

HHS COVID-19 April 17, 2020 Update

Testing Updates

A New Swab Option Helps Address Shortages: The U.S. Food and Drug Administration announced a further [expansion of COVID-19 testing options](#) through the recognition that spun synthetic swabs – with a design similar to Q-tips – could be used to test patients by collecting a sample from the front of the nose. As part of this effort, U.S. Cotton, the largest manufacturer of cotton swabs and a subsidiary of Parkdale-Mills, developed a polyester-based Q-tip-type swab that is fully synthetic for compatibility with COVID-19 testing. Harnessing its large-scale U.S.-based manufacturing capabilities, U.S. Cotton plans to produce these new polyester swabs in large quantities to help meet the needs for coronavirus diagnostic testing. The finding that spun synthetic swabs could be used for COVID-19 testing is based on results from a clinical investigation that represents a collaboration between the FDA, UnitedHealth Group, the Gates Foundation, and Quantigen.

Serology Testing: CDC released information on [Serology Testing for COVID-19](#). CDC has developed a new laboratory test to assist with efforts to determine how much of the U.S. population has been exposed to SARS-CoV-2, the virus that causes COVID-19. Currently, CDC’s serologic test is designed and validated for broad-based surveillance and research that will give us information needed to guide the response to the pandemic and protect the public’s health. The test is not currently designed to test individuals who want to know if they have been previously infected with COVID-19. Additionally, CDC is evaluating commercially manufactured serologic tests in collaboration with the Biomedical Research and Development Authority (BARDA), the FDA, the NIH, the DOD, and the White House Office of Science and Technology Policy. This evaluation is expected to be completed in late April.

Treatment Updates

New Partnership to Develop National Strategy for Treatment and Vaccines: The National Institutes of Health and the Foundation for the NIH (FNIH) are bringing together more than a dozen leading biopharmaceutical companies, the HHS Office of the Assistant Secretary for Preparedness and Response, the CDC, , and the European Medicines Agency to develop an [international strategy for a coordinated research response to the COVID-19 pandemic](#). The planned Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership will develop a framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes and/or leveraging assets among all partners to rapidly respond to the COVID-19 and future pandemics. This is part of the whole-of-government, whole-of-America response the Administration has led to beat COVID-19. Secretary Azar notes, “By bringing together 16 pharmaceutical companies and five government agencies here and

abroad, the ACTIV partnership will accelerate the amazing work being done every day by scientists and innovators inside and outside of government.”

Vaccine Trial Enrolling Older Adults: An NIH [clinical trial of a vaccine for COVID-19 is now enrolling older adults](#) in Seattle, Atlanta and Bethesda. A Phase 1 clinical trial of an investigational vaccine designed to prevent COVID-19 is now enrolling older adults. The trial began on March 16, 2020 and was originally designed to enroll 45 healthy volunteers ages 18 to 55 years. Enrollment of the first 45 participants is now complete, and investigators have expanded the trial to enroll an additional 60 participants: 30 adults ages 56 to 70 years and 30 adults ages 71 years and older. The trial is supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. Enrolling older adult volunteers in the trial will help investigators better understand vaccination safety and immune response among older people, who face a higher risk of complications from COVID-19 than younger individuals.

Study of Remdesivir Shows Promise: NIH released a study on [Remdesivir that supports clinical testing underway across the US](#). The antiviral Remdesivir was shown to prevent disease progression in monkeys with COVID-19. Early treatment with the experimental antiviral drug Remdesivir significantly reduced clinical disease and damage to the lungs of rhesus macaques infected with SARS-CoV-2, the coronavirus that causes COVID-19, according to NIH scientists.

Consumer Warning About Chloroquine Phosphate Used in Aquariums: The FDA [issued](#) warning letters to [Fishman Chemical of North Carolina, LLC.](#), and [Dr. G’s Marine Aquaculture](#), which distribute chloroquine phosphate products intended to treat disease in aquarium fish which the FDA has not approved, conditionally approved, or indexed for said fish treatment. Although neither product identified in today’s warning letters made claims about use in people, the agency is [concerned](#) that consumers may mistake unapproved chloroquine phosphate animal drugs for the human drug chloroquine phosphate, which is currently under study as a potential treatment for COVID-19. People should not take any form of chloroquine unless it has been prescribed by a licensed health care provider.

More Fraudulent Product Warnings: The FDA and Federal Trade Commission (FTC) issued a warning letter to a seller of fraudulent COVID-19 products, as part of the agency’s effort to protect consumers. The seller warned, [The Art of Cure](#), which offers homeopathic drug products for sale in the U.S. that are unapproved and misbranded with misleading claims that the products are safe and/or effective for the prevention and treatment of COVID-19. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.

Updated Clinical Trial Guidance: The FDA added 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 includes new content on conducting remote clinician-reported outcome or performance outcome assessments; remote site monitoring; [electronic common technical document](#) requirements; investigational product administration by a local health care provider who is not a sub-investigator; and information for sponsors on who

they should contact at the FDA regarding certain changes to ongoing trials. There is also updated information about obtaining informed consent from a patient who is unable to travel to the clinical trial site due to COVID-19 illness or travel restrictions, in situations where electronic informed consent is not an option.

Diagnostics Update to Date: During the COVID-19 pandemic, the FDA has worked with more than 315 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for COVID-19 tests. To date, 37 [emergency use authorizations](#) have been issued for COVID-19 tests. The FDA has been notified that more than 190 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its [COVID-19 Diagnostics FAQs](#) up to date.

Guidance for Specific Populations

No Evidence of COVID-19 Transmission via Food: The FDA posted tips on [Shopping for Food During the COVID-19 Pandemic - Information for Consumers](#) and a downloadable [PDF](#). These materials reassure consumers that there is currently no evidence of human or animal food or food packaging being associated with transmission of the coronavirus that causes COVID-19. In an [interview](#) posted on the FDA's webpage, Deputy Commissioner for Food Policy and Response Frank Yiannas talks about the state of the U.S. food supply, both now and beyond this public health crisis. The topics he covers include food safety and food availability, as well as an update on implementation of the FDA Food Safety Modernization Act and FDA plans to release a blueprint for the New Era of Smarter Food Safety initiative.

Strategies for Long-Term Care Facilities: CDC released new guidance on [Key Strategies to Prepare for COVID-19 in Long-Term Care Facilities](#). COVID-19 cases have been reported in all 50 states, the District of Columbia, and multiple U.S. territories; many having wide-spread community transmission. Given the high risk of spread once COVID-19 enters a LTCF, facilities must act immediately to protect residents, families, and staff from serious illness, complications, and death. Strategies include keeping COVID-19 from entering your facility, identify infections early, prevent spread of COVID-19, assess supply of PPE and initiate measures to optimize supply, and identify and manage severe illness.

Considerations for Assisted Living Facilities: CDC released information with [Considerations When Preparing for COVID-19 in Assisted Living Facilities](#). Given their congregate nature and population served, assisted living facilities (ALFs) are at high risk of COVID-19 spreading and affecting their residents. If infected with SARS-CoV-2, the virus that causes COVID-19, assisted living residents—often older adults with underlying chronic medical conditions—are at increased risk of serious illness. As states are responsible for licensing and regulating ALFs, the structure and care provided within ALFs can be distinctly different from that of nursing homes. As such, implementing that guidance might present some unique challenges or additional considerations state by state.

Guidance for Exposed Healthcare Personnel: CDC released updates to their Interim U.S. Guidance for [Risk Assessment and Public Health Management of Healthcare Personnel with](#)

[Potential Exposure in a Healthcare Setting to Patients with COVID-19](#) to align with revisions to the public health recommendations for community-related exposure to COVID-19, which changed the period of exposure risk from “onset of symptoms” to “48 hours before symptom onset.” Given the ongoing transmission of COVID-19 in communities across the United States and the role that asymptomatic and pre-symptomatic individuals with COVID-19 play in transmission, the feasibility and benefits of formal contact tracing for exposures in healthcare settings are likely limited and this guidance is being archived. No further updates are planned. Healthcare facilities should consider foregoing contact tracing for exposures in a healthcare setting in favor of universal source control for healthcare personnel (HCP) and screening for fever and symptoms of COVID-19 before every shift. Additional infection prevention and control recommendations, including more details about universal source control in healthcare settings are available.

Guidance for Public Health Management of Exposed Workers in Non-US Settings: CDC released Interim Operational Considerations for [Public Health Management of Healthcare Workers Exposed to or Infected with COVID-19: non-US Healthcare Settings](#). Healthcare workers (HCWs) are not only at higher risk of infection but can also amplify outbreaks within healthcare facilities if they become ill. Identifying and managing HCWs who have been exposed to a patient with COVID-19 is of great importance in preventing healthcare transmission and protecting staff and vulnerable patients in healthcare settings. These operational considerations are intended to be used by healthcare facilities and public health authorities in non-US healthcare settings, particularly focusing on low- and middle-income countries, assisting with the management of HCWs exposed to a person with confirmed or suspected COVID-19.

Resources for Hospitals and Healthcare Workers Preparing for COVID-19 Patients: CDC updated their suite of resources for [Hospitals and Healthcare Workers Preparing for COVID-19](#). The resources include checklists, guidances, print resources, phone scripts and other information to help these entities with preparation of COVID-19 patients.

Information for High Risk Populations: CDC updated the information and steps for [Groups at Higher Risk for Severe Illness](#) related to COVID-19. The information includes steps to take to reduce your risk of getting sick with COVID-19 and specific actions that can be taken based on conditions and other risk factors. As new information becomes available, CDC continues to add to this page.

Information for Pediatric Healthcare Providers: CDC updated their information for [Pediatric Healthcare Providers](#). The resource should be used to inform pediatric healthcare providers of information available on children with COVID-19. The information includes guidance on maintaining childhood vaccines during the pandemic, burden of disease and risk factors, clinical presentation in children, clinical course and complications for children, treatment and prevention and additional information.

Funding Update

Funding Opportunity for Tribes: The Health Resources and Services Administration’s (HRSA), Federal Office of Rural Health Policy will announce an upcoming notice of funding

opportunity (NOFO) announcement that will be available to tribal organizations. Through the CARES Act, [HRSA received \\$15M to allocate to tribes, tribal organizations, urban Indian health organizations, and health service providers to tribes](#). The funding will provide support for the Tribes to prevent, prepare, and respond to COVID-19 in rural communities. The funding opportunity will be posted at the following link soon: www.grants.gov/web/grants/search-grants.html?keywords=hrsa-20-135.