



COVID-19 Scientific and Public Health Policy Update¹ (11 May 2022)

This biweekly brief details the latest developments in scientific knowledge and public health policy from around the world as well as updates to the COVID-19-related guidance from Africa CDC, WHO and other public health agencies. This brief complements the Weekly Outbreak Brief and other documents on COVID-19 and the actions that the African Union/Africa CDC and WHO/AFRO are taking to help African Union Member States. Contents are <u>not intended to serve as</u> <u>recommendations</u> from the African Union-Africa CDC or WHO/AFRO; rather, the brief serves as a summary of the scientific information available in the public space to Member States. The outbreak is evolving rapidly and 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 on the science and public health best practices related to COVID-19.

A. Trending Topics

Status of Vaccines in Africa



*Received two doses of a two dose COVID-19 vaccine series or one dose of the Johnson & Johnson vaccine https://africacdc.org/COVID-19-vaccination/_____

Updated 11th May, 2022

Note: Subsequently Africa CDC will change the denominator of the calculation for percentage fully vaccinated from 2020 population to 2022 population estimates (UNFPA) to give accurate projections from effective population size (Ne) perspectives.

The resulting effect is that there will be a slight reduction in fully vaccinated coverage percentages of member states and the continent at large.

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 does not represent policy decisions, recommendations, or final conclusions of the African Union- Africa CDC or WHO/AFRO**.







Variants of Concern (VOC)

The Omicron variant (B.1.1.529), first reported in South Africa on 24th November 2021, has spread to 198 countries/territories/areas worldwide. As of 11 May 2022, 48 (87.3%) of the 55 Member States in Africa have reported this variant. For more information visit <u>https://africacdc.org/institutes/africa-pathogen-genomics-initiative/</u>.



Updated 11th May, 2022

B. New guidelines and resources

Since 26th April 2022,

- Africa CDC² has published new guidance and resources on:
 - o Epidemiological and Economic Impact of COVID-19 Vaccine Rollout Scenarios in Africa
 - o Outbreak Brief 120: Coronavirus Disease 2019 (COVID-19) Pandemic
 - o Africa CDC Mastercard Foundation: Saving Lives and Livelihoods Newsletter, April 2022
- U.S. CDC³ has published new guidance and resources on:
 - <u>Selected Adverse Events Reported after COVID-19 Vaccination</u>
 - Post-COVID Conditions: CDC Science

² Africa CDC: Africa Centres for Disease Control and Prevention

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







- Testing Strategies for SARS-CoV-2
- Interim Guidance on Management of Coronavirus Disease 2019 (COVID-19) in Correctional and Detention Facilities
- WHO⁴ has published new guidance and resources on:
 - o Estimating global and country-specific excess mortality during the COVID-19 pandemic
 - WASH FIT manual for trainers
 - <u>Strengthening pandemic preparedness planning for respiratory pathogens: policy brief, 27 April</u> 2022
- U.S. FDA⁵ has issued press releases on:
 - On 10 May, FDA approved a new indication for Olumiant (baricitinib) for the treatment of COVID-19 in hospitalised adults
 - o On 5 May, FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals
 - As of 10 May, 433 tests and sample collection devices are authorised by the FDA under emergency use authorisations (EUAs)
- ECDC⁶ has issued new resources on:
 - <u>COVID-19 Aviation Health Safety Protocol: Operational guidelines for the management of air</u> passengers and aviation personnel in relation to the COVID-19 pandemic
 - Public health considerations and evidence to support decisions on the implementation of a second mRNA COVID-19 vaccine booster dose
- UKHSA⁷ has issued new guidance and press releases on:
 - o COVID-19 vaccination programme
 - o COVID-19 therapeutic agents: technical briefings
 - National protocol for Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])
 - Lateral flow evaluation prioritisation criteria for rapid diagnostic assays for specific SARS-CoV-2 antigens
 - COVID-19: genomic surveillance of patients treated with neutralising monoclonal antibody or immunosuppressed
 - o Investigation of SARS-CoV-2 variants: technical briefings
 - o Investigation of SARS-CoV-2 variants of concern: variant risk assessments

C. Scientific updates

- Basic Science
 - This <u>study</u> in South Africa identified two new Omicron lineages (BA.4 and BA.5) after sequencing nasopharyngeal and oropharyngeal swab samples collected between 1 November 2021 and 20 April 2022 from cases identified by routine surveillance. The spike proteins of BA.4 and BA.5 are identical, and comparable to BA.2 except for the addition of 69-70del, L452R, F486V and the wild type amino acid at Q493. The 69-70 deletion in spike allows these lineages to be identified by the proxy marker of S-gene target failure with the TaqPath™ COVID-19 qPCR assay. BA.4 and BA.5 have rapidly replaced BA.2, reaching more than 50% of sequenced cases in South Africa from the first week of April 2022 onwards. The authors estimate growth advantages for BA.4 and BA.5 of 0.08 (95% CI: 0.07 0.09) and 0.12 (95% CI: 0.09 0.15) per day respectively over BA.2 in South Africa. Their findings highlight the importance of continued global genomic surveillance and variant analysis in real-time to characterize the continuing evolution of SARS-CoV-2.[*not peer reviewed*]

⁴ WHO: World Health Organization

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

⁶ ECDC: European Centre for Disease Prevention and Control

⁷ UKHSA: United Kingdom Health Security Agency







- This <u>human challenge study</u> in the United Kingdom assessed safety, tolerability and viral kinetics following SARS-CoV-2 infection. The study involved 36 volunteers aged 18-29 years without evidence of previous infection or vaccination who were inoculated with 10 TCID₅₀ of a wild-type virus intranasally. Two participants were excluded from per protocol analysis due to seroconversion between screening and inoculation. Eighteen (~53%) became infected, with viral load (VL) rising steeply and peaking at ~5 days post-inoculation. Virus was first detected in the throat but rose to significantly higher levels in the nose, peaking at ~8.87 log₁₀ copies/ml (median, 95% CI [8.41,9.53). Viable virus was recoverable from the nose up to ~10 days post-inoculation, on average. There were no serious adverse events reported, with mild-to-moderate symptoms reported by 16 (89%) infected individuals, beginning 2-4 days post-inoculation. Anosmia/dysosmia developed more gradually in 12 (67%) participants. No quantitative correlation was noted between VL and symptoms, with high VLs even in asymptomatic infection, followed by the development of serum spike-specific and neutralising antibodies. However, lateral flow results were strongly associated with viable virus and modelling showed that twice-weekly rapid tests could diagnose infection before 70-80% of viable virus had been generated.
- This <u>study</u> in Germany assessed SARS-CoV-2-specific T-cell responses in convalescent individuals recovered from SARS-CoV-2 infection (n = 19) as well as individuals after 2 (n = 16) and 3 (n = 7) doses of SARS-CoV-2 vaccination (Pfizer/BioNTech messenger RNA vaccine). Spike-derived epitopes were not dominantly targeted in convalescent individuals compared to non-spike epitopes. In vaccinees, however, a broader spike-specific T-cell response compared to convalescent individuals was detected. Booster vaccination increased the breadth of the spike-specific T-cell response in convalescent individuals but not in vaccinees with complete initial vaccination. In convalescent individuals and vaccinees, the targeted T-cell epitopes were broadly conserved between wild-type SARS-CoV-2 variant B and Omicron/B.1.1.529. Their findings emphasise the relevance of vaccine-induced spike-specific CD8⁺ T-cell responses in combating variants of concern including Omicron/B.1.1.529 and support the benefit of boosting convalescent individuals with mRNA vaccines.
- This <u>cohort study</u> in China assessed the antibody and T-cell responses to SARS-CoV-2 Wuhan and Omicron strains in individuals recovered from COVID-19. The study included 113 adults who were discharged from a research Center in Wuhan. The neutralisation efficacy of individuals recovered from Wuhan strain without repeated infection and vaccination against Omicron (median (IQR) ID50 titers were (76.7 [44.0-163.6]), lower than the original Wuhan strain (764.2 [332.1-1370.0]) and Delta variant (76.7 [44.0-163.6]). Their findings suggest that Omicron is resistant to vaccine- and infection-elicited antibody responses, but elicits T-cell responses similar to other variants. Omicron may be less likely to cause severe disease in those who have previously been vaccinated or infected because of T-cell cross-reactivity.

Vaccines

- This <u>randomised</u>, <u>double-blind</u>, <u>placebo-controlled</u>, <u>phase 3 trial</u> assessed the efficacy and safety of ZF2001 (a vaccine that contains a dimeric form of the receptor-binding domain of SARS-CoV-2 and aluminium hydroxide as and adjuvant). The study involved 25,193 adults who completed the 3 dose regimen and 6 months followup at 31 clinical centers across Uzbekistan, Indonesia, Pakistan, and Ecuador. An additional center in China was included in the safety analysis only. The efficacy to prevent symptomatic infection was found to be 75.7% (95% CI, 71.0 to 79.8). Severe-to-critical COVID-19 occurred in 6 participants in the ZF2001 group and in 43 in the placebo group, for a vaccine efficacy of 87.6% (95% CI, 70.6 to 95.7); COVID-19–related death occurred in 2 and 12 participants, respectively, for a vaccine efficacy of 86.5% (95% CI, 38.9 to 98.5). The incidence of adverse events and serious adverse events was balanced in the two groups, and there were no vaccine-related deaths. Most adverse reactions (98.5%) were of grade 1 or 2.
- This <u>phase 3</u>, <u>multinational</u>, <u>randomised</u>, <u>placebo-controlled trial</u> assessed the efficacy and safety of CoVLP+AS03, a coronavirus-like particle vaccine that has been produced in a plant-based platform combined with an adjuvant (Adjuvant System 03 [AS03]). The trial involved 24,141 volunteers at 85 sites in Argentina, Brazil, Canada, Mexico, the United Kingdom, and the United States. Vaccine efficacy was 69.5% (95% CI, 56.7 to 78.8) against any symptomatic COVID-19 caused by five variants that were identified by sequencing. Vaccine efficacy was 78.8% (95% CI, 55.8 to 90.8) against moderate-







to-severe disease and 74.0% (95% CI, 62.1 to 82.5) among the participants who were seronegative at baseline. No severe cases of COVID-19 occurred in the vaccine group, in which the median viral load for breakthrough cases was lower than that in the placebo group by a factor of more than 100. Solicited adverse events were mostly mild or moderate and transient and were more frequent in the vaccine group than in the placebo group; local adverse events occurred in 92.3% and 45.5% of participants, respectively, and systemic adverse events in 87.3% and 65.0%. The incidence of unsolicited adverse events was similar in the two groups up to 21 days after each dose (22.7% and 20.4%) and from day 43 through day 201 (4.2% and 4.0%).

- This prospective, population-based cohort study in Denmark assessed the incidence of multisystem inflammatory syndrome in children (MIS-C), and described the clinical phenotype, following the Delta variant of SARS-CoV-2. A total of 51 MIS-C cases were identified from 1 August 2021, to 1 February 2022 via a nationwide research collaboration involving real-time data collection from all 18 paediatric departments. The incidence of MIS-C was one in 3,400 unvaccinated individuals (95% CI 2,600–4,600) with the delta variant and one in 9,900 vaccinated individuals (95% CI ,1800–390,000) with breakthrough infection. The estimated vaccine effectiveness against MIS-C after the delta variant was 94% (95% CI 55–99; p=0.0061) in individuals aged 5–17 years. The clinical phenotype during the delta wave was comparable to the pre-delta era.
- This <u>case report</u> in the United States describes a previously healthy 27-year-old woman who presented with urticaria after receiving a third dose of COVID-19 mRNA vaccine (Moderna). She had not experienced adverse effects after the first 2 vaccine doses on 17 January and 5 February 2021. Twelve days after the booster vaccination, she developed pruritic wheals on her face and bilateral, transient eyelid swelling. Over the next week, a pruritic rash spread over her neck, chest, trunk, and arms; each lesion faded without scarring within 24 hours. She did not experience lip, tongue, or neck swelling; shortness of breath; wheezing; chest pain; or palpitations. Application of pressure to her forearm in a circular motion using a pen cap elicited wheal and flare lesions.

Diagnostics

- This prospective cohort study in the United States assessed the diagnostic performance of home antigen tests compared with reverse transcription–polymerase chain reaction (RT-PCR) and viral culture by days from illness onset. The study involved 225 adults and children with RT-PCR confirmed SARS-Cov-2 infection. Antigen test sensitivity was 50% (95% CI, 45%-55%) during the infectious period, 64% (95% CI, 56%-70%) compared with same-day RT-PCR, and 84% (95% CI, 75%-90%) compared with same-day cultures. Antigen test sensitivity peaked 4 days after illness onset at 77% (95% CI, 69%-83%); a second test 1 to 2 days later showed improved sensitivity (81%-85). Six days after illness onset, antigen test result positivity was 61% (95% CI, 53%-68%). Almost all (216 [96%]) surveyed individuals reported that they would be more likely to get tested for SARS-CoV-2 infection if home antigen tests were available over the counter. The findings suggest that symptomatic individuals with an initial negative home antigen test result for SARS-CoV-2 infection should test again 1 to 2 days later.
- This prospective repeated cross-sectional study in Canada assessed the adequacy of serial self-performed SARS-CoV-2 rapid antigen detection testing (RADT) in the workplace, in terms of the frequency of correct execution of procedural steps and accurate interpretation of the range of possible RADT results. The study involved 647 participants who performed 1892 tests overall. The authors compared interpretation and performance between participants who received instructions provided by the manufacturer vs those who received modified instructions that were informed by the most frequent or most critical errors they observed. Better accuracy in test interpretation was observed among participants using the modified quick reference guide than those using the manufacturer's instructions for reading results that were weak positive (64/115 participants [55.6%] vs 20/163 participants [12.3%]; difference, 43.3 [95% CI, 33.0-53.8] percentage points), positive (103/115 participants [89.6%] vs 84/163 participants [51.5%]; difference, 38.1 [95% CI, 28.5-47.5] percentage points), strong positive (219/229 participants [95.6%] vs 274/326 participants [84.0%]; difference, 11.6 [95% CI, 6.8-16.3]







percentage points), and invalid (200/229 participants [87.3%] vs 252/326 participants [77.3%]; difference, 10.0 [95% CI, 3.8-16.3] percentage points)

• This <u>retrospective cohort study</u> in the UK assessed whether peripheral oxygen saturation (SpO2) accurately predicted arterial blood gas (SaO2), and whether disparities between ethnicities existed. Paired O2 saturation measurements from 16,818 inpatient spells between 1st January 2017 and 18th February 2021 were analysed. Across the cohort, SpO2 was statistically significantly higher than SaO2 (p < 0.0001), with medians of 98% (interquartile range [IQR]: 95–100%) vs. 97% (IQR: 96–99%), and a median difference of 0.5% points (pps; 95% CI: 0.5–0.6). The size of the difference varied with the magnitude of SaO2, with SpO2 overestimating by a median by 3.8pp (IQR: 0.4, 8.8) for SaO2 values <90% but underestimating by a median of 0.4pp (IQR: -2.0, 1.4) for an SaO2 of 95%. The differences between SpO2 and SaO2 were also found to vary by ethnicity, with this difference being 0.8pp (95% CI: 0.6–1.0, p < 0.0001) greater in those of Black vs. White ethnicity. These differences resulted in 8.7% vs. 6.1% of Black vs. White patients who were classified as normoxic on SpO2 actually being hypoxic on the gold standard SaO2 (odds ratio: 1.47, 95% CI: 1.09–1.98, p = 0.012).

Care and Treatment

- This adaptive, open label trial evaluated the effects of remdesivir among 14.221 adult COVID-19 inpatients from 454 hospitals in 35 countries in all six WHO regions. The patients were randomly allocated (1:1) either to remdesivir (10 daily infusions, unless discharged earlier) or to its control (allocated no study drug). Compliance was high in both groups. Overall, 602/4146 (14.5%) of patients assigned to remdesivir died versus 643/4129 (15.6%) assigned to control (mortality rate ratio [RR] 0.91 [95% CI 0.82–1.02], p=0.12). Of those already ventilated, 151/359 (42.1%) assigned to remdesivir died versus 134/347 (38.6%) assigned to control (RR 1.13 [0.89-1.42], p=0.32). Of those not ventilated but on oxygen, 14.6% assigned to remdesivir died versus 16.3% assigned to control (RR 0.87 [0.76–0.99], p=0.03). Of 1730 not on oxygen initially, 2.9% assigned to remdesivir died versus 3.8% assigned to control (RR 0.76 [0.46–1.28], p=0.30). Combining all those not ventilated initially, 11.9% assigned to remdesivir died versus 13.5% assigned to control (RR 0.86 [0.76-0.98], p=0.02) and 14.1% versus 15.7% progressed to ventilation (RR 0.88 [0.77-1.00], p=0.04). The non-prespecified composite outcome of death or progression to ventilation occurred in 19.6% assigned to remdesivir versus 22.5% assigned to control (RR 0.84 [0.75–0.93], p=0.001). Allocation to daily remdesivir infusions (vs openlabel control) delayed discharge by about 1 day during the 10-day treatment period. A meta-analysis of mortality in all randomised trials of remdesivir versus no remdesivir yielded similar findings.
- This <u>cohort study</u> in 30 countries across 5 continents assessed the effect of extracorporeal membrane oxygenation (ECMO) compared with conventional mechanical ventilation on outcomes of patients with COVID-19 associated respiratory failure. The study included 7,345 adults admitted to the intensive care unit with clinically suspected or laboratory confirmed SARS-CoV-2 infection. 11.5% (844/7345) of the eligible patients received ECMO. Adherence adjusted mortality was 26.0% (95% CI: 24.5% to 27.5%) for a treatment strategy that included ECMO if the PaO₂/FiO₂ ratio decreased <80 mm Hg compared with 33.2% (31.8% to 34.6%) had patients received conventional treatment without ECMO (risk difference –7.1%, 95% CI: –8.2% to –6.1%; risk ratio 0.78, 95% CI: 0.75 to 0.82). In secondary analyses, ECMO was most effective in patients aged <65 years and with a PaO₂/FiO₂ <80 mm Hg or with driving pressures >15 cmH₂O during the first 10 days of mechanical ventilation. Age, severity of hypoxaemia, and duration and intensity of mechanical ventilation should be considered when deciding to initiate ECMO in patients with COVID-19.
- This <u>case series</u> in Brazil reports on 6 children with SARS-CoV-2 infection who were supported by extracorporeal membrane oxygenation (ECMO) due to refractory hypoxemic respiratory failure. The children were admitted in 2 hospitals between 1 March 2020 and 30 June 2021. The mean time between the onset of symptoms and cannulation, ECMO duration, and ventilation time were 15 days (range: 6–24 days)], 11 days (range: 6–19 days), and 20.5 days (range: 14–33 days), respectively. Five (83.3%) children were successfully decannulated and four survived with hospital discharge. One child died on ECMO support due to multiple organ dysfunction syndromes after 13 days and another







one died 3 days after decannulation due to extensive hemorrhagic stroke. ECMO appears as a viable intervention in selected patients who failed conventional therapies in the pediatric population.

• This <u>multiphase, prospective mixed methods study</u> in the UK describes the development and validation of a novel patient reported outcome measure for symptom burden from long covid, the symptom burden questionnaire for long covid (SBQ-LC). Thirteen adults (aged ≥18 years) with self-reported long covid and 10 clinicians evaluated content validity. The draft questionnaire was field tested by 274 adults with long covid. The instrument is composed of 17 independent scales developed using modern psychometric methods with promising psychometric properties. Respondents rate their symptom burden during the past seven days using a dichotomous response or 4 point rating scale. Each scale provides coverage of a different symptom domain and returns a summed raw score that can be transformed to a linear (0-100) score. Higher scores represent higher symptom burden. Across the 17 scales, person reliability ranged from 0.34 to 0.87, person separation ranged from 0.71 to 2.56, item separation ranged from 1.34 to 13.86, and internal consistency reliability (Cronbach's alpha) ranged from 0.56 to 0.91. SBC-LC may be used to evaluate the impact of interventions and inform best practice in clinical management.

Epidemiology

- This <u>study</u> examined the extent to which pre-existing medical conditions are related to COVID-19 incidence and mortality in Nigeria from a geographical perspective. The authors conducted a geographically weighted regression analysis using several sources of publicly available data that included 188,880 confirmed COVID-19 cases and 2,288 deaths from 27 February to 25 August 2021. Their findings show that besides the remarkable spatial variation in COVID-19 incidence and mortality, obesity was a significant predictor of COVID-19 with its effect strongest in southwest Nigeria and other parts of the country. They recommended that there should be a spatially explicit intervention on the reduction of exposure to COVID-19 among states with high prevalence of pre-existing medical conditions through vaccination.
- This <u>case-control study</u> in the United States assessed the severity of infection with the B.1.1.529 (Omicron) variant of SARS-CoV-2. The authors linked state-level vaccination data with quality-controlled electronic health records from a large healthcare system, including 13 hospitals, in Massachusetts. They compared risks of hospital admission and mortality across the SARS-CoV-2 waves in over 130,000 COVID patients. Although the unadjusted rates of hospital admission and mortality appeared to be higher in previous waves compared to the Omicron period, after adjusting for confounders including various demographics, Charlson comorbidity index scores, and vaccination status (and holding the healthcare utilization constant), they found that the risks of hospitalisation and mortality were nearly identical between periods (adjusted hospitalisation risk of Omicron to Spring 21' (OR:1.10, 95% CI: 0.99 1.21, p = 0.06) or Omicron to Delta (OR: 1.00, 95% CI: 0.99 1.01, p = 0.67). Compared to the Omicron period, the risk of mortality during the Winter 20'-21'period (OR: 1.00, 95% CI: 1.00 1.01, p = 0.4) and Delta period (OR: 1.00, 95% CI: 1.00 1.01, p = 0.08). Their findings suggest that the intrinsic severity of the Omicron variant may be as severe as previous variants.[*not peer reviewed*]
- This systematic review and meta-analysis in the U.S assessed how reported household secondary attack rates (SARs) changed over time and whether SARs varied by viral variant and index case and contact vaccination status. The authors included 135 studies with more than 1.3 million participants in 36 countries. Household SARs increased over time and were higher for Omicron (42.7%), Alpha (36.4%), and Delta (29.7%) variants than previously reported estimates (18.9%). Full vaccination was associated with reductions in susceptibility and infectiousness, but more so for Alpha than Delta and Omicron. These results suggest that emerging SARS-CoV-2 variants of concern have increased transmissibility. Vaccination for SARS-CoV-2 transcends protection of the individual by conferring indirect protection to other household members, but the degree of protection is seemingly lower for emerging variants.







Infection prevention & control

- This <u>review</u> of intra-action review (IAR) reports of the national responses to the COVID-19 pandemic in 18 countries in Africa highlights best practices and challenges and offers perspectives for the future. The authors conducted a thematic analysis across 10 preparedness and response domains. The COVID-19 pandemic response in African countries has relied on many existing response systems such as laboratory systems, surveillance systems for previous outbreaks of highly infectious diseases and a logistics management information system. These best practices were backed by strong political will. The key challenges included low public confidence in governments, inadequate adherence to infection prevention and control measures, shortages of personal protective equipment, inadequate laboratory capacity, inadequate contact tracing, poor supply chain and logistics management systems, and lack of training of key personnel at national and subnational levels. The IARs demonstrate that many technical areas still require immediate improvement to guide decisions in subsequent waves or future outbreaks.
- This <u>observational study</u> in Germany describes the infection control measures undertaken in a tertiary care children's hospital during the first year of the pandemic. The authors evaluated frequency of SARS-CoV-2 detection in admitted patients, in-hospital transmission and infection related findings with local infection control measures in place. Local infection control measures comprised the formation of a task force, triage, protective hygiene measures and an adaptable SARS-CoV-2 test strategy. Between January 2020 and March 2021, SARS-CoV-2 infection was detected in 37 children presenting to the hospital, 21 of these were admitted. One hospital-acquired infection occurred. About 90% of health-care staff perceived the majority of measures as effective and appropriate. However, visitor restrictions and cancellation of scheduled treatments were perceived least effective by hospital staff and as a particular burden for patients and their caregivers. Visits at the pediatric emergency department significantly decreased during the pandemic. The authors drafted a pandemic action plan by ranking infection control measures according to local transmission stages.
- This <u>systematic review</u> assessed the types of skin lesions caused by PPE use in health professionals during the COVID-19 pandemic and verified the recommended prevention measures. The main types of skin lesions related to mask use were stage 1 pressure ulcers, acne and cutaneous depression. Regarding the use of glasses and face shields, the most frequent were stage 1 and 2 pressure ulcers. Xerosis and irritant contact dermatitis occurred due to using gloves and protective clothing, respectively. The main preventive measures recommended were using hydrocolloid or foam dressing in the pressure regions, moisturizers and emollients. Their findings can guide health professionals in identifying risks associated with use of PPE, and promoting preventive measures to avoid their occurrence.

Non-pharmaceutical interventions, social distancing

- This <u>systematic review</u> assessed the physiological effects the different types of masks have on healthy adults when doing physical exercise. A total of 633 studies were found, of which 8 articles met the inclusion criteria. There were significant changes in the following physiological variables when engaging in physical exercise using masks: 25% in the heart rate and dyspnea, 37.5% in the rating of perceived exertion, 50% in the pulmonary variables, and 37.5% in discomfort. The oxygen saturation, blood pressure, systolic blood pressure, diastolic blood pressure, and the concentration of blood lactate did not present any significant effect in this study. These findings indicate that the use of masks is not harmful to individuals' health. It does not present any significant detrimental effect on physical performance or risk to their well-being. However, further experiments are required to corroborate the findings of this review.
- This <u>review</u> discusses the positive and long-term negative impacts of COVID-19 on the environment, waste management, and energy sectors. Remarkable reduction in the levels of CO (3 65%), NO₂ (17 83%), NO_x (24 47%), PM_{2.5} (22 78%), PM₁₀ (23 80%), and VOCs (25 57%) was observed during the lockdown across the world. However, the pandemic put enormous strain on the present waste collection and treatment system, resulting in ineffective waste management practices, damaging the







environment. The extensive usage of face masks increased the release of microplastics/nanoplastics (183 to 1247 particles piece⁻¹) and organic pollutants in land and water bodies. Furthermore, the significant usages of anti-bacterial hand sanitizers, disinfectants, and pharmaceuticals have increased the accumulation of various toxic emerging contaminants (e.g., triclocarban, triclosan, bisphenol-A, hydroxychloroquine) in the treated sludge/biosolids and discharged wastewater effluent, posing great threats to the ecosystems. The authors also suggest strategies to create long-term environmental advantages.

D. Clinical Trials Updates

Key updates:

Vaccine trials:

- On 5 May 2022, the U.S. Food and Drug Administration has limited the authorised use of the Janssen COVID-19 vaccine to individuals 18 years of age and older for whom other authorised or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 vaccine because they would otherwise not receive a COVID-19 vaccine. The decision based on an updated analysis, evaluation and investigation of reported cases which determined the risk of thrombosis with thrombocytopenia syndrome (TTS). TTS is a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets. The TTS onset of symptoms was noticed from reported cases approximately one to two weeks following administration of the Janssen COVID-19 vaccine. The known and potential benefits of the vaccine for the prevention of COVID-19 outweigh the known and potential risks for individuals 18 years of age and older for whom other authorised or approved COVID-19 vaccines are not accessible or clinically appropriate, and for individuals 18 years of age and older who elect to receive the Janssen COVID-19 vaccine because they would otherwise not receive a COVID-19 vaccines are not accessible or clinically appropriate, and for individuals 18 years of age and older who elect to receive the Janssen COVID-19 vaccine.
- On 5 May 2022, <u>Bavarian Nordic announced additional results from its Phase 2 clinical trial of ABNCoV2, a VLP-based, non-adjuvanted COVID-19 vaccine candidate.</u> Data from subjects, who were previously vaccinated with approved mRNA or adenoviral vaccines, demonstrated that vaccination with ABNCoV2 induced a significant boost to the neutralising antibodies against the Omicron variant in the majority of subjects with a fold increase in the same range as previously reported for the original Wuhan SARS-CoV2 variant. The phase 2 results revealed a single vaccination with 50µg or 100µg ABNCoV2 can boost neutralising antibodies to levels reported to be highly efficacious (>90%) against SARS-CoV2 irrespective of type of vaccine previously received (mRNA or adenovirus-based), or the initial level of neutralising antibody titers before booster vaccination with ABNCoV2. Clinical trial registration #: (NCT05329220).
- On 4 May 2022, <u>Novavax announced the submission of a request to the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain to expand the authorisation of Nuvaxovid (NVX-CoV2373) COVID-19 Vaccine (recombinant, adjuvanted), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in adolescents aged 12 through 17 years. The vaccine is given as a primary vaccination in two doses administered 21 days apart. The request is based on clinical data from the ongoing pediatric expansion of PREVENT-19, a pivotal Phase 3 trial of 2,247 adolescents aged 12 through 17 years across 73 sites in the U.S., to evaluate the safety, effectiveness (immunogenicity), and efficacy of Nuvaxovid. The vaccine achieved its primary effectiveness endpoint in the trial and demonstrated 80 percent efficacy overall at a time when the Delta variant was the predominant circulating SARS-CoV-2 strain in the U.S. Clinical trial registration #: (NCT04611802).</u>
- On 29 April 2022, <u>Moderna announced it has submitted for a variation to the conditional marketing authorisation (CMA) with the European Medicines Agency (EMA) for the evaluation of a 25 µg two-dose series of COVID-19 vaccine, Spikevax in children six months to under six years of age. The submission is supported by interim data from KidCOVE study which is an ongoing randomized, observer-blind, placebo-controlled expansion study to evaluate the safety, tolerability, reactogenicity, and effectiveness of Spikevax given to healthy children 28 days apart. The study population is divided into three age groups (6 to <12 years, 2 to <6 years, and six months to <2 years). Positive interim results from the Phase 2/3 KidCOVE study showed a robust neutralising antibody response in the six</p></u>







months to under six years of age group after a two-dose primary series of mRNA-1273, along with a favorable safety profile. The antibody titers in the pre-specified six months to 23 months and two years to under six years age sub-groups met the statistical criteria for similarity to the adults in the COVE Study, which satisfied the primary objective of the study. Clinical trial registration #: (NCT04796896).

- On 26 April 2022, <u>Pfizer and BioNTech submitted an application to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorisation (EUA) of a 10-µg booster dose of the Pfizer-BioNTech COVID-19 vaccine for children 5 through 11 years of age. The submission included data from the Phase 2/3 clinical trial in children ages 5 through 11 years who received a booster dose approximately 6 months after the second dose of the Pfizer-BioNTech COVID-19 vaccine 10-µg two-dose primary series. Data from this study demonstrated a strong immune response in this age group following a booster dose of the Pfizer-BioNTech COVID-19 vaccine with no new safety signals. Clinical trial registration #: (NCT04816643).</u>
- On 29 April 2022, <u>SK bioscience and GSK announced submission of a biologics license application for SKYCovione a recombinant protein-based COVID-19 vaccine candidate adjuvanted with GSK's pandemic adjuvant, to the Korean Ministry of Food and Drug Safety (KMFDS) following positive Phase 3 clinical data. The phase 3 clinical trial in 4,037 adults over 18-year-old across 6 countries (Thailand, Vietnam, New Zealand, Ukraine, the Philippines and South Korea) the vaccine demonstrated superior neutralising antibody titres against SARS-CoV-2 parental strain, 2.93 times that of a control vaccine 2 weeks after the second dose. In addition, the proportion of participants who seroconverted, (with a greater than four-fold increase in neutralising antibody titres compared to baseline), was 98.06% in the SKYCovione group and 87.30% in the control group. The vaccine candidate also showed a clinically favorable safety profile. Clinical trial registration #: (NCT05007951).
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- On 28 April 2022, <u>Moderna announced that it has submitted a request for emergency use authorisation (EUA) for its COVID-19 vaccine (mRNA-1273) in children 6 months to under 2 years and 2 years to under 6 years of age to the U.S. Food and Drug Administration (FDA). The requests are based on a 25 µg two-dose primary series of mRNA-1273. Positive interim results from the Phase 2/3 KidCOVE study demonstrated a robust neutralising antibody response in the 6 month to under 6 years of age group after a two-dose primary series of mRNA-1273, along with a favorable safety profile. The antibody titers in the pre-specified 6 month to 23 month and 2 years to under 6 years age sub-groups met the statistical criteria for similarity to the adults in the COVE study, which satisfied the primary objective of the study. Clinical trial registration #: (NCT04796896).</u>

Therapeutics trials:

- On 6 May 2022, <u>Sen-Jam has begun enrolling patients into their Phase 2 Clinical Trial for the investigational therapeutic SJP-002C for the treatment of COVID-19</u>. This trial involve research partnership between Sen-Jam, Duke-NUS Medical School, Duke University School of Medicine, and Global Clinical Research. The trial is a Randomized, Double-Blind, Placebo-Controlled to Evaluate the Efficacy of Ketotifen and Indomethacin for Mild and Moderate COVID-19 in Adults. The purpose of the study is to evaluate the safety and effectiveness of ketotifen and indomethacin taken together to improve symptoms related with COVID-19. Ketotifen and indomethacin are medications approved by the Food and Drug Administration (FDA) to treat diseases other than COVID-19. Clinical trial registration #: (NCT05007522).
- On 29 April 2022, <u>Pfizer shared top-line results from the Phase 2/3 EPIC-PEP (Evaluation of Protease Inhibition for COVID-19 in Post-Exposure Prophylaxis) study evaluating PAXLOVID (nirmatrelvir [PF-07321332] tablets and ritonavir tablets) for post-exposure prophylactic use. In this trial, the investigational drug PAXLOVID compared to placebo demonstrated risk reductions of 32% and 37% in adults in the treatment group for five and ten days respectively to prevent infection. These results, however, were not statistically significant and, as such, the primary endpoint of reducing the risk of confirmed and symptomatic COVID-19 infection in adults who had been exposed to the virus through a household contact was not met. Clinical trial registration #: (NCT05047601).
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Immunotherapies trials:

On 9 May 2022, <u>Bril Biosciences announced new data demonstrating that its long-acting COVID-19</u> neutralising antibody therapy, the amubarvimab/romlusevimab combination, retains neutralising activity against the Omicron BA.2 SARS-CoV-2 subvariant. The data, were assessed both in vitro pseudovirus neutralisation testing and through live virus neutralisation assays conducted at independent labs, suggest that exposures of intravenous amubarvimab 1000mg and romlusevimab 1000mg are expected to remain above the level required for neutralising activity against BA.2, for the treatment of COVID-19 based on the human pharmacokinetic data gathered on the amubarvimab/romlusevimab combination. The live virus neutralisation assay data suggest that total serum concentrations of the amubarvimab/romlusevimab combination will remain 60 times the level required for greater than 90% neutralisation (Neut99: 2.50 µg/mL) against the live virus isolate BA.2, 14 days post dose. As a result, even though the mutations found in the BA.2 subvariant spike protein increase the IC50 relative to wild-type SARS-CoV-2, adequate therapeutic exposures are expected to persist for a minimum of 2 weeks and longer.

For further detailed information for each country, refer to the full table <u>here</u>

Contributors

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