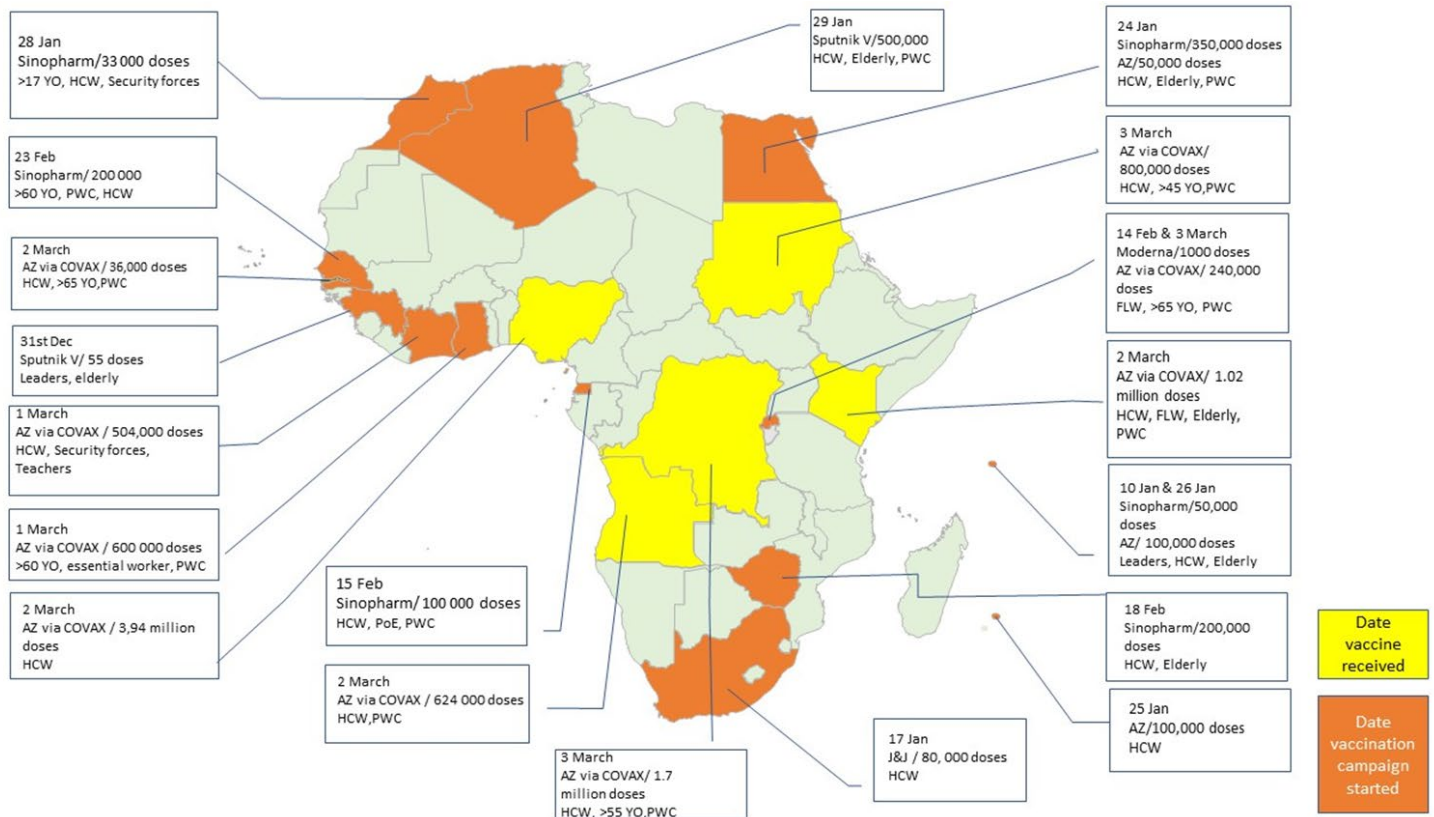


COVID-19 Scientific and Public Health Policy Update¹ – (02 March 2021)

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



Updated 02 March 2021

- Data from Israel's largest health care organization were used to evaluate the effectiveness of the BNT162b2 mRNA vaccine. Results suggest at 7 days or more after the second shot, Pfizer's vaccine was 94% effective at preventing COVID-19 and 92% effective against severe disease.

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

B. New guidelines and resources

Since 13 February 2020,

- Africa CDC has published new guidance and resources on:
 - [Policy Paper: Research and Development Priorities for COVID-19 in Africa](#)
 - [Call to action: Safe Reopening of Borders to Save Lives, Economies and Livelihoods in Africa](#)
 - [Statement on the Use of Ivermectin for COVID-19](#)

- US CDC has published new guidance and resources on:
 - [COVID-19 Considerations for Animal Activities at Fairs, Shows, and Other Events](#)
 - [Interim Guidance on Unsheltered Homelessness and Coronavirus Disease 2019 \(COVID-19\) for Homeless Service Providers and Local Officials](#)
 - [Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing](#)
 - [Operational Considerations for Community Isolation Centers for COVID-19 in Low-Resource Settings](#)
 - [Contact Tracing for COVID-19](#)
 - [Guidance for Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools, and Homes](#)
 - [Standard Operating Procedure \(SOP\) for Triage of Suspected COVID-19 Patients in non-US Healthcare Settings: Early Identification and Prevention of Transmission during Triage](#)
 - [Interim Guidance for Homeless Service Providers to Plan and Respond to Coronavirus Disease 2019 \(COVID-19\)](#)
 - [Interim Operational Considerations for Public Health Management of Healthcare Workers Exposed to or with Suspected or Confirmed COVID-19: non-U.S. Healthcare Settings](#)
 - [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#)
 - [Operational Considerations for the Identification of Healthcare Workers and Inpatients with Suspected COVID-19 in non-US Healthcare Settings](#)
 - [Guidance for COVID-19](#)
 - [Prioritizing Case Investigations and Contact Tracing for COVID-19 in High Burden Jurisdictions](#)

- WHO has published new guidance and resources on:
 - [COVID-19 vaccine introduction and deployment costing tool \(CVIC tool\)](#)
 - [Maintaining a safe and adequate blood supply and collecting convalescent plasma in the context](#)
 - [Operational considerations to expedite genomic sequencing component of GISRS surveillance of SARS-CoV-2](#)

- FDA has issued press releases on:
 - [Clarification on RT-PCR Testing for COVID-19 using Saliva as Sample by the Philippine Red Cross versus Saliva Antigen Tests](#)

- [FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine](#)
- [Coronavirus \(COVID-19\) Update: FDA Issues Policies to Guide Medical Product Developers Addressing Virus Variants](#)
- [COVID-19 Update: USDA, FDA Underscore Current Epidemiologic and Scientific Information Indicating No Transmission of COVID-19 Through Food or Food Packaging](#)
- ECDC has issued new resource on:
 - [Risk assessment: SARS-CoV-2 - increased circulation of variants of concern and vaccine rollout in the EU/EEA, 14th update](#)
 - [Using face masks in the community: first update - Effectiveness in reducing transmission of COVID-19](#)
 - [Detection and characterisation capability and capacity for SARS-CoV-2 variants within the EU/EEA](#)
- PHE has issued new resource on:
 - [COVID-19: guidance on shielding and protecting people defined on medical grounds as extremely vulnerable](#)
 - [COVID-19: guidance for the public on mental health and wellbeing](#)
 - [COVID-19: guidance on supporting children and young people's mental health and wellbeing](#)

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

C. Scientific updates

Basic Science

- This study reports [18 pseudotyped viruses showed that the 501Y.V2 variants do not confer increased infectivity in multiple cell types except for murine ACE2-overexpressing cells, where a substantial increase in infectivity was observed](#). Reports suggest that 501Y.V2 showed no higher infectivity in cells with hACE2 comparing to 614G variant. 501Y.V2 showed increased infectivity in cells with mACE2 compared to 614G variant. 501Y.V2 escaped neutralization by most neutralizing monoclonal antibodies. 501Y.V2 significantly compromised the inhibitory effects of polyclonal antibodies.
- This study maps how all mutations to the receptor binding domain (RBD) of SARS-CoV-2 affect binding by the antibodies in the REGN-COV2 cocktail and the antibody LY-CoV016. [Results uncover a single amino acid mutation that fully escapes the REGN-COV2 cocktail, which consists of two antibodies, REGN10933 and REGN10987, targeting distinct structural epitopes](#). The maps also identify viral mutations that are selected in a persistently infected patient treated with REGN-COV2 and during in vitro viral escape selections. Finally, the maps reveal that mutations escaping the individual antibodies are already present in circulating SARS-CoV-2 strains.
- Using large-scale phylogenetic analyses combined with epidemiological and travel data, this study quantified the size, spatiotemporal origins, and persistence of genetically distinct UK transmission lineages. [Rapid fluctuations in virus importation rates resulted in >1000 lineages; those introduced prior to national lockdown tended to be larger and more](#)

[dispersed. Lineage importation and regional lineage diversity declined after lockdown, whereas lineage elimination was size-dependent.](#)

- This study evaluates whether acute infection with B.1.1.7 is associated with higher or more sustained nasopharyngeal viral concentrations, the authors assessed longitudinal PCR tests performed in a cohort of 65 individuals infected with SARS-CoV-2 undergoing daily surveillance testing, including seven infected with B.1.1.7. [Findings suggest people infected with B.1.1.7, infections lasted an average of 13.3 days, compared with 8.2 days in people with other variants. These data offer evidence that SARS-CoV-2 variant B.1.1.7 may cause longer infections with similar peak viral concentration compared to non-B.1.1.7 SARS-CoV-2. This extended duration may contribute to B.1.1.7 SARS CoV-2's increased transmissibility.](#)
- Researchers engineered S mutations from the B.1.351 lineage into USA-WA1/2020, a relatively early isolate of the virus to analyse effects on neutralization elicited by BNT162b2. 50% plaque reduction neutralization testing (PRNT50) was performed using 20 serum samples that had been obtained from 15 participants in the pivotal trial 2 or 4 weeks after the administration of boost immunization. [Results indicate that all the serum samples neutralized USA-WA1/2020 and all mutant viruses at titers of 1:40 or greater. As compared with neutralization of USA-WA1/2020, neutralization of Δ242-244+D614G virus was similar and neutralization of the B.1.351-spike virus was weaker by approximately two thirds. The data shows poorer neutralization of the virus with the full set of B.1.351-spike mutations than the virus with either subset of mutations. Findings suggest that virus with mutant residues in the receptor-binding site is more poorly neutralized than virus with Δ242-244, which is located in the N-terminal domain of the spike protein.](#)

Epidemiology

- A prospective systematic post-mortem surveillance study using Zambia's largest tertiary care referral hospital. [Results suggest that contrary to expectations, deaths with COVID-19 were common in Lusaka. Most occurred in the community, where testing capacity is lacking. However, few people who died at facilities were tested, despite presenting with typical symptoms of COVID-19.](#)

Care and Treatment

- This randomized clinical trial investigated the effect of a single high dose of vitamin D3 on hospital length of stay, in 240 hospitalized patients with moderate to severe COVID-19. [Findings suggest that among hospitalized patients with COVID-19, a single high dose of vitamin D3, compared with placebo, did not significantly reduce hospital length of stay. The findings do not support the use of a high dose of vitamin D3 for treatment of moderate to severe COVID-19](#)
- This study evaluated the efficacy of tocilizumab and sarilumab (interleukin-6 receptor antagonists) in critically ill adult patients with Covid-19, within 24 hours after starting organ support in the intensive care unit (ICU). The primary outcome was respiratory and cardiovascular organ support-free days, on an ordinal scale combining in-hospital death and days free of organ support to day 21. [Results indicate that in critically ill patients with Covid-19 receiving organ support in ICUs, treatment with the interleukin-6 receptor](#)

[antagonists tocilizumab and sarilumab improved outcomes, including survival.](#)

- This randomized, double-blind, controlled trial conducted remotely throughout the United States, adult outpatients with laboratory-confirmed COVID-19 infection were randomly assigned to receive hydroxychloroquine (HCQ) with or without azithromycin (AZ) or placebo-equivalent (ascorbic acid (HCQ) and folic acid (AZ)). [Findings suggest neither HCQ nor HCQ/AZ shortened the clinical course of outpatients with COVID-19, and HCQ, but not HCQ/AZ, had only a modest effect on SARS-CoV-2 viral shedding.](#)

Vaccines

- Data from three single-blind randomised controlled trials—one phase 1/2 study in the UK (COV001), one phase 2/3 study in the UK (COV002), and a phase 3 study in Brazil (COV003)—and one double-blind phase 1/2 study in South Africa (COV005). [Overall vaccine efficacy more than 14 days after the second dose was 66.7% \(95% CI 57.4–74.0\), with 84 \(1.0%\) cases in the 8597 participants in the ChAdOx1 nCoV-19 group and 248 \(2.9%\) in the 8581 participants in the control group. The results of this primary analysis of two doses of ChAdOx1 nCoV-19 were consistent with those seen in the interim analysis of the trials and confirm that the vaccine is efficacious](#)
- In this study, data from Israel's largest health care organization were used to evaluate the effectiveness of the BNT162b2 mRNA vaccine. [Results suggest at 7 days or more after the second shot, Pfizer's vaccine was 94% effective at preventing COVID-19 and 92% effective against severe disease. The results were consistent across all age groups, including in people aged 70 and older. The study also covered a period when the emerging variant called B.1.1.7 was circulating widely in Israel, which suggests that the vaccine is effective at preventing COVID-19 caused by that variant.](#)
- The SIREN study is a prospective cohort study among staff working in publicly funded hospitals, documented the vaccine effectiveness of the BNT162b2 mRNA vaccine in healthcare workers (HCW). [A single dose of BNT162b2 vaccine demonstrated vaccine effectiveness of 72% 21 days after first dose and 86% seven days after two doses in the antibody negative cohort. The study demonstrates that the BNT162b2 vaccine effectively prevents both symptomatic and asymptomatic infection in working age adults; this cohort was vaccinated when the dominant variant in circulation was B1.1.7 and demonstrates effectiveness against this variant. \(Not peer-reviewed\)](#)

D. Clinical Trials Updates

Key updates:

Vaccine approval and roll out:

- On 15th February 2021, [WHO listed two versions of the AstraZeneca/Oxford COVID-19 vaccine for emergency use](#), giving the green light for these vaccines to be rolled out globally through COVAX. The vaccines are produced by AstraZeneca-SKBio (Republic of Korea) and the Serum Institute of India. On 24th February 2021, [COVAX launched its first international delivery](#) with 600,000 doses of Oxford-AstraZeneca COVID-19 vaccines delivery to Accra, Ghana. **The status of vaccine roll-out on the African continent is highlighted in the Vaccine distribution.**

- On 13th February 2021, the University of Oxford, together with three partner sites in London, Southampton and Bristol, [launched the first study to assess the safety and immune responses in children and young adults](#) of the ChAdOx1 nCoV-19 coronavirus vaccine. This trial will assess if children and young adults aged 6-17 years make a good immune response with the ChAdOx1 nCoV-19 vaccine. This new trial, a single-blind, randomised phase II trial, will enrol 300 volunteers, with up to 240 of these volunteers receiving the ChAdOx1 nCoV-19 vaccine and the remainder a control meningitis vaccine, which has been shown to be safe in children but is expected to produce similar reactions, such as a sore arm.
- On [16th February 2021, Johnson & Johnson submitted a conditional Marketing Authorisation Application \(MAA\) to the European Medicines Agency \(EMA\)](#) seeking authorisation for its single-dose Janssen COVID-19 vaccine candidate. The European Medicines Agency plans to issue an opinion in mid-March.
- The UK will be the first country to run a Covid-19 human challenge study, following a favourable opinion from the UK's clinical trials ethics body . [On 17th February 2021, Imperial College London, the Royal Free London NHS Foundation Trust and the clinical company hVIVO announced an upcoming Covid-19 human vaccine challenge study](#) funded by the UK government. It will involve up to 90 healthy adult volunteers, between 18 and 30 yo, at the lowest risk of complications resulting from coronavirus and which will be exposed to the virus in a safe and controlled environment.
- On 25th February 2021, [Pfizer and BioNtech announced that 144 participants from the Phase I study of their COVID-19 vaccine \(BNT162b2\) in the US will be offered a second booster dose of the vaccine](#), 6 to 12 months after receiving their initial two-dose regimen to understand the effect of this booster on immunity against COVID-19 caused by circulating and potential newly emerging SARS-CoV-2.
- [Discussions are also ongoing between Pfizer and BioNtech and regulatory authorities \(FDA and EMA\), regarding a registration to permit a clinical study to evaluate a variant-specific vaccine having a modified mRNA sequence based on the B.1.351 lineage, first identified in South Africa](#)
- On 27th February 2021, the [US FDA granted an emergency use authorization to the Johnson & Johnson Covid-19 vaccine](#), the first that requires only one dose, for use in adults aged 18 and older.
- On 8th March 2021, the director of Science and Innovation of the BioCubaFarma Business Group, Rolando Pérez Rodríguez, [announced the launch of the phase III trial of the Cuban anti-COVID-19 Soberana 02 vaccine candidate developed by the Finlay Vaccine Institute](#). Soberana 02 is a conjugate subunit vaccine in which the virus receptor-binding domain (RBD), is chemically bound to the tetanus toxoid. The vaccine [will be evaluated](#) in more than 40 000 volunteers aged 19-80 years old. Production of about 100,000 doses of the vaccine is set to begin in April.

Therapeutics trials:

- On 17th February 2021, the National Institutes of Health [announced the International Maternal Pediatric Adolescent AIDS Clinical Trials \(IMPAACT\) 2032 study \(NCT04582266\)](#) that will look at the effects of remdesivir in pregnant women. The study will be conducted at 17 sites in the continental United States and Puerto Rico. It aims to evaluate the pharmacokinetics of

remdesivir as well as potential side effects and adverse events of the drug when used to treat COVID-19 during pregnancy.

Immunotherapy trials:

- On 21st January 2021, [Eli Lilly announced the Phase 3 BLAZE-2 COVID-19 prevention trial of Bamlanivimab \(LY-CoV555\)](#), (dose 4,200 mg) conducted in partnership with the National Institute of Allergy and Infectious Diseases (NIAID), among residents and staff of long-term care facilities ([NCT04497987](#)). After 8 weeks of follow-up of 965 participants, results indicated that the frequency of symptomatic COVID-19 (primary study endpoint) was significantly lower in the bamlanivimab treatment arm versus placebo (odds ratio 0.43, $p=0.00021$).
- On 26th January 2021, [findings from Eli Lilly phase 3 BLAZE-4 trial](#), which assessed amlanivimab (LY-CoV555) 2800 mg and etesevimab (LY-CoV016) 2800 mg together for the treatment of high-risk patients recently diagnosed with COVID-19 ([NCT04634409](#)), demonstrated that COVID-19-related hospitalizations and deaths were significantly reduced. Among 1035 patients evaluated, a 70 % risk reduction ($p= 0.0004$) was observed in patients taking therapy compared to those receiving placebo.
- On 26th January 2021, [Regeneron announced positive initial results from the ongoing Phase 3 clinical trial of REGEN-COV™ for the prevention of COVID-19 in household contacts](#) of a COVID-19 patient. REGEN-COV™ is a cocktail of casirivimab (REGN10933) and imdevimab (REGN10987) monoclonal antibodies, which, when used as passive vaccination confers short term passive immunity against SARS-CoV-2. Results of the trial indicated that REGEN-COV provided 100% prevention of symptomatic infection and approximately 50% lower overall rates of infection (symptomatic and asymptomatic). Furthermore, on 27th January 2021, [Columbia University researchers](#) and [Regeneron](#) independently confirmed that REGEN-COV™ successfully neutralizes the circulating the 501Y.V1 SARS-CoV-2 variant first identified in the UK as well as the 501Y.V2 identified in South Africa. [Regeneron is collaborating with Roche](#) to increase global supply of REGEN-COV.

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

Contributors

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