

HHS COVID-19 Update – May 19, 2020

Today, HHS Secretary Azar released a strongly worded [statement](#) to the World Health Assembly, noting “a failure by this organization to obtain the information that the world needed, and that failure cost many lives.”

On Friday, [an important RFI \(Request for Information\)](#) was released asking for input from external audiences on HHS ASPR’s proposed strategy and structure of the Strategic National Stockpile, particularly the role of public-private partnerships in making sure the nation has the right items and quantities accessible for SNS 2.0. Input is also being sought to understand the constraints associated with meeting pandemic demand and how the U.S. Government can contribute to improving supply availability. Responses are due by 5/29 at 2pm. Many of you have expertise that should be shared so we can learn from this pandemic and be better situated for the future.

Today, HHS ASPR notified State Health Officers and other stakeholders that Gilead plans to provide an additional donation of remdesivir in June, taking the total supply of remdesivir up from 607,000 vials to a total of 940,000 vials. This is very good news.

Testing

First At-Home Testing Kit Authorized: FDA [Authorizes First Standalone At-Home Sample Collection Kit That Can Be Used at Multiple Authorized Labs](#). The FDA issued an [emergency use authorization \(EUA\) to Everlywell, Inc.](#) for the Everlywell COVID-19 Test Home Collection Kit. Everlywell’s kit is authorized to be used by individuals at home who have been screened using an online questionnaire that is reviewed by a health care provider. This allows an individual to self-collect a nasal sample at home using Everlywell’s authorized kit. The FDA has also authorized two COVID-19 diagnostic tests, performed at specific laboratories, for use with samples collected using the Everlywell COVID-19 Test Home Collection Kit. These tests have been authorized under separate, individual EUAs. Additional tests may be authorized for use with the Everlywell at-home collection kit in the future, provided data are submitted in an EUA request that demonstrate the accuracy of each test when used with the Everlywell at-home collection kit.

Primer on Testing Basics: The FDA issued a [Consumer Update, Coronavirus Testing Basics](#), to provide information about the different types of tests available and the steps involved in obtaining results. The fact sheet describes the different types of tests, outlines what they do, how long it takes to get results and the limitations of each test. A diagnostic test can show if you have an active coronavirus infection and should take steps to quarantine or isolate yourself from

others. An antibody test looks for antibodies that are made by the immune system in response to a threat, such as a specific virus. Because of this, antibody tests should not be used to diagnose an active coronavirus infection. At this time researchers do not know if the presence of antibodies means that you are immune to the coronavirus in the future.

Information on Serology Surveillance: CDC updated their information on [COVID-19 Serology Surveillance](#). CDC is working with state, local, territorial, academic, and commercial partners to better understand COVID-19 in the United States. Serology tests look for antibodies in blood. If antibodies are found, that means there has been a previous infection. Antibodies are proteins that can fight off infections. The webpage includes information about CDC serology surveillance, serology surveillance surveys and information on COVID-19 testing.

Information on Serology Surveillance Strategy: CDC released new information on their [COVID-19 Serology Surveillance Strategy](#). CDC has an overarching strategy for learning more about how many people have been infected with SARS-CoV-2, the virus that causes COVID-19, and how it is spreading through the U.S. population. This strategy includes using serology testing for surveillance to better understand how many infections with SARS-CoV-2 have occurred: At different points in time, In different locations, and Within different populations in the United States. A key CDC priority is to track COVID-19 infections to determine how much of the U.S. population is infected over time. CDC uses a variety of surveillance systems to track COVID-19 cases based on people who seek medical care. However, these systems can miss infections that occur in people who had mild or asymptomatic illness (i.e., no signs or symptoms) who did not seek medical care or get tested.

Different Seroprevalence Survey Types: CDC released information on [Seroprevalence Survey Types](#). CDC is collaborating with public health and private partners on a variety of surveys of different sizes, locations, populations studied, and purposes. By using seroprevalence surveys, CDC can learn about the total number of people that have been infected, including those infections that might have been missed. These surveys also can help estimate how much of the population has not yet been infected, helping public health officials plan for future healthcare needs. These surveys can also track how infections progress through the population over time. This is done by taking “snap shots” of the percentage of people who have antibodies against SARS-CoV-2 (also called the seroprevalence) at different time points. The seroprevalence surveys CDC is conducting include large-scale geographic surveys, community level surveys, and smaller-scale surveys focusing on specific populations in order to learn information about COVID-19.

Updated Information on Contact Tracing: CDC updated their information in their [Contact Tracing Protocol](#) and their [Contact Tracing Training](#). The protocol includes all of the contact tracer learning objectives, sample learning plans, and other resources. The sample training plan includes training topics that may be helpful for state and local public health jurisdictions to consider when designing their own training plans for COVID-19 contact tracers, case investigators, and team leads. Suggested training modalities/formats are provided, as well as information about sample existing trainings and resources. This site may be updated as new resources become available. After completing all training with the training plans, learners should

be able to conduct contact tracing, case investigation or supervision of contact tracers or case investigators according to the established protocol.

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 100 tests under EUAs, which include 87 molecular tests, 12 antibody tests, and 1 antigen test.

Treatment

Updates for Children and Multi-Inflammatory Syndrome in Children (MIS-C): CDC released a health advisory for [Multisystem Inflammatory Syndrome in Children \(MIS-C\) Associated with Coronavirus Disease 2019 \(COVID-19\)](#). The webpage includes 1) background information on several cases of a recently reported multisystem inflammatory syndrome in children (MIS-C) associated with coronavirus disease 2019 (COVID-19); and 2) a case definition for this syndrome. CDC recommends healthcare providers report any patient who meets the case definition to local, state, and territorial health departments to enhance knowledge of risk factors, pathogenesis, clinical course, and treatment of this syndrome. Related to MIS-C, CDC update their information and webpage on [Caring for Children](#) with the warning signs on when to seek pediatric care, added an FAQ on what is MIS-C and who is at risk in the [COVID-19 and Children](#) webpage, and added new sections on the webpages with [information for pediatric healthcare providers](#) and [clinical care guidance for healthcare professionals](#) about COVID-19.

Role of Public-Private Partnerships to Defeat COVID-19: NIH Director Dr. Collins and Johnson & Johnson executives published an article in JAMA today on [Accelerating COVID-19 Therapeutic Interventions and Vaccines \(ACTIV\)](#). In it, they note that to respond to the generational public health crisis caused by the global COVID-19 pandemic, a swift, coordinated effort across many sectors of society is necessary, say National Institutes of Health (NIH) Director Francis S. Collins, M.D., Ph.D., and Johnson & Johnson Vice Chairman of the Executive Committee and Chief Scientific Officer Paul Stoffels, M.D. Drs. Collins and Stoffels outline the innovative efforts of Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), a public-private initiative organized by NIH and the Foundation for the NIH. ACTIV's partners, which include at least 18 leading biopharmaceutical companies, multiple U.S. federal agencies, and the European Medicines Agency, are developing an international strategy for an integrated research response to COVID-19.

FDA Role and Progress in the Pandemic: The FDA issued an updated [At-A-Glance](#) that provides a quick look at facts, figures and highlights of agency's response efforts. Major focus areas of the FDA's response include increasing the availability of testing, therapeutics, and devices such as ventilators and personal protective equipment, and many other important items necessary for the response. The FDA is also monitoring the human and animal food supply and taking swift action on fraudulent COVID-19 products.

FDA Resources: The FDA has also published and continues to update [extensive resources on COVID-19 and medical devices](#) to help answer questions. In addition, the FDA published [Contacts for Medical Devices During the COVID-19 Pandemic](#), a detailed list of email addresses that may be used to ask questions about COVID-19 related to specific devices, Emergency Use Authorizations (EUAs) or guidance documents today.

Clinical Guidance Updates: CDC updated their information on [Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease \(COVID-19\)](#). The updates include new information for pediatric management as well as information about COVID-19-associated hypercoagulability and updates and resources to include new NIH treatment guidelines.

Sepsis and COVID-19: ASPR published a blog on [Raising Awareness: Many Roads Lead to Sepsis, Even for COVID-19 Patients](#). The blog discusses why the timely recognition and treatment of sepsis –whether bacterial or viral—is key to saving lives. The blog also highlights the interception of sepsis and COVID-19, a BARDA-sponsored partnership to develop a diagnostic for viral sepsis, a BARDA-sponsored hand-held ultrasound system to diagnose pneumonia, and announcement of FDA EUA authorization for a BARDA-supported rapid diagnostic test.

Expanding Remote Monitoring Capabilities: The FDA issued an [EUA for the G Medical VSMS ECG Patch](#) intended to be used by health care professionals in the hospital setting for remote monitoring of the QT interval of an electrocardiogram (ECG) in general care patients who are 18 years of age or older and are undergoing treatment for COVID-19 with drugs that can prolong QT intervals (measurements used to evaluate some of the electrical properties of the heart) and may cause life-threatening arrhythmias (such as, hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). The VSMS Patch is not intended for use on critical care patients. Such remote monitoring may reduce health care professional exposure to SARS-CoV-2, the virus that causes COVID-19.

Updates on Information for Researchers Conducting Clinical Trials: The FDA added more 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 new content includes information on reporting serious adverse events (SAEs) among patients with COVID-19 in certain clinical trials that are not focused on developing COVID-19 therapeutics.

Administering Naloxone During the Pandemic: CDC released information on how to [safely administer naloxone](#) during the COVID-19 pandemic. The fact sheet includes steps to respond to a suspected opioid overdose while reducing risk of COVID-19 exposure and the recommended PPE based on the situation.

Information on Alternative Care Sites: ASPR’s Technical Resources, Assistance Center, Information Exchange (TRACIE), in partnership with the HHS/FEMA Healthcare Resilience Task Force, opened registration for its May 22 webinar: [“Funding Sources for the Establishment and Operationalization of Alternate Care Sites.”](#) Alternate Care Sites (ACSs) are one of many alternate care strategies intended to provide additional hospital surge capacity and capability for

communities overwhelmed by COVID-19 patients. ACS can be established by an individual hospital, a group or partnership of hospitals or health systems, a local or state health department, or the federal government.

Warning Against Fraudulent Actors: The FDA and Federal Trade Commission (FTC) issued warning letters to two companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. 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. The first seller warned, [Benjamin McEvoy](#), participates in the Amazon Associates program. As an Amazon associate, the company earns commissions by promoting the sale of products, including dietary supplements, on the company's website, with misleading claims that the products can mitigate, prevent, treat, diagnose or cure COVID-19 in people. The second seller warned, [White Eagle Native Herbs](#), offers herbal products for sale in the U.S. with misleading claims that the products are safe and/or effective for the treatment and prevention of COVID-19.

PPE Updates

State-by-State PPE Data: FEMA released [State-by-State PPE Data](#) which outlines how many respirators, surgical masks, face shields, surgical gowns, gloves, ventilators and federal medical station beds that FEMA, HHS, and private sector have coordinated the delivery of or are shipping to states. The data in the tables below are separate from the supplies delivered through Project Airbridge.

Expanding the Supply Chain: FEMA released a new fact sheet on [COVID-19 Pandemic: Supply Chain Expansion Line of Effort](#). Manufacturing expansion is one part of a four-pronged supply chain stabilization approach for the coronavirus disease (COVID-19) pandemic response. The expansion line of effort is focused on increasing manufacturing production capacity of critical medical supplies and equipment needed to defeat the pandemic and make our Nation stronger and better prepared for future needs. The Supply Chain Task Force works with U.S. manufacturing companies to rapidly increase supply, expand domestic production of critical resources and to also increase long-term supply through two approaches: Increasing existing traditional medical supply and equipment manufacturing capabilities; and Exploring creative opportunities within the private sector to boost manufacturing capacity of critical medical supplies using non-traditional manufacturers. The fact sheet details the different avenues for manufacturing expansion.

Reopening America

CDC Role in the Pandemic and for Opening Up America Again: CDC released an updated document on [CDC Activities and Initiatives for COVID-19](#). This document briefly summarizes CDC's initiatives, activities, and tools in support of the Whole-of-Government response to COVID-19. It includes an overview of CDC's Surveillance and Control Goals and Activities. The principal objectives of COVID-19 surveillance are to monitor the spread and intensity of the pandemic, to enable contact tracing to slow transmission, and to identify disease clusters

requiring special intervention. Secondary objectives include understanding the severity and spectrum of disease, identifying risk factors for and methods of preventing infection, and producing data essential for forecasting. In addition to tracking the disease itself, monitoring of healthcare capacity and essential supplies through the National Healthcare Safety Network (NHSN) is critical to ensure adequacy of care.

CMS Guidance for Reopening Nursing Homes: CMS released new guidance for states and local officials to [ensure safe reopening of nursing homes across the country](#). The guidance details critical steps nursing homes and communities should take prior to relaxing restrictions implemented to prevent the spread of coronavirus disease 2019 (COVID-19), including rigorous infection prevention and control, adequate testing, and surveillance. The vulnerable nature of the nursing home population requires aggressive efforts to limit COVID-19 exposure and to prevent the spread within facilities. The recommendations issued today would allow states to make sure nursing homes are continuing to take the appropriate and necessary steps to ensure resident safety and are opening their doors when the time is right. This also serves to help states and nursing homes reunite families with their loved ones in a safe, phased manner. CMS is recommending that nursing homes do not advance through any phases of reopening or relax any restrictions until all residents and staff have received results from a baseline test. In addition, CMS recommends that state survey agencies inspect nursing homes that experienced a significant COVID-19 outbreak prior to reopening. Finally, CMS recommends that nursing homes remain in the current state of highest restriction even when a community begins to relax restrictions for other businesses, and should be among the last to reopen within the community, to ensure safety of the residents.

Information for Specific Populations

CMS Blanket Waivers: CMS updated their list of [COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers](#). The updates include modifications to information for hospitals, CAHs, psychiatric hospitals, Cancer Centers and Long-Term Care Hospitals on physical location as well as updates on ambulance services.

Information for Wildland Firefighters: CDC has published [FAQs for Wildland Firefighters](#) as part of its information for [First Responders and Law Enforcement](#). During fire season, members of each fire crew module should make an effort to operate and isolate as a unit. Crews should not interchange personnel or equipment between units (when possible) and should limit the number of personnel who must interact with people in the community. When personnel arrive to their duty stations, it is recommended that management provide separate spaces for the personnel to socially distance themselves from others on their crew for 14 days, if possible. After the initial 14-day period is over, fire crews and modules who work together and do not have regular interactions with other people can isolate as a unit.

Checklist for Homeless Service Providers: CDC released a [Checklist for Homeless Service Providers During Community Re-Opening](#). Across the United States, some states and local areas are preparing to reopen businesses and community centers after closing. Even if COVID-19 cases have decreased in your area, quick spread of this disease in homeless shelters or

encampments is possible. Protection of clients and staff remains necessary. During this time, continue to refer to the guidance for [homeless service providers](#) and [unsheltered homelessness](#). This checklist was designed to provide homeless service providers – many of whom have remained open during the COVID-19 pandemic – with a reminder of important considerations for service delivery as the surrounding community reopens.

Testing in Animals: CDC, in collaboration with USA released information on [Testing for COVID-19 in Animals](#). Generally, routine testing of animals is not recommended. The decision to test an animal (including companion animals, livestock, and wild or zoo animals) should be agreed upon using a One Health approach between appropriate local, state, and/or federal public health and animal health officials. This document provides recommendations to guide priorities for animal SARS-CoV-2 testing given limited resources. Veterinarians are strongly encouraged to rule out other, more common causes of illness in animals before considering SARS-CoV-2 testing.

National EMS Week: This week is National [Emergency Medical Services](#) personnel week, celebrating emergency medical technicians and paramedics. HHS Secretary Azar noted: “Since the beginning of the COVID-19 pandemic, we have been especially grateful for EMS personnel, who define what it means to be on the frontlines of our response. Emergency medical technicians and paramedics have stepped up to the challenge, serving Americans in need and often putting their own lives at risk to help preserve the health of others.”