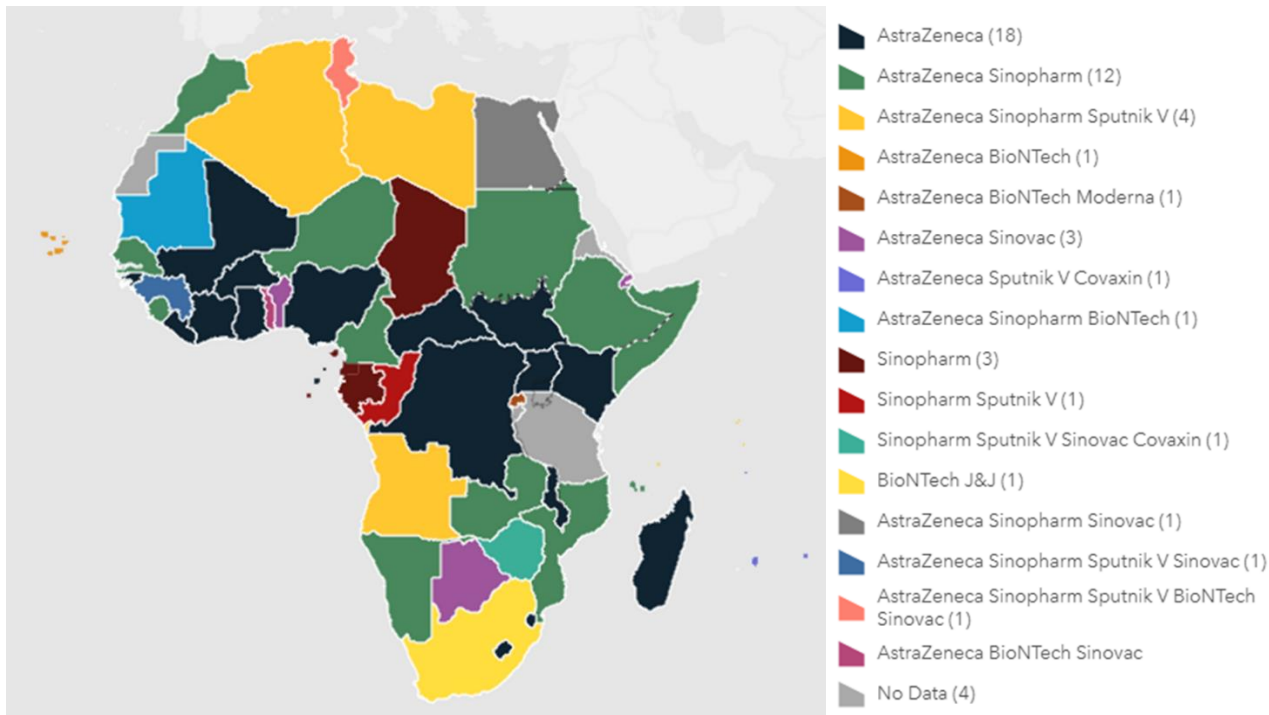


# COVID-19 Scientific and Public Health Policy Update<sup>1</sup> – (07 June 2021)

*In addition to the Weekly Outbreak Brief and other documents on the spread of COVID-19 and the actions that the African Union- Africa CDC and WHO/AFRO are taking to help African Union Member States, we share a weekly 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



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

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

54.9 M  
Acquired

35.9 M  
Administered

Updated 07 June 2021

## Variants of Concern

- The **B.1.617.2** (Delta variant) , first reported in India, has spread to more than 62 countries worldwide; 10 Member States in Africa have reported this variant. <https://africacdc.org/institutes/africa-pathogen-genomics-initiative/>

## B. New guidelines and resources

Since 15 May 2021,

- Africa CDC has published new guidance and resources on:
  - [Guidance on Diagnosis and Management of People with Post-Acute COVID-19 Syndrome](#)
  - [The Use of Pulse Oximeter by Public & Healthcare Providers in the Community for Suspected and Confirmed COVID-19 Cases](#)
  - [COVID-19 CHECKLIST FOR PRIMARY CARE FACILITIES](#)
  - [Africa CDC Biosafety and Biosecurity Initiative Report on the Consultative Process to Identify Priorities for Strengthening Biosafety and Biosecurity](#)
  - [Advocacy and Communication Strategy for the Biosafety and Biosecurity Legal Framework](#)
  - [African Union and the Africa CDC's Africa Regulatory Taskforce has endorsed the Emergency Used Authorization for Janssen COVID-19 Vaccine](#)
  - [Adapted Africa Joint Continental Strategy for COVID-19 Pandemic](#)
- US CDC has published new guidance and resources on:
  - [Guidance for Institutions of Higher Education \(IHEs\)](#)
  - [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)
  - [Return to Work Criteria for Healthcare Personnel with SARS-CoV-2 Infection \(Interim Guidance\)](#)
  - [COVID-19 Considerations for Animal Activities at Fairs, Shows, and Other Events](#)
  - [Communication Resources for COVID-19 Vaccines](#)
  - [Interim Public Health Recommendations for Fully Vaccinated People](#)
  - [Guidance for Operating Youth Camps](#)
  - [Testing Strategies for SARS-CoV-2](#)
  - [Guidance for Administrators in Parks and Recreational Facilities](#)
  - [Guidance for Adult Day Services Centers: Strategies for Administrators and Staff to Prevent the Spread of COVID-19](#)
  - [Interim Guidance for Homeless Service Providers to Plan and Respond to Coronavirus Disease 2019 \(COVID-19\)](#)
  - [Guidance for Organizing Large Events and Gatherings](#)

- [Guidance for Group Homes for Individuals with Disabilities](#)
- [Operational Strategy for K-12 Schools through Phased Prevention](#)
- WHO has published new guidance and resources on:
  - [Interim recommendations for use of the inactivated COVID-19 vaccine, CoronaVac, developed by Sinovac](#)
  - [Use of medical and non-medical/fabric masks for community outreach activities during the COVID-19 pandemic](#)
  - [Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines](#)
  - [Annexes to the recommendations for use of the Sinovac-CoronaVac vaccine against COVID-19: Grading of evidence, Evidence to recommendation tables](#)
  - [Background document on the inactivated vaccine Sinovac-CoronaVac against COVID-19](#)
  - [Critical preparedness, readiness and response actions for COVID-19](#)
  - [Technical note on delayed shipments for theChAdOx1-S \[recombinant\] vaccines: what are the implications for the administration of second doses?](#)
  - [WHO Pharmaceuticals Newsletter - N°2, 2021](#)
  - [Evidence review – Public health measures in the aviation sector in the context of COVID-19: quarantine and isolation - 21 May 2021](#)
  - [Preventing and mitigating COVID-19 at work](#)
- FDA has issued press releases on:
  - [As of 4th June, 380 tests and sample collection devices are authorized by the FDA under emergency use authorizations \(EUAs\).](#)
  - [The FDA has authorized nine antigen tests and three molecular tests for serial screening programs. The FDA has also authorized 525 revisions to EUA authorizations.](#)
  - [The FDA reissued the Letter of Authorization for REGEN-COV \(Casirivimab and Imdevimab\) treatment for COVID-19 to authorize.](#)
  - [An update to the SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests web page to share the latest information.](#)
  - [FDA approved an abbreviated new drug application for albuterol sulfate inhalation aerosol 90 mcg \(base\)/actuation.](#)
  - [A safety communication to warn the public to stop using the Lepu Medical Technology SARS-CoV-2 Antigen Rapid Test Kit and the Leccurate SARS-CoV-2 Antibody Rapid Test Kit \(Colloidal Gold Immunochromatography\).](#)
  - [Coronavirus \(COVID-19\) Update: FDA Authorizes Additional Monoclonal Antibody for Treatment of COVID-19](#)
  - [Update: FDA Recommends Transition from Use of Non-NIOSH-Approved and Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities](#)
- ECDC has issued new resource on:
  - [Stress test on logistical aspects of COVID-19 vaccination deployment plans for the Western Balkans: final report](#)
  - [Introducing a coherent European framework for tuning COVID-19 response measures](#)
  - [Considerations on the use of self-tests for COVID-19 in the EU/EEA](#)
  - [Guidance for COVID-19 quarantine and testing of travellers](#)
  - [One-day in-action review \(IAR\) protocol in the context of COVID-19](#)
  - [Guidance for COVID-19 quarantine and testing of travellers](#)
- PHE has issued new resource on:
  - [The use of antibody tests for SARS-COV-2 in the context of Digital Green Certificates](#)

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

## C. Scientific updates

### Basic Science

- In this study, the authors investigated the immune response in acute or convalescent COVID-19 patients. [Their report suggests that SARS-CoV-2 infection leads to disrupted CD8+ T cytotoxic functions and changes the overall metabolic functions of immune cells.](#)
- This study reports that SARS-CoV-2 encoded proteins and some currently used anti-COVID-19 drugs [are able to induce lytic reactivation of Kaposi's sarcoma-associated herpesvirus \(KSHV\), one of major human oncogenic viruses, through manipulation of intracellular signaling pathways. Their data indicate that in KSHV + patients especially in endemic areas, exposure to COVID-19 or undergoing the treatment may have increased risks to develop virus-associated cancers, even after they have fully recovered from COVID-19.](#)
- This is a case report on prolonged infection of greater than 6 months with the shedding of high titer SARS-CoV-2 in an individual with advanced HIV and antiretroviral treatment failure. [Through whole-genome sequencing at multiple time points, the authors demonstrated the early emergence of the E484K substitution associated with escape from neutralizing antibodies, followed by other escape mutations and the N501Y substitution found in most variants of concern. The study provides support to the hypothesis of intra-host evolution as one mechanism for the emergence of SARS-CoV-2 variants with immune evasion properties.](#) [not peer reviewed]
- This study assessed the efficacy of the stable and ultrapotent homotrimeric Pittsburgh inhalable Nanobody 21 (PiN-21) in preventing and treating SARS-CoV-2 infection in Syrian hamsters that model moderate to severe COVID-19 disease. They found that intranasal delivery of PiN-21 at 0.6 mg/kg [quickly reverses animals' weight loss after infection, decreases lung viral titers by 6 logs leading to drastically mitigated lung pathology, and prevents viral pneumonia. Combined with the marked stability and low production cost, this innovative therapy may provide a convenient and cost-effective option to mitigate the ongoing pandemic.](#)
- This study developed a previously unknown subunit vaccine comprising the receptor binding domain (RBD) of the spike protein fused with the tetanus toxoid epitope P2 (RBD-P2) and tested its efficacy in rodents and nonhuman primates (NHPs). They also investigated whether the SARS-CoV-2 nucleocapsid protein (N) could increase vaccine efficacy. They found that [immunization with N and RBD-P2 \(RBDP2/N\) + alum increased T cell responses in mice and neutralizing antibody levels in rats compared with those obtained using RBD-P2 + alum. Furthermore, in NHPs, RBD-P2/N + alum induced slightly faster SARS-CoV-2 clearance than that induced by RBD-P2 + alum, albeit without statistical significance. This study supports further development of RBD-P2 as a vaccine candidate against SARS-CoV-2. Also, it provides insights regarding the use of N in protein-based vaccines against SARS-CoV-2.](#)
- This study assessed the infectivity and virulence of prototypic VoC from both B.1.1.7 and B.1.351 variants in female Syrian golden hamsters. They directly compared them to two basal SARS-CoV-2 strains isolated in early 2020. They detected a particularly strong elevation of proinflammatory cytokines in hamsters infected with VoC B.1.1.7. [They established relevant preclinical infection models that will be pivotal to assess the efficacy of current and future vaccine\(s\) \(candidates\) as well as therapeutics \(small molecules and antibodies\) against two important SARS-CoV-2 VoC.](#)
- This randomized, double-blind, single-dose, phase 3 clinical trial aimed to determine the effect of bamlanivimab (a neutralizing monoclonal antibody against SARS-CoV-2) on the incidence of COVID-



19 among residents and staff of skilled nursing and assisted living facilities. [They included 966 participants \(666 staff and 300 residents\) enrolled from August to November 2020. The incidence of COVID-19 infection among those treated with bamlanivimab vs placebo was 8.5% vs 15.2%, respectively, a difference that was statistically significant. Authors recommend further research to assess preventive efficacy with current patterns of viral strains with combination monoclonal antibody therapy.](#)

- This study investigated how human antibodies specific to SARS-CoV-2 spike protein may contribute to exacerbated inflammation. [The authors found that spike protein-specific antibodies from patients with COVID-19 who were hospitalized had altered glycosylation, with an enrichment in low-fucosylated antibodies. These antibodies were able to activate human macrophages in vitro to secrete proinflammatory cytokines.](#)
- This non-interventional study investigated whole blood expression of cholinergic system members and correlated it with COVID-19 severity. The study included 37 patients with confirmed SARS-CoV-2 infection and 14 healthy aged-matched controls. [Expression of CHRFAM7A was significantly lower in critical COVID-19 patients compared to controls. COVID-19 patients not expressing CHRFAM7A had higher levels of CRP, more extended pulmonary lesions and displayed more pronounced lymphopenia. COVID-19 patients without CHRFAM7A expression also showed increased TNF pathway expression in whole blood. AchE was also expressed in 30 COVID-19 patients and in all controls. COVID-19-induced hypercytokinemia is associated with decreased expression of the pro-inflammatory dominant negative duplicate CHRFAM7A. Expression of this duplicate might be considered before targeting the cholinergic system in COVID-19 with nicotine.](#)

## Epidemiology

- This study aimed to externally validate a risk prediction algorithm (QCovid) to estimate mortality outcomes from COVID-19 in adults in England. They included 34 897 648 adults aged 19–100 years resident in England. [The QCovid population-based risk algorithm performed well, showing high levels of discrimination for COVID-19 deaths in men and women for both time periods. QCovid has the potential to be dynamically updated as the pandemic evolves and, therefore, has potential use in guiding national policy.](#)
- This cross-sectional study tracked population-based SARS-CoV-2 antibody seropositivity duration across the United States using observational data from a national clinical laboratory registry of patients tested by nucleic acid amplification (NAAT) and serologic assays. Seropositivity of IgG antibodies to both SARS-CoV-2 S and N-proteins followed a linear trend reaching approximately 90% positivity at 21 days post-index. [The rate of N-protein seropositivity declined at a sharper rate, decaying to 68.2% after 293 days, while S-antibody seropositivity maintained a rate of 87.8% through 300 days. In addition to antigen type and the number of days post-positive PCR, age and gender were also significant factors in seropositivity prediction, with those under 65 years of age showing a more sustained seropositivity rate.](#)
- The aim of this review was to detail the prevalence of clinical features and identify potential predictors for acute and chronic post-COVID syndrome. [Fatigue and dyspnea were the most prevalent symptoms in acute post-COVID \(0.37 and 0.35\) and fatigue and sleep disturbance in chronic post-COVID syndrome \(0.48 and 0.44\), respectively. The available evidence is generally of poor quality, with considerable risk of bias, and are of observational design.](#)
- This study aimed to evaluate the presence of SARS-CoV-2 IgG antibodies in patients with Systemic Lupus Erythematosus with or without previous COVID-19-related symptoms or RT-PCR-confirmed SARS-CoV-2 infection. [Most patients with SLE and confirmed COVID-19 were able to produce and maintain a serological response despite the use of a variety of immunosuppressants, providing](#)

[reassurance about the efficacy and durability of humoral immunity and possible protection against re-infection with SARS-CoV-2.](#)

- This systematic review of 45 cohort studies included 9571 participants with COVID-19. They aimed to examine the frequency, variety, and severity of persistent symptoms among individuals with previous COVID-19 infection. [The median proportion of individuals who experienced at least 1 persistent symptom was 73%; symptoms occurring most frequently included shortness of breath or dyspnea, fatigue or exhaustion, and sleep disorders or insomnia. However, the studies were highly heterogeneous and needed longer follow-up and more standardized designs.](#)
- This cohort study of 1935 adults aimed to evaluate the association between T2R phenotype and patient clinical course after infection with SARS-CoV-2. [This study suggests that bitter taste receptor allelic variants are associated with innate immune fitness toward SARS-CoV-2 and can be used to correlate with clinical course and prognosis of COVID-19.](#)
- This single-center cohort study of 152 patients aimed to investigate the association of concentrations of serum testosterone, estradiol, and insulin like growth factor 1 (IGF-1, concentrations of which are regulated by sex hormone signaling) with COVID-19 severity. [They found that lower testosterone concentrations during hospitalization were associated with increased disease severity and inflammation in men. Hormone signaling pathways in monocytes did not parallel serum hormone concentrations, and further investigation is required to understand their pathophysiologic association with COVID-19.](#)
- This study provides an in-depth characterization of disease incidence and mortality and their dependence on demographic and socioeconomic strata in Santiago, a highly segregated city and the capital of Chile. Their analyses show a strong association between socioeconomic status and both COVID-19 outcomes and public health capacity. [People living in municipalities with low socioeconomic status did not reduce their mobility during lockdowns as much as those in more affluent municipalities. Testing volumes may have been insufficient early in the pandemic in those places, and both test positivity rates and testing delays were much higher. They found a strong association between socioeconomic status and mortality, measured by either COVID-19-attributed deaths or excess deaths. They also found higher infection fatality rates in young people in low-income municipalities.](#)
- This study reports on a community-wide national representative surveillance program in England based on self-administered swab results from ~594,000 individuals tested for SARS-CoV-2, regardless of symptoms, between May and the beginning of September 2020. The epidemic declined between May and July 2020 but then increased gradually from mid-August, accelerating into early September 2020 at the start of the second wave. [When compared with cases detected through routine surveillance, they report a longer period of decline and a younger age distribution. Representative community sampling for SARS-CoV-2 can substantially improve situational awareness and feed into the public health response even at low prevalence.](#)
- This is a systemic review of published studies to determine if individuals with Cystic Fibrosis (CF) are disproportionately affected by SARS-CoV-2 and development of COVID-19. Six evaluable studies reporting on a total of 339 individuals with CF who developed COVID-19 were reviewed. The results show [that although individuals with CF generally experience acute exacerbations of lung disease from infectious agents, COVID-19 incidence estimates in CF appear to be lower than in the general population. However, there are reports of subsets of CF, such as those who had organ transplants that may experience a more severe COVID-19 course. Potential protective mechanisms in the CF population include pre-pandemic social isolation practices, infection prevention and control knowledge, altered expression of angiotensin-converting enzyme, and the use of certain medications.](#)
- In this modelling study the authors developed and validated a supervised machine learning pipeline to distinguish COVID-19 and influenza infections using the available vital signs and demographic

dataset from the first hospital/emergency room encounters of 3883 patients who had confirmed diagnoses of influenza A/B, COVID-19 or negative laboratory test results. [The models were able to achieve an area under the receiver operating characteristic curve \(ROC AUC\) of at least 97% using their multiclass classifier. The predictive models were externally validated on 15,697 encounters in 3125 patients available on TrinetX database. The influenza vs COVID-19-positive model had an AUC of 98.8%, and 92.8% on the internal and external test sets, respectively. The code is made available at <https://github.com/ynaveena/COVID-19-vs-Influenza> and may have utility as a frontline diagnostic tool to aid healthcare workers in triaging patients.](#)

## Care and Treatment

- This retrospective observational study involving 16 healthcare centers across India aimed to compare epidemiology and outcomes among cases of coronavirus disease (COVID-19)–associated mucormycosis (CAM). [Among 287 mucormycosis patients, 187 \(65.2%\) had CAM; CAM prevalence was 0.27% among hospitalized COVID-19 patients. They noted a 2.1-fold rise in mucormycosis during the study period compared with September–December 2019. Uncontrolled diabetes mellitus was the most common underlying disease among CAM and non-CAM patients. COVID-19 was the only underlying disease in 32.6% of CAM patients. COVID-19–related hypoxemia and improper glucocorticoid use independently were associated with CAM.](#)
- This study assessed factors (ie, human and facility resources, patient comorbidities, and critical care interventions) that were associated with mortality in adult patients from the ACCCOS study. This was a multicentre, prospective, observational cohort study in adults (aged 18 years or older) with suspected or confirmed COVID-19 infection who were referred to intensive care or high-care units in 64 hospitals in ten African countries. They found that [mortality in critically ill patients with COVID-19 was higher in African countries than reported from studies done in Asia, Europe, North America, and South America. Increased mortality was associated with insufficient critical care resources, as well as the comorbidities of HIV/AIDS, diabetes, chronic liver disease, and kidney disease, and severity of organ dysfunction at admission.](#)
- This systematic review and meta-analysis intended to quantify the impact of clinical frailty scale (CFS) by increasing severity of frailty and to identify other personal prognostic factors associated with increased mortality from COVID-19. Thirty-four studies were eligible for systematic review and seventeen for meta-analysis. All 34 studies included patients from a hospital setting, comprising a total of 18,042 patients with a mean age of 72.8 years. [Their findings suggest a differential stratification of CFS scores in the context of COVID-19 infection, in which CFS 1–3 patients may be considered at lower risk, CFS 4–5 at moderate risk, and CFS 6–9 at high risk of mortality regardless of age. The study aimed to alert clinicians of the value of CFS scores and also highlight the multiple dimensions to consider such as age, gender and co-morbidities, even among moderately frail patients in relation to COVID-19 mortality.](#)
- This phase 3, randomized, double-blind, adaptive, placebo-controlled, multicenter trial aimed to investigate the effect of colchicine on the composite of COVID-19-related death or hospital admission. The study was done in Brazil, Canada, Greece, South Africa, Spain, and the USA. They found that [among patients with PCR-confirmed COVID-19, colchicine led to a lower rate of the composite of death or hospital admission than placebo. Given the absence of orally administered therapies to prevent COVID-19 complications in community-treated patients and the benefit of colchicine in patients with PCR-proven COVID-19, this safe and inexpensive anti-inflammatory agent could be considered for use in those at risk of complications.](#)
- This cohort study assessed the prevalence of myocarditis in athletes with COVID-19 and compared

screening strategies for safe return to play. The study included 1597 US competitive collegiate athletes undergoing comprehensive cardiovascular testing. The prevalence of clinical myocarditis based on a symptom-based screening strategy was only 0.31%. Screening with cardiovascular magnetic resonance imaging increased the prevalence of clinical and subclinical myocarditis by a factor of 7.4 to 2.3%. [These cardiac magnetic resonance imaging findings provide important data on the prevalence of clinical and subclinical myocarditis in college athletes recovering from symptomatic and asymptomatic COVID-19 infections.](#)

- This systematic review and meta-analysis of 69 nonrandomized studies aimed to evaluate the association of tracheostomy with COVID-19 patient outcomes and the risk of SARS-CoV-2 transmission among health care professionals. [They found that use of enhanced personal protective equipment in tracheostomy in patients with COVID-19 was associated with low SARS-CoV-2 transmission among Health Care Professionals and early tracheostomy was associated with reduced intensive care unit length of stay but not time to mechanical ventilation wean or decannulation, there was no difference in mortality between surgical and percutaneous tracheostomy.](#)

## Vaccines

- This prospective cohort study evaluated rates of antispikes (anti-S) antibody response to a BNT162b2 vaccine in Israeli patients with cancer who are undergoing systemic treatment vs healthy controls. They found that [90% of patients exhibited adequate antibody response to the BNT162b2 vaccine, although their antibody titers were significantly lower than those of healthy controls. Further research into the clinical relevance of lower titers and their durability is required. Nonetheless, the data support vaccinating patients with cancer as a high priority, even during therapy.](#)
- This pre-specified interim analysis of a randomized double-blind, phase 3 clinical trial aimed to evaluate the efficacy and adverse events of 2 inactivated COVID-19 vaccines. They included 40,382 participants who received at least 1 dose of a 2-dose inactivated vaccine series developed from either SARS-CoV-2 WIV04 (5 µg/dose) or HB02 (4 µg/dose) strains or an aluminum hydroxide-only control, with a primary end point of the incidence of symptomatic COVID-19 at least 14 days after the second injection. [The efficacy for the 2 vaccines, compared with an aluminum hydroxide-only control, was 72.8% in the WIV04 group and 78.1% in the HB02 group; both comparisons were statistically significant. Serious adverse events were rare. Data collection for final analysis is pending.](#)
- In this ongoing multinational, placebo-controlled, observer-blinded trial, 2260 adolescents 12 to 15 years of age received injections; 1131 received BNT162b2, and 1129 received placebo. As has been found in other age groups, [BNT162b2 had a favorable safety and side-effect profile, with mainly transient mild-to-moderate reactogenicity \(predominantly injection-site pain \[in 79 to 86% of participants\], fatigue \[in 60 to 66%\], and headache \[in 55 to 65%\]\); there were no vaccine-related serious adverse events and few overall severe adverse events.](#)
- This is a case series comprising of [7 cases of clinical myocarditis or myopericarditis that developed in 14- to 19- year-old males within 4 days of receiving the second dose of the Pfizer-BioNTech COVID-19 vaccine with no evidence of acute SARS-CoV-2 infection and who did not fulfill criteria for multi system inflammatory syndrome in children \(MIS-C\). Extensive diagnostic evaluation for other myocarditis etiologies was negative, including respiratory pathogens from nasopharyngeal swabs, serum PCR tests, and infectious serologies. All cardiac MRIs were diagnostic for myocarditis. No causal relationship between vaccine administration and myocarditis has been established.](#) Authors strongly recommend continued monitoring and reporting to the Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (VAERS).
- This case series reports findings in [five patients who presented with venous thrombosis and](#)



thrombocytopenia 7 to 10 days after receiving the first dose of the ChAdOx1 nCoV-19 adenoviral vector vaccine against Covid-19. The patients were health care workers who were 32 to 54 years of age. All the patients had high levels of antibodies to platelet factor 4–polyanion complexes; however, they had had no previous exposure to heparin. Because the five cases occurred in a population of more than 130,000 vaccinated persons, the authors propose that they represent a rare vaccine-related variant of spontaneous heparin-induced thrombocytopenia that they refer to as vaccine-induced immune thrombotic thrombocytopenia.

- This case series reports on clinical and laboratory features of 11 patients in Germany and Austria in whom thrombosis or thrombocytopenia had developed after vaccination with ChAdOx1 nCov-19. Of the 11 original patients, 9 were women, with a median age of 36 years (range, 22 to 49). Beginning 5 to 16 days after vaccination, the patients presented with one or more thrombotic events, with the exception of 1 patient, who presented with fatal intracranial hemorrhage. Of the patients with one or more thrombotic events, 9 had cerebral venous thrombosis, 3 had splanchnic-vein thrombosis, 3 had pulmonary embolism, and 4 had other thromboses; of these patients, 6 died. Five patients had disseminated intravascular coagulation. Platelet activation was inhibited by high levels of heparin, Fc receptor–blocking monoclonal antibody, and immune globulin (10 mg per milliliter).

#### Non-pharmaceutical interventions: social distancing

- This agent-based decision analytical study assessed the association of simulated COVID-19 vaccine efficacy and coverage scenarios with and without non-pharmaceutical interventions with infections, hospitalizations, and deaths. Simulation outcomes suggest that removing NPIs while vaccines are distributed may result in substantial increases in infections, hospitalizations, and deaths. Furthermore, as NPIs are removed, higher vaccination coverage with less efficacious vaccines can contribute to a larger reduction in risk of SARS-CoV-2 infection compared with more efficacious vaccines at lower coverage.
- This study investigated how different schooling strategies influenced COVID-19 transmission risk in adult household contacts and the wider community. The authors found that when mitigation measures are in place, transmission within schools is limited and infection rates mirror that of the surrounding community.
- This study showed that variations in mask efficacy can be explained by different regimes of virus abundance and related to population-average infection probability and reproduction number. For SARS-CoV-2, the viral load of infectious individuals can vary by orders of magnitude. The authors find that most environments and contacts are under conditions of low virus abundance (virus-limited) where surgical masks are effective at preventing virus spread. More advanced masks and other protective equipment are required in potentially virus-rich indoor environments including medical centers and hospitals.

#### Diagnostics

- This study evaluated the sensitivity and specificity of Lateral flow device (LFD) viral antigen immunoassays for mass testing in the UK. They report that 4/64 LFDs so far have desirable performance characteristics (orient Gene, Deepblue, Abbott and Innova SARS-CoV-2 Antigen Rapid Qualitative Test). All these LFDs have a viral antigen detection of >90% at 100,000 RNA copies/ml. 8951 Innova LFD tests were performed with a kit failure rate of 5.6% , false positive rate of 0.32% Viral antigen detection/sensitivity across the sampling cohort when performed by laboratory scientists was 78.8%. Their results suggest LFDs have promising performance characteristics for mass

[population testing and can be used to identify infectious positive individuals.](#)

#### Quarantine, isolation, contact management

- This cross-sectional study aimed to quantify proportions of cases and their contacts reached by public health authorities and the amount of time needed to reach them and to compare the risk of a positive COVID-19 test result between contacts and the general public during 4-week assessment periods. [Testing named contacts was a high-yield activity for case finding. However, this assessment suggests that contact tracing had suboptimal impact on SARS-CoV-2 transmission, largely because 2 of 3 cases were either not reached for interview or named no contacts when interviewed. Their findings are relevant to decisions regarding the allocation of public health resources among the various prevention strategies and for the prioritization of case investigations and contact tracing efforts.](#)

## D. Clinical Trials Updates

### Key updates:

#### Vaccine trials:

- On 4<sup>th</sup> June 2021, United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) [granted the extension of the current UK approval of the Pfizer/BioNTech COVID-19 vaccine Pfizer and BioNTech's Covid-19 vaccine to include individuals between 12 and 15 years of age.](#) This came after a rigorous review of the safety, quality and effectiveness of the vaccine in this age group by the MHRA and the Government's independent advisory body, the Commission on Human Medicines (CHM). [European Union has also extended approval of Pfizer/BioNTech COVID-19 vaccine Pfizer and BioNTech's Covid-19 vaccine to include individuals between 12 and 15 years of age.](#)
- On 25<sup>th</sup> May 2021, Moderna, Inc. [announced that the Phase 2/3 study of its COVID-19 vaccine \(mRNA-1273\) in adolescents has met its primary immunogenicity endpoint, successfully bridging immune responses to the adult vaccination. In the study, no cases of COVID-19 were observed in participants who had received two doses of the Moderna COVID-19 vaccine using the primary definition.](#) Also, a vaccine efficacy of 93% in seronegative participants was observed starting 14 days after the first dose using the secondary CDC case definition of COVID-19, which tested for milder disease. This study, known as the TeenCOVE study, enrolled more than 3,700 participants ages 12 to less than 18 years in the U.S. The participants were randomized in a 2:1 ratio to receive two 100µg doses of the vaccine or placebo. The Company plans to submit these data to regulators globally in early June.
- On 12<sup>th</sup> May 2021, INOVIO, a biotechnology company, [announced that its next-generation Pan-COVID-19 vaccine candidate, INO-4802, induced potent neutralizing antibodies and T cell responses against the original Wuhan strain as well as against B.1.1.7 \(UK variant\), B.1.351 \(South African variant\) and P.1. \(Brazilian variant\) in preclinical models.](#) These results demonstrate the potential of INOVIO's Pan-COVID-19 vaccine to induce cross-reactive immune responses against current and emerging viral variants as either a first-line vaccine, or potentially as a boost for individuals previously immunized with various Wuhan-matched vaccines. INOVIO plans to conduct Phase I/II clinical trials this year with INO-4802.

#### Therapeutics trials:

- On 3<sup>rd</sup> June 2021, Innovation Pharmaceuticals (OTCQB: IPIX), a clinical stage biopharmaceutical company, [announced that it has achieved full patient enrollment in its randomized, double-blind, placebo-controlled Phase 2 clinical trial of Brilacidin for the treatment of moderate-to-severe COVID-](#)

19 in hospitalized patients. The company is developing Brilacidin for treatment of COVID-19 under U.S. FDA Fast Track designation. Complete trial enrollment comprised 120 dosed patients recruited across multiple sites. Based on pre-clinical studies, Brilacidin is exhibiting an ability to directly disrupt viral integrity, a potent virucidal property, enabling it to be unaffected by mutations that give rise to variants—a beneficial trait differentiating Brilacidin from other antivirals.

- On 2<sup>nd</sup> June 2021, Centivax Inc. announced its strategic partnership with the U.S. Naval Medical Research Center (NMRC) for Phase I clinical development of Centi-B9, Centivax's SARS-CoV-2 broad-spectrum injectable antibody therapeutic and prophylactic. Centi-B9 has been engineered to broadly neutralize the mutated emerging coronavirus variants, with demonstrated broad-spectrum reactivity against 99.5% of all coronavirus variants in the U.S.A, and over 98% of coronavirus variants globally, including critical mutations found in the UK B.1.1.7, South African B.1.351, Brazilian P.1, New York B.1.526 and California B.1.429 strains. The Phase I trial will demonstrate safety and pharmacokinetics of the Centivax monoclonal in healthy volunteers and is planned to begin in July of this year.
- On 27<sup>th</sup> May 2021, Novartis and Molecular Partners announced the start of the clinical trial EMPATHY, a Phase II and III study, to explore the use of its novel DARPIn® therapeutic candidate ensovibep (MP0420) for the treatment of COVID-19. The EMPATHY clinical trial program is investigating the safety and efficacy of ensovibep in patients with COVID-19, who are in the early stages of infection, to prevent worsening symptoms and hospitalization. The study will enroll 400 patients in Phase 2 to identify a dose with optimal safety and activity, with initial results anticipated in August 2021. At that point Phase 3 will move ahead with an additional 1,700 patients with results anticipated in the first half of 2022.
- On 20<sup>th</sup> May 2021, Sorrento Therapeutics, Inc. (Nasdaq: SRNE, “Sorrento”) announced receipt of clearance from the Brazilian regulatory agency (ANVISA) to proceed with a Phase 2 Pivotal clinical trial of COVI-MSC™, an injectable infusion of mesenchymal stem cells, for the treatment of hospitalized COVID-19 patients suffering from acute respiratory distress syndrome (ARDS). The Brazil Phase II study is Pivotal, multi-center, randomized, controlled study to evaluate the safety and efficacy of three infusions of COVI-MSC™, administered every other day, to hospitalized patients experiencing moderate or severe COVID-19 with ARDS. The study is expected to enroll 100 patients (33 placebo and 67 treated patients) in three months from the date of first enrollment.
- On 19<sup>th</sup> May 2021, Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company, announced that it has enrolled the first patient in its Phase 3 clinical trial of sabizabulin, a novel, proprietary, oral cytoskeleton disruptor with anti-inflammatory and anti-viral properties, to combat the effects of COVID-19, the global pandemic disease caused by the novel coronavirus SARS-CoV-2. Phase III study is a double-blind, multi-centre, multinational, randomised, placebo-controlled clinical trial that aims to assess daily oral 9mg doses of sabizabulin for 21 days as against placebo. The study plans to enrol a total of 300 subjects, of which 200 will receive sabizabulin while the remaining 100 participants will be given a placebo. The participants in both sabizabulin and placebo groups will also be given standard of care.

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

## E. Public Health and Social Measures

The table below highlights changes in public health and social measures (PHSMs) based on data from the [Oxford COVID-19 Government Response Tracker](#). An up arrow indicates new PHSMs were announced; a horizontal arrow indicates PHSM were extended; a down arrow indicates PHSMs were loosened/expired. Member States are organized by tiers based on current epidemiological data from 4-11 June 2021.

Country	PHSM Trend	PHSM Change
<b>Tier 4 (High Alert):</b> Daily case incidence per 1M people/day $\geq 80$ and/or positivity rate $\geq 12\%$		
<a href="#">South Africa</a>	→	Officials in <b>South Africa</b> <a href="#">extended</a> the national state of disaster until 15 July. Several lockdown measures remain in place, including a nightly curfew and limits on public gatherings.
<a href="#">Tunisia</a>	↑	<b>Tunisia</b> <a href="#">imposed</a> a one-week lockdown in the Kairouan governante to slow COVID-19 transmission. Measures include a nightly curfew, suspension of all religious services and cultural and sports activities, and restrictions on restaurants and cafes.
<a href="#">Uganda</a>	↑	<b>Uganda</b> <a href="#">implemented</a> a 42-day lockdown to address the recent surge in COVID-19 transmission. Measures include the closure of schools, the suspension of inter-district travel, and the suspension of religious services.
<b>Tier 3 (Moderate Alert):</b> Daily case incidence per 1M people/day is 20 to $<80$ and/or positivity rate is 5% to $<12\%$		
<a href="#">Sao Tome and Principe</a>	→	<b>Sao Tome and Principe</b> <a href="#">extended</a> the national state of calamity and accompanying measures, including a nightly curfew and limits on public gatherings, until 30 June.
<b>Tier 2 (Low Alert):</b> Daily case incidence per 1M people/day is 5 to $<20$ and/or positivity rate is 3% to 5%		
<a href="#">Angola</a>	→	Officials in <b>Angola</b> <a href="#">extended</a> the national state of calamity for an additional 30 days, which include restrictions on movements and operation hours for most businesses. Stricter measures are in effect in Luanda, including shorter hours of operation for restaurants and other businesses, and the closure of some entertainment venues, such as cinemas.
<a href="#">Gabon</a>	↓	Some domestic restrictions in <b>Gabon</b> have been <a href="#">loosened</a> . The nightly curfew has been reduced by 3 hours, and hotels and bars are permitted to reopen. Restrictions for international travelers have been tightened, as authorities imposed a 24-hour quarantine on incoming travelers upon arrival at their expense.
<a href="#">Morocco</a>	↓	<b>Morocco</b> will <a href="#">reopen</a> airports to international flights starting 15 June, primarily to repatriate nationals living abroad. Foreign nationals will also be permitted to enter with a negative PCR test or proof of COVID-19 vaccination.
<b>Tier 1 (Standard Precautions):</b> Daily case incidence per 1M people/day is $<5$ and/or positivity rate is $<3\%$		

## Contributors

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