U.S.

When, in late December 2019, Chinese authorities announced a cluster of pneumonia cases of unknown etiology centered in Wuhan, China, CDC began monitoring the outbreak. At the beginning of January, CDC began developing regular situation reports, including input from our respiratory disease experts in the CDC Country Office in China, which were shared with HHS, and reached out to the Chinese Center for Disease Control and Prevention to offer CDC support. By January 7, 2020, CDC began expanding its incident management (IM) and response

Prior to COVID-19, there were about 2,000 contact tracers in the U.S. Various studies estimate that about 100,000 contact tracers may be needed for COVID-19

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Beginning in April, the White House, and Federal partners including CDC, convened calls with all 50 states, Puerto Rico, and the District of Columbia to identify testing capacities and needs. Through these calls and other outreach efforts, CDC has worked with individual jurisdictions to identify needs, develop plans, and offer technical assistance to enhance testing capacity, state surveillance, contact tracing, and surge staffing. Through CDC funding, CDC, the HHS Office of Assistant Secretary for Health, and the Association of Public Health Laboratories are currently reviewing individual state testing plans with a focus on achieving increased monthly testing targets. These discussions and plans for action emphasize the need to serve vulnerable populations and include focused efforts for long-term care facilities, federally qualified health centers, and Tribal Nations, among others.

CDC is working with state and local health departments to support forward-looking testing strategies that ensure that vulnerable or high-risk populations, such as persons of color, have adequate access to testing. CDC is working with the HHS Health Resources and Services Administration and Federally Qualified Health Centers to develop and implement a strategy to increase testing in these clinics and to provide the clinics with the tools and resources to diagnose, treat, and monitor COVID-19 illness in the populations they serve.

CDC has developed a new serologic laboratory test to assist with efforts to determine how much of the U.S. population has been infected with SARS-CoV-2, the virus that causes COVID-19. The serology test looks for the presence of antibodies, which are specific proteins made in response to infections. It typically takes one to three weeks after someone becomes sick with COVID-19 for their body to make antibodies; some people may take longer to develop antibodies. The antibodies detected by this test indicate that a person has had an immune response to SARS-CoV-2, regardless of whether symptoms developed from infection or the infection was asymptomatic. However, it is important to point out that, at this point, we do not know whether the presence of antibodies provides immunity to the virus. & X U U H Q W O \ & ’ & ¶ V serologic test is designed and validated exclusively for broad-based surveillance and research that is giving us information needed to guide the response to the pandemic and protect the S X E O L F ¶ V Given the uncertainty of when an individual may develop antibodies and how long the antibodies may be present, the test is currently not designed to test individuals who want to know if they have been previously infected with SARS-CoV-2. It is only intended for population-based, surveillance and research use.

In March 2020, CDC and public health partners began seroprevalence surveys of community transmission of SARS-CoV-2, the virus that causes COVID-19. These studies use serum samples collected across the nation, including household studies in some states. Seroprevalence surveys help track how infections progress through the population over time and identify infections that might have been missed due to lack of symptoms or testing not being performed. CDC is conducting many seroprevalence studies and has recently published the results from a study that used remnants of samples collected during routine clinical care. This was done in conjunction with two commercial companies and results indicated that it is likely that greater than 10 times more SARS-CoV-2 infections occurred than the number of reported COVID-19 cases.

On April 27, 2020, CDC updated testing prioritization and focused testing guidelines for those who may have or who are at risk for active SARS-CoV-2 infection. Clinicians considering testing of persons with possible COVID-19 should use a diagnostic laboratory test that has been properly validated for the detection of SARS-CoV-2. Healthcare providers should coordinate testing through clinical or public health laboratories that are certified to perform diagnostic testing. Increasing testing capacity will allow clinicians to consider the medical necessity of COVID-19 testing for a wider group of symptomatic patients and persons without symptoms in certain situations. CDC recommends that clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Other considerations that may guide testing are epidemiologic factors such as known exposure to an individual who has tested positive for SARS-CoV-2, and the occurrence of local community transmission or transmission within a specific setting/facility (e.g., nursing homes) of COVID-19.

CDC has also developed a new multiplex laboratory test that checks for three viruses at the same time, two types of influenza viruses (A and B) and SARS-CoV-2, the virus that causes COVID-19, using a single sample collected from an individual. Testing for all three viruses simultaneously will allow public health laboratories to continue surveillance for influenza while testing for COVID-19. This will save public health laboratories both time and resources, including testing materials that are in short supply. Another benefit of the new test is that laboratories will be better able to find co-infections of influenza and SARS-COV-2, which is

important for doctors to diagnose and treat people properly. The FDA issued an Emergency Use $XWKRUL]DWLRQ DW &'&¶V UHTXHVW IRU WKLV FRPELQHG ODE assay is accessible to the public health laboratory community and technical information is SXEOLFO\ DYDLODEOH RQ &'&¶V ZHEVLWH VR WKDW FRPPHUFL developing proprietary tests if they wish. CDC expects that private sector laboratory test developers may be creating similar multiplex assays to meet clinician needs during influenza season.

Accurate data are critical as we continue to assess the burden placed on the American healthcare system to inform reopening. CDC is leveraging all available surveillance systems to monitor COVID-19 and protect vulnerable communities, including influenza and viral respiratory disease systems. In collaboration with STLT public health partners, CDC is committed to making data available to the public, while protecting individual privacy. CDC is using diverse systems to define a more complete picture of the outbreak, including race/ethnicity data and is working with communities of color to protect communities at risk. CDC has recently updated the COVID-19 Case Report Form to allow for better collection of data on populations that have previously been under-represented in reporting. The initial Case Report Form included questions for sex, age, race and ethnicity and whether the case is part of a recognized outbreak. The revised form includes additional variables for populations, such as tribal nations, that may be at higher risk for severe illness and risk factors such as homelessness and disabilities. States have improved the completeness of their reporting in the past three months. In particular, the percentage of reports that include race data has increased from 21 percent in April to 59 percent in late July, while the percentage of reports that include ethnicity data increased from 18 percent to 50 percent during the same time period. While progress has been made, CDC will continue to work with states to improve completeness of the data. New reporting requirements require states to report race, ethnicity and other important demographic information with test results providing information on those impBT/F2 8(L)21(TTJETQq0.00000912 0 612 792 reW*nBT/F2 12 Tf1 0 0 1 265.61 Tm0

staff also have access to HHS Protect, a platform for sharing healthcare information that allows the U.S. government to harness the full power of data for the COVID-19 response. & ' & ¶ V existing National Healthcare Safety Network (NHSN) continues to collect COVID-19 data from nursing homes and long-term care facilities. The NHSN also collects data from hospitals across the U.S. to address healthcare-associated infections and fight against antibiotic resistance.

The American people, communities, public health professionals, medical providers, businesses, and schools look to CDC for trusted guidance on responding to COVID-19. CDC develops and disseminates guidance for a range of audiences, individuals and communities, including business, schools, and healthcare professionals. These recommendations include

chronic medical conditions, and some racial and ethnic minorities. Modernization efforts include support for the surveillance and data workforce, a key asset of the public health system. The vision is a real-time, interoperable networked health data system capable of moving faster than the health threats we combat, and we are moving toward that goal.

COVID-19 is the most significant public health challenge to face our nation in more than a century. CDC is providing the American public with the information and assistance it needs to address COVID-19 head on. As we work together to fight COVID-19 and end this pandemic, CDC is committed to its mission to protect all Americans from disease threats and to save lives.

National Institute of Allergy and Infectious Diseases

NIH is the HHS agency leading the research response to COVID-19 and the novel coronavirus that causes the disease, SARS-CoV-2. Within NIH, NIAID is responsible for conducting and supporting research on emerging and re-emerging infectious diseases, including COVID-19.

NIAID responds rapidly to threats of emerging infectious diseases, by accelerating fundamental basic research efforts, engaging a domestic and international basic and clinical research infrastructure that can be quickly mobilized, and leveraging collaborative and highly productive partnerships with industry. NIAID also provides preclinical research resources to scientists in academia and private industry throughout the world to advance translational research on emerging and re-emerging infectious diseases. These research resources help bridge gaps in the product development pipeline, thereby lowering the scientific, technical, and financial risks incurred by product developers and incentivizing companies to partner with us in developing safe and effective countermeasures including vaccines, therapeutics, and diagnostics.

NIAID has a longstanding commitment to coronavirus research, including extensive efforts to combat two other serious diseases caused by coronaviruses: SARS and MERS. This research has enhanced our fundamental understanding of coronaviruses in general and provides a strong foundation for our accelerated efforts to address the specific challenge of COVID-19 by developing vaccines, therapeutics, and diagnostics.

Developing Vaccines to Prevent SARS-CoV-2 Infection

A safe and effective vaccine for SARS-CoV-2 will be essential to stopping the spread of infection, reducing rates of morbidity and mortality, and preventing future outbreaks.

NIAID recently established the COVID-19 Prevention Network (CoVPN) by leveraging four existing NIAID-funded clinical trials networks: the HIV Vaccine Trials Network (HVTN), the HIV Prevention Trials Network (HPTN), the Infectious Diseases Clinical Research Consortium (IDCRC), and the AIDS Clinical Trials Group (ACTG), in partnership with the DOD. The CoVPN aims to enroll thousands of volunteers in large-scale clinical trials testing a variety of investigational vaccines, monoclonal antibodies, and drugs intended to treat and protect people from COVID-19. The CoVPN is a I X Q F W L R Q D O X Q L W R I ‡ 2 S H U D W L R
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Effective therapeutics for COVID-19 are critically needed to treat patients who have been infected with SARS-CoV-2. On February 21, 2020, NIAID launched a multicenter, randomized placebo-controlled clinical trial, the Adaptive COVID-19 Treatment Trial (ACTT), to evaluate the safety and efficacy of therapeutics for COVID-19, initially examining the antiviral drug remdesivir for treatment of severe COVID-19 in hospitalized adults (ACTT-1). An analysis of preliminary data from ACTT-1 indicated that those who received remdesivir had a 32 percent faster time to recovery, a median of 11 days compared with 15 days for those who received placebo. Additionally, the analysis found that remdesivir may benefit survival, although the mortality data did not reach statistical significance. A mortality rate of 7.1 percent was observed for the group receiving remdesivir versus 11.9 percent for placebo. These initial findings were published on May 22, 2020, in the New England Journal of Medicine. The adaptive design of this trial will enable the evaluation over time of additional promising therapies, such as the anti-inflammatory drug baricitinib. This drug was added to the second iteration of the study (ACTT-2); enrollment for ACTT-2 is now complete. NIAID plans to evaluate the use of interferon beta-1a, which is used to treat individuals with multiple sclerosis, in the third iteration of the study (ACTT-3).

Monoclonal antibodies are another promising approach for the treatment of COVID-19. At least 21 companies are developing monoclonal antibodies that target SARS-CoV-2 and several of them have started early clinical trials. Monoclonal antibodies that target over-exuberant immune responses also are being studied. As part of the ACTIV partnership, and in collaboration with other NIH Institutes, NIAID plans to launch a series of OWS-supported studies to evaluate monoclonal antibodies in both outpatient and hospitalized settings. Outpatient studies of direct-acting antivirals also are scheduled to begin in August. NIAID also

BARDA, DOD, the Department of Veterans Affairs, CDC, and FDA. NIAID has been asked to

clinical, regulatory, business, and manufacturing experts to increase the odds of success. In addition, NIAID is using CARES Act funds to support diverse SARS-CoV-2 diagnostic platforms including RT-PCR and enzyme-linked immunosorbent assays, and facilitating development of sensitive, specific, and rapid diagnostic tests by providing critical SARS-CoV-2 isolates and reagents to the developers of tests.

The RADx Underserved Populations (RADx-UP) initiative will augment the reach and power of technologies developed and enhanced through RADx by identifying and addressing implementation factors that present barriers to testing and follow-up in vulnerable populations. On June 12, 2020, NIH announced four new funding opportunities for community-engaged projects within RADx-UP. The goal of this is to understand factors that have led to disproportionate burden of the pandemic on vulnerable populations so that interventions can be implemented to decrease these disparities.

The National Cancer Institute (NCI) is coordinating with FDA and NIAID to assess the sensitivity and specificity of certain SARS-CoV-2 serological tests, which can detect antibodies

alone tool to make decisions about personal safety related to SARS-CoV-2 exposure until additional information about SARS-CoV-2 immunity is available.

NIAID, NCI, NCATS, and NIBIB also are partnering on a new study to investigate whether adults in the United States without a confirmed history of infection with SARS-CoV-2

Office of the Assistant Secretary for Health

Diagnostics and Testing

Testing for the presence of SARS-CoV- L V D Q H V V H Q W L D O F R P S R Q H Q W R I response to the COVID

In addition, the Administration is now reviewing testing plans from each state, territory, and major city public health unit, as a requirement of $10.25 billion in cooperative agreement funding distributed by the CDC. The State Testing Plans serve as a roadmap for e D F K V W D W H ¶ V testing strategy for SARS-CoV-2. The overall goals for each state were determined in collaboration with the state and Federal experts considering multiple factors, including the rate of new cases, plans for mitigation, percent positivity. The plans submitted by the states will be continually improved through the ongoing collaboration of states with federal experts to meet the

- Diagnose COVID

health labs, high-throughput commercial laboratories, academic and hospital laboratories, laboratories at CDC, the Indian Health Service, the Department of Defense, and the Department of Veterans Affairs. In addition, the ecosystem now includes POC testing that can be done in rural areas at high risk without sophisticated supporting infrastructure, or as a tool to investigate outbreaks in nursing homes or other confined settings.

As of July 23rd, our nation has performed over 51 million tests. We are now conducting approximately 770,000 tests per day; and this number will continue to increase. Commercial laboratories are working more efficiently, processing tests in rapid succession, which ensures patients receive their results, on average, within three days. Hospital and academic laboratories typically provide results within 2 days, and often much sooner. POC tests provide results within 15 minutes.

To expand capacity and scale without impinging on the traditional health care system like emergency rooms and urgent care clinics, HHS worked closely with FEMA, interagency, and state and local partners to establish Community Based Testing Sites (CBTS). At the inception of this effort, the 41 federally supported sites were developed and established by the U.S. Public Health Service Commissioned Corps (Corps), in CDC-prioritized locations across the country. The Corps had unique expertise in COVID-19 testing, since many officers had deployed to Japan and elsewhere to assist in infection control, diagnosis, and eventual repatriation of American citizens. The initial objectives of CBTS were to screen and test healthcare facility workers and first responders, as prioritized by local jurisdiction. The CBTS model has been a success, having tested over 390,000 individuals, with an overall SARS-CoV-2 test positivity rate of approximately 15 percent, and serving as a model for all future iterations of community based testing. This positivity rate means that the CBTS are testing the right individuals at the right time. This effort has also supported and co-evolved with technological advances such as the validation of nasal self-swabbing, which minimizes the need for trained health professionals and personal protective equipment. The CBTS initiative was an early example to states and localities on how to conduct community based COVID-

In May and through July 23, working collaboratively with FEMA and utilizing their

On May 24th

Protecting the Vulnerable

We recognize that vulnerable populations in many underserved communities are among

million homeless individuals, and nearly 1 million migrant agricultural workers. Health centers are uniquely situated in communities to serve those that are most vulnerable and 93 percent of these centers offer COVID-19 testing. As of July 17, Health Centers have reported testing nearly 2.1 million individuals in total and racial and/or ethnic minority patients represent 54 percent of those tested.

To promote and protect the health and safety of vulnerable older adults, HHS has undertaken a large-scale procurement of FDA-authorized rapid point-of-care diagnostic test instruments and tests to be distributed to every nursing home in the United States. This bold action to facilitate on-site testing among nursing home residents and staff will provide nursing homes the ability to augment their current capacity for SARS-CoV-2 testing, bolstering their response and helping to prevent the spread of this virus. Distribution has already begun with nursing homes prioritized by the Centers for Medicare & Medicaid Services (CMS).

United States Public Health Service Commissioned Corps

Since the early stages of the COVID-19 outbreak, the Corps has been an indispensable asset leveraged to address the public health needs of the nation in response to this crisis. The Corps is one of the eight uniformed services of the United States and the only uniformed service committed to protecting, promoting, and advancing the health and safety of the nation. Corps officers serve throughout the nation in communities that are most in need by providing essential healthcare services to underserved and vulnerable populations.

In January, the Corps deployed officers to provide expert outbreak response in direct support of CDC. Deployment expanded rapidly from 38 officers on February 1, 2020 to more than 5,600 deployments as of July 23, 2020. Corps officers provided critical assistance to community-based testing sites throughout the nation and their contributions to this effort are immeasurable. In response to the escalating crisis, the Corps established COVID-19 Clinical Strike Teams, which include officers from the variety of disciplines needed on the frontlines. This kind of ready- P D G H X Q L W D O O R Z V W K H & R U S V W R G H S O R \ D ‡ F D Y

assistance to provide care amidst a surge of COVID-19 cases. Since that time, the Corps has deployed teams to support the response. The Corps has also deployed two teams, totaling more than 70 officers, to the Pennsylvania and the Florida State Health Departments to provide infection control, personal protective equipment (PPE) training, and consultation to long term care facilities.

The United States Public Health Service Commissioned Corps stands ready and willing to respond to the public health needs of our country and to provide essential healthcare services.

Food and Drug Administration

From the beginning of this public health emergency, FDA has taken an active leadership role in the all-of-government response to the COVID-19 pandemic, inspired by the resiliency of the American people and our great innovators. FDA stood up an internal cross-agency group that continues to ensure we are doing everything possible to protect the American public, helps ensure the safety and quality of FDA-regulated products, and provides the industries we regulate with the tools and flexibility to do the same. Work has focused on facilitating the development and availability of medical countermeasures to diagnose, treat, and prevent COVID-19, surveilling the medical product and food supply chains for potential shortages or disruptions and helping to mitigate such impacts, as necessary to protect the public health. This work is a key component of the federal government's efforts to address the COVID-19 pandemic so Americans can get back to work and school.

Diagnostic Testing

FDA has been proactive and supportive of test development by all interested parties † including laboratories, and large and small commercial manufacturers † to speed development and to quickly authorize tests that the science supports. The Agency has worked with over 500 developers since January, and has been working around the clock to issue over 180 Emergency Use Authorizations (EUAs) for tests, including molecular, antigen, serology and tests with at-home specimen collection indications.

This pandemic has created a demand for new tests that is unprecedented in both volume DQG XUJHQF\ )’$¶V LPSRUWDQW UROH LQ WHVWLQJ LQFOXGHV for use in the U.S. provide sufficiently accurate and reliable results and helping to provide timely access to such tests.

In a public health emergency, obtaining an accurate test result is important not only for the individual patient, but for the public at large. False positive or false negative results can contribute to the spread of SARS-CoV-2, so all tests used for COVID-19 should be validated before use. Similarly, timely access to diagnostic tests is critically important. To best address these dual, and sometimes competing, needs, FDA has used its EUA authorities. EUAs permit the emergency use of a product, in this case a test, when FDA determines that certain criteria are met based on the totality of the scientific evidence available. The EUA process made it possible for molecular diagnostic tests to be developed, validated, and offered for clinical use within

FDA has and will continue to take appropriate action against firms and individuals that place the public health at risk. Importantly, FDA continues to update its website to make clear which tests have been authorized by the Agency, and which tests have not.

FDA also announced our participation in the COVID-19 Diagnostics Evidence Accelerator, a multi-stakeholder collaborative project to advance the development of diagnostics through the generation of real-world evidence. Organized by the Reagan-Udall Foundation for FDA in collaboration with Friends of Cancer Research, this initiative is designed to allow the community to analyze both diagnostic and clinical data in real time, which has the potential to contribute to the scientific evaluation of diagnostic tools and medical interventions for COVID-19.

Evidence generated by the Accelerator project is intended to be complementary to other studies that have been conducted or are underway as well as to provide actionable information about the prevalence of SARS-CoV-2 in specific populations and highlight individual risk factors for patients. This helps improve our understanding of the disease, allows us to tailor public health interventions and strategies to mitigate risks for individuals and communities, and will help to stop the spread of SARS-CoV-2.

FDA has worked around the clock to 1) support t

that commercial manufacturers would submit EUA requests, with their validation data, within 10 business days from the date they notified FDA of their validation testing or from the publication date of the policy, whichever was later. FDA also provided specific performance recommendations for serology tests. FDA is constantly reassessing the evolving situation and updates its policies as needed.

The policy for laboratories certified under CLIA to perform high-complexity testing regarding their developing and performing their own serology tests has

under the policy fail to submit an EUA within 10 business days of notification, we have been removing those tests from our website notification list and are sharing this information publicly.

FDA will continue to appropriately balance assurances that an antibody test is accurate and reliable with timely access to such tests as the continually evolving circumstances and public health needs warrant. Importantly, we continue to work with developers of serological tests and are reviewing submitted EUA requests to authorize even more of these tests. FDA continues to

The guidance provides an overview of key considerations to help manufacturers satisfy requirements for chemistry, manufacturing and controls, and nonclinical and clinical data needed for development and licensure, and for post-licensure safety evaluation of vaccines. The guidance explains that, given our current understanding of SARS-CoV-2 immunology, the goal of development programs at this time should be to support traditional FDA approval by conducting studies to directly evaluate the ability of the vaccine to protect humans from SARS-CoV-2 infection and/or disease.

In its interactions with vaccine developers, FDA provides sponsors with advice regarding the data needed to support the manufacturing, clinical development, and approval of vaccines, including such advice to those sponsors pursuing development of vaccines to prevent COVID-19. The size of clinical trials to evaluate the efficacy of COVID-19 vaccines will depend on a number of factors including the criteria for demonstrating safety, efficacy and the incidence of COVID-19 in the population and areas where the trials are conducted. The guidance document conveys that FDA would expect that a COVID-19 vaccine would be at least 50 percent more effective than placebo in preventing COVID-19 or SARS-CoV-2 infection among the clinical trial participants. FDA anticipates that clinical trials to demonstrate vaccine efficacy would also be of sufficient size to provide an acceptable safety database. However, further pre-licensure safety evaluation may be needed if safety concerns arise during clinical development.

While FDA is committed to expediting this work, we will not cut corners in our decisions and are making clear through this guidance what data should be submitted to meet our regulatory standards. This is particularly important, as we know that some people are skeptical of efforts to develop a safe and effective COVID-19 vaccine.

It is clear that manufacturing and fill finish capacity will need to be scaled up on U.S. soil in order to have a safe and effective vaccine widely available in a timely manner. FDA is committed to working with sponsors by providing timely regulatory advice and technical assistance regarding manufacturing to help support such scale-up activities, including sponsors who may be proceeding at risk to scale-up manufacturing while clinical trials are being completed.

We have not lost sight of our responsibility to the American people to maintain our regulatory independence and ensure our decisions related to all medical products, including

appropriate.