NIH-Wide Strategic Plan for COVID-19 Research

July 2020

National Institutes of Health

Cover Image

Novel Coronavirus SARS-CoV-2

This scanning electron microscope image shows SARS-CoV-2 (yellow)—also known as 2019-nCoV, the virus that causes COVID-19—isolated from a patient in the United States, emerging from the surface of cells (blue/pink) cultured in the laboratory.

Credit: Rocky Mountain Laboratories, National Institute of Allergy and Infectious Diseases, NIH

FOREWORD

To the American People,

With the aim of turning discovery into better health for all, the National Institutes of Health (NIH) invests in biomedical research that spurs innovations in science and technology. NIH research has proven its value to the United States and the world over the years by rising to meet the challenges of polio, AIDS, and many other formidable health foes. Now, we face what may be the greatest public health crisis of our generation: coronavirus disease 2019 (COVID-19).

To address the unprecedented challenge that the COVID-19 pandemic poses to our health and economy, it is imperative that NIH and all sectors of society work together in unprecedented ways with unprecedented speed. Enabled by the strong support of Congress and other partners in the public and private sectors, NIH has mounted a vigorous research response against COVID-19 since the beginning of the pandemic. The breathtaking pace and scope of this response has been made possible by decades of NIH-funded basic research, which built a priceless foundation for the current efforts to combat COVID-19.

In this strategic plan for COVID-19 research, NIH shares its framework for funding work across the scientific spectrum. Our mission is to ensure that no stone goes unturned in the scientific response to COVID-19, as well as to inspire the collective efforts of NIH's researchers, collaborators, and diverse stakeholders. We will carry out this mission by improving, advancing, and optimizing COVID-19-related research in five key areas: fundamental knowledge, detection and diagnosis, treatment, prevention, and health disparities. Given the urgency of this health threat and the pressing need to develop tools to help people return to their daily routines safely, our mindsets must go far beyond "business as usual." Among the out-of-the-box initiatives now underway under NIH's leadership is a highly innovative, competitive effort to expand capacity and accuracy of testing and an unprecedented public-private partnership to accelerate development of therapeutics and vaccines. NIH research also will tackle the disturbing disparities seen in the COVID-19 response, with the aim of developing effective, evidence-based methods to ensure that diagnostics, treatments, and vaccines reach all populations, particularly those disproportionately affected by this devastating disease.

NIH acknowledges that the goals set forth in this plan are very ambitious and the scientific and logistical challenges truly daunting. Yet, we remain optimistic because of our agency's strong track record of encouraging ingenuity, even in the most difficult of times. We are convinced that pulling together the best minds in science is the best way to meet the twin challenges of curtailing the COVID-19 pandemic and preparing us to respond far better to future pandemics.

Sincerely,

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

NIH-Wide Strategic Plan for COVID-19 Research

A BOLD COMMITMENT TO AN UNPRECEDENTED HEALTH CHALLENGE

GOALS

- **UNDERSTAND** SARS-CoV-2 and COVID-19
- **PREVENT** SARS-CoV-2 infection
- **DETECT and TREAT** COVID-19
- **MITIGATE** the threat of COVID-19

Guided by **FIVE STRATEGIC PRIORITIES**

PRIORITY 1
Improve Fundamental Knowledge of SARS-CoV-2 and COVID-19 disease progression, outcomes, and recovery

PRIORITY 2
Advance Research To Improve Detection by developing and validating new assays and retooling existing diagnostic platforms

PRIORITY 3
Support Research To Advance Treatment by evaluating new or repurposing existing treatments and defining implementation strategies

PRIORITY 4
Accelerate Research To Improve Prevention by developing vaccines, other methods to prevent transmission, and implementation models

PRIORITY 5
Prevent and Redress Poor COVID-19 Outcomes in health disparity and vulnerable populations

CROSSCUTTING STRATEGIES

PARTNERING to promote collaborative science

SUPPORTING the research workforce and infrastructure

INVESTING in data science

NIH National Institutes of Health

GOAL

Improve basic understanding of SARS-CoV-2 and COVID-19 and develop the necessary tools and approaches to better diagnose, prevent, and treat this disease.

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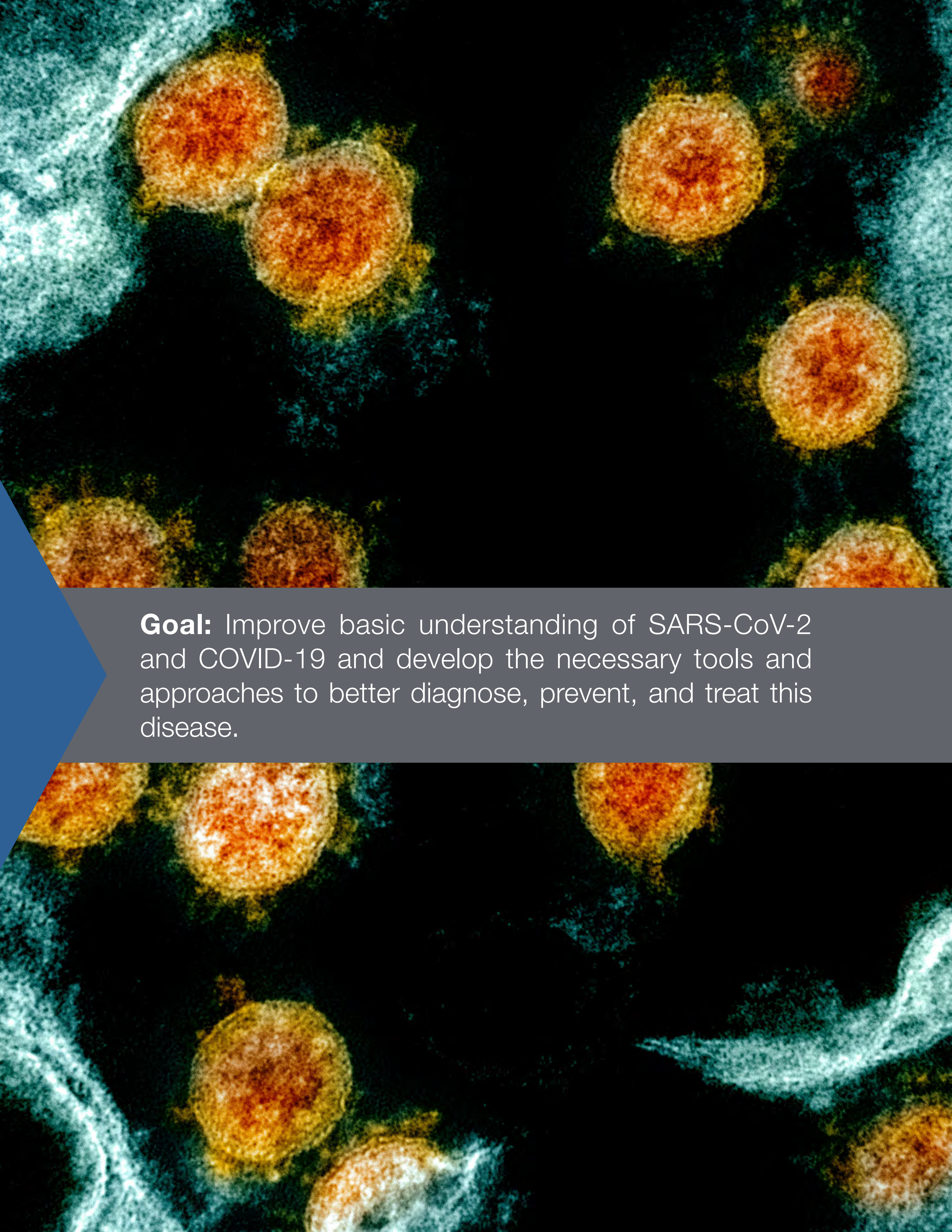


Goal: Improve basic understanding of SARS-CoV-2 and COVID-19 and develop the necessary tools and approaches to better diagnose, prevent, and treat this disease.

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is a newly emergent human disease caused by a naturally arising, novel coronavirus—the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus spreads easily from person to person through respiratory droplets, and infection typically causes fever, loss of taste or smell, shortness of breath, a dry cough, and/or other symptoms and complications associated with COVID-19. The ease with which the virus spreads and the virus's ability to be transmitted by asymptomatic individuals have caused possibly the most severe worldwide infectious disease pandemic of the modern age. More than 100,000 Americans died from COVID-19 within the first four months of the pandemic, contributing to more than 350,000 deaths worldwide in the same time period.

NIH is uniquely positioned to lead a swift, coordinated research response to this public health crisis. By leveraging existing funding mechanisms and establishing new programs, NIH is rapidly mobilizing the disbursement of emergency government funding to the biomedical research community while still maintaining a scientifically rigorous review process and strong scientific stewardship to support the most promising and meritorious science in the face of a public health emergency.

Researchers have already established—and will continue to build on—an immense fundamental knowledge base on viruses and their effects on humans built from decades of NIH-supported research. Leveraging the most modern technologies and techniques—as well as a rich reservoir of existing diagnostics, prevention strategies, and treatment options used to combat viruses—researchers are rapidly identifying characteristics of SARS-CoV-2 and human responses to infection to speed the development of sorely needed interventions for COVID-19.

To hasten the development of interventions, NIH is capitalizing on the strengths of its intramural and extramural (domestic and international) research infrastructure and working in close collaboration with its partners in industry, academia, nonprofit organizations, and other government agencies and offices. NIH's intramural scientists are engaging in foundational studies, creating models, and identifying or screening existing therapeutic drugs against SARS-CoV-2, as well as modifying existing vaccine and diagnostic platforms to prevent and detect the virus. Likewise, NIH's leadership role in the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership (Box 1) and its participation in the trans-government

Box 1 – ACTIV: An Unprecedented Partnership for Unprecedented Times

The rapid spread of COVID-19 and limited resources highlight the need to coordinate and streamline research processes to optimize biomedical research and testing of potential therapeutic and vaccine candidates. In April 2020, NIH launched the Accelerating COVID-19 Therapeutic Interventions and Vaccines (**ACTIV**) public-private partnership to develop a coordinated research strategy for prioritizing and speeding the clinical evaluation of the most promising treatments and vaccines. Through ACTIV, NIH has partnered with more than 15 biopharmaceutical companies; NIH's sibling agencies and offices within the Department of Health and Human Services, including the Biomedical Advanced Research and Development Authority, Centers for Disease Control and Prevention, and U.S. Food and Drug Administration; other government agencies, including the Department of Defense and Department of Veterans Affairs; European Medicines Agency; and representatives from academia and philanthropic organizations. Through the ACTIV partnership, NIH is pursuing four fast-track focus areas most ripe for opportunity, each led by a working group of senior scientists representing government, industry, nonprofit, philanthropic, and academic organizations. The **four areas** include (1) develop a collaborative, streamlined forum to identify preclinical treatments, (2) accelerate clinical testing of the most promising vaccines and treatments, (3) improve clinical trial capacity and effectiveness, and (4) accelerate the evaluation of vaccine candidates to enable rapid authorization or approval.

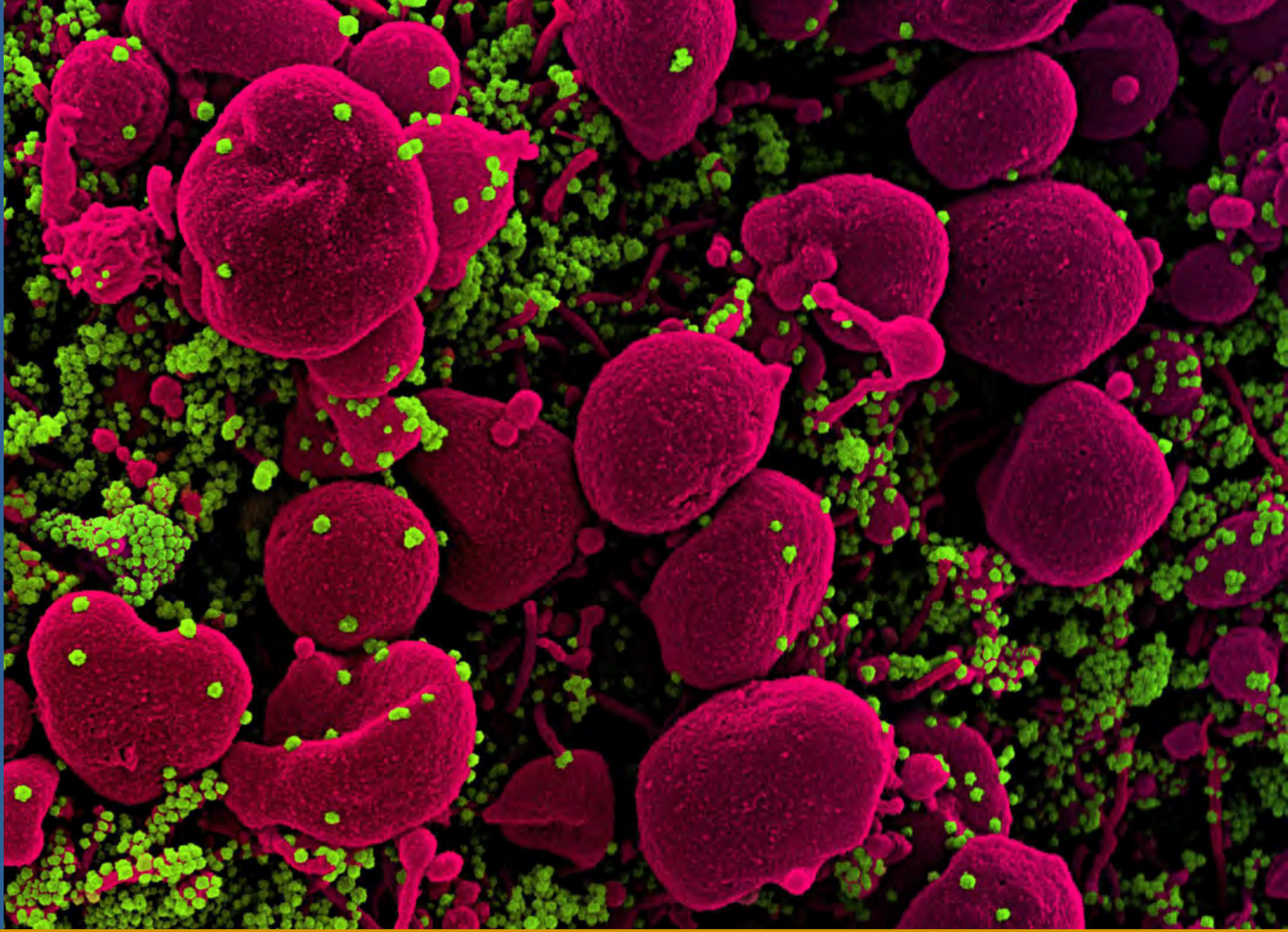
partnership called Operation Warp Speed (Box 3) are forging groundbreaking approaches to ramp up the identification, development, evaluation, and manufacturing of promising candidate therapeutics and vaccines.

Recognizing the disproportionate impact of COVID-19 on health disparity and specific vulnerable populations, NIH-funded researchers are working to identify the underlying factors and barriers that contribute to the staggering losses in these communities. Inclusion of these populations in clinical trials for diagnostics and interventions will be a critical part of NIH's pandemic response, as will exploring communication strategies and ways to improve access to care and interventions for at-risk populations.

In keeping with the urgency of the pandemic, NIH will rapidly communicate findings to the scientific community, health care providers, and the public. For the scientific community, NIH is moving as quickly as possible to disseminate data in multiple data-sharing platforms. Preprint and peer-reviewed publications relevant to all aspects of the research effort now are available, including literature compendiums and analysis tools, such as the newly established LitCovid and *iSearch* COVID-19 Portfolio tools. For health care providers, NIH convened a panel of experts who developed treatment guidelines that will evolve as new data and clinical expertise become available. Last, NIH will strive to provide the latest scientific information to the public, investing in research to identify the best methods for disseminating scientific findings to the populations who need them most, especially underserved and vulnerable populations.

NIH aims to actualize the response to the COVID-19 pandemic by supporting research to understand SARS-CoV-2 and mitigate the threat of COVID-19 for the health of all people. NIH will build on existing research initiatives—and accelerate the development of new ones—that are focused on the five research priorities detailed in this strategic plan. Through its pursuit of research in these priority areas, NIH hopes to achieve the vision of a world safe from COVID-19 by improving basic understanding of SARS-CoV-2 and COVID-19 and developing the necessary tools and approaches to better diagnose, prevent, and treat this devastating disease.

PRIORITY 1



Improve Fundamental Knowledge of SARS-CoV-2 and COVID-19

NIH-supported researchers will continue to work together with their partners to understand the biology of SARS-CoV-2 infection and COVID-19 outcomes, as well as the impact that infection and disease have on individuals, communities, and public health. This fundamental knowledge will be used to identify novel approaches for developing effective diagnostics, prevention strategies, and treatments.

Objective 1.1: Advance fundamental research for SARS-CoV-2 and COVID-19

NIH-supported researchers will continue to build upon an already strong foundation of knowledge to understand SARS-CoV-2 infection and COVID-19, including the research priorities outlined in the National Institute of Allergy and Infectious Diseases's *NIAID Strategic Plan for COVID-19 Research*. For example, researchers are working to understand essential SARS-CoV-2 proteins and host-virus protein interactions that mediate infection and disease to enable the development of effective treatment and prevention strategies.

Researchers also will seek to advance knowledge of the body's immune response to SARS-CoV-2 infection. The immune system plays a critical role in preventing and fighting off infection. Early studies have shown that patients with COVID-19 develop SARS-CoV-2–specific antibodies in their blood. Antibodies are blood proteins produced by the immune system to fight viruses and, in some cases, prevent future infection from the same virus. More follow-up work is needed to determine how protective SARS-CoV-2 antibodies are and for how long.

The immune system, although typically protective, sometimes can overreact and contribute to tissue and vascular damage, as observed in COVID-19. Thus, patients with severe COVID-19 may benefit from therapies that turn down the immune response or directly target the virus. NIH will support research to understand the mechanisms of infection and how the infection contributes to disease in different systems. Researchers have begun looking at changes in blood proteins, sugars, and fats to identify markers that may be signs of COVID-19 outcomes or protection from future infection.

Understanding SARS-CoV-2 transmission—how the virus spreads—and why some individuals are more susceptible to severe disease than others is an important piece of the COVID-19 response. To shed new insight on these topics, NIH will support research to identify potential animal reservoirs, understand animal-to-human and human-to-human transmission, and characterize the virus's genetic diversity. Studies to examine biological factors that influence individual susceptibility to infection—such as age, sex and gender, genetics, and environment—already are in progress. Researchers also are examining social factors related to COVID-19, such as health disparities based on race and ethnicity, including their influence on biological factors. This information will be critical to understanding infection and disease progression and outcomes, and it may inform the development of interventions and vaccines.

Objective 1.2: Support research to develop preclinical models of SARS-CoV-2 infection and COVID-19

Animal models, particularly those that replicate human disease, are essential to understanding the basic biology of coronaviruses, including transmission, incubation periods, and host immune responses to infection. They also are critical to testing potential preventive and therapeutic strategies. For example, researchers are using mice and nonhuman primates to study responses to experimental therapeutics and vaccines. NIH will leverage existing animal models of infection with other coronaviruses and develop preclinical models to study and understand SARS-CoV-2 infection and COVID-19.

Previous experience with related coronavirus diseases suggests that replicating COVID-19 in animal models may be challenging. Thus, researchers are exploring new ways to increase access to validated animal models and enhance comparison of approaches to identify informative assays. NIH plans to develop and validate human cell–based models of SARS-CoV-2 infection—such as tailoring tissue chips, which are three-dimensional (3D) platforms engineered to support living human tissues and cells—to study viral infections in relevant human tissues, such as the lung. Systems biology and computational techniques will be used to complement preclinical models of the tissue injury and immune system activation seen in patients with severe COVID-19, as well as therapeutic effects against SARS-CoV-2 and COVID-19.

Objective 1.3: Advance the understanding of SARS-CoV-2 transmission and COVID-19 dynamics at the population level

Researchers will continue work to understand the progression of COVID-19 through natural history studies exploring why some populations, such as children, generally may not exhibit symptoms of infection and how these factors contribute to the spread of SARS-CoV-2. NIH has launched studies to illuminate the extent to which SARS-CoV-2 has spread undetected in the United States and to provide insights into which communities and populations are most affected. For example, one study will determine how many adults in the United States without a confirmed history of infection with SARS-CoV-2 have antibodies to the virus, indicating a prior infection.

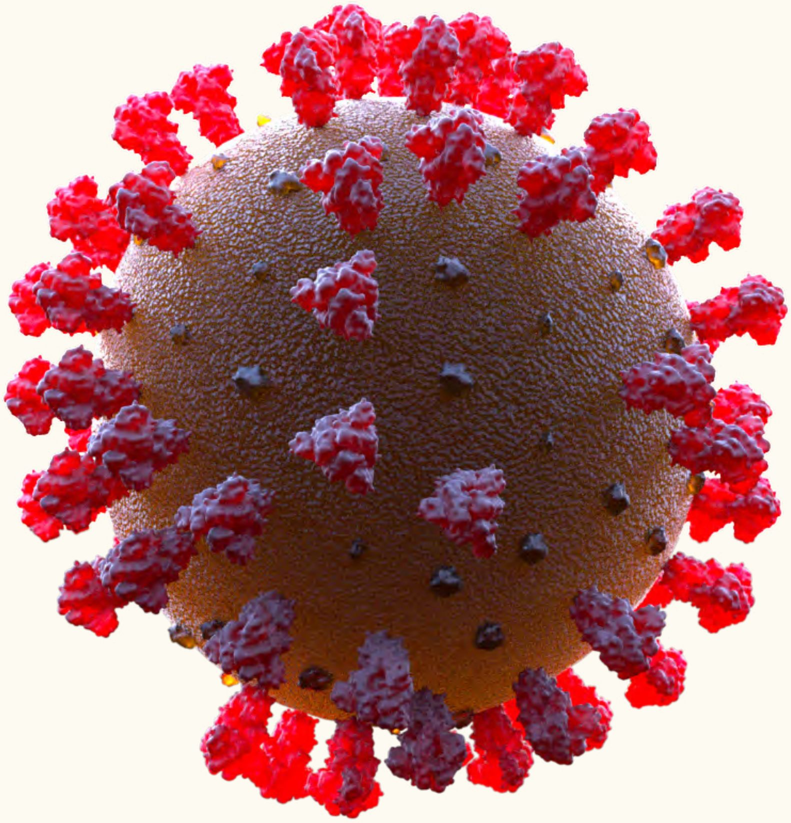
Gaps exist in our understanding of the dynamics of disease transmission in different populations over time and the factors that influence a population's susceptibility to severe disease. NIH will support research to understand and address the behavioral and social factors that impact the spread of the virus. NIH-supported clinical epidemiology programs will leverage existing clinical and community-based research platforms to characterize the clinical features and disease course of COVID-19. Population-level studies will be used to explain the role of different factors in driving disease severity and outcomes, including but not limited to older age; sex; social determinants of health; and such comorbidities as diabetes, cancer, cardiovascular disease, kidney and digestive diseases, and pain and substance use disorders.

Objective 1.4: Understand COVID-19 disease progression, recovery, and psychosocial and behavioral health consequences

As people across the United States and around the world respond to the COVID-19 pandemic, the body of research from prior disasters and other stressful and traumatic events indicates that this experience likely will have a negative impact on people and their health through psychosocial, behavioral, and economic factors. NIH will support research to understand and address the impacts of the virus and the public health measures used to prevent its spread—such as physical distancing, shelter-in-place orders, and quarantining—on social epigenomic pathways (how social experiences affect genes and biology); mental and physical health; substance use; and well-being, illness, and recovery. In addition, studies will explore the health consequences from delayed care not only for COVID-19, but also for routine preventive practices (e.g., vaccinations) and detection and treatment of diseases and conditions (e.g., cancer).

These studies will focus on the effects of COVID-19 across the lifespan and in different populations, including vulnerable populations. Research also will investigate the long-term effects of recovering from COVID-19, as well as physical, environmental, neurobiological, social, and behavioral factors. Researchers, clinicians, and public health professionals across various disciplines will need to work together to understand which therapies work in specific populations, find any disparities in effectiveness, and understand why some individuals respond to available treatments differently than others.

PRIORITY 2



Advance Detection and Diagnosis of COVID-19

As Americans return to public spaces, a vital component of the Nation's strategy is detecting, diagnosing, and surveilling the population to identify and quarantine COVID-19 cases and track the spread of the virus. Despite an exponential increase, current testing capacity still is insufficient to meet the Nation's needs—both in terms of the number of tests available and their ability to deliver answers rapidly at the point of care. To develop more accurate, rapid, scalable, and accessible tests, NIH is committed to aggressively accelerating the development, validation, and commercialization of innovative COVID-19 testing technologies, focusing efforts both on viral tests—which indicate whether a person has a current infection—and on antibody, or serological, tests—which indicate if a person has had a previous infection. To this end, NIH will continue to advance a wide range of initiatives to improve or repurpose current technologies and advance new ones.

Objective 2.1: Support research to develop and validate new diagnostic technologies

NIH will support the development and validation of new diagnostics, including nucleic acid tests and viral antigen detection tests, that can identify the presence of the virus in biospecimens. Most current testing for the virus depends on detection of the viral RNA using a polymerase chain reaction test. These tests are accurate, but they generally require a central laboratory with expert technical staff and specialized equipment. Newer alternatives may be able to carry out this kind of nucleic acid detection with a simple point-of-care device. Another alternative that NIH-supported researchers are pursuing is called viral antigen testing, which detects the virus protein capsule. Antigen tests are traditionally less sensitive, but they can be modified for at-home use, enabling easier and more frequent testing.

To address the need for better diagnostics, NIH has launched the Rapid Acceleration of Diagnostics (RADx) initiative to speed innovation in COVID-19 testing technologies, with the potential of delivering rapid, widely accessible testing strategies to the public (Box 2). The RADx Tech arm of RADx aims to speed the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improve clinical laboratory tests that can detect the virus directly. RADx Tech will expand the existing Point-of-Care Technology Research Network and use a flexible approach to infuse funding and enhance technology designs at key stages of development. New technologies may employ less invasive sampling techniques, such as saliva collection, or other approaches, such as viral antigen testing to detect the virus protein capsule, and they will be designed to meet the needs of various settings, such as hospitals, schools, and places of business.

A range of additional NIH intramural and extramural activities will catalyze the development of other new diagnostic technologies. RADx Radical (RADx-rad) (Box 2) will support nontraditional approaches that address current gaps in COVID-19 testing, including breath detection of SARS-CoV-2, community wastewater detection, and changes in sensory functions (e.g., taste, smell). The program also will support new or nontraditional applications of existing approaches to make them more usable, accessible, or accurate. Other NIH intramural and extramural activities will focus on the development or adaptation of diagnostic approaches that include wearable, implantable, and remote sensors; medical imaging technologies combined with informatics solutions and artificial intelligence for detection and monitoring; and noncontact sensing and imaging for rapid mass screening and vital sign assessment.

Objective 2.2: Retool existing diagnostics for detection of SARS-CoV-2

In addition to catalyzing the development of novel COVID-19 diagnostic technologies, NIH will support efforts by scientists to repurpose, modify, or improve diagnostic tools currently available or under development. For example, researchers are developing microfluidic chip models of COVID-19 to enable rapid detection of SARS-CoV-2 infection. Researchers in the NIH intramural program are shifting their focus to repurpose diagnostic technologies and improve the speed, accuracy, and utility of tests that are available currently, including the use of imaging technologies for early detection of COVID-19 in the lungs and the use of artificial intelligence to improve diagnosis based on imaging.

As part of the repurposing effort, diagnostic technologies must be scaled up rapidly to increase access to and throughput of COVID-19 testing. Another component of the RADx initiative (Box 2), RADx Advanced Technology Platforms (RADx-ATP), seeks to scale up existing technologies (e.g., high-throughput platforms), expand the use of platforms suitable for testing centers providing access to underserved populations, and identify next-generation diagnostic testing platforms that could be scaled to population-level testing. NIH also will refocus efforts on research to alleviate potential supply chain issues. For example, to address potential shortages, researchers in the NIH intramural program are producing and evaluating the viability of several 3D-printed swabs.

Objective 2.3: Support research to develop and validate serological assays

Serology tests—also called antibody tests—detect the presence of antibodies in a person's blood. Someone who has antibodies to a virus, such as SARS-CoV-2, was infected at some point in time. However, because antibody tests do not look for pieces of the virus itself, they cannot be used to diagnose COVID-19 or determine if someone is infectious.

Currently, it is unclear whether the presence of SARS-CoV-2 antibodies correlates with lasting immunity and, if so, how durable and protective the antibodies are. However, if that correlation can be proven, serology tests will play an important role in facilitating the shift back to a more open and public environment and may help determine who can return to work or school safely. NIH's focus on accelerating the availability of high-quality serology tests is a key part of its participation in the interagency team to develop a national strategy for serology diagnostics to support return to work. Serology tests also are crucial for determining the efficacy of promising therapeutic or vaccine candidates and for studies of disease prevalence and

Box 2 – RADx: Rising to the Challenge of Widespread Testing

Over the last century, advances in biotechnology have improved medical treatment and saved lives. Now, as the United States fights a devastating public health threat, the Rapid Acceleration of Diagnostics (RADx) initiative is calling on scientists and engineers to put forward their most promising biomedical technologies and implementation strategies to answer the pressing need for SARS-CoV-2 testing. RADx is a nationwide program aimed at speeding the development and commercialization of rapid, easy-to-use diagnostic tests. The program also will support innovative approaches for implementation, expansion, accessibility, and acceptance of existing diagnostic testing. The RADx initiative consists of four key components:

- **RADx Tech** supports scientists and inventors through a nationwide competition to expand the type of access to testing technologies for point-of-care COVID-19 diagnostics and improved laboratory-based testing. NIH began the initiative with a call for innovative technologies that can be developed or repurposed to meet the pressing need for COVID-19 tests. Candidates are advancing through a phased review process, which will include appropriate funding for specific deadlines and deliverables and mentorship from experts in business, technical, and regulatory fields.
- **RADx Radical (RADx-rad)** will advance nontraditional, but potentially transformational, approaches and repurposing of existing approaches for COVID-19 testing. With longer development timelines, RADx-rad projects will address gaps in SARS-CoV-2 testing through technology platforms that can be used in future outbreaks of COVID-19 and that could be applicable to other, as yet unknown, infectious organisms.
- **RADx Advanced Technologies Platform (RADx-ATP)** will focus on reducing barriers for scaling up advanced technologies to increase the capacity for rapid, high-throughput testing infrastructure. Additionally, RADx-ATP will seek to identify next-generation diagnostic testing platforms that are reduced to practice at modest scale but could be scaled rapidly to population-level testing.
- **RADx Underserved Populations (RADx-UP)** will leverage existing community partnerships to build community-engaged demonstration projects focused on identifying effective implementation strategies to enable and enhance testing for underserved and vulnerable populations. This will include development of a Coordination and Data Collection Center, a collaborative network of clinical research centers across the country, and a program studying the social, ethical, and behavioral implications.

RADx aims to support innovative technologies to provide millions of additional rapid, easy-to-use, diagnostic tests for the United States by the fall of 2020 and identify and employ evidence-based implementation strategies to increase accessibility and acceptance in those populations most affected by this deadly pandemic. By calling on the ingenuity and inventiveness of U.S. scientists and engineers, NIH will advance diagnostic tools to prevent the spread of COVID-19, improve health, and save lives.

spread through communities. For example, NIH, in partnership with the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA), is developing tests that identify antibodies to SARS-CoV-2 to determine how many people have been infected, including asymptomatic people. These efforts also could potentially be used to distinguish antibody responses in individuals receiving vaccines. To understand where and when COVID-19 arrived in the United States, the *All of Us* Research Program is performing serology testing on blood samples from its hundreds of thousands of participants, working backwards until the timepoint at which antibodies first show up in samples.

Serological tests are improving, and it is vital that the tests being developed and authorized for use are as accurate as possible. NIH is collaborating with the Biomedical Advanced Research and Development Authority (BARDA), CDC, and FDA to validate commercial and academically developed tests. Other validation efforts are leveraging NIH programs already in place. The Recipient Epidemiology and Donor Evaluation Study (REDS) Program, which works to protect the Nation's blood supply, will analyze blood samples from before and after the start of SARS-CoV-2 community transmission to validate serology tests. The REDS Program also will establish a repository for sharing data with government, academic, and industry scientists to advance serological testing and vaccine development.

PRIORITY 3

Advance the Treatment of COVID-19

When the COVID-19 pandemic began, FDA-approved treatments for coronaviruses did not exist. Normally, the discovery and development of a new therapeutic is a years-long process. The unprecedented need brought on by the COVID-19 pandemic has compelled a paradigm shift in that process to enhance the sharing of knowledge, resources, and infrastructure among academics, Federal agencies, and industry. Through such a shift, the goal is to compress the timeline for discovery and development of therapeutics to treat COVID-19 from years to months while continuing to apply rigorous standards to ensure safety and efficacy. To this end, NIH assembled the ACTIV partnership (Box 1) and will continue to work closely with other government agencies organized through Operation Warp Speed (Box 3).

Box 3 – Operation Warp Speed: Accelerating Delivery of Countermeasures to Americans

In response to the pandemic sweeping the United States and the world, the White House has launched a national program called **Operation Warp Speed**, whose marquee goal is to develop, produce, and distribute 300 million doses of safe and effective vaccines for COVID-19 by January 2021. This aim is part of a larger effort to develop diagnostics, therapeutics, and vaccines (collectively known as countermeasures) for COVID-19 and was undertaken by trans-governmental partners from the Department of Health and Human Services (HHS)—including NIH, Biomedical Advanced Research and Development Authority, Centers for Disease Control and Prevention, and U.S. Food and Drug Administration—and the Department of Defense. Operation Warp Speed will coordinate ongoing HHS-wide efforts—for example, NIH's ACTIV public-private partnership and the Rapid Acceleration of Diagnostics (RADx) initiative—and facilitate collaborations with private partners and other Federal agencies to accelerate the pace of countermeasures development without sacrificing safety or efficacy. This Federal collaboration is selecting the most promising candidates for evaluation, coordinating centralized clinical evaluation protocols for use by collaborators in evaluating candidate countermeasures, and jumpstarting the manufacturing process for promising candidates. This ambitious effort is made possible by simultaneously managing multiple steps, such as starting manufacturing of a vaccine candidate at industrial scale before the demonstration of vaccine efficacy and safety has concluded, as would happen normally. The program also will build the distribution infrastructure in advance of the approval and manufacturing of countermeasures, leveraging pandemic preparedness protocols developed during the 2009 H1N1 pandemic influenza response. Companies with candidates being tested in cooperation with Operation Warp Speed will provide the government with a portion of any countermeasures produced to ensure safe, affordable diagnostics and interventions for the American people.

Objective 3.1: Identify and develop new or repurposed treatments for SARS-CoV-2

NIH has established a multipronged approach to discover or repurpose promising candidate therapies for SARS-CoV-2 using advanced screening methods, such as human cell–based models, as well as animal models, to identify promising therapies that may interfere with the production of the virus or the ability of the virus to infect cells. NIH-supported researchers will continue to seek out and characterize candidate therapeutics that target viral and host proteins that play an important biological role in SARS-CoV-2 replication and infection. Data science tools will be critical to this endeavor; NIH intramural and NIH-supported researchers already are creating complex computer-generated models of SARS-CoV-2 and its biological processes to determine key interactions and pathways to target for therapeutics development.

Other therapeutic approaches involve passively boosting the immunity of people infected with SARS-CoV-2 by infusing convalescent plasma from patients recovered from COVID-19, pooling such blood products into hyperimmune globulin, or by developing monoclonal antibodies designed to target and neutralize the virus. NIH researchers and partners from across the globe have begun isolating, cloning, producing, and evaluating such protective, neutralizing antibodies from people who have recovered from COVID-19. Some of these monoclonal antibodies already are on a pathway to clinical testing.

In addition to new therapeutics, researchers are looking for ways to repurpose drugs approved for other indications to treat COVID-19. NIH-supported researchers, partners, and intramural staff are screening existing FDA-approved therapeutics for activity against SARS-CoV-2, strategically targeting pathways identified in fundamental coronavirus research studies as essential to virus production or infection. Within a few months of the pandemic's beginning, NIH collaborated with industry partners to show that the antiviral remdesivir, a drug formerly tested for the treatment of Ebola, accelerates the recovery of hospitalized, oxygen-supplemented patients with severe COVID-19. Additional clinical trials are planned or are underway to evaluate the efficacy of other repurposed drugs that have shown signs of antiviral activity in cell-based assays.

Objective 3.2: Evaluate new, repurposed, or existing treatments and treatment strategies for COVID-19

The multiorgan, multisystem involvement of severe COVID-19 prompts critical questions about its immediate and long-term impact, particularly in people with preexisting conditions. The severity of COVID-19 varies widely and can involve a number of different systems, including the cardiovascular, nervous, renal, and respiratory systems. It is unknown at this time if COVID-19 results in long-term health consequences, so continued evaluation of COVID-19 patients and the development of long-term treatment strategies may be necessary.

The multifaceted nature of COVID-19's impact on body systems necessitates evaluating a wide range of therapies that target disease processes resulting from SARS-CoV-2 infection. As part of this broad approach to therapy, NIH will evaluate treatment strategies that target the body's response to the virus, as well as evidence-based complementary health approaches. Treatment strategies could include approaches to address disease processes resulting from COVID-19, such as tissue injury, blood clotting, overreaction of the immune system, and inflammation. NIH also will evaluate medical care strategies that seek to improve COVID-19 outcomes, recognizing that individuals who receive critical care interventions, in particular, may require ongoing rehabilitation during recovery.

To facilitate the testing of both antiviral and disease process-targeted treatments for COVID-19 and its complications, NIH will create new research networks and leverage clinical trial networks supported by Institutes, Centers, and Offices across NIH, including the Clinical Center. These networks will be used to conduct a variety of flexible, adaptive clinical trials and support clinical trials designed in real-world hospital settings, called pragmatic clinical trials. NIH is collaborating with Federal, industry, and academic organizations through such partnerships as ACTIV (Box 1) to increase the capacity to conduct clinical trials across all phases, from pilot studies to large safety and efficacy trials. These partnerships will streamline recruitment and hasten the collection of data needed for FDA approval to ensure that new or repurposed interventions will be advanced as quickly as possible.

Interventions and treatment strategies will cover the breadth of populations affected by COVID-19, including populations with other medical conditions and diseases (e.g., HIV infection, diabetes, cancer). For example, the NIH intramural program is adapting clinical protocols to evaluate therapeutics, such as the inflammatory mediator tocilizumab, in cancer patients with COVID-19.

Objective 3.3: Investigate strategies for access to and implementation of COVID-19 treatment

The resolution of the COVID-19 pandemic will depend on the expeditious and broad dissemination of treatment strategies and care practices for use by health care practitioners while ensuring that all members of the public have access to COVID-19 treatment. Delays in the adoption of the updated clinical practices could result in unnecessary prolongation of the pandemic, additional lives lost, and increased economic burden.

NIH will build on existing dissemination and implementation science research, both by testing the adaptation of strategies that have been successful in other disease areas, such as HIV and tuberculosis treatment, and by supporting new studies that examine methods to disseminate, provide access to, and facilitate uptake of interventions for COVID-19. Community-engaged research strategies will be critical to the success of implementing interventions, particularly for underserved and vulnerable populations (e.g., African Americans). These populations are disproportionately affected by, have the highest infection rates of, or are the most at risk for complications or poor outcomes from COVID-19. Community-engaged research will provide access to local communication channels, resources, and social infrastructure that can aid the design of tailored, local strategies to mitigate implementation barriers for underserved and vulnerable populations, such as barriers resulting from social determinants of health.

Essential to these goals is the consideration of cultural, ethical, social, behavioral, historical, and economic factors associated with evaluating interventions, as well as the collection, storage, and dissemination of health-related data. NIH will support in-depth examinations of such topics as barriers to and implications of treatment; stigma and financial burden associated with COVID-19 treatment and follow-up care; and privacy, confidentiality, and data sharing.

PRIORITY 4

Improve Prevention of SARS-CoV-2 Infection

Critical to resolving the current COVID-19 pandemic and preventing future outbreaks is the development of countermeasures to stop transmission of the virus and prevent new infections. By supporting the development of new vaccines, behavioral and community interventions, and effective strategies for implementation of these countermeasures, NIH will create preventive interventions that have the potential to reduce the incidence of new SARS-CoV-2 infections across the country. The NIH approach will leverage existing knowledge, tools, networks, and infrastructure—in addition to developing and implementing novel approaches—to prevent new SARS-CoV-2 infections.

Objective 4.1: Develop novel vaccines for the prevention of COVID-19

To prevent future outbreaks of COVID-19, safe and effective vaccines for SARS-CoV-2 must be developed and distributed as quickly as possible. As soon as the SARS-CoV-2 genetic sequence became public in January 2020, NIH-funded scientists began working at an unprecedented pace to identify, develop, and test promising vaccine candidates, several of which are described in the *NIAID Strategic Plan for COVID-19 Research.* The NIH intramural program has played an important role in the early testing and development of several vaccine candidates, including those that showed potential for preventing infection from similar coronaviruses.

Advancing promising vaccine candidates through preclinical study, clinical testing, and regulatory approvals will require extraordinary coordination of Federal and industry partners via collaborations and partnerships. As is the case for therapeutics, the ACTIV public-private partnership (Box 1) is playing a critical role in coordinating research efforts between NIH, FDA, and industry. The multiple governmental roles and decisions about government funding are being coordinated by the Operation Warp Speed initiative (Box 3). For preclinical identi-fication of promising candidates, NIH and its partners are ensuring that needed resources, such as appropriate animal models, are available. Across the developmental spectrum, NIH and its partners also are ensuring the availability of vital vaccine supplies, including samples, adjuvants to increase the effectiveness of vaccines, and reagents. In addition, several vaccine formulations—which save time in development by using common, basic components that can be quickly adapted for new genetic targets—also are being studied for potential use against SARS-CoV-2 infection.

To coordinate and accelerate clinical testing, NIH and its partners are leveraging existing clinical trial networks, such as the HIV Vaccine Trials Network; HIV Prevention Trials Network; Infectious Diseases Clinical Research Consortium; and Prevention and Early Treatment of Acute Lung Injury Network (PETAL Network), which conducts trials to improve prevention and treatment of acute respiratory distress syndrome. NIH also has created the COVID-19 Prevention Network, which will provide centralized data coordination and integrated clinical site use and use novel epidemiological disease tracking tools to speed the evaluation of potential vaccines. Ensuring the participation of a broad range of populations in clinical testing, including high-risk groups, is a priority. Efficacy studies will be designed to include older individuals, people with comorbidities, and underserved populations. Once safety tests are completed, vaccines will be evaluated in pregnant women and children. With the strategy outlined here, NIH will work to end the pandemic by supporting research into multiple effective and broadly distributable SARS-CoV-2 vaccines.

Objective 4.2: Develop and study other methods to prevent SARS-CoV-2 transmission

Until a SARS-CoV-2 vaccine is developed, alternative methods to slow the spread of the virus will be necessary. NIH will support studies on preventive treatments, behavioral and community prevention practices, and policies to rigorously study and determine the most effective approaches to promote individual and community safety. NIH has worked to study and inform effective prevention practices through basic research into the mechanisms of viral survival, infection, and transmission.

Antibody treatments, in addition to their potential therapeutic use, hold promise as a method to prevent COVID-19 in individuals exposed to SARS-CoV-2 and those who are at high risk of serious illness, and they will be investigated as a potential prevention strategy. Research into the survival of SARS-CoV-2 in the environment and its transmission through respiratory droplets already has guided the understanding of how physical distancing and personal protective equipment (PPE) can be applied to prevent viral spread. Modifiable risk factors, such as environment and nutrition, and interactions with preexisting biological factors, such as epigenetics and metabolomics, that may contribute to a person's susceptibility to SARS-CoV-2 infection will be studied to better understand a broad range of prevention methods.

Some research results suggest that SARS-CoV-2 can be transmitted to an uninfected person through contact with an infected person who does not show signs of disease (i.e., is asymptomatic). In that case, traditional containment strategies (e.g., testing only people with symptoms, contact tracing, quarantining) may not be effective. NIH is supporting research into alternative tracing methods, including digital tracing via smartphones, to intervene and reduce transmission of SARS-CoV-2.

NIH also supports further research into effective practices for PPE use and reuse, as well as the development of new PPE, to protect health care workers, caregivers, and the public. NIH prioritizes the safety of health care workers and caregivers and will work to build scientific knowledge of the best decontamination methods and other safety measures specific to the needs of health care environments, such as nursing homes, dental practices, and hospitals. The National Institute of Environmental Health Sciences Worker Training Program will support grants to create virtual worker-based trainings for COVID-19 frontline responders and will serve as a clearinghouse for sharing training resources. NIH also is supporting research into the development of practices and innovative decontamination technologies and procedures, such as the use of ultraviolet light, heat, and chemical procedures to decontaminate and reuse N95 respirator masks.

Objective 4.3: Develop effective implementation models for preventive measures

NIH and its funded scientists will leverage existing and new interagency collaborations to determine the best possible methods for developing, implementing, and distributing vaccines and behavioral prevention methods against SARS-CoV-2. Before vaccines are made available, rigorous research will be needed to ensure critical questions about the most effective distribution practices are answered. Ensuring vaccines are delivered to at-risk individuals, in high-need areas, and with proper administration techniques will be critical to preventing further outbreaks. Key to this research will be finding methods to address social, ethical, and behavioral factors likely to influence the use of vaccines and other prevention practices.

NIH will leverage its existing infrastructure and create new infrastructure to address and promote vaccine readiness and investigate effective communication strategies and implementation procedures for all prevention methods. Communities with limited access to technology and timely and accurate information will be a focus of the implementation of any studies on effective preventative measures. In addition, overcoming fears and addressing concerns about vaccine use will be an aspect of NIH's implementation research and communication efforts using community-engaged research methods. NIH will complete studies into the social and ethical implications of proposed approaches to prevent SARS-CoV-2 infection, from vaccines to community practices, and will create the opportunity to address ongoing health disparities and ensure adequate protection across diverse communities.

PRIORITY 5

Prevent and Redress Poor COVID-19 Outcomes in Health Disparity and Vulnerable Populations

The impact of COVID-19 on health disparity,[1] underserved, and vulnerable populations in the United States and abroad must be urgently addressed. Preliminary data show consistent differences in COVID-19 prevalence and mortality across different age, racial, and ethnic groups, and among specific populations (e.g., people with asthma or diabetes).[2] The underlying causes are complex and include social and structural determinants of health—such as social, economic, and political mechanisms that generate inequalities in society

[1] Health disparity populations include Blacks/African Americans, Hispanics/Latinos, American Indians/Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities.

[2] Populations with increased risk of COVID-19 include residents of chronic care and assisted living facilities; community-dwelling older adults; individuals with rare diseases; individuals with cognitive impairment or dementia; homeless populations; incarcerated populations and those involved with the criminal justice system; adults with medical comorbidities; pregnant women; children and adolescents; individuals with substance use disorders or severe mental illness; those living in congregate housing; persons who are deaf or with disabilities, including visual, hearing, communication, or mobility impairment; detainees in immigration centers; migrant communities; individuals living on tribal lands or reservations; and communities that are exposed to high rates of air pollution or other toxic exposures. Individuals who are on the frontlines of health care during the COVID-19 pandemic and those working in essential business operations also are at higher risk for COVID-19.

(e.g., discrimination, economic and educational disadvantages)—and differences in health care access and quality. These concerns are amplified in lower- and middle-income countries with fragile health care systems, densely populated urban areas where physical distancing is not possible, and communities with high rates of chronic health conditions. A deeper understanding of the underlying causes that may exacerbate the spread and morbidity or mortality of COVID-19 in the United States, as well as different countries around the globe, may allow the scientific, public health, and clinical communities to efficiently implement interventions to mitigate negative outcomes through better prevention, testing, and treatment of COVID-19. NIH aims to address key questions related to the differential impacts of the COVID-19 pandemic. These include understanding barriers to adherence to different mitigation strategies among populations and differences in risk and resilience based on biological factors, gender, race and ethnicity, socioeconomic status, ability, and other social and structural determinants of health. Ultimately, the United States will not be able to control the global pandemic alone. NIH will continue to collaborate with the global scientific community not only to understand the spread of COVID-19 but also to develop and distribute the diagnostics, treatments, and vaccines needed to control COVID-19 on a global scale.

Objective 5.1: Understand and address COVID-19 as it relates to health disparities and COVID-19–vulnerable populations in the United States

As part of the RADx initiative, NIH will fund a series of interlinked community-engaged projects to enhance testing of underserved, underresourced, and rural populations across the United States for COVID-19. This initiative will develop infrastructure to assess and expand evidence-based testing capacity for those populations that are most at risk for infection and adverse outcomes from contracting the virus. RADx Underserved Populations (RADx-UP) projects will establish pragmatic and other clinical trials at multiple sites across the country to investigate a variety of testing methods and approaches to better understand the uptake, acceptance, and effectiveness in specific populations (Box 2). RADx-UP projects will partner with community health centers (e.g., Tribal health centers, Health Resources and Services Administration community health centers, Federally Qualified Health Centers), medical libraries, houses of worship, homeless shelters, jails and prison systems, and other community resources to address the unique needs of different communities. The implementation and evaluation of new community interventions addressing the impact of mitigation strategies to prevent SARS-CoV-2 transmission—as well as the adverse psychosocial, behavioral, and socioeconomic consequences of the pandemic on health disparity populations—are crucial. Related efforts include holding an emergency consultation with Tribal leaders and others in the American Indian/Alaska Native community to discuss programs focused on enhancing testing capacity to better understand the best strategies for redressing the COVID-19 pandemic in these populations. Importantly, NIH is committed to including individuals who have been traditionally underrepresented in biomedical research in clinical trials for treatments and vaccines to understand how interventions may affect these populations differently and ensure the applicability of findings to all. For example, the trans-NIH INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) initiative will support research that explores the effects of COVID-19 on individuals with Down syndrome.

Objective 5.2: Understand and address COVID-19 maternal health and pregnancy outcomes

Pregnancy is associated with alterations in the immune system, resulting in increased susceptibility to certain viral, bacterial, and parasitic infections, which may adversely impact maternal morbidity, preterm birth, and infant health. More specifically, other respiratory viral infections, such as influenza, are associated with more severe disease outcomes in pregnant women and an increased risk of pregnancy and neonatal complications. Yet, there is a scarcity of information about SARS-CoV-2 infection and disease in pregnant women. Independent of COVID-19, women in the United States from underserved populations face substantially higher rates of pregnancy-related complications (i.e., severe maternal morbidity) and pregnancy-related death compared to non-Hispanic white women. Up to 60 percent of pregnancy-related deaths are preventable, highlighting inequities in health care access and quality-of-care factors that contribute to racial disparities in maternal mortality and severe morbidity. As such, NIH will leverage existing research on maternal morbidity and mortality to investigate questions related to pregnancy and COVID-19, including the effects of SARS-CoV-2 infection and treatment of COVID-19 on maternal and fetal health during pregnancy, as well as pregnancy outcomes. NIH has initiated large-scale studies to investigate the effects of COVID-19 on such factors as pre- and postnatal care, rate of Cesarean section delivery, and maternal health complications. Research also is needed to understand possible mother-to-fetus transmission, possible mother-to-child transmission at birth, and possible transmission via breastfeeding. NIH also will support research on the use of therapeutics to treat COVID-19 during pregnancy and breastfeeding.

Objective 5.3: Understand and address age-specific factors in COVID-19

Certain age groups are at higher risk for serious complications from SARS-CoV-2 infection, such as older adults (65 years and older). NIH will support studies of neurological and neurocognitive symptoms in COVID-19 and complications associated with SARS-CoV-2 infection in older adults. In addition, NIH will fund research to explore the role of inflammation in older populations with COVID-19 and subsequent progression to more severe disease, including lung pathology and acute respiratory distress syndrome. NIH also will seek to develop aged animal models (including nonhuman primates) or *in vitro* models suitable for studies on pathogenesis of the virus or preclinical testing of therapeutics and vaccines against SARS-CoV-2.

Although the majority of children and young adults have mild, moderate, or asymptomatic cases of COVID-19 compared to adults, new reports suggest that studies are needed to address the dynamics of the virus and the immune response in children and adolescents, as well as short- and long-term outcomes. For example, the NIH Human Epidemiology and Response to SARS-CoV-2 (HEROS) study will help determine what percentage of children infected with SARS-CoV-2 develop symptoms of the disease. Recent data also suggest that undiagnosed infections in children may present later as a pediatric inflammatory syndrome similar to Kawasaki disease called multisystem inflammatory syndrome in children (MIS-C). MIS-C is a condition in which different body parts—including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs—can become inflamed. Although the causes of MIS-C are unknown, the weight of evidence supports a postinfectious inflammatory mechanism. It is known that many children with MIS-C either were infected with SARS-CoV-2 or were exposed to someone with COVID-19. A trans-NIH effort is underway, in coordination with other Federal partners, to implement a research plan to investigate MIS-C that will describe the spectrum of pediatric SARS-CoV-2 infection and identify MIS-C risk factors, natural history, long-term outcomes for patients, treatment response, potential therapies, and other critical research questions to impact patient health. NIH also will study the impact of the COVID-19 pandemic on brain development and other outcomes from birth through adolescence.

Furthermore, NIH will ensure that treatments and vaccines developed for COVID-19 are applicable for all, including children. To that end, the Pediatric Trials Network will use more than 50 established research sites to evaluate drugs given to children diagnosed with COVID-19. Researchers will analyze blood samples collected from routine medical procedures to under-stand how these drugs move through the bodies of children, as well as collect information on potential side effects and patient outcomes, such as the duration and type of respiratory support that may be needed. These studies are designed to refine dosing and improve safety for use in children. Researchers can expand the products to be tested as scientists learn more about the treatment needs of patients with COVID-19.

Objective 5.4: Address global health research needs from COVID-19

NIH recognizes that a global pandemic requires a global response and will work with international partners to improve fundamental knowledge of SARS-CoV-2 and COVID-19, as well as optimize the development and delivery of diagnostic tests, treatments, and vaccines to populations most in need. Much of the initial knowledge regarding the basic science, epidemiology, and disease characteristics of COVID-19 was gained from or developed in collaboration with the international scientific and medical communities. Collaborations with scientists around the globe have been essential to piecing together the emergence and spread of SARS-CoV-2, and they have helped identify the populations most severely affected. Critical to these efforts are open lines of communication and a collaborative, unified perspective among the international biomedical community. NIH will continue to foster international collaborations to address the COVID-19 public health response on a global level, drawing on a worldwide network of grantees and former trainees, many of whom have leadership roles in global and national responses.

Robust international scientific collaboration will be critical to the development and distribution of diagnostics, treatments, and vaccines needed to control COVID-19 on the global scale necessary for full social and economic recovery. NIH is coordinating efforts with other international COVID-19 product development accelerators to share best practices and information about clinical trials and the advancement of promising new medical countermeasures. Academic and industry collaborations outside the United States will provide critical perspective on SARS-CoV-2 transmission, track molecular changes in the virus, establish epidemiological tools to help monitor outbreaks and new infection patterns, and help develop countermeasures against the virus. By applying lessons learned from implementation and dissemination science studies in low- and middle-income countries, where health care providers do not have ready access to advanced technologies for infectious and other diseases, NIH will employ its international clinical infrastructure and academic relationships and create new collaborations to ensure swift distribution of these diagnostics and interventions to the populations that need them most.

Partnering to promote collaborative science

Supporting the research workforce and infrastructure

Investing in data science

CROSSCUTTING STRATEGIES

To support the five strategic priorities, NIH will pursue crosscutting strategies that build upon its existing strengths as the Nation's premier biomedical research agency. Specific examples of these strategies have been provided throughout this plan.

Partnering to promote collaborative science

NIH will continue current collaborative efforts and establish new ones, including training opportunities, to build a well-prepared academic workforce in the United States and internationally to accelerate research on COVID-19. By leveraging existing NIH-funded global research networks, coordinating closely with its Federal partners, and creating new public-private partnerships, NIH will continue to employ every opportunity to deepen the understanding of and develop interventions for COVID-19. Many NIH-funded research networks already have been mobilized to address COVID-19—including those focused on specific practice areas, particular demographics, or otherwise at-risk populations—such as the PETAL Network managed by the National Heart, Lung, and Blood Institute.

NIH will both continue and expand collaborations with its fellow agencies and offices within the Department of Health and Human Services (HHS) (e.g., BARDA, CDC, FDA) and beyond (e.g., Department of Defense) to ensure efficient and rapid dissemination of diagnostics, treatments, and vaccines to the public. Furthermore, NIH and its Federal partners, including those involved in Operation Warp Speed (Box 3), will continue to work closely and recognize the importance of collaboration with the private sector, scientific societies, nonprofit organizations, patient communities, and health care providers.

Supporting the research workforce and infrastructure

Despite challenges presented by the pandemic and measures put in place to limit its spread, NIH has worked with the scientific community to advance COVID-19 research. By adapting its processes to work within the physical distancing constraints of the pandemic, NIH will continue to process proposals and fund research projects in a timely manner. For example, NIH has expanded its use of virtual meetings to conduct peer reviews to protect the health of reviewers and NIH staff while facilitating the funding of COVID-19 and other research. NIH also will continue to support researchers by providing validated biosamples and funding the expansion and retooling of research facilities. Furthermore, NIH will solicit innovative ideas to aid the COVID-19 response, potentially from investigators outside of infectious disease or virology research, through such mechanisms as the NIH Common Fund High-Risk, High-Reward Program. Ideas may relate to basic research, novel diagnostic strategies, vaccines, or therapeutics.

In addition to funding COVID-19 research in the extramural community, NIH will continue to mobilize its Intramural Research Program and the Clinical Center in support of COVID-19 research. Talented investigators will use NIH's specialized infrastructure that supports unique patient cohorts and clinical trials networks, as well as its state-of-the-art equipment, to deliver one-of-a-kind services relevant to COVID-19. These efforts will take advantage of a unique and wide range of research and technological expertise, as well as partnerships and collabo-rations with extramural investigators. Projects are underway to evaluate and validate serology tests, design and assess PPE, and complete onsite clinical trials and basic science research. NIH will maximize the capacity and use of its vaccine treatment and evaluation units to enroll participants rapidly and evaluate vaccine candidates in a safe and effective manner.

Investing in data science

To accelerate the pace of scientific discovery, NIH will support multiple data science efforts to ensure that COVID-19 research data are findable, accessible, interoperable, and reusable (the FAIR principles). By enhancing existing and creating new data science resources and analytical tools, NIH will facilitate the use of COVID-19 data to the greatest extent possible, both by those generating the data and by other researchers. These investments will support development of diagnostic tools, survey instruments, risk assessment models, public health surveillance tools, and portals to share data, among others (e.g., NIH Repository of COVID-19 Research Tools, OpenData Portal, PhenX, SHIELD [Systemic Harmonization and Interoperability Enhancement for Laboratory Data Collaborative], and SPHERES [SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance]). NIH investments to develop shared metrics and terminologies across research projects will facilitate and maximize the use of a wide breadth of data, from chemical structures to clinical trial results.

Through these approaches, NIH will continue to explore and implement innovative ways to leverage its domestic and global infrastructure to address the needs of the COVID-19 pandemic and speed its resolution.

CONCLUSION

At the start of the COVID-19 pandemic, NIH and the biomedical community immediately began an unprecedented effort to diagnose, prevent, and treat this rapidly spreading disease. NIH has collected innovative and creative ideas from across the country, built new partnerships, and in alignment with interagency partners has designed a bold and ambitious plan for protecting the American people from the novel coronavirus. These efforts already have shed light on the virus, its biology, and promising approaches to mitigate the pandemic. Preparing for future epidemics and enhancing response capacity will be a vital legacy of this work.

The discoveries made by NIH scientists and NIH-funded investigators have built on countless technological advances to biomedical science. Genome sequencing, imaging technologies, data science and bioinformatics, and implementation science all have contributed to our knowledge of SARS-CoV-2 and COVID-19. To meet current needs, the approach to biomedical research has shifted in groundbreaking ways. By bringing together teams across a range of sectors and scientific disciplines and building on discoveries of the past, NIH will continue to take a crosscutting, integrative view of public health to put forward creative and bold strategies to end the COVID-19 pandemic.

The COVID-19 pandemic is the latest reminder of the constant threat of emerging and re-emerging infectious diseases to the health of the American people. These pathogens require constant surveillance as they evolve and adapt to environmental pressures. Likewise, NIH must maintain a flexible, adaptable infrastructure to support research programs that aim to understand the fundamental biology of new organisms and their potential impact on human health. These efforts will prepare scientific groundwork to protecting life through this and future public health threats. Under these extraordinary circumstances, NIH will continue to act swiftly to turn discoveries into health.

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