SPECIAL REPORT

Rapid Scaling Up of Covid-19 Diagnostic Testing in the United States — The NIH RADx Initiative

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The first reports of an unusual cluster of pneumonia cases in the city of Wuhan, China, emerged in December 2019, heralding a global pandemic. As of July 13, 2020, more than 3.3 million U.S. residents have received a diagnosis of coronavirus disease 2019 (Covid-19), and more than 135,000 have died.[1] Of great concern are the data showing the disproportionate effect of Covid-19 on ethnic and racial minorities.[2,3] Since January 2020, the National Institutes of Health (NIH) has been involved in multiple wide-ranging collaborative efforts spanning the development of vaccines and diagnostic strategies, the identification and evaluation of safe and effective treatments, the understanding of the natural history of the disease, and the study of racial and ethnic disparities.[4] In this article, we describe the additional role of the NIH in the effort to increase the range and availability of diagnostic tests for the causative virus, SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2).

We begin with a review of current and projected testing capacity needs and review different types of diagnostic tests. We then describe the Rapid Acceleration of Diagnostics (RADx) program, its goals, and its focus on underserved populations. As will become clear, this program represents a dramatic extension of the usual NIH mode of supporting research. RADx was established in just a few days; it covers the entire life cycle of the target technologies; it is tightly focused on timelines and outcomes; it receives applications primarily from small companies; it is partnering with other agencies such as the Office of the Assistant Secretary for Health, the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense; and it is expressly focused on health disparities. We describe here the four components of RADx and their goals, and we end with a review of the challenges ahead.

On April 24, 2020, Congress appropriated $1.5 billion, from the $25 billion provided in the Paycheck Protection Program and Health Care Enhancement Act for SARS-CoV-2 testing, to the NIH. Within 5 days after the legislation was signed into law, the NIH launched RADx to support the development, production scale-up, and deployment of accurate, rapid tests across the country. From a timing perspective, the RADx initiative was conceived by Congress to provide near-term solutions to increase the number of tests available by the fall of 2020, as schools and universities evaluate the safety of in-person classes and as the annual influenza season begins. In the slightly longer term, RADx also aims to support the development and production of innovative diagnostic technologies as well as strategies for making testing available to diverse, vulnerable, and underserved populations through 2021. One of the goals of the RADx initiative is to expand capacity so that by December 2020, approximately 2% of the U.S. population (6 million persons) can be tested per day, with more tests ready for rapid deployment in proportion to national demand.

CURRENT TESTING CAPACITY AND PROJECTIONS

In the week leading up to July 13, 2020, daily diagnostic testing capacity in the United States was fluctuating between 520,000 and 823,000 tests.[5] Models that provide robust estimates of the number of tests needed per day vary widely. Some experts estimated that 900,000 tests per day would be needed in May.[6] Others forecasted the need for 5 million tests per day by June, in-

creasing to 20 million tests per day by July.[7] Although national totals are helpful benchmarks, the models must account for a range of variables, including different levels of regional prevalence and community spread, the needs of high-risk communities (e.g., nursing homes, shelters, prisons, and factories), and the frequencies and types of testing to be conducted. For example, the type and characteristics of a test that are required will differ when testing is conducted to determine personal infection status as compared with evaluating population-level surveillance. Test performance (the limit of detection, sensitivity, specificity, and the positive predictive value), turnaround time, cost, accessibility, and acceptance are critical factors in a successful testing strategy that can meet the needs of individual persons and communities across the country.

TYPES OF DIAGNOSTIC TESTS

Current diagnosis of acute SARS-CoV-2 infection relies on tests that detect either viral RNA or viral antigens.[8] Most existing methods for Covid-19 testing use reverse-transcriptase–polymerase-chain-reaction (RT-PCR) tests that detect nucleic acid sequences specific to SARS-CoV-2. These tests are highly sensitive and specific when conducted in centralized laboratories with standardized protocols, but they require a large amount of laboratory space, complex equipment, regulatory approvals for the laboratory operations, and skilled laboratory leadership and technicians. Results generally take time to become available, with windows ranging from hours to days, and the need for transport of specimens to a central laboratory leads to further delays. For this reason, low-complexity molecular diagnostic point-of-care tests with rapid turnaround have substantial practical advantages.[9] A number of point-of-care tests have now received Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA).[10]

Antigen tests work by detecting the presence of viral proteins and can provide rapid results, similar to the way pregnancy tests operate.[9] Antigen tests can offer fast and scalable point-of-care performance, but they have lower sensitivity than most nucleic acid–based assays.[11] This limitation can be a concern in high-risk settings such as nursing homes, where missing the detection of an infected person can lead to serious consequences. Although a number of manufacturers are known to be developing antigen-based tests, to date only two have received an FDA EUA.[12,13]

Serologic tests that detect antibody response are also being developed by numerous companies, but these tests are not suitable for the diagnosis of acute infection, since human antibodies are not formed until 2 to 3 weeks after viral infection. Thus, their primary use is to document previous exposure to the virus.[14] The development and scaling of serologic tests are not under the auspices of the NIH RADx program.

COMPONENTS OF THE RADx PROGRAM

The RADx program has four components. RADx-tech aims to identify, accelerate the development of, scale up, and deploy innovative point-of-care technologies as early as the fall of 2020. RADx–Advanced Technology Platforms (RADx-ATP) will support the scale-up of somewhat more advanced technologies that can achieve immediate, substantial increases in capacity. RADx-rad (shorthand for radical) will focus on truly nontraditional approaches for testing that have a slightly longer horizon. RADx–Underserved Populations (RADx-UP) will establish community-engaged implementation projects to improve access to testing in underserved and vulnerable populations.

LEVERAGING OUR SCIENTIFIC CREATIVITY — RADx-TECH

The RADx-tech program offers extensive expertise and support to bring the diagnostic technologies that require additional clinical, regulatory, and commercialization assistance from development to deployment. The RADx-tech program uses a rigorous, rapid-review process that provides independent evaluation of the technology and the potential to scale. The program leverages the long-standing Point-of-Care Technology Research Network (POCTRN), which is run by the National Institute of Biomedical Imaging and Bioengineering.[15] In a process based on an "innovation funnel," applications move rapidly through multiple review gates that involve increasing selection pressure (Fig. 1).

On entering the innovation funnel, each project is evaluated by a team with wide-ranging expertise. Projects that are deemed to be promising enter into to a weeklong intensive review pro-

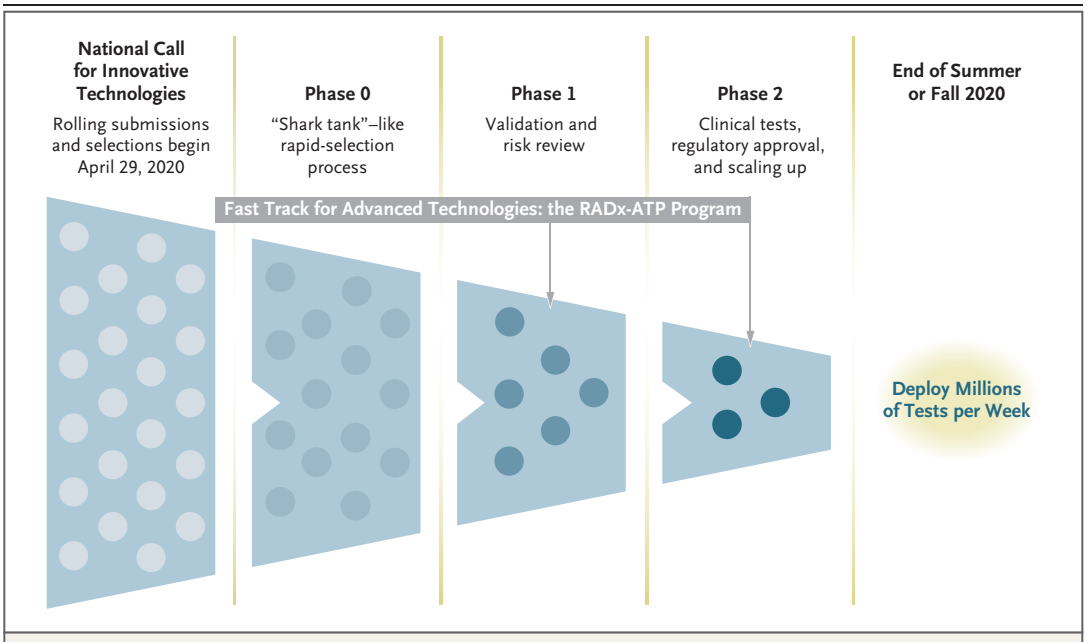

Figure 1. RADx-tech Innovation Funnel to Evaluate Testing Technologies for Covid-19.

Applications to the Rapid Acceleration of Diagnostics (RADx)–tech program for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes coronavirus disease 2019 (Covid-19), move rapidly through an "innovation funnel" from phase 0 to phase 1 to phase 2, with increasing selection pressure at each gate. The RADx–Advanced Technologies Platforms (RADx-ATP) program identifies projects that are more advanced and that can be moved immediately to phase 1 or even phase 2.

cess, which we refer to as a "shark tank" or "deep dive."[16] In phase 0, multiple expert reviewers provide a detailed assessment of the technology and give critical feedback to the NIH and the project teams. Approximately 15 to 20% of completed RADx-tech applications enter phase 0. For those projects that are successful (25 to 30% of phase 0 projects), detailed, milestone-driven work packages are developed in order for projects to enter phase 1. Technologies are then rigorously tested and validated in the independent POCTRN validation core over a monthlong process to ensure that these new tests meet or exceed their predicted analytic performance. If a project is judged to be successful at that point, rapid scale-up and clinical testing in phase 2 gets under way, with substantial financial assistance provided.

Applications that have been received to date by the RADx-tech program span nearly every stage of technology development, with submissions coming from small and midsize companies, academic laboratories, early-stage start-up companies, and large commercial manufacturers (Fig. 2). It is not uncommon for applicants to

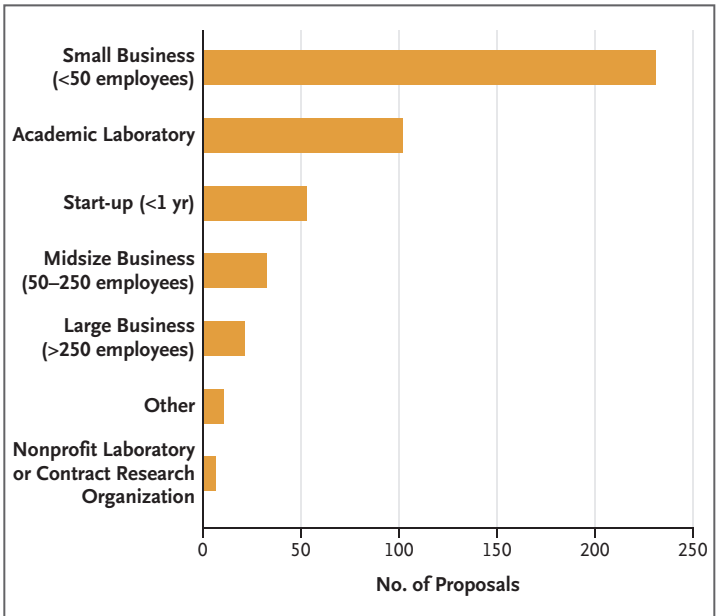

Figure 2. Number of RADx-tech Proposals, According to Organization Type.

The majority of applications to the RADx-tech and the RADx-ATP programs have come from small businesses, academic laboratories, and early-stage start-up companies.

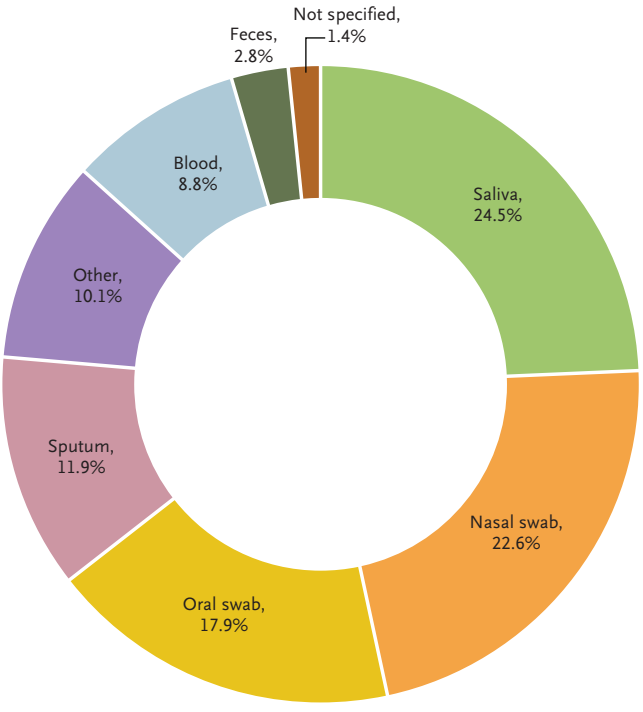

Figure 3. Sample Types in RADx-tech and RADx-ATP Proposals.
Applications to RADx-tech and RADx-ATP include multiple alternative sampling strategies for viral testing, not just traditional nasal swabs.

still be preparing for their EUA submission to the FDA. Promising technologies that have been reviewed by the program include innovations that allow high-throughput, portable, and point-of-care platforms, from CRISPR (clustered regularly interspaced short palindromic repeats) technologies for the detection of viral nucleic acids to lateral flow strips for both nucleic acid and viral antigen testing.[17] Many platforms integrate advanced microfluidic components and state-of the-art readout strategies that use compact optics and electronics. Overall performance, ease of use, and digital reporting are facilitated by smartphone systems that are designed for nonexperts. In addition, alternatives to conventional nasopharyngeal and anterior nasal swab sampling are being explored,[18] and a majority of prototypes involve the use of saliva, oral swabs, and other collection sites (Fig. 3).

As of July 13, 2020, a total of 2587 expressions of interest have been received, and more than 600 full applications have been submitted from 41 U.S. states and the District of Columbia. Within 8 weeks after the launch, 27 projects had successfully made it through the shark tank to phase 1, and the entry of the first project into phase 2 is imminent. As technologies and companies go through this process, the RADx program is also seeking to identify testing platforms that may be especially suitable for testing small groups or isolated, underserved populations at point-of-care sites or in rural or remote areas that do not have access to high-throughput robotic testing systems. Technologies that reduce the facility footprint, decrease overall testing complexity, and provide rapid results will be especially helpful, and the program will work to assist in the deployment of these systems in these specialized environments. As part of this process, ease of use, including specimen-collection methods and clear and easy-to-understand instructions to facilitate widespread uptake, will be integrated into the process.

Active collaborations with other government agencies are critical during this process. The NIH is closely coordinating with the Office of the Assistant Secretary for Health, BARDA, and Department of Defense to ensure that each party is aware of the discussions and existing relationships taking place with private-sector companies, to ensure no duplication of funding, to streamline communications, and to leverage the experience, knowledge, and technical capacities of different agencies within the government.

ACHIEVING SHORT-TERM, RAPID SCALE-UP — RADx-ATP

Not all emerging technologies need the shark tank approach. As shown in Figure 1, a bypass pathway is also provided to catalyze the rapid development of technologies that are already at a more advanced stage of development. The RADx–Advanced Technologies Platforms (RADx-ATP) program provides a rapid-response application process for companies with an existing point-of-care technology that has already been authorized by the FDA for the detection of SARS-CoV-2 and that has the ability to scale production to between 20,000 and 100,000 tests per day by the fall of 2020. In addition, the company must have infrastructure and a deployment or placement strategy that enables tests to be made rapidly available in point-of-care settings. Companies are asked to develop a robust plan to collect data continuously to support a submission to the FDA for a Premarket Approval (PMA) or a Premarket Notification (510[k]).

The RADx-ATP program is also seeking to expand high-throughput laboratories (also called "mega-labs") that are in a position to increase testing capacity to 100,000 to 250,000 tests per day. These laboratories have been certified according to the Clinical Laboratory Improvement Amendments regulations and are already in operation with the necessary equipment and trained staff to guarantee a test-turnaround time of 24 hours (from the time that the sample is obtained to the availability of the result). Such high-throughput laboratories generally have the equipment to analyze large numbers of tests with well-developed automated workflows to process samples and obtain results rapidly. Newer technologies, such as next-generation sequencing, can read out hundreds to thousands of genes or gene regions simultaneously[19] and should be able to support large-scale, population-level testing for surveillance purposes, possibly on the order of millions per day.

Pooling strategies are also being considered for population-level surveillance, because they can greatly increase throughput when testing resources are limited.[20] If a pooled test result is negative, then the patients who provided the samples are considered to be negative for active SARS-CoV-2 infection. If a pooled test result is positive, then each sample from the pool of patients needs to be tested individually. The efficiency of pooling has been shown to depend on the prevalence of SARS-CoV-2, test sensitivity, and patient-pool size and will need further evaluation before widespread implementation.[21] Molecular bar-coding is another promising approach. In the first step, the individual sample is labeled with a DNA tag, in order for it to be identifiable at the molecular level. Massive pooling can then be done to increase the number of tests that can be processed at once. Positive samples can be identified by their unique tag, but the pooling step can greatly decrease the use of reagents, equipment, and labor.[22] This approach may even allow for a range of other viral pathogens to be detected during the same analysis.

LOOKING FURTHER AHEAD — RADx-RAD

Not all technologies will be ready for near-term production scale-up and deployment. A special component of the program (RADx-rad) has been established to evaluate the usability, access, robustness, or accuracy of a wide range of nontraditional technologies or new settings (e.g., home-based testing technologies) for the detection of SARS-CoV-2 infections. Projects under the RADx-rad component will be focused not just on the development of new technologies or approaches but also on the novel repurposing of existing technologies. Furthermore, RADx-rad will support those innovative technologies that are on a more extended timescale and that will take longer to develop than a 6-month time frame. Such technologies include, for example, the use of biologic or physiological biomarkers to detect an infection or predict the severity of disease,[23] including the likelihood of the multisystem inflammatory syndrome in children,[24] or the use of chemosensory changes as an early indicator of viral positivity.[25] Other examples include the use of biosensors to detect the presence of the virus in the breath[26] or the analysis of wastewater to conduct community-based surveillance.[27]

FOCUS ON UNDERSERVED POPULATIONS — RADx-UP

It is clear that racial and ethnic minorities are bearing a higher burden of disease and mortality from Covid-19.[3] In particular, non-Hispanic Blacks, Hispanics, and American Indians and Alaska Natives are hospitalized and die at disproportionately higher rates than other groups.[28-31] This disproportionate burden in health outcomes for underserved populations and racial and ethnic minorities shines a bright light on long-standing health disparities in the United States and is of profound concern.[32]

The goal of this part of the RADx program (RADx-UP) is to understand factors that have led to the disproportionate burden of the pandemic on underserved populations and to support improved access and uptake of SARS-CoV-2 testing. The program aims to examine infection patterns and efforts in order to increase access to and effectiveness of testing methods by building an infrastructure that can be leveraged for the ongoing Covid-19 public health efforts, especially as the impending influenza season begins in the fall. Through engagement with communities and in close alignment with their leaders, a series of interlinked, pragmatic implementation science projects at multiple sites across the country are being planned to investigate, in real time, the effective approaches to testing within these

populations. In addition, in order to be responsive to the communities that this initiative will partner with and to understand more clearly the multitude of factors influencing the ability and willingness of a group to be tested for SARS-CoV-2, the program is obtaining strong guidance on social, ethical, and behavioral issues by means of the establishment of a research program focused solely on these issues.

CHALLENGES AHEAD

The NIH has been engaged almost continuously in battling epidemic diseases over the past several decades. From human immunodeficiency virus (HIV) infection to influenza, SARS, Middle East respiratory syndrome (MERS), Ebola, and Zika, each pandemic brings its own idiosyncratic issues that require unique solutions. We anticipate that challenges to the RADx program are likely to arise on several fronts. First, on the technical side, many promising prototypes under consideration are in the early proof-of-concept stage. It is likely that many will fail along the way. Much effort will be needed to conduct clinical validation rapidly and to obtain regulatory authorizations and approvals. Access to clinical samples for clinical validation has already emerged as an issue that is impeding progress for companies.

Another challenge will be to identify digital health platforms that provide connectivity among test results, electronic health records, and public health organizations. Many smaller diagnostic companies do not have expertise in this area, and it will be important to ensure their access to this expertise in the planning stages. Data should be able to be transmitted to the patient and health care provider and to state and local public health authorities with the use of national interoperability standards and common data elements to collect key demographic, test result, and clinical outcome information.[33] This will lay the foundation for the future point-of-care clinical practice and research enterprise in the years to come, in which deidentified, privacy-protected, patient-level test data can be linked to clinical outcomes to form curated, analyzable data sets.

Second, on the manufacturing side, scaling up of production is a complex enterprise that involves a wide range of factors, from ensuring sufficient supplies of swabs, raw materials, reagents, and equipment to establishing new production lines and manufacturing facilities within aggressive timelines. These are likely to be logistic feats that will require rapid access to capital, equipment, and skilled staff.

Third, on the distribution side, once increased testing capacity is available, managing the distribution and implementation of tests into the appropriate venues and geographic localities will be critical. We anticipate coordinating closely with Operation Warp Speed[34] and leveraging the logistic expertise of the Department of Defense. Uptake of testing may also be an issue.

All these challenges are being addressed with unprecedented levels of coordination and collaboration across academia, government, industry, and nonprofit foundations.[35] We anticipate that these interactions will substantially affect traditional barriers and facilitate the first burst of increased testing capacity by the fall of 2020.

CONCLUSIONS

Expanding the capacity, throughput, speed of returning results, analytic performance, and regional placement of diagnostic technologies is urgently needed and, if successful, will contribute importantly to the current national efforts to curb the Covid-19 pandemic and help to reduce inequities for underserved populations. As we embark on this initiative, the challenges ahead are considerable, and the timetable is truly daunting. Aiming to achieve this rapid evaluation, validation, and scale-up has rarely, if ever, been attempted at this pace. However, the NIH is in a position to serve as a "venture investment" organization and is currently striving to operate in that entrepreneurial spirit. The success of the RADx program will depend on truly innovative ideas coming forward from the minds and laboratories of technology developers, a robust and rapidly responsive expert evaluation system, extensive collaborations in validation and scale-up with experts from all sectors, and strong community partnerships to support testing availability and uptake. All these partners are profoundly energized by a sense of urgency, opportunity, and responsibility to provide testing at scale in the face of this global pandemic.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the National Institute of Biomedical Imaging and Bioengineering (B.J.T.), the National Institute of Nursing Research (T.A.S.), the Office of the Director (T.A.S., R.A.B., R.L.F., F.S.C.), the National Institute on Minority Health and Health Disparities (E.J.P.-S.), the National Institute on Aging (R.J.H.), and the National Institute of Environmental Health Sciences, National Toxicology Program (R.P.W.), National Institutes of Health, Bethesda, MD. Address reprint requests to Dr. Collins at the Office of the Director, National Institutes of Health, 1 Center Dr., Bldg. 1, Rm. 126, Bethesda, MD 20892, or at collinsf@od.nih.gov.

This article was published on July 22, 2020, at NEJM.org.

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DOI: 10.1056/NEJMsr2022263