

COVID-19 Scientific and Public Health Policy Update¹ – (01 December 2020)

In addition to our Weekly Outbreak Brief on the spread of COVID-19 and the actions that Africa CDC is taking to help African Union Member States. Africa CDC shares 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 WHO and other public health agencies. Contents of this document are not intended to serve as recommendations from the Africa CDC; 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. Executive summary

- A whole genome sequence study of SARS-CoV2 isolated from 61 Egyptian COVID-19 patients showed 204 mutations in the genomes of the Egyptian isolates.
- An analysis of laboratory findings in COVID-19 patients suggest that the generation of spike protein (S-), receptor-binding domain (RBD), and N-specific IgG occurs one week later in patients with severe/critical COVID-19 compared to patients with mild/moderate disease
- A study conducted at Oxford University Hospitals in the UK suggests that prior SARS-CoV-2 infection that generated antibody responses offered protection from reinfection for most people in the six months following infection.
- This research assesses how low-income households in rural Kenya coped with the immediate economic consequences of the COVID-19 pandemic. Findings suggest that income from work decreased with almost one-third and income from gifts and remittances reduced by more than one-third after the start of the pandemic.
- This report of the phase 2 component of the ChAdOx1 nCoV-19 vaccine trial suggests that the ChAdOx1 nCoV-19 vaccine may be better tolerated in older adults than in younger adults and has similar immunogenicity across all age groups after a boost dose.
- This study showed that immunization of mice with a candidate subunit vaccine consisting of SARS-CoV-2 RBD and Fc fragment of human IgG elicited high titer of RBD-specific antibodies with robust neutralizing activity against both pseudotyped and live SARS-CoV-2 infections.

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

B. New guidelines and resources

Since 17 November 2020,

- US CDC has published new guidance and resources on:
 - [Public Health Guidance for Potential COVID-19 Exposure Associated with International or Domestic Travel](#)
 - [Contact Tracing for COVID-19](#)
 - [Strategies for Optimizing the Supply of Facemasks](#)
 - [Investigating a COVID-19 Case](#)
 - [Prioritizing Case Investigations and Contact Tracing for COVID-19 in High Burden Jurisdictions](#)
 - [Polling Locations and Voters](#)
 - [Strategies for Optimizing the Supply of N95 Respirators](#)
 - [Collection and Submission of Postmortem Specimens from Deceased Persons with Confirmed or Suspected COVID-19](#)
 - [Operational Considerations for Personal Protective Equipment in the Context of Global Supply Shortages for Coronavirus Disease 2019 \(COVID-19\) Pandemic: non-US Healthcare Settings](#)
 - [Considerations for Restaurant and Bar Operators](#)
 - [Interim Operational Considerations for Public Health Management of Healthcare Workers Exposed to or with Suspected or Confirmed COVID-19: non-U.S. Healthcare Settings](#)
 - [Screening K-12 Students for Symptoms of COVID-19: Limitations and Considerations](#)
 - [COVID-19 Critical Infrastructure Sector Response Planning](#)
 - [Care for Breastfeeding Women](#)
 - [Guidance for Pharmacies](#)
- WHO has published new guidance and resources on:
 - [Therapeutics and COVID-19: living guideline](#)
 - [Diagnostics, therapeutics, vaccine readiness, and other health products for COVID-19](#)
 - [Rapid hospital readiness checklist: Interim Guidance](#)
 - [Evidence to recommendations: COVID-19 mitigation in the aviation sector](#)
 - [Draft landscape of COVID-19 candidate vaccines.](#)
 - [Continuity of essential health services: Facility assessment tool](#)
- FDA has issued press releases on:
 - [FDA issued an EUA for the drug baricitinib, in combination with remdesivir, for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation](#)

- [FDA issued an EUA for the first COVID-19 diagnostic test for self-testing at home and that provides rapid results](#)
- [FDA updated its guidance on investigational COVID-19 convalescent plasma](#)
- [FDA authorized 288 tests under Emergency Use Authorizations \(EUAs\); these include 224 molecular tests, 58 antibody tests and 8 antigen tests as of November 12, 2020. The FDA continues to monitor authorized tests and emerging scientific evidence and may revise or revoke an EUA, when appropriate, including when a test's benefits no longer outweigh its risks. The FDA provides continuous updates to make clear which tests have been issued EUAs by the agency, and which tests should not be used](#)
- ECDC has issued new resource on:
 - [Update projections of COVID-19 in the EU/EEA and UK](#)
 - [Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK](#)
 - [Contact tracing: public health management of persons, including healthcare workers, who have had contact with COVID-19 cases in the European Union – third update.](#)
- PHE has issued new resource on:
 - [PHE publishes COVID-19 vaccine guidance for health and social care workers](#)
 - [COVID-19: vaccinator training recommendations](#)

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 the present study, investigators performed a complete genome sequence of SARS-CoV2 isolated from Egyptian coronavirus disease (COVID-19) patients. [The whole genomic sequence of SARS-CoV2 showed 204 variations in the genomes of the Egyptian isolates, where the Asp614Gly \(D614G\) substitution is the most common among the samples \(60/61\).](#)
- In this systematic review and meta-analysis authors characterised viral load dynamics, duration of viral RNA shedding, and viable virus shedding of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in various body fluids, and to compare SARS-CoV-2, SARS-CoV, and Middle East respiratory syndrome coronavirus (MERS-CoV) viral dynamics. Findings suggest that SARS-CoV-2 RNA shedding in respiratory and stool samples can be prolonged, duration of viable virus is relatively short-lived. [SARS-CoV-2 titres in the upper respiratory tract peak in the first week of illness. Early case finding and isolation, and public education on the spectrum of illness and period of infectiousness are key to the effective containment of SARS-CoV-2.](#)

- This study described the dynamic changes of the SARS-CoV-2-specific antibody levels, including the total, S-, RBD-, and N-specific IgM and IgG levels on admission, during hospitalization, and on discharge, and the relationship between viral shedding and the antibody response. [Findings of 1,850 patients suggests that the generation of spike protein \(S\)-, receptor-binding domain \(RBD\), and N-specific IgG occurs one week later in patients with severe/critical COVID-19 compared to patients with mild/moderate disease, while S- and RBD-specific IgG levels are 1.5-fold higher in severe/critical patients during hospitalization. The RBD-specific IgG levels are 4-fold higher in older patients than in younger patients during hospitalization.](#)
- This study analyzed multiple compartments of circulating immune memory to SARS-CoV-2 in 185 COVID-19 cases, including 41 cases at ≥6 months post-infection. [Spike IgG was relatively stable over 6+ months. Spike-specific memory B cells were more abundant at 6 months than at 1 month. SARS-CoV-2-specific CD4+ T cells and CD8+ T cells declined with a half-life of 3-5 months.](#) (Not peer reviewed)
- Genomic data from SARS-CoV-2 isolated from infected minks provides a natural case study of a secondary host jump of the virus, in this case from humans to animals, and occasionally back again. [The study identified 23 recurrent mutations including three nonsynonymous mutations in the Receptor Binding Domain of the SARS-CoV-2 spike protein that independently emerged at least four times but are only rarely observed in human lineages. The repeat emergence of mutations across phylogenetically distinct lineages of the virus isolated from minks points to ongoing adaptation of SARS-CoV-2 to a new host.](#) (Not peer reviewed)
- This study investigated the incidence of SARS-CoV-2 PCR-positive results in seropositive and seronegative healthcare workers (HCWs) attending asymptomatic and symptomatic staff testing at Oxford University Hospitals, UK. Baseline antibody status was determined using anti-spike and/or anti-nucleocapsid IgG assays and staff followed for up to 30 weeks. [Findings suggest that prior SARS-CoV-2 infection that generated antibody responses offered protection from reinfection for most people in the six months following infection. Further work is required to determine the long-term duration and correlates of post-infection immunity.](#) (Not peer reviewed)

Epidemiology

- This observational cohort study evaluated adverse outcomes associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in pregnancy and described clinical management, disease progression, hospital admission, placental abnormalities, and neonatal outcomes. [Results indicate adverse pregnancy outcomes were similar, and neonatal infection occurred in 3% of infants, predominantly among infants born to asymptomatic or mildly symptomatic women and placental abnormalities were not associated with disease severity. These findings suggest that SARS-CoV-2 infection in pregnancy is not associated with adverse pregnancy outcomes.](#)
- This multicenter cohort study determined the frequency in which older adults with COVID-19 present to the emergency department (ED) with delirium and their associated hospital outcomes. [Results indicate that of 817 older ED](#)

patients with COVID-19, 28% had delirium at presentation, and delirium was the sixth most common of all presenting symptoms and signs. These findings suggest that older adults with COVID-19 commonly present to the ED with delirium and that delirium should be considered an important presenting symptom of COVID-19.

- This cohort study described testing for SARS-CoV-2 and the epidemiology of the SARS-CoV-2 infection among 135,794 US pediatric patients. Results indicate that 96% of patients tested had negative results, and rates of severe cardiorespiratory presentation of COVID-19 illness were low. Results further indicate that minority race/ethnicity, chronic illness, and increasing age were associated with SARS-CoV-2 infection. This study suggests that for most pediatric patients, the risk of SARS-CoV-2 infection appears low, but higher concern may be warranted for patients with medically complex conditions or those of minority race/ethnicity.
- In this repeated, cross-sectional study of 177,919 residual clinical specimens across 52 US jurisdictions, the estimated percentage of persons in a jurisdiction with detectable SARS-CoV-2 antibodies ranged from fewer than 1% to 23%. Findings suggest while SARS-CoV-2 antibody prevalence estimates varied widely across jurisdictions, most people in the US did not have evidence of previous SARS-CoV-2 infection.

Care and Treatment

- This randomized, open-label, parallel-arm, multicenter, Phase III trial COVID-19 adults with mild-to-moderate symptoms (were randomized 1:1 to oral favipiravir plus standard supportive care versus supportive care alone. Median time to cessation of viral shedding was 5 days versus 7 days, and median time to clinical cure was 3 days versus 5 days for favipiravir and control, respectively. Significant improvement in time to clinical cure suggests favipiravir may be beneficial in mild-to-moderate COVID-19.
- This study evaluates the in vivo efficacy of this antibody cocktail (REGN10987 and REGN10933) in both rhesus macaques, which may model mild disease, and golden hamsters, which may model more severe disease. Results demonstrate that REGN-COV-2 can greatly reduce virus load in the lower and upper airways and decrease virus-induced pathological sequelae when administered prophylactically or therapeutically in rhesus macaques.
- This double-blinded, placebo-controlled, multicenter trial conducted at 12 clinical sites in Argentina evaluated the safety and efficacy of convalescent plasma in the treatment of SARS-CoV-2 pneumonia. Findings indicate no significant differences observed in clinical status or overall mortality between patients treated with convalescent plasma and those who received placebo.
- An open-label, cluster-randomized trial investigated the efficacy and safety of hydroxychloroquine to prevent secondary PCR-confirmed, symptomatic Covid-19 and SARS-CoV-2 infection in contacts exposed to a PCR-positive case patient with Covid-19 during the early stages of the outbreak in Catalonia, Spain. Findings suggest that post exposure therapy with hydroxychloroquine did not prevent SARS-CoV-2 infection or symptomatic Covid-19 in healthy persons exposed to a PCR-positive case patient.

Diagnostics

- This study compared AgPOCT products by seven suppliers: the Abbott Panbio™ COVID-19 Ag Rapid Test; the RapiGEN BIOCREDIT COVID-19 Ag; the Healgen® Coronavirus Ag Rapid Test Cassette (Swab); the Coris Bioconcept Covid.19 Ag Respi-Strip; the R-Biopharm RIDA®QUICK SARS-CoV-2 Antigen; the NAL von minden NADAL COVID19-Ag Test; and the Roche/SD Biosensor SARS-CoV Rapid Antigen Test. [Results suggest that the sensitivity range of most AgPOCT overlaps with viral load figures typically observed during the first week of symptoms, which marks the infectious period in the majority of patients.](#) (Not peer reviewed)

Infection Prevention and Control

- This study reports a multi-tiered infection control strategy was implemented across a healthcare campus in Singapore, a total of 16,162 admissions campus-wide were screened; 7% (1,155/16,162) tested positive for COVID-19. Less than 5% of COVID-19 cases (39/1,155) were initially detected outside of isolation wards in multi-bedded wards. [Improved distancing and enhanced IPC measures successfully mitigated onward spread even amongst COVID-19 cases detected outside of isolation. COVID-19 rates amongst HCWs were kept low 0.13% and reflected community acquisition rather than nosocomial spread.](#)
- A retrospective analysis of adult COVID-19 patients admitted to a large community hospital in Northeast Georgia between 1 March 2020 to 10 June 2020. Findings suggest that of 1,565 patients, 140 separate HAIs from 73 different organisms developed in 59 patients. Of these, 23 were gram positive, 39 were gram negative and 11 were fungal. [Patients developing HAI did not have higher odds of death. HAIs were associated with use of tocilizumab, steroids, hydroxychloroquine and acute kidney injury requiring hemodialysis.](#)

Economic studies

- This research assesses how low-income households in rural Kenya coped with the immediate economic consequences of the COVID-19 pandemic. Based on household-level fixed-effects regressions, [the results suggest that income from work decreased with almost one-third and income from gifts and remittances reduced by more than one-third after the start of the pandemic. Nevertheless, household expenditures on food remained at pre-COVID levels.](#)

Other

- This study analysed popularity of searches related to smell loss and taste loss, recently listed as symptoms of COVID-19. Searches on sight loss and hearing loss, which are not considered as COVID-19 symptoms, were used as control. The COVID-19 incidence did not correlate with searches for non-

symptoms, but in some weeks had high correlation with taste and smell loss searches, which also correlated with each other. [Results show that popularity of symptom searches is not reliable for pandemic monitoring.](#)

D. Clinical Trials Updates

Key updates:

Vaccine trials:

- On 16th November 2020, [Bharat Biotech announced the launch of the Phase III trial of their COVAXIN Covid-19 vaccine candidate](#). COVAXIN is India first anti-coronavirus vaccine and has been developed in partnership with the Indian Council of Medical Research (ICMR). As part of this phase III trial ([CTRI/2020/11/028976](#)), the enrolment of 26,000 adult participants in 25 sites across India is planned. The vaccine candidate will be administered in two doses for 0.5ml via intramuscular injection on day 0 and day 28.
- On 18th November 2020, [Pfizer and BioNTech announced](#) the final efficacy analysis of the Phase III study ([NCT04368728](#)) of the mRNA-based BNT162b2 COVID-19 vaccine candidate, indicating a vaccine efficacy rate of 95% ($p < 0.0001$) in participants without prior SARS-CoV-2 infection as well as in participants with and without prior SARS-CoV-2 infection from 7 days after the second dose in both cases. Further, with over 43,000 participants enrolled; no serious safety concerns were observed: the most frequent adverse event reported included fatigue at 3.8% and headache at 2.0%. Efficacy was consistent across age, gender, race and ethnicity demographics. Notably, the observed efficacy in adults over 65 years of age was over 94%. The analysis was based on 170 cases of COVID-19, of which 162 cases of COVID-19 were observed in the placebo group versus 8 cases in the BNT162b2 group. On 20th November 2020, [the companies submitted a request the U.S. Food and Drug Administration \(FDA\) for Emergency Use Authorization \(EUA\)](#) of the BNT162b2 vaccine candidate to potentially permit the use of the vaccine in high-risk populations in the USA by December 2020.
- On 18th November 2020, the Phase III clinical trial for inactivated novel coronavirus pneumonia (COVID-19) vaccine (Vero cells) was retrospectively registered ([ChiCTR2000039000](#)). Sponsored by the Wuhan Institute of Biological Products, the trial is conducted at the Hospital Ibn Sina, Hospital militaire d'instruction Mohammed V de Rabat and Hospital Ibn Rochd in **Morocco**. The trial aims to have enrolled 600 participants aged 18 years and older by end of December 2020.
- On 23rd November 2020, [Astra Zeneca announced the interim data analysis](#) of the phase III trial ([NCT04516746](#)) of their AZD1222 COVID-19 vaccine candidate in the UK and Brazil, which included 131 COVID-19 cases. The analysis indicated that a dosing regimen consisting of half dose of the AZD1222 vaccine, followed by a full dose at least one month apart ($n=2,741$ participants) showed an efficacy of 90% whereas another dosing regimen consisting of 2 full doses of the vaccine administered at least one month apart ($n=8,895$ participants) showed 62% efficacy. The combined analysis for both dosing regimens ($n=11,636$) indicated an average efficacy of 70% in preventing COVID-19 (primary trial endpoint). No serious safety events related to the vaccine have been confirmed. Astra Zeneca announced that it will seek Emergency Use Listing from the WHO to enable accelerated pathway to vaccine availability in low-income countries
- On 24th November 2020, the EDCTP Phase IV trial led by the University of Southern Denmark and titled "BCG to Reduce Absenteeism Among Health Care Workers During

the COVID-19 Pandemic” was registered ([NCT04641858](#)). The study will be conducted at the Manhica hospital in **Mozambique**, Central Hospital Dr. Agostinho Neto and Central Hospital Dr. Baptista de Sousa in **Cape Verde** and Hospital Nacional Simão Mendes and other hospitals in the capital Bissau in **Guinea-Bissau** and aims to enroll 1050 HCW (nurses/physicians/others) aged 18 years and above.

- On 30th November 2020, [Novavax announced completion of the enrollment for the Phase IIb trial of the NVX-CoV2373](#) vaccine candidate against COVID-19 underway in **South Africa** ([NCT04533399](#)). A total of 4,422 volunteers, including 245 HIV-positive participants, have been enrolled in this trial which aims to evaluate the safety of the vaccine candidate and provide an early indication of its efficacy, increasing the body of data in racially and geographically diverse populations and in older adults. The trial is conducted in collaboration with Wits University and is funded in part by the Bill & Melinda Gates Foundation.

Therapeutics trials:

- On 19th November, 2020 Eli Lilly’s [Olumiant drug \(baricitinib, a Janus kinase inhibitor already approved as a rheumatoid arthritis treatment\), was granted an Emergency Use Authorization \(EUA\)](#) by the U.S Food and Drug Administration (FDA) for use in combination with remdesivir (brand name Velkury) for hospitalized adult and pediatric patients aged 2 years with suspected or laboratory confirmed COVID-19 that require supplemental oxygen, invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO). This EUA comes as [WHO issued a conditional recommendation against the use of remdesivir](#) in hospitalized COVID-19 patients on 20th November 2020, [after interim results analysis from the SOLIDARITY trial](#) indicated no evidence that the medicine improves survival and other outcomes in these patients.
- On 25th November 2020, the US National Institute of Allergy and Infectious Diseases (NIAID) [announced the launch of the fourth iteration of the Adaptive COVID-19 Treatment Trial \(ACTT-4\)](#); The phase III trial ([NCT04640168](#)) will enroll up to 1,500 hospitalized COVID-19 adult patients requiring supplemental oxygen that will be assigned to either one of two treatment arms: dexamethasone and remdesivir, or baricitinib and remdesivir. ACTT-4 aims to determine whether baricitinib or dexamethasone, when administered with remdesivir, is more effective at preventing progression to requiring mechanical ventilation or death, or if they are similar.
- On 23rd November 2020, [Glenmark Pharmaceuticals announced](#) that the recently published data of the phase III trial of Favipiravir ([NCT04600999](#)), a drug that prevents the replication phase of the virus, led to significant improvement in time to clinical cure when used as treatment in adults (18-75 years) with RT-PCR-confirmed COVID-19 and mild-to-moderate symptoms. Median time to clinical cure was 3 days (95% CI: 3 days, 4 days) versus 5 days (95% CI: 4 days, 6 days), P = 0.030, for favipiravir and control arms respectively.

Immunotherapy trials:

- On 17th November 2020, [CytoDyn biotechnology company, announced](#) it has filed a protocol with the U.S. Food and Drug Administration (FDA) for a Phase 2 clinical trial of its leronlimab drug as a treatment for COVID-19 patients suffering from long-hauler symptoms. Leronlimab (or PRO 140), is a CCR5 antagonist that appears to play a central role in modulating immune cell trafficking to sites of inflammation and has the potential for

multiple therapeutic indications, including in HIV infection and cancer. The trial targets the enrolment of 102 participants in up to 10 sites.

- On 21st November 2020, [Regeneron Pharmaceuticals announced](#) that the REGN-COV2 antibody cocktail (or casirivimab and imdevimab administered together) had received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the treatment of mild to moderate COVID-19 in adults and in pediatric patients (at least 12 years of age and weighing at least 40 kg) with a positive SARS-CoV-2 viral testing result and at high risk for progressing to severe COVID-19 and/or hospitalization. Casirivimab and imdevimab are not authorized in hospitalized COVID-19 patients or those requiring oxygen therapy.

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

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