

# COVID-19 Scientific and Public Health Policy Update<sup>1</sup> (25 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 **not intended to serve as recommendations** 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

812 Million

Vaccines Supplied

572 Million

Vaccines Administered

### African Population Vaccinated

21.9%

Partially Vaccinated

16.9%

Fully Vaccinated\*

\*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 25<sup>th</sup> May, 2022

**Note:** Africa CDC has changed 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.

<sup>1</sup> This update compiled for use by African Union Member States and is developed collaboratively by the African Union-Africa CDC and World Health Organization - Regional Office for Africa. **This is a preliminary summary of information and 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 24<sup>th</sup> November 2021, has spread to 198 countries/territories/areas worldwide. As of 25 May 2022, 48 (87.3%) of the 55 Member States in Africa have reported this variant. For more information visit <https://africacdc.org/institutes/africa-pathogen-genomics-initiative/>.



Updated 25<sup>th</sup> May, 2022

## B. New guidelines and resources

Since 10<sup>th</sup> May 2022,

- Africa CDC<sup>2</sup> has published new guidance and resources on:
  - [Outbreak Brief 122: Coronavirus Disease 2019 \(COVID-19\) Pandemic](#)
- U.S. CDC<sup>3</sup> has published new guidance and resources on:
  - [CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity](#)
  - [CDC Strengthens Recommendations and Expands Eligibility for COVID-19 Booster Shots](#)
  - [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19](#)

<sup>2</sup> Africa CDC: Africa Centres for Disease Control and Prevention

<sup>3</sup> U.S. CDC: United States Centers for Disease Control and Prevention

- [Post-COVID Conditions: CDC Science](#)
- WHO<sup>4</sup> has published new guidance and resources on:
  - [Global report on infection prevention and control](#)
  - [Understanding the behavioural and social drivers of vaccine uptake WHO position paper](#)
  - [Background document on the Cansino Ad5-nCoV-S vaccine \(Convidecia ®\) against COVID-19](#)
  - [Interim recommendations for use of the Cansino Ad5-nCoV-S vaccine \(Convidecia ®\) against COVID-19](#)
  - [Annexes to the interim recommendations for use of the Cansino Ad5-nCoV-S vaccine \(Convidecia ®\) against COVID-19](#)
- U.S. FDA<sup>5</sup> has issued press releases on:
  - [On 16 May, FDA authorised first COVID-19 test available without a prescription that also detects flu and RSV](#)
  - [On 17 May, FDA expanded eligibility for Pfizer-BioNTech COVID-19 Vaccine booster dose to children 5 through 11 years](#)
  - [As of 24 May, 435 tests and sample collection devices are authorised by the FDA under emergency use authorisations \(EUAs\)](#)
- ECDC<sup>6</sup> has issued new resources on:
  - [COVID-19 Aviation Health Safety Protocol: Operational guidelines for the management of air passengers and aviation personnel in relation to the COVID-19 pandemic](#)
- UKHSA<sup>7</sup> has issued new guidance and press releases on:
  - [Reducing the spread of respiratory infections, including COVID-19, in the workplace](#)
  - [Organisation testing registration: record of users](#)
  - [Ventilation to reduce the spread of respiratory infections, including COVID-19](#)

## C. Scientific updates

### Basic Science

- This [cross-sectional study](#) in Germany assessed the coordinated adaptive immune responses to the SARS-CoV-2 infection by sequencing both human leukocyte antigen (HLA) restricted T cell receptor beta chain (TRB) and unrestricted T cell receptor delta chain (TRD) and immunoglobulin heavy chain (IgH) immune receptor repertoires. The study involved 70 participants enrolled from 3 centers in Berlin. The authors used an immune repertoire primer extension target enrichment method (immunoPETE) and identified very few individual B and T cell clones, which appeared to be associated with a severe course of COVID-19. These findings suggest a potentially relevant contribution of both cell types in the immune response to SARS-CoV-2.
- This [study](#) in the United States assessed the efficacy of an oral prodrug of the remdesivir parental nucleoside, GS-621763, against SARS-CoV-2. GS-621763 exhibited antiviral activity against SARS-CoV-2 in lung cell lines and two different human primary lung cell culture systems. GS-621763 was also potently antiviral against Middle East respiratory syndrome CoV (MERS-CoV). The dose-proportional pharmacokinetic profile observed after oral administration of GS-621763 translated to dose-dependent antiviral activity in mice infected with SARS-CoV-2. Therapeutic GS-621763 administration reduced viral load and lung pathology. Treatment with GS-621763 also improved pulmonary function in a COVID-19 mouse model. A direct comparison of GS-621763 with molnupiravir

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

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

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

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

proved both drugs to be similarly efficacious in mice. These findings support the exploration of GS-441524 oral prodrugs for the treatment of COVID-19.

### Vaccines

- This [randomised, double-blind, placebo-controlled trial](#) in South Africa evaluated BCG for reduction of morbidity and mortality due to COVID-19 in healthcare workers. The study involved 1000 healthcare workers who were recruited at 3 facilities in the Western Cape. Participants received BCG or saline intradermally (1:1) and were contacted once every 4 weeks for 1 year. Hospitalisation due to COVID-19 occurred in 15 participants (1.5%); 10 (66.7%) in the BCG group and 5 (33.3%) in the placebo group, hazard ratio (HR) 2.0 (95% CI 0.69–5.9,  $p=0.20$ ), indicating no statistically significant protection. Similarly, BCG had no statistically significant effect on COVID-19 ( $p=0.63$ , HR = 1.08, 95% CI 0.82–1.42). Two participants (0.2%) died from COVID-19 and two (0.2%) from other reasons, all in the placebo group.
- This [test-negative, case-control study](#) in the United States assessed BNT162b2 vaccine effectiveness (VE) against laboratory-confirmed COVID-19 leading to hospitalisation and against critical COVID-19 among patients 5 to 11 and 12 to 18 years of age. The study enrolled 1185 cases and 1627 controls at 31 hospitals in 23 states. During the delta-predominant period, VE against hospitalisation for COVID-19 among adolescents 12 to 18 years of age was 93% (95% CI: 89 to 95) 2 to 22 weeks after vaccination and was 92% (95% CI: 80 to 97) at 23 to 44 weeks. Among adolescents 12 to 18 years of age (median interval since vaccination, 162 days) during the omicron-predominant period, VE was 40% (95% CI: 9 to 60) against hospitalisation for COVID-19, 79% (95% CI: 51 to 91) against critical COVID-19, and 20% (95% CI, –25 to 49) against noncritical COVID-19. During the omicron period, VE against hospitalisation among children 5 to 11 years of age was 68% (95% CI: 42 to 82; median interval since vaccination, 34 days).
- This ongoing [phase 2-3, placebo-controlled trial](#) in the United States assessed safety, immunogenicity and efficacy of the mRNA-1273 vaccine in children 6 to 11 years. The study enrolled 4016 children to receive two doses of mRNA-1273 (50 µg each) or placebo and were followed for a median of 82 days (interquartile range, 14 to 94) after the first injection. This dose level was associated with mainly low-grade, transient adverse events, most commonly injection-site pain, headache, and fatigue. No vaccine-related serious adverse events, multisystem inflammatory syndrome in children, myocarditis, or pericarditis were reported. A month after the second injection (day 57), the neutralising antibody titer in children who received mRNA-1273 at a 50-µg level was 1610 (95% CI: 1457 to 1780), as compared with 1300 (95% CI: 1171 to 1443) at the 100-µg level in young adults. There were serologic responses in at least 99.0% of the participants in both age groups, these findings met the prespecified noninferiority success criterion. Estimated vaccine efficacy was 88.0% (95% CI: 70.0 to 95.8) against COVID-19 occurring 14 days or more after the first injection, at a time when B.1.617.2 (delta) was the dominant circulating variant.
- This [cohort study](#) in the Republic of San Marino assessed potential short- and long-term adverse events following immunisation (AEFIs) to Gam-COVID-Vac (Sputnik V) vaccine through a 3-month follow-up. The study involved 6190 adults, 4383 of which (70.8%, 95% CI 69.9–71.7) developed some AEFIs from the vaccine within 3 weeks of the first dose. Symptoms were classified as grade 1, 2, 3 and 4 in severity by 58.7%, 11.1%, 0.8% and 0.3% of the individuals, respectively. AEFIs occurred after a few seconds or minutes in 2.6% of the subjects, after one or two days in 66.3%, after three to seven days in 1.7%, and after one to three weeks in 0.2%. Systemic reactions were reported by 3557 persons (57.5%, 95% CI 56.5–58.4), while reactions at the injection site were reported by 2888 persons (46.7%, 95% CI 45.7–47.6). Vaccine recipients reported higher rates of AEFIs after dose 2 than dose 1. An estimated 4692 participants (75.8%, 95% CI 74.6–77.0) had some AEFIs within three months. Symptoms were classified as grade 1, 2, 3 and 4 in severity by 58.6%, 13.4%, 2.7% and 1.1% of the individuals, respectively. These findings confirm a good tolerability profile for the population aged 18 and over providing useful data for vaccination campaigns ongoing in countries planning to use Gam-COVID-Vac.
- This [randomised, open-label, controlled trial](#) in China assessed the safety and immunogenicity of an aerosolised Ad5-nCoV COVID-19 vaccine administered orally as a heterologous booster after two-

dose priming with an inactivated SARS-CoV-2 vaccine, CoronaVac, versus homologous immunisation of a third dose. The study enrolled 420 adults between 14 and 16 September 2021. Participants were randomly assigned (1:1:1) to receive a heterologous booster vaccination with a low dose ( $1.0 \times 10^{11}$  viral particles per mL; 0.1 mL; low dose group), or a high dose ( $1.0 \times 10^{11}$  viral particles per mL; 0.2 mL; high dose group) aerosolised Ad5-nCoV, or a homologous intramuscular vaccination with CoronaVac (0.5 mL). Adverse reactions were reported by 26 (19%) participants in the low dose group and 33 (24%) in the high dose group within 14 days after the booster vaccination. This was significantly less than the 54 (39%) participants in the CoronaVac group ( $p < 0.0001$ ). The low dose group had serum neutralising antibodies (NAbs) geometric mean titres (GMTs) of 744.4 (95% CI 520.1–1065.6) and the high dose group had a GMT of 714.1 (479.4–1063.7) 14 days after booster dose, significantly higher than the GMT in the CoronaVac group (78.5 [60.5–101.7];  $p < 0.0001$ ).

- This [systematic review](#) of 156 articles sought to synthesize the current evidence regarding the potential role of social media in shaping COVID-19 vaccination attitudes, and to explore its potential for shaping public health interventions to address the issue of vaccine hesitancy. Cross-sectional studies reporting the association between reliance on social media and vaccine intentions mainly observed a negative relationship. Studies that performed thematic analyses of extracted social media data, mainly observed a domination of vaccine hesitant topics. Studies that explored the degree of polarization of specific social media contents related to COVID-19 vaccines observed a similar degree of content for both positive and negative tone posted on different social media platforms. Studies that explored the fluctuations of vaccination attitudes/opinions gathered from social media identified specific events as significant cofactors that affect and shape vaccination intentions of individuals.
- This [study](#) in France developed a next-generation CD40-targeting vaccine, CD40.CoV2, including T- and B-cell epitopes spanning sequences from spike and nucleocapsid proteins from SARS-CoV-2 and highly homologous to 38 sarbecoviruses, including SARS-CoV-2 variants of concern (VOCs). CD40.CoV2 immunisation elicited high levels of cross-neutralising antibodies against SARS-CoV-2, VOCs, and SARS-CoV-1 in K18-hACE2 transgenic mice, associated with viral control and survival after SARS-CoV-2 challenge. A direct comparison of CD40.CoV2 with the mRNA BNT162b2 vaccine showed that the two vaccines were equally immunogenic in mice. The authors demonstrated the potency of CD40.CoV2 to recall *in vitro* human multi-epitope, functional, and cytotoxic SARS-CoV-2 S- and N-specific T-cell responses that are unaffected by VOC mutations and cross-reactive with SARS-CoV-1 and, to a lesser extent, MERS epitopes.

## Diagnosics

- This [study](#) in Brazil developed an in-house urine-based enzyme-linked immunosorbent assay (ELISA) using recombinant SARS-CoV-2 nucleocapsid protein. The study involved 139 adult COVID-19 patients with qRT-PCR confirmation. The authors collected 209 urine and 187 serum paired samples, they also included unpaired negative samples collected before 2019. SARS-CoV-2 antibodies were detected with 94% sensitivity and 100% specificity with the urine-based ELISA and 88% sensitivity and 100% specificity with a paired serum-based ELISA. The urine-based ELISA is a noninvasive method with potential application as a facile COVID-19 immunodiagnostic platform, which can be used to report the extent of exposure at the population level and/or to assess the risk of infection at the individual level.
- This [study](#) in France developed a nanobody-functionalised electrochemical platform for the rapid detection of whole SARS-CoV-2 viral particles in complex media such as saliva and nasopharyngeal swab samples. The sensor relies on the functionalisation of a gold electrode surface with highly-oriented Llama nanobodies specific to the spike protein receptor binding domain. The device provides results in 10 min of exposure to 200  $\mu$ L of unprocessed samples. The sensor could discriminate between different human coronavirus strains and other respiratory viruses, with 90% positive and 90% negative percentage agreement on 80 clinical samples, as compared to RT-qPCR.

## Care and Treatment

- This [prospective cohort study](#) evaluated risk factors of hospitalisation and mortality among COVID-19 cases in Juba, South Sudan (SSD) and North and South Kivu in eastern Democratic Republic of the Congo (DRC). The study involved 751 individuals across 5 facilities (1 in SSD, 4 in DRC). Overall mortality was 4.8% (95% CI: 3.2% to 6.9%); there were no outpatient deaths. Patients presenting with any symptoms had higher odds of hospitalisation (adjusted OR (AOR) 2.78, 95% CI 1.47 to 5.27) and all deaths occurred among symptomatic individuals. Odds of both hospitalisation and mortality were greatest among cases with respiratory symptoms; presence of low oxygen levels on enrolment was strongly associated with both hospitalisation (AOR 7.77, 95% CI 4.22 to 14.29) and mortality (AOR 25.29, 95% CI 6.42 to 99.54). Presence of more than one chronic comorbidity was associated with 4.96 (95% CI 1.51 to 16.31) times greater odds of death; neither infectious comorbidities evaluated, nor malnutrition, were significantly associated with increased mortality
- This [prospective, observational study](#) evaluated factors associated with mortality in critically ill children hospitalised for COVID-19 children from 18 high and low-middle income countries. The study involved 557 patients enrolled from 55 sites throughout North America, Latin America, and Europe. Invasive (41%) or non-invasive (20%) ventilation and vasopressors (56%) were the most common support modalities. Hospital mortality was 10% and higher in children <2 years old (15%; odds ratio 1.94, 95%CI 1.08-3.49). Most who died had pulmonary disease. When adjusted for age, sex, region, and illness severity, mortality-associated factors included cardiac (aOR 2.89; 95%CI 1.2-6.94) or pulmonary comorbidities (aOR 4.43; 95%CI 1.70-11.5), admission hypoxemia (aOR 2.44; 95%CI 1.30-4.57), and lower respiratory symptoms (aOR 2.96; 95%CI 1.57-5.59). Multisystem inflammatory syndrome in children (aOR 0.25; 95%CI 0.1-0.61) and receiving methylprednisolone (aOR 0.5; 95%CI 0.25-0.99), intravenous immune globulin (aOR 0.32; 95%CI 0.16-0.62), or anticoagulation (aOR 0.49; 95%CI 0.25-0.95) were associated with lower mortality although these associations might be limited to children >2 years old.
- This [observational cohort study](#) in the United Kingdom assessed the relationship between COVID-19 vaccination and long covid symptoms in adults with SARS-CoV-2 infection before vaccination. The study involved 28,356 participants aged 18-69 years who were followed-up from 3 February to 5 September 2021. Among them, 6729 participants (23.7%) reported long covid symptoms of any severity at least once during follow-up. A first vaccine dose was associated with an initial 12.8% decrease (95% CI: -18.6% to -6.6%,  $p < 0.001$ ) in the odds of long covid, with subsequent data compatible with both increases and decreases in the trajectory (0.3% per week, 95%CI: -0.6% to 1.2% per week,  $p = 0.51$ ). A second dose was associated with an initial 8.8% decrease (95%CI: -14.1% to -3.1%,  $p = 0.003$ ) in the odds of long covid, with a subsequent decrease by 0.8% per week (-1.2% to -0.4% per week,  $p < 0.001$ ).
- This [systematic review and meta-analysis](#) of 14 observational studies assessed the effect of statin use on clinical outcomes in COVID-19. The studies involved 19,988 patients with COVID-19. Pooled analysis of unadjusted data showed that statin use was not associated with improved clinical outcomes (OR 1.02; 95% CI 0.69 to 1.50,  $p = 0.94$ ,  $I^2 = 94%$ , random-effects model). However, on pooling adjusted risk estimates, the use of statin was found to significantly reduce the risk of adverse outcomes (OR 0.51; 95% CI 0.41 to 0.63,  $p < 0.0005$ ,  $I^2 = 0%$ , fixed-effects model). Individuals with multiple comorbidities on statin therapy should be advised not to discontinue the drug amid the ongoing pandemic. The role of statins as an adjunct to standard therapy in statin-naïve COVID-19 patients needs to be further explored.

## Epidemiology

- This [cohort study](#) in South Africa assessed the clinical severity of COVID-19 in patients admitted to hospital during the omicron wave and whether it differed from the Asp614Gly mutation, beta variant, and delta variant waves. The authors analysed 335,219 laboratory-confirmed SARS-CoV-2 hospital admissions. During the omicron wave, 52,038 (8.3%) of 629 617 cases were admitted to hospital, compared with 71,411 (12.9%) of 553,530 in the Asp614Gly wave, 91,843 (12.6%) of 726,772 in the beta wave, and 131,083 (10.0%) of 1,306,260 in the delta wave ( $p < 0.0001$ ). During the omicron wave, 15,421 (33.6%) of 45,927 patients admitted to hospital had severe disease, compared with 36,837

(52.3%) of 70,424 in the Asp614Gly wave, 57,247 (63.4%) of 90,310 in the beta wave, and 81,040 (63.0%) of 128,558 in the delta wave ( $p < 0.0001$ ). The in-hospital case-fatality ratio during the omicron wave was 10.7%, compared with 21.5% during the Asp614Gly wave, 28.8% during the beta wave, and 26.4% during the delta wave ( $p < 0.0001$ ). Compared with those admitted to hospital during the omicron wave, patients admitted during the other three waves had more severe clinical presentations (adjusted odds ratio 2.07 [95% CI 2.01–2.13] in the Asp614Gly wave, 3.59 [3.49–3.70] in the beta wave, and 3.47 [3.38–3.57] in the delta wave).

- This [retrospective matched cohort study](#) in Reunion Island compared the prognosis of patients with acute respiratory failure (ARF) due to the SARS-CoV-2 variant 501Y.V2 to that of patients with ARF due to the original strain. The study enrolled 218 patients with ARF between March 2020 and March 2021. Of these, 83 (38.1%) were infected with the 501Y.V2 variant. During intensive care unit stay, 104 (47.7%) patients received invasive mechanical ventilation and 20 (9.2%) patients were supported by venovenous extracorporeal membrane oxygenation. Patients infected with the 501Y.V2 variant were younger (58 [51–68] vs. 67 [56–74] years old,  $p = 0.003$ ), had less hypertension (54.2% vs 68.1%,  $p = 0.04$ ), and had less chronic kidney disease (13.3% vs. 31.9%,  $p = 0.002$ ) than patients infected with the original strain. After controlling for confounding variables, 28-day mortality was higher in the group of patients infected with the 501Y.V2 variant (30.6%) than in the group of patients infected with the original strain (19.4%,  $p = 0.04$ ).
- This multicountry [analysis of surveillance data](#) explored the association between HIV infection and clinical outcomes in people hospitalised with COVID-19. The authors utilised the WHO Global Clinical Platform on COVID-19. The platform had 197,479 patients reporting HIV status, of which 16 955 (8.6%) were people living with HIV (PLHIV). Among the PLHIV 16 283 (96.0%) were from Africa. Compared with individuals without HIV, PLHIV had 15% increased odds of severe presentation with COVID-19 (aOR 1.15, 95% CI 1.10–1.20) and were 38% more likely to die in hospital (aHR 1.38, 1.34–1.41). Among PLHIV, male sex, age 45–75 years, and having chronic cardiac disease or hypertension increased the odds of severe COVID-19; male sex, age older than 18 years, having diabetes, hypertension, malignancy, tuberculosis, or chronic kidney disease increased the risk of in-hospital mortality. The use of ART or viral load suppression were associated with a reduced risk of poor outcomes; however, HIV infection remained a risk factor for severity and mortality regardless of ART and viral load suppression status.
- This [modelling study](#) in the United States described XGBoost machine learning models that use the National COVID Cohort Collaborative (N3C) database to identify patients with potential long COVID, trained using electronic health record data from patients who attended a long COVID specialty clinic at least once. The models achieved areas under the receiver operator characteristic curve of 0.92 (all patients), 0.90 (hospitalised), and 0.85 (non-hospitalised). The most powerful predictors in their models are outpatient clinic utilisation after acute COVID-19, patient age, dyspnoea, and other diagnosis and medication features that are readily available. The model is transparent and reproducible, and can be widely deployed in individual health-care systems to enable local research recruitment or secondary data analysis.

## Infection Prevention & Control

- This [systematic review and meta-analysis](#) of 21 studies assessed the acceptance rate and possible reasons for COVID-19 vaccine non-acceptance or hesitancy amongst healthcare workers (HCWs) in Africa. The estimated pooled COVID-19 vaccine acceptance rate was 46% [95% CI: 37%-54%]. The pooled estimated COVID-19 vaccine acceptance rate was 37% [95% CI: 27%-47%] in North Africa, 28% [95% CI: 20%-36%] in Central Africa, 48% [CI: 38%-58%] in West Africa, 49% [95% CI: 30%-69%] in East Africa, and 90% [CI: 85%-96%] in Southern Africa. The estimated pooled vaccine acceptance was 48% [95% CI:38%-57%] for healthcare workers, and 34% [95% CI:29%-39%] for the healthcare students. Major drivers and reasons were the side effects of the vaccine, vaccine's safety, efficacy and effectiveness, short duration of the clinical trials, COVID-19 infections, limited information, and social trust. The authors emphasize that the misconceptions and barriers to COVID-19 vaccine

acceptance amongst HCWs must be addressed as soon as possible in the continent to boost COVID-19 vaccination rates in Africa.

- This [study](#) in the United States investigated the development of a personal and closed-environment membrane filter with enhanced aerosol and particle capture, along with the ability to inactivate coronaviruses (specifically, SARS-CoV-2) through enzyme functionalisation, greatly reducing both individual transmissibility of the virus and overall disease spread. Thin, asymmetric membranes with subtilisin enzyme and methacrylic functionalisation show more than 98.90% filtration efficiency for 100-nm unfunctionalised and protein-functionalised polystyrene latex aerosol particles. Unfunctionalised membranes provided a protection factor of  $540 \pm 380$  for coronavirus-sized particle, above the Occupational Safety and Health Administration's standard of 10 for N95 masks. SARS-CoV-2 spike glycoprotein on the surface of coronavirus-sized particles was denatured in 30 s by subtilisin enzyme-functionalised membranes with 0.02-0.2% water content on the membrane surface.

### Non-pharmaceutical interventions, social distancing

- This [cross-sectional study](#) in Nigeria assessed the associations between face masks and acne vulgaris. The study involved 1,316 participants from 2 local government areas of Abuja. New onset acne or worsening of acne following consistent wearing of face masks was reported by 323/1,316 (24.5%) of the participants. Surgical face mask was the least likely to predispose to acne  $p < 0.05$ . Compared with the surgical mask, persons using N95 face mask and cloth mask were 1.89 and 1.41 times more likely to have acne respectively. Persons with prior history of acne were more likely to develop new acne or experience worsening of acne following wearing of face mask OR 3.89, 95% CI 2.85, 5.33;  $p < 0.05$ ). The length of time of daily mask wearing was not significantly associated with occurrence of new onset acne or worsening of acne. Persons reporting prior histories of allergy were more likely to develop acne (OR 2.01, 95% CI 1.50, 2.88;  $p < 0.05$ ). In this study, 192 (59.4%) of those who reported having acne following face masks use responded they have a negative predisposition to wearing masks.
- This [review article](#) provides an overview on applications of Geographic Information Systems (GIS) into infectious disease research. The review follows the framework of human-environment interactions, focusing on the environmental and social factors that cause the disease outbreak and the role of humans in disease control, including public health policies and interventions such as social distancing/face covering practice and mobility modeling. Their work identifies key spatial decision-making issues where GIS becomes valued in the agenda for infectious disease research and highlights the importance of adopting science-based policies to protect the public during the current and future pandemics.

## D. Clinical Trials Updates

### Key updates:

#### Vaccine trials:

- On 23 May 2022, [Pfizer and BioNTech announced topline safety, immunogenicity and vaccine efficacy data from a Phase 2/3 trial evaluating a third 3- \$\mu\$ g dose of the Pfizer-BioNTech COVID-19 Vaccine in children 6 months to under 5 years of age. In the Phase 2/3 trial, 1,678 children received a third dose of the 3- \$\mu\$ g formulation at least two months after the second dose at a time when Omicron was the predominant variant.](#) The immunogenicity analysis of geometric mean titer (GMT) ratio and seroresponse rate was conducted on a subset of study participants one month following the third dose in children 6 months to under 5 years of age, compared to the second dose in the 16- to 25-year-old population. Non-inferiority was met for both the 6- to 24-month-old population and the 2- to under 5-year-old population for both co-primary endpoints. Three 3- $\mu$ g doses of the Pfizer-BioNTech COVID-19 vaccine was well-tolerated in this age group, and no new safety signals were identified. The majority of adverse events were mild or moderate. Vaccine efficacy, a secondary endpoint in this trial, was 80.3% in children 6 months to under 5 years of age. This descriptive analysis was based on 10 symptomatic COVID-19 cases identified from seven days after the third dose and accrued as of April 29, 2022. Clinical trial registration #: (NCT04816643).



- On 23 May 2022, [AstraZeneca's COVID-19 vaccine, Vaxzevria \(ChAdOx1-S \[Recombinant\]\), has been granted approval in the European Union \(EU\) by the European Medicine Agency \(EMA\) as a third dose booster in adults.](#) Approval follows CHMP recommendation for use in patients previously vaccinated with Vaxzevria or an EU-approved mRNA COVID-19 vaccine. The authorisation is based on a review by the Committee for Medicinal Products for Human Use (CHMP) of the substantial body of evidence demonstrating an increased immune response after a third dose booster with Vaxzevria following a primary vaccine schedule of either Vaxzevria or an mRNA COVID-19 vaccine. Vaxzevria is estimated to have helped prevent 50 million COVID-19 cases, five million hospitalisations, and saved more than one million lives worldwide, based on model outcomes assessing COVID-19 worldwide.
- On 19 May 2022, [the World Health Organization \(WHO\) issued an emergency use listing \(EUL\) for CONVIDECIA, a vaccine manufactured by CanSino Biologics, China, adding to a growing portfolio of vaccines validated by WHO for the prevention of COVID-19 caused by SARS-CoV-2.](#) CONVIDECIA is based on a modified human adenovirus that expresses the spike S protein of SARS-CoV-2. It is administered as a single (0.5mls) dose in all age groups 18 years and above. CONVIDECIA was found to have 58% efficacy against symptomatic disease and 92% against severe COVID-19. CONVIDECIA was assessed under the WHO EUL procedure based on the review of data on quality, safety, efficacy, a risk management plan, programmatic suitability and a manufacturing site inspection. The Technical Advisory Group for Emergency Use Listing, made up of regulatory experts from around the world has determined that the CONVIDECIA meets WHO standards for protection against COVID-19 and that the benefits of the vaccine far outweigh risks.
- On 17 May 2022, [Pfizer and BioNTech announced the U.S. Food and Drug Administration \(FDA\) expanded emergency use authorisation \(EUA\) to include a booster dose after completion of the primary series of the Pfizer-BioNTech COVID-19 Vaccine in children 5 through 11 years of age.](#) The booster dose is given at least five months after the second dose of the two-dose primary series and is the same 10-µg dose of the Pfizer-BioNTech COVID-19 Vaccine. The expanded EUA is based on data from the Phase 2/3 clinical trial, which showed that a booster dose of the Pfizer-BioNTech COVID-19 Vaccine elicited a strong immune response in this age group, generating neutralising antibodies against both the Omicron variant and wild-type SARS-CoV-2 virus regardless of prior SARS-CoV-2 infection. No new safety signals were observed. The third dose was well tolerated, with a safety profile similar to the two-dose primary series. Clinical trial registration #: (NCT04816643).
- On 17 May 2022, [the World Health Organization, with the support of the Strategic Advisory Group of Experts \(SAGE\) on Immunisation and its COVID-19 Vaccines Working Group, continues to review the emerging evidence on the need for and timing of additional booster doses for the currently available COVID-19 vaccines which have received Emergency Use Listing \(EUL\).](#) The WHO recommends, booster doses should be offered based on evidence that doing so would have substantial impact on reducing hospitalisation, severe disease and death, and protect health systems. Available data for WHO EUL COVID-19 vaccine products suggest that vaccine effectiveness and immunogenicity are lower in immunocompromised persons (ICPs), compared to persons without immunocompromising conditions. An additional dose included in an extended primary series enhances immune responses in some ICPs. For longer-term considerations, there are significant uncertainties related to the evolution of the virus and the characteristics of future variants. Given widespread transmission of Omicron globally, continued viral evolution with the emergence of new variants or sub lineages as is already being seen. Development of a pan-SARS-CoV-2 or pan-sarbecovirus vaccines are needed, but the timeframe for their development is uncertain.
- On 12 May 2022, [Akston announced it dosed the first set of volunteers in an open-label study of AKS-452, its protein subunit COVID-19 vaccine, as a booster.](#) The phase 2 booster study is designed to investigate the response of the immune system in up to 600 volunteers who have previously been vaccinated with EMA-registered vaccines from Pfizer, Moderna, Johnson & Johnson (Janssen) and AstraZeneca. The study is being conducted at the University Medical Center Groningen (UMCG) in the Netherlands. The AKS-452 vaccine induces a Th1/Th2 mixed immune response against the Receptor Binding Domain (RBD) of the coronavirus spike protein. The participants are healthy adults between the ages of 18 and 85 whose last COVID-19 vaccine shot at least received three months earlier and

will not have received a COVID-19 booster shot. Each participant will receive one dose of the AKS-452 antigen (90 µg). Clinical trial registration #: (NCT05124483).

#### Therapeutics trials:

- On 18 May 2022, [AIM ImmunoTech provided an update on its ongoing efforts to develop an effective therapeutic for “Long COVID” with its investigational drug, Ampligen.](#) A Phase 3 prospective, double-blind, randomised, placebo-controlled trial of rintatolimod (Ampligen) in ME/CFS (AMP-516) produced objective improvement in exercise tolerance. An analysis of a subset of patients in that trial with early onset of symptoms showed a statistically significant 51.2% positive response (p=0.003). In an expanded access program (EAP), AIM enrolled four post-COVID patients with new onset ME/CFS following acute COVID-19. Following at least 12 weeks of Ampligen treatment, each of these four patients indicated they had experienced a reduction in fatigue, as measured via Patient-Reported Outcomes questionnaires. A statistical analysis of these data indicated that the decrease in fatigue compared to baseline was statistically significant (p<0.003), despite the small number of patients. Clinical trial registration #: (NCT00215813).
- On 16 May 2022, [The U.S. Food and Drug Administration decided not to authorise the antidepressant fluvoxamine to treat COVID-19 based on the data that has not shown the drug to be an effective therapeutic for fighting the SARS-CoV-2 virus.](#) The review of available scientific evidence, the FDA has determined that the data are insufficient to conclude that fluvoxamine may be effective in the treatment of nonhospitalised patients with COVID-19 to prevent progression to severe disease and/or hospitalisation. A generic drug, fluvoxamine maleate belongs to a class of selective serotonin reuptake inhibitors (SSRIs). The decline follows an application submitted in December 2021, seeking EUA for the antidepressant to treat adults aged 24 years and above suffering with Covid-19 in the outpatient setting to prevent the disease progression. The submission was based on findings from three clinical trials, including a Phase 3 TOGETHER trial with 1,497 non-hospitalised Covid-19 patients enrolled in Brazil. The randomised, double-blind, placebo-controlled platform TOGETHER trial enrolled high-risk, symptomatic adults. According to the results, the trial met the primary endpoint of a decline in the emergency department visits lasting more than six hours. A nearly 30% decline in hospitalisations in the fluvoxamine group was also observed. However, the regulatory agency noted that there are uncertainties on the analysis of this endpoint and whether the six-hour timepoint indicates a clinically meaningful threshold.
- On 11 May 2022, [Eli Lilly and Incyte announced the U.S. Food and Drug Administration \(FDA\) has approved OLUMIANT \(baricitinib\) for the treatment of COVID-19 in hospitalised adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation \(ECMO\) with a recommended dose of 4-mg once daily for 14 days or until hospital discharge, whichever comes first.](#) Baricitinib is a once-daily oral Janus Kinase inhibitor blocking the subtypes JAK1 and JAK2, approved for medical use to treat adults with moderate to severe rheumatoid arthritis. The FDA’s approval is supported by results from two randomised, double-blind, placebo-controlled Phase 3 studies (ACTT-2 and COV-BARRIER, including the COV-BARRIER OS 7 addendum study). No new safety signals potentially related to the use of OLUMIANT were identified in the studies. Clinical trial registration #: (NCT04401579 and NCT04421027).
- On 10 May 2022, [Moleculin Biotech announced that it has received approval from the United Kingdom’s \(UK\) MHRA to proceed with a first-in-human Phase 1a study to evaluate the safety and pharmacokinetics of WP1122 in healthy volunteers for the treatment of COVID-19 \(MB-301\).](#) The approval follows Moleculin’s having submitted a protocol amendment allowing for a higher ratio of diluting excipients to drug substance to facilitate a faster and simpler mixing procedure before drug administration. WP1122 is a metabolism/glycosylation inhibitor, is a prodrug of a well-known glucose decoy called 2-deoxy-D-glucose (2-DG), currently being developed for inhibition of viral replication and disease manifestations in humans infected with SARS-CoV-2, the virus responsible for COVID-19. Clinical trial registration #: (NCT05195723).

#### Immunotherapies trials:

On 17 May 2022, [AstraZeneca entered into a licence agreement with RQ Biotechnology Ltd \(RQ Bio\) for a portfolio of early-stage monoclonal antibodies \(mAbs\) targeted against SARS-CoV-2, the virus that causes COVID-19.](#) The capability to direct monoclonal antibodies to fight SARS-CoV-2 – the virus that causes COVID-19 – has been underway for some time, as mAbs are ideally suited for this application, acting in a way that mimics the body's immune system.

#### Contributors

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