

HHS COVID-19 Update – June 4, 2020

Race, Ethnicity, Age and Sex Now Required for Labs to Report Along With Test Results: HHS announced [new Guidance that specifies what additional data must be reported to HHS](#) by laboratories along with COVID-19 test results. The Guidance standardizes reporting to ensure that public health officials have access to comprehensive and nearly real-time data to inform decision making in their response to COVID-19. The new reporting requirements will provide information needed to better monitor disease incidence and trends by initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and anticipating potential supply chain issues. The requirement to include demographic data like race, ethnicity, age, and sex will enable us to ensure that all groups have equitable access to testing, and allow HHS to accurately determine the burden of infection on vulnerable groups.

Related to this, CDC released an [update on the effects of COVID-19 on the health of racial and ethnic minority groups](#). Current data suggest a disproportionate burden of illness and death among racial and ethnic minority groups. A recent [CDC MMWR report](#) included race and ethnicity data from 580 patients hospitalized with lab-confirmed COVID-19. Although only 18% of the surrounding community was black, 33% of the hospitalized COVID patients were black. These data suggest an overrepresentation of blacks among hospitalized patients.

Funding

\$750 million for Head Start Program: ACF announced that in addition to the 2020 appropriation of \$10.6 billion for the Head Start program, the recently signed Coronavirus Aid, Relief and Economic Security (CARES) Act designates [\\$750 million more for the federal program to help prepare low-income children for kindergarten](#). This funding will support the growth and development of children and families by creating a positive environment for them during this public health crisis. To support low-income children who have experienced a disruption of services during this time, programs will provide supplemental summer Head Start programs as they are able. Funds will be released directly to all 1,600 local Head Start and Early Head Start programs, including tribal programs, in every state and territory beginning this week.

Testing

Publicly Posted Antibody Test Performance Data: FDA publicly posted [test performance data from four more antibody, or serology, test kits](#) on open.fda.gov from its independent performance validation study effort with the National Institutes of Health's (NIH) National Cancer Institute (NCI). These results are among the first to come from a collaborative effort by the FDA, NIH, Centers for Disease Control and Prevention (CDC) and Biomedical Advanced

Research and Development Authority (BARDA). Additional performance data will be made available as the FDA reviews and determines if any further actions are appropriate for those test kits prior to publication.

The Continued Need for Reliable Antibody Testing: FDA posted a blog on [The Continued Need for Reliable Antibody Testing](#). There's been a great deal of discussion about whether people who recover from coronavirus disease 2019 (COVID-19), have neutralizing antibodies in their bloodstream to guard against another infection. This study and others remind us of just how essential antibody tests will be going forward to learn more about this challenging pandemic. These assays must have high sensitivity and specificity, meaning there would be few false negatives and false positives, to tell us more about a person's exposure to SARS-CoV-2. While there are some good tests out there, not all are equally reliable.

Testing Supply Substitution Strategies: FDA announced a new web-based resource, titled [Testing Supply Substitution Strategies](#). This file contains detailed information to help support labs performing authorized COVID-19 tests. This interactive tool includes validated supply alternatives that labs can use to continue performing testing when there is a supply issue with some components of a test. The information in this resource is not intended to alter any already issued EUA for a COVID-19 diagnostic test nor is it intended to speak to any specific FDA regulatory requirement.

Contact Tracing Resources: CDC updated [Contact Tracing Resources](#) for reopening America. They have recently added contact tracing resources that include the [self-isolation and self-quarantine home assessment checklist](#) and the [daily temperature system log](#). The self-isolation home assessment aids case investigators and contact tracers in assessing ability to safely isolate or quarantine at home, and the need for additional social support. The daily temperature log tracks symptoms for those who have been exposed to COVID-19. They have also updated their webpage on [Identify the Primary Components of Contact Tracing](#) as part of the plan.

Health Department Checklist: CDC released a [Health Department Checklist: Developing a Case Investigation and Contact Tracing Plan](#) to supplement their initial Health Department Guidance. It is a tool that can assist health departments in developing a comprehensive plan. This tool does not describe mandatory requirements or standards; rather, it highlights important areas for consideration.

Testing Updates: During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted, or said they will be submitting, EUA requests to the FDA for tests that detect the virus or antibodies to the virus. To date, the FDA has authorized 120 tests under EUAs, which include 104 molecular tests, 15 antibody tests, and 1 antigen test.

Treatment

Partnership with Evidation Health: [BARDA announced a partnership with Evidation Health](#) of San Mateo, California, to monitor healthcare workers and first responders by leveraging de-identified, patient-generated health data from existing wearable devices as an early warning

algorithm to identify early symptoms of COVID-19. This study is part of BARDA's Rapidly Deployable Capabilities program to identify and pilot near term innovative solutions for identifying individuals who have COVID-19 infections. Individual and population-based data will be collated into computer models to improve "real-time" COVID-19 incidence prediction of both symptomatic and asymptomatic patients and enhance current disease surveillance systems to detect respiratory infections prior to the onset of symptoms.

In Vitro Antiviral Activity to Fight COVID-19: FDA released a [research spotlight on in vitro antiviral activity](#). Significant effort by scientists to identify drugs with antiviral activity against the SARS-CoV-2 virus has led to investigations involving new drugs or FDA-approved drugs for other indications. Identification of these potentially effective candidates is occurring at an unprecedented speed, and a necessary step in this process is translating in vitro antiviral activity to appropriate clinical dosing regimens. This step is complex and multifactorial, but essential to finding the right products, administered at the right doses, to the right patients, at the right time for successful treatment of COVID-19.

Clinic Trial Conduct Update: FDA updated content to the question-and-answer appendix in its guidance titled [Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#). The updated guidance has a new question-and-answer pertaining to 21 CFR Part 11 compliance for electronic systems used to generate electronic signatures on clinical trial records.

Paralyzing Agent Warning Statement: FDA is [notifying health care professionals about the temporary absence of the "paralyzing agent" warning statement](#) embossed on the vial caps of two neuromuscular blocking agents. Vecuronium bromide for injection 10 mg per vial and 20 mg per vial and rocuronium bromide injection 50 mg/5 mL, 100 mg/10 mL, commonly used to provide muscle relaxation during surgery or mechanical ventilation, usually include a warning statement embossed on the vial cap to identify the product as a paralyzing agent. During the COVID-19 pandemic, there has been increased use of vecuronium bromide for injection and rocuronium bromide injection in intensive care unit (ICU) patients requiring mechanical ventilation.

Highlights of CDER's Work: FDA released a new webpage highlighting [CDER's Work to Protect Public Health During the COVID-19 Public Health Emergency](#). CDER is responsible for the regulation of drug therapies, engages in many activities to support much of the FDA's work during this unprecedented time. So far, they have issued more than 12 [guidance documents](#) for industry related to therapeutic development since the start of the COVID-19 outbreak and granted more than 1,000 expanded access requests to support access to therapies with the potential to help patients.

Information for Specific Populations

Others at Risk: CDC updated their [information on at risk populations](#) for pregnant people, people experiencing homelessness, and people with disabilities.

CMS Updates

COVID-19 Nursing Home Data: CMS is posting the [first set of underlying COVID-19 nursing home data](#). On April 19, 2020, CMS announced the requirement that nursing homes to inform residents, their families, and their representatives of COVID-19 cases in their facilities. In addition to this, nursing homes are required to report COVID-19 cases and deaths directly to the Centers for Disease Control and Prevention (CDC) and today CMS is making this data publicly available. As part of today’s announcement CMS is also posting the results from the targeted inspections announced on March 4, 2020, to allow inspectors to focus on the most serious health and safety threats like infectious diseases and abuse during the pandemic. As of May 31, 2020, about 13,600 nursing homes – approximately 88 percent of the 15,400 Medicare and Medicaid nursing homes – had reported the required data to the (CDC). These facilities reported over 95,000 confirmed COVID-19 cases and almost 32,000 deaths. The next set of data will be updated in two weeks. Going forward after that date, CMS plans to update the data weekly.

Targeted Inspection Results: CMS and its network of state-based inspectors have conducted over 8,300 surveys with the [results of a total of 5,700 available today](#). The results of the completed surveys and the reports are available on Nursing Home Compare. CMS plans to post the results of the inspections monthly on an ongoing basis as they are completed. They also released an [FAQ document](#) that further explains the data.

Research Updates

Will Warm Weather Slow the Spread of COVID-19? NIH published a blog addressing what is known on [Warm Weather and the Spread of COVID-19](#). With the start of summer coming soon, many are hopeful that the warmer weather will slow the spread of SARS-CoV-2, the novel coronavirus that causes COVID-19. There have been hints from lab experiments that increased temperature and humidity may reduce the viability of SARS-CoV-2. Meanwhile, other coronaviruses that cause less severe diseases, such as the common cold, do spread more slowly among people during the summer. We’ll obviously have to wait a few months to get the data. But for now, many researchers have their doubts that the COVID-19 pandemic will enter a needed summertime lull. Among them are some experts on infectious disease transmission and climate modeling, who ran a series of sophisticated computer simulations of how the virus will likely spread over the coming months. This research team found that humans’ current lack of immunity to SARS-CoV-2—not the weather—will likely be a primary factor driving the continued spread of the novel coronavirus this summer and into the fall.

COVID-19 Forecasts: CDC updated their [COVID-19 national and state forecasts](#). This week CDC received 20 individual national forecasts. This week’s national ensemble forecast suggests that the number of newly-reported COVID-19 deaths per week will continue to decline. It predicts between 118,000 and 143,000 cumulative COVID-19 deaths by June 27. Ensemble forecasts indicate that the rate of newly-reported deaths will vary among the states. In some states, cumulative deaths will increase at roughly the same rate as they have in recent weeks, while other states are likely to experience only a small number of additional deaths from COVID-19.