

- PHE[7] has issued new guidance and press releases on:
  - Monitoring reports of the effectiveness of COVID-19 vaccination
  - Guidance on coronavirus (COVID-19) measures for grassroots sport participants, providers and facility operators
  - Preventing and controlling outbreaks of COVID-19 in prisons and places of detention
  - COVID-19 vaccination: booster dose resources
  - COVID-19 vaccination observation period
  - COVID-19: stepdown of infection control precautions and discharging patients to home settings

Scientific updates

Basic Science

- This cross-sectional study in France used a multi-omics approach to identify drivers of critical COVID-19 in a young, comorbidity-free patient cohort. The authors used an ensemble of machine learning, deep learning, quantum annealing, and structural causal modelling to identify multiple candidate driver genes, including the metalloprotease, *ADAM9*. Ex vivo *ADAM9* inhibition decreased severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) uptake and replication in human lung epithelial cells. Their findings suggest that drivers of critical COVID-19, and thus treatment, may differ based on the cohort.
- The authors in this study of two independent COVID-19 outpatient cohorts in the U.S aimed to characterise the pre-progressive antibody responses during early, mild COVID-19 and to identify antibody characteristics associated with distinct disease outcomes and SARS-CoV-2 mRNA vaccination. They developed an in vivo model that revealed that human IgG-Fc gamma receptor (FcγR) interactions could regulate inflammation in the lung. Afucosylated IgG immune complexes isolated from COVID-19 patients induced inflammatory cytokine production and robust infiltration of the lung by immune cells. By contrast, vaccine-elicited IgG did not promote an inflammatory lung response. Their findings begin to suggest that an early assessment for non-neutralising, afucosylated IgG1 may be able to identify those patients at risk of developing severe disease in response to SARS-CoV-2 infection or infection by other viruses.
- This U.S study aimed to define the neutralising antibody titres against the wildtype (D614), Beta, Delta, and Omicron variants of SARS-CoV-2 after infection or mRNA vaccination. The authors observed that boosting increases the magnitude of the antibody response to the variants; however, the Omicron variant was the most resistant to neutralisation. They further observed that vaccinated healthy adults had robust and broad antibody responses whereas responses may have been reduced in vaccinated pregnant women, underscoring the importance of learning how to maximize mRNA vaccine responses in pregnant populations. Their findings suggest that supplementing spike protein-based vaccines with other more conserved viral antigens would likely elicit greater breadth of immunity and likely enable less frequent updating of SARS-CoV-2 vaccines.

[5] U.S. FDA: United States Food and Drug Administration
[6] ECDC: European Centre for Disease Prevention and Control
[7] PHE: Public Health England

Vaccines

- This retrospective cohort study in India aimed to assess the incidence density of reinfection among health care workers (HCWs) and estimate the effectiveness of the inactivated whole virion vaccine BBV152 against reinfection. The study involved 4978 HCWs who were infected with SARS-CoV-2 from 3rd March 2020 to 18th June 2021. The authors found that the incidence density of reinfection was 7.26 (95% CI: 6.09-8.66) per 100 person-years. A protective association of 86% (95% CI, 77%-92%) against reinfection was observed among HCWs who completed the 2-dose schedule of BBV152 and for whom at least 15 days elapsed without reinfection after vaccination. Their findings suggest that BBV152 was associated with protection against both symptomatic and asymptomatic reinfection in HCWs after a complete vaccination schedule, when the predominant circulating variant was B.1.617.2.
- This prospective cohort study in Israel aimed to estimate the association of a BNT162b2 booster dose with SARS-CoV-2 infections among health care workers who were previously vaccinated with a 2-dose series of BNT162b2. The study cohort included 1928 immunocompetent HCWs at a single centre. The authors found that administration of a booster dose compared with not receiving one was significantly associated with lower risk of SARS-CoV-2 infection during a median of 39 days of follow-up (adjusted hazard ratio, 0.07). They recommend ongoing surveillance to assess the durability of their findings.
- This test-negative case-control study in the U.S aimed to assess the effectiveness of 2 doses of BNT162b2 vaccine received ≥28 days before hospital admission in preventing multisystem inflammatory syndrome in children (MIS-C). The study included 102 MIS-C case-patients and 181 hospitalised controls aged 12–18 years at 24 paediatric hospitals in 20 states. The authors found that the estimated effectiveness of 2 doses of Pfizer-BioNTech vaccine against MIS-C was 91% (95% CI = 78%–97%). All 38 MIS-C patients requiring life support were unvaccinated. Their findings show that receipt of 2 doses of the Pfizer-BioNTech vaccine is highly effective in preventing MIS-C in persons aged 12–18 years, highlighting the importance of vaccination among all eligible children.
- This randomised, placebo-controlled Phase I trial with an unblinded dose escalation and a double-blind treatment phase at 2 sites in France and Belgium aimed to evaluate the safety and immunogenicity of V591. V591 (TMV-083) is a live recombinant measles vector-based vaccine candidate expressing a pre-fusion stabilized SARS-CoV-2 spike protein. Their results show that the V591 candidate was well tolerated by intramuscular injection. But immune responses induced by V591 were lower than expected from the previous results with MV-CHIK in Phase I and II trials and from the strong immunogenicity of V591 observed during pre-clinical development. The authors also noted that pre-existing anti-measles immunity appeared to impact V591, whereas this was not observed with MV-CHIK, despite leveraging of the same technology.
- This phase 1/2, randomised, double-blind, placebo-controlled, dose-ranging trial aimed to evaluate the safety and immunogenicity of multiple regimens of V591 in healthy adults. The study was conducted among 263 participants enrolled at 9 centres across the US, Austria, and Belgium. Their findings show that V591 was generally well tolerated, but immunogenicity was insufficient to warrant continued development.

Diagnostics

- This study in Italy aimed to validate an intralaboratory molecular detection method for SARS-CoV-2 on saliva samples collected in a new storage saline solution, comparing the results to nasopharyngeal (NP) swabs to determine the difference in sensitivity between the two tests. The study enrolled and tested 156 patients and 1005 asymptomatic subjects (controls) simultaneously by RT-PCR on both NP swab and saliva samples. Saliva samples were collected in a preservative and inhibiting saline solution (Biofarma Srl). Their results on tests conducted on oral samples showed a clinical sensitivity of 95.1% and specificity of 97.8% compared to NP swabs. The positive predictive value was 81% while the negative predictive value was 99.5%. Test concordance was 97.6% (Cohen's Kappa = 0.86; 95% CI 0.81-0.91). The limit of detection of the test was 5 viral copies for both samples. Their findings show that tests conducted on stored saliva samples achieved similar performance to those on NP swabs. This may provide a very effective tool for population screening and diagnosis. Collection of saliva in a stabilizing solution makes the test more convenient and widely available.

- This study investigated the incidence of false-positive results in a large sample of rapid antigen tests used to serially screen asymptomatic workers throughout Canada. A total of 903,408 rapid antigen tests were conducted over 537 workplaces. There were 1322 positive results (0.15%), of which 1103 had PCR information. Approximately two-thirds of screens were trackable with a lot number. The number of false-positive results was 462 (0.05% of screens and 42% of positive test results with PCR information). Of these, 278 false-positive results (60%) occurred in 2 workplaces 675 km apart run by different companies between September 25 and October 8, 2021. All of the false-positive test results from the 2 workplaces were drawn from a single batch of Abbott's Panbio COVID- 19 Ag Rapid Test Device. Their results demonstrate the importance of having a comprehensive data system to quickly identify potential issues. With the ability to identify batch issues within 24 hours, workers could return to work, problematic test batches could be discarded, and the public health authorities and manufacturer could be informed.

Care and Treatment

- This prospective cohort study in Canada aimed to examine myocardial metabolic changes early after recovery from COVID-19 using fluorodeoxyglucose (FDG) – positron emission tomography (PET) and associate these changes to abnormalities in cardiac magnetic resonance imaging (MRI)–based function and tissue characterization measures and inflammatory blood markers. The study included 47 participants at a single-centre tertiary referral hospital. The authors found that 8 patients (17%) had focal FDG uptake on PET consistent with myocardial inflammation. FDG uptake was associated with cardiac magnetic resonance imaging T1, T2, and extracellular volume abnormalities, and systemic inflammatory blood markers (interleukin 6, interleukin 8, and high-sensitivity C-reactive protein) at baseline. All findings improved at follow-up performed a mean (SD) of 52 (17) days after baseline PET/MRI.
- This randomised, double-blind, placebo-controlled, phase 3 trial aimed to evaluate the effect of combination subcutaneous casirivimab and imdevimab on progression from early asymptomatic SARS-CoV-2 infection to symptomatic COVID-19. The study included 314 participants who were enrolled across 112 sites in the US, Romania and Moldova. The authors found that treatment with subcutaneous casirivimab and imdevimab, 1200mg, antibody combination compared with placebo significantly reduced the incidence of symptomatic COVID-19 among recently exposed, asymptomatic individuals (29/100 [29.0%] vs 44/104 [42.3%]; OR, 0.54 [95% CI, 0.30-0.97]; $P = .04$; absolute risk difference, −13.3% [95% CI, −26.3% to −0.3%]).
- This review summarises the capacity of advanced imaging modalities such as computed tomography, single-photon emission tomography, and electrical impedance tomography to assess ventilation-perfusion mismatch in COVID-19. Despite having limitations, these modalities provide vital information on blood volume distribution, pulmonary embolism, pulmonary vasculature and are useful to assess severity of lung disease and effectiveness of treatment in COVID-19 patients.

Epidemiology

- This sub study of the Sisonke large phase 3B implementation study in South Africa aimed to evaluate the asymptomatic carriage rate of SARS-CoV-2 in persons with no signs or symptoms of COVID-19 on the day of sampling in the study. The authors recruited 577 health care workers (HCWs) who were vaccinated with 1 dose of Ad26.CoV.2. Testing was performed prior administration of the 2nd Dose. They found that 16% (91/577) of the HCWs had asymptomatic COVID-19 due to Omicron VOC. The proportion of vaccinated (with Ad26.CoV.2) volunteers with asymptomatic carriage of COVID-19 was 2.6% during the Beta and Delta outbreaks. Their results suggest a high Omicron carriage rate even in those known to be vaccinated. [*not peer reviewed*].
- This multicentre phase 3 clinical trial in South Africa aimed to assess the relative efficacy of the mRNA-1273 (Moderna) in adults living with HIV (PLWH) and/or with at least one comorbidity known to be associated with severe COVID-19. The authors enrolled a total of 330 asymptomatic adults across 7 provinces from 2nd to 17th December 2021. They conducted baseline testing including SARS-COV-2 testing by RT-PCR. Results were available for 230/330 participants. They found that 31% of the

participants had evidence of acute SARS-CoV-2 infection. Their findings strongly suggest that Omicron has a much higher rate of asymptomatic carriage than other VOC. This is likely a major factor in the widespread, rapid dissemination of the variant globally. [*not peer reviewed*]

- This cohort study compared outcomes of laboratory-confirmed SARS-CoV-2 infections across 4 successive waves in those aged ≥20 years using public sector services in the Western Cape Province, South Africa, accounting for prior infection and vaccination. The authors also assessed whether protection against severe disease conferred by prior diagnosed infections and/or vaccination was maintained in those infected during the Omicron-driven fourth wave. Furthermore, the authors examined the extent to which undiagnosed prior infection may account for observed reductions in clinical severity during the Omicron wave. Their findings show that in the Omicron-driven wave, severe COVID-19 outcomes were reduced mostly due to protection conferred by prior infection and/or vaccination, but intrinsically reduced virulence may account for an approximately 25% reduced risk of severe hospitalisation or death compared to Delta. [*not peer reviewed*]
- This cohort study aimed to investigate dynamic longitudinal shifts in the distribution of SARS-CoV-2 variants over time and identify potential correlates of breakthrough infections in a progressively vaccinated community in California, U.S. The authors performed whole-genome sequencing and viral load measurements of nasal swabs in conjunction with retrospective medical chart review from 1,373 COVID-19 infected persons over a 5-month period. They found that 9.1% of the cases were vaccine breakthrough infections. Breakthrough infections were more commonly associated with circulating antibody-resistant variants carrying ≥1 mutation associated with decreased antibody neutralization (L452R/Q, E484K/Q and/or F490S) than infections in unvaccinated individuals (78% versus 48%, $P = 1.96 \times 10{-}8$). Their findings show that vaccine breakthrough infections are overrepresented by antibody-resistant SARS-CoV-2 variants, and that symptomatic breakthrough infections may be as efficient in spreading COVID-19 as unvaccinated infections, regardless of the infecting lineage.
- This cohort study of 255 infants born between March and December 2020 in the US aimed to examine the associations between maternal SARS-CoV-2 infection during pregnancy, being born during the COVID-19 pandemic regardless of maternal SARS-CoV-2 status, and neurodevelopment at age 6 months. The authors found that exposure to maternal SARS-CoV-2 infection was not associated with differences on any Ages & Stages Questionnaire, 3rd Edition, subdomain at age 6 months, regardless of infection timing or severity. However, both exposed and unexposed infants born during that period had significantly lower scores on gross motor, fine motor, and personal-social subdomains compared with a historical cohort of infants born before the onset of the COVID-19 pandemic. Their findings support the need for long-term monitoring of children born during the COVID-19 pandemic.
- This non-randomised controlled trial aimed to investigate the feasibility of surveillance among children and childcare workers and to model the efficacy of surveillance on viral spread prevention. The study was conducted at 9 day-care centres in Germany. The authors found that surveillance testing for SARS-CoV-2 among 954 eligible individuals was well accepted by children, parents, and childcare workers if saliva sampling at home was used. Mathematical modelling based on study and literature data identified biweekly testing of at least 50% of children and childcare workers as minimal requirements to limit secondary infections.
- This cohort study aimed to evaluate the association between a COVID-19 diagnosis and change in mobility and physical function of adults in Canada aged 50 years or older during the initial pandemic lockdown. The authors used data from 24114 participants from the Canadian Longitudinal Study on Aging (CLSA) COVID-19 study. They found that community-living middle-aged and older adults with confirmed, probable, or suspected COVID-19 had nearly 2-fold higher odds of worsening mobility and physical function compared with adults without COVID-19, even in the absence of hospitalisation. Their findings suggest that interventions may be needed for individuals with mild to moderate COVID-19 who do not require hospitalisation.
- This prospective cohort study aimed to estimate the proportion of children with severe outcomes within 14 days of testing positive for SARS-CoV-2 in an emergency department (ED). The study enrolled 3221 SARS-CoV-2–positive youths between March 2020 and June 2021 from 41 EDs across 10 Countries. The Countries included Argentina, Australia, Canada, Costa Rica, Italy, New Zealand, Paraguay, Singapore, Spain, and the US. The authors found that approximately 3% of SARS-CoV-2–positive

youths tested in EDs experienced severe outcomes within 2 weeks of their ED visit. Among children discharged home from the ED, the risk was much lower. Risk factors such as age, underlying chronic illness, and symptom duration may be useful to consider when making clinical care decisions.

Infection Prevention and Control

- This study in Japan examined the duration of infectious virus shedding in Omicron cases. The authors collected a total of 83 respiratory specimens from 21 cases (19 vaccinees and 2 unvaccinated cases; 4 asymptomatic and 17 mild cases). Samples were subjected to SARS-CoV-2 RNA quantification using quantitative RT-PCR and virus isolation tests. They found that the amount of viral RNA was highest on 3-6 days after diagnosis or 3-6 days after symptom onset, and then gradually decreased over time, with a marked decrease after 10 days since diagnosis or symptom onset. Positive virus isolation results showed a similar trend as the viral RNA amount, and no infectious virus in the respiratory samples was detected after 10 days since diagnosis or symptom onset. Their findings suggest that vaccinated Omicron cases are unlikely to shed infectious virus 10 days after diagnosis or symptom onset.
- The authors in this study developed an imidazolium-based zwitterionic polymer that demonstrated effective contact deactivation and adhesion repelling of a human coronavirus, HCoV-OC43. The polymer was synthesized using a substrate-independent and solvent-free process, leveraging an all-dry technique named initiated chemical vapor deposition (iCVD). The zwitterionic polymer and the synthesis approach used present an effective solution to mitigate viral transmission without the need for manual disinfection, reducing the health and economic impact of the ongoing pandemic.

Non-pharmaceutical interventions, social distancing

- This modelling study utilised data from 26 European countries to develop a framework to identify quarantine and testing strategies that enable travel from specific origins without increasing infection rates per capita within destinations. Their results for the pandemic situation observed on 21st November 2021 demonstrate that there are often less burdensome quarantine and testing strategies that can serve as effective alternatives to strict border closure. The estimated sufficient quarantine durations are especially dependent on COVID-19 prevalence and immunity within the two countries. They also found that asymmetry in the travel flow can also influence the estimated sufficient quarantine durations. Using data on variants of concern, including Omicron, they found that the adequacy of a border control strategy to limit variant spread depends strongly on the geographical distribution of the variant.
- The authors in this study present the dynamics of the proportion of COVID-19 cases that were traced and of delays in confirmation during a substantial outbreak that was suppressed by NPIs without lockdown in Hong Kong. They found that: i) restoring social distancing measures without maintaining tracing and testing efficiency was not enough to prevent growth of the outbreak; ii) a rise in number of daily cases increased the probability of confirmation delay among contact-traced cases; iii) testing at-risk groups reduced the probability and the duration of confirmation delay among contact-traced cases.

D. Clinical Trials Updates

Key updates:

Vaccine trials:

- On 17th January 2022, HDT Bio and SENAI CIMATEC reported to dose the first healthy volunteers in Brazil in a phase 1 trial of its RNA COVID-19 vaccine, HDT-301. The vaccine uses HDT Bio's proprietary lipid nanoparticle RNA-delivery technology. This double-blind, placebo-controlled, dose-ranging phase 1 clinical trial will enrol 90 healthy adult volunteers. The trial will assess the safety, tolerability, and immunogenicity of the vaccine at three dose levels, 1 µg, 5 µg and 25 µg. Safety and tolerability will be the primary endpoints assessed by incidence of adverse events for each dose through 12 months after the vaccination. Scheduled interim evaluations to measure immunogenicity also will be conducted. Clinical trial registration #: (NCT04844268).
- On 12th January 2022, Ocugen and its partner Bharat Biotech announced that sera from people vaccinated with a booster dose of COVID-19 vaccine candidate Covaxin (BBV152) showed to

neutralise the Omicron and Delta variants of the SARS-CoV-2 virus. Human immune sera from participants (n=13) in an ongoing phase 2 clinical trial were tested in a neutralization assay. The sera were collected at day 28 post six months booster following the primary two-dose series. Following three doses, the FRNT50 geometric mean titres (GMTs) of neutralizing antibodies against the Omicron variant measured in the samples was 75, compared to 480 against the Delta variant and 706 against the vaccine strain, D614G. Clinical trial registration #: (NCT04471519).

- On 11th January 2022, The World Health Organization (WHO) made an interim statement on COVID-19 vaccines in the context of the circulation of the Omicron SARS-CoV-2 Variant based on the recommendation from the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC). The TAG-CO-VAC considers that COVID-19 vaccines that have high impact on prevention of infection and transmission, in addition to the prevention of severe disease and death, are needed and should be developed. Until such vaccines are available, and as the SARS-CoV-2 virus evolves, the composition of current COVID-19 vaccines may need to be updated, to ensure that COVID-19 vaccines continue to provide WHO-recommended levels of protection against infection and disease by VOCs, including Omicron and future variants.
- On 7th January 2022, The US Food and Drug Administration (FDA) made amendments to the emergency use authorisation (EUA) for Moderna's COVID-19 vaccine. The amendments reduce the duration between the conclusion of an initial vaccine regimen and a booster shot to a minimum of five months. Therefore, individuals aged 18 years and above can receive a booster after at least five months.

Therapeutics trials:

- On 18th January 2022, Sorrento announced that the US phase 2 study with intranasal COVI-DROPS treatment in COVID-19 outpatients has completed enrolment. This randomised, placebo-controlled study aimed to evaluate the efficacy, safety and pharmacokinetics of intranasal STI-2099 (COVI-DROPS) in outpatient adults with COVID-19. It enrolled 72 adult outpatients who received either a single administration of COVI-DROPS (10 mg, 20 mg or 40 mg) or placebo. The primary endpoint was viral load reduction from baseline. Key secondary endpoints included the proportion of subjects with medically-attended visits or hospitalisations and the change from baseline in the WHO Clinical Progression Scale score. Clinical trial registration #: (NCT04906694).
- On 18th January 2022, Resverlogix announced that enrolment and dosing of patients has commenced at the University of Alberta Hospital in Edmonton for its phase 2b clinical trial of apabetalone (RVX-208) for treatment of COVID-19. Apabetalone is a first-in-class, small molecule, therapeutic candidate with an epigenetic mechanism of action. This randomised, open-label phase 2b trial will recruit up to 100 participants who will either receive apabetalone or standard of care alone. The trial will evaluate the safety and efficacy of Apabetalone as a potential oral treatment for COVID-19. The primary outcome measure will be a change in the WHO Ordinal Scale for Clinical Improvement and secondary endpoints will include evaluation of the effect of apabetalone on biomarkers of inflammation. Clinical trial registration #: (NCT04894266).
- On 17th January 2022, Bod Australia reported to start a clinical trial of its medicinal cannabis product, MediCabilis 5%, to treat long-Covid after the UK Medicines and Healthcare Products Regulatory Agency (MHRA) granted the company a clinical trial authorisation (CTA). The six-month open-label trial will be carried out in collaboration with Drug Science UK. The trial intends to enrol up to 30 subjects aged ≥18 years with long-Covid. In the trial, subjects will be given MediCabilis daily for six months.
- On 10th January 2022, Adamis Pharmaceuticals Corporation announced the submission of a Fast Track Application to the U.S. Food and Drug Administration (FDA) for its oral antiviral, Tempol for the treatment and prevention of COVID-19. Tempol is currently being studied in a phase 2/3 clinical trial in adult patients with confirmed COVID-19 infection. Tempol has been shown to have antiviral, anti-inflammatory, and antioxidant activity. Clinical trial registration #: (NCT04729595).
- On 7th January 2022, PaxMedica announced it has received approval from the South African Health Products Regulatory Agency (SAHPRA) for its clinical trial application to study the effects of PAX-101 (suramin intravenous (IV) infusions) in patients with Long COVID-19 Syndrome (LCS). LCS is a serious, multi-system illness that results in significant impairment of functioning in many individuals

after acute infection with COVID-19. This prospective, randomised, placebo-controlled, double-blind, multiple-dose phase 1B study anticipates to enrol patients with persistent signs and symptoms of LCS, after a previously documented infection with the COVID-19 virus. The aim is to study the safety and tolerability, efficacy, and PK of two doses of suramin (5 mg/kg and 10 mg/kg) in LCS patients aged ≥ 18.

- On 6th January 2022, First Wave BioPharma announced that it has completed enrolment for part 2 of the RESERVOIR phase 2 trial evaluating FW-COV as an outpatient treatment for COVID-19-related gastrointestinal (GI) infections. FW-COV is a proprietary, oral, tablet formulation of micronized niclosamide being developed to remove SARS-CoV-2 (SARS2) from the GI tract. RESERVOIR is designed as a two-part, two-arm, randomised, placebo-controlled phase 2 study with a primary purpose to confirm the safety of FW-COV and assess the drug's ability to remove the SARS-CoV-2 (SARS2) virus from the digestive tract. The 150 patients successfully enrolled in part 2 of the trial were randomised to receive either FW-COV or a placebo treatment for 14 days and will be observed for six weeks following the end of treatment. Clinical trial registration #: (NCT04542434).
- On 5th January 2022, Humanigen announced target enrolment in the phase 2/3 ACTIV-5/BET-B study had been achieved. The study enrolled over 400 patients in y 55 clinical sites including international sites. Hospitalised COVID-19 patients enrolled in ACTIV-5/BET-B were randomised to receive either lenzilumab and remdesivir or placebo and remdesivir. Patients in both arms also received current standard of care for hospitalised COVID-19 patients, including corticosteroids. The primary analysis population in ACTIV-5/BET-B comprises all randomised patients with a baseline C-reactive protein ("CRP") less than 150 mg/L, age < 85, and do not require mechanical ventilation at the time of enrolment. The primary endpoint of ACTIV-5/BET-B is the incidence of invasive mechanical ventilation or death through day 29. Lenzilumab is a variant-agnostic therapeutic that targets the dysregulated host immune response, an approach which may be of greater value than targeting the virus in hospitalised patients. Clinical trial registration #: (NCT04583969).

Immunotherapies trials:

- On 14th January 2022, The World Health Organization (WHO) recommended two new drugs for COVID-19: baricitinib and sotrovimab. Baricitinib is strongly recommended for patients with severe or critical COVID-19 administered along with corticosteroids. It is part of a class of drugs called Janus kinase (JAK) inhibitors that suppress the overstimulation of the immune system. On the other hand, sotrovimab, a monoclonal antibody, is recommended, for treating mild or moderate COVID-19 in patients who are at high risk of hospitalisation. This includes patients who are older, immunocompromised, having underlying conditions like diabetes, hypertension, and obesity, and those unvaccinated.

For further detailed information for each country, refer to the full table here

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