

RADx-UP: Understanding the Factors Associated with Disparities in COVID-19 Morbidity and Mortality

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Executive Summary

The Rapid Acceleration of Diagnostics ([RADx[®]-Underserved Populations \(UP\)](#)) program was launched by the National Institutes of Health (NIH) in 2020 as part of the Rapid Acceleration of Diagnostics (RADx[®]) initiative. The overarching mission of RADx-UP has been to assess and expand SARS-CoV-2 (COVID-19) testing in the United States (U.S.) to promote protective strategies and reduce disparities in morbidity and mortality for racial and ethnic minoritized populations and other socially or medically vulnerable populations who have been known to be disproportionately affected by COVID-19. This includes populations most affected by health disparities, particularly persons identified as Black or African American, Hispanic or Latino, American Indian, Alaska Native, Hawaiian and Pacific Islander; those in nursing homes, jails, rural, or underserved urban areas; pregnant people; people with disabilities through the life course and people experiencing homelessness.

Previous and ongoing projects supported by the RADx-UP program have been designed to rapidly respond to an evolving COVID-19 pandemic through coordinating the efforts of existing research infrastructures across the U.S. and its territories. Each of the independent RADx-UP research projects has been required to build and expand existing community partnerships to identify and collaboratively develop strategies to address the unique needs of underserved and vulnerable populations. The 142 awarded projects that have been funded through this program were conceived of and implemented as a consortium to build further collaborations, share research results with community partners and beyond, disseminate and implement results, and increase trust and inclusion in research under the leadership of a Coordination and Data Collection Center (CDCC).

Establishment of the Program

Scientific leaders from NIH presented a framework to significantly increase the number, quality, and type of daily tests to detect SARS-CoV-2 and to help reduce inequities for underserved populations. Based on disparities in the testing landscape in 2020, an urgent need was identified for nationwide deployment of diagnostic tests that could be implemented in community and



home settings and to rapidly return results to all individuals. In response, NIH created the RADx initiative just five days after Congress provided a supplemental appropriation to the NIH Office of the Director as part of the Paycheck Protection Program and Health Care Enhancement Act of April 24, 2020. In 2021, funding support of the RADx initiative transitioned to the American Rescue Plan Act of 2021. As part of efforts to reduce the excess morbidity and mortality impacting specific populations disproportionately affected by COVID-19, NIH established RADx-UP, representing the largest investment in underserved communities in the history of NIH.

Program Overview and Structure

Research project teams that have been supported by RADx-UP are grounded in academic-community collaborations. They have worked together to culturally and linguistically adapt research approaches and data collection instruments to identify and address disparities in infection rates, protective factors, health outcomes, and access to health care among underserved and vulnerable populations. While most RADx-UP research projects are focused on implementing and evaluating testing interventions, some focus on the social, ethical, and behavioral implications (SEBI) of testing. SEBI data identifies factors that create ethical dilemmas, behavioral conflicts, or have social implications that affects access and uptake of COVID-19 mitigation measures specific to certain groups. For example, some [migrant workers](#) do not have access to health insurance or guaranteed income to support their families in the case of a positive COVID-19 test; thus, there may be hesitation to undergo testing to reduce the economic threat to the worker and to the family. In addition, the [Safe Return to School Diagnostic Testing](#) (R2S) component of RADx-UP has sought ways to understand strategies to facilitate the return to in-person learning for schools and districts serving underserved communities. The initiative has evaluated testing and mitigation intervention approaches for children and families, as well as faculty and staff members in public schools and has also explored vaccine hesitancy and uptake.



Data Collection and Sharing

To ensure comparability of data collected across all the projects in the RADx-UP consortium, the CDCC has worked with the funded research projects as well as NIH to identify and define a set of Common Data Elements (CDEs). The tier 1 CDEs are 169 items covering demographics, COVID-related behaviors and outcomes, risk behaviors, and selected social determinants of health. The collection and reporting of the NIH RADx-UP CDEs across this large set of community-engaged projects has presented a unique opportunity to facilitate cross-consortium analyses of research questions. Researchers can access curated and de-identified COVID-19 data through the NIH RADx Data Hub, a resource of RADx-generated data that can help researchers better understand the impact of the pandemic, including the outcomes, disparities, and potential solutions.

Within the RADx initiative, 11 funded research projects have focused on understanding and addressing COVID-19 disparities within American Indian and Alaska Native (AI/AN) communities. Important aspects of these studies have included ensuring responsible data sharing and access with respect for Tribal sovereignty and appropriate governance to maximize partnerships, participation, and community benefit. To address unique cultural, governance, and sovereignty needs of the AI/AN communities engaged in the RADx initiative, NIH launched the RADx Tribal Data Repository (TDR). TDR is designed for sovereignty-based governance of AI/AN data collected through RADx projects; this will enable Tribal controlled sharing and use of data to better understand and address the impact of COVID-19 and other health disparities.

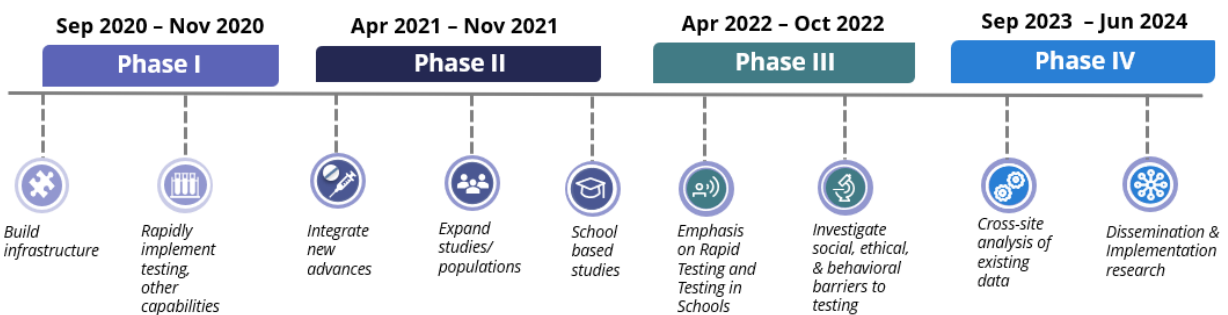
Funding Phases

The RADx-UP program has been implemented in four phases to permit a flexible response to the rapidly evolving pandemic and impact on communities across the nation. Phase I projects have supplemented pre-existing large-scale networks, consortia, centers, and individual research projects to examine SARS-CoV-2 infection patterns. Projects have utilized community-engaged research principles to investigate a variety of COVID-19 diagnostic testing methods that received Food and Drug Administration (FDA) Emergency Use Authorization to increase access, use, and



effectiveness of testing methods. The SEBI research has sought to identify, analyze, and address the social, ethical, and behavioral factors likely to influence access and uptake of COVID-19 testing in underserved and vulnerable populations. Phase II projects have advanced the scientific mission of the program and have addressed new developments in the landscape of COVID-19 testing and diagnostic approaches as well as vaccine confidence, hesitancy, and uptake. Phase III projects have supported the evaluation of rapid testing interventions to prevent and control COVID-19 transmission and advance community driven research. Phase IV projects leverage existing RADx-UP data to gain novel insights through cross-project analyses and support dissemination and implementation (D&I) research focused on increasing access to and uptake of COVID-19 testing interventions to reduce COVID-19 disparities and promote health equity.

The figure below displays the objectives of the four RADx-Up program phases and the months in which these projects were initially awarded funding (i.e., these dates reflect release of awards by phase and not total duration of project).



Phase I. Understanding COVID-19 Testing Patterns by Focusing on NIH Funded Projects with Established Community Engaged Research Infrastructures and Partnerships

The initial phase of the RADx-UP program has focused on mobilizing research teams with established research infrastructures and community-engaged partnerships. These teams have been funded to study COVID-19 testing patterns and to implement strategies or interventions with the potential to rapidly increase reach, access, acceptance, and uptake of COVID-19 diagnostics (only those that received EUA) among underserved and other socially or medically vulnerable populations.



Phase I projects were awarded in September through November of 2020 with awards to 69 projects and the establishment of the RADx-UP CDCC, a central leadership and support team that assisted the NIH and RADx-UP projects as they served their communities. These project awards have been administered by 15 NIH institutes at 55 research institutions within 34 states, the District of Columbia, and Puerto Rico.

Data collected by each RADx-UP project, with special consideration for Tribal Nation practices and policies concerning data sovereignty, have been harmonized, de-identified and uploaded quarterly to the RADx-UP CDCC then transferred to the RADx Data Hub. To date more than 55 million responses to the CDEs collected from more than 400,000 participants have been uploaded to the Data Hub.

Phase II. New Advances in COVID-19 Testing

Phase II has focused on the integration of new technological advances in COVID-19 testing, including point-of-care or at-home rapid testing. In conjunction with the expansion of the scope and reach of testing interventions, these projects have sought to increase access and uptake of COVID-19 testing among underserved and vulnerable populations. RADx-UP has been able to focus on understanding and addressing the social, ethical, and behavioral implications on the testing interventions in these populations during this phase.

This new phase also has added school-based research to address high-priority topics related to the use of COVID-19 testing as part of a strategy to facilitate the safe return to school for students and families, as well as faculty and staff members.

Phase II began with 16 Return-to-School awards in April and June 2021 followed by 42 additional awards related to advances in COVID-19 testing in community settings in November 2021, for a total of 58 new projects. These projects have been administered by 11 NIH institutes at 58 research institutions within 28 states. During this phase of the program, COVID-19 vaccination uptake research became a secondary focus and RADx-UP began to collaborate with



the NIH Community Engagement Alliance¹ ([CEAL](#)) projects through 11 administrative supplements for Phase I projects to further study testing and vaccine hesitancy and uptake.

Phase III. Rapid Testing

New awards in Phase III have primarily focused on community-engaged research to implement and evaluate SARS-CoV-2 rapid testing and testing in schools, referred to as Safe-in-School. Projects have also continued SEBI research to gain insights to reduce barriers in COVID-19 testing and the associated COVID-19 disparities. Other projects awarded in this phase evaluated the rapid COVID-19 testing, typically administered outside of healthcare settings, to prevent and control COVID-19 transmission as well as the partnership-driven research for the implementation and evaluation of rapid testing for the reduction of COVID-19 disparities in underserved and vulnerable populations.

In October 2022, 10 projects received Phase III awards and have been administered by three NIH institutes at nine research institutions within eight states.

Phase IV. Cross-site Analysis of Existing RADx-UP Data, and New Dissemination and Implementation Research

Phase IV of the program has focused on two areas: cross-site analysis of existing RADx-UP data to gain novel insights and projects focused on dissemination and implementation of effective COVID-19 testing interventions in underserved populations. Four cross-site analysis projects were awarded in September 2023. These projects have been administered by the National Institute on Minority Health and Health Disparities at four research institutions in four states. Dissemination and implementation research projects will explore how evidence-based RADx-UP practices, interventions, and policies translate effectively for use in real-world settings. Additional dissemination and implementation research awards are expected in June 2024.

Through these phases, the RADx-UP program has identified several key findings, including:

¹ Formerly known as the Community Engagement Alliance Against COVID-19 Disparities.



- Community-engaged and directed research has been integral to implementing testing and mitigation strategies, and has required time and attention to build trust, adequate compensation for community collaborators, and investment of full partnership among researchers, community participants, and NIH scientific staff.
- There have been racial, ethnic, and socioeconomic status disparities in testing motivation and vaccine access and uptake, although these disparities have not been uniform across the different racial and ethnic groups.
- Developing public health strategies (such as health education), providing trusted sources of information, and addressing barriers have been positively impacting reliance on COVID-19 testing and vaccination.
- Racial and ethnic minority groups experience elevated challenges related to social determinants of health (e.g., limited English proficiency, access to quality healthcare, transportation and geographical barriers) that may impact access to COVID-19 testing and managing recommendations following a positive COVID-19 test.
- Mitigation strategies have been effective at reducing SARS-CoV-2 virus transmission in schools.

Program Accomplishments

The RADx-UP program has played a critical role in advancing the overarching RADx goal that all persons living in the U.S. have access to COVID-19 testing. Research teams and community leaders across the country have access to research data to identify and develop effective strategies for reducing disparities and addressing community needs.

As of December 2023, the RADx-UP program has reflected on the following accomplishments and highlights:

- NIH published 16 funding opportunities and has awarded 142 projects, including the RADx-UP [Coordination and Data Collection Center \(CDCC\)](#).
- More than 404,000 participants have enrolled in RADx-UP research studies.



- Participation has included substantial representation from underserved communities disproportionately affected by COVID-19 and often underrepresented in research, including AI/AN, Hawaiian, and Pacific Islander groups.
- Socioeconomically disadvantaged persons and members from 18 additional underserved groups that have been known to experience barriers to accessing health care services, to have had inadequate healthcare coverage, or to have been vulnerable to COVID-19 due to specific medical conditions, social determinants, or living situations have participated in the research.
- Names, contact information, and basic socio-demographic information for all participants who agreed to both share their identifiers with the CDCC and to be re-contacted for future research when they enrolled in RADx-UP studies have become available in the [RADx-UP Re-contact Registry](#).
- Project sites have been supported in all 50 States, the District of Columbia, and the U.S. territories, including Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. Nine distinct research settings included community health centers, in-home, underserved urban and rural communities, school, public housing, nursing home or long-term care facilities, and prison or correctional facility.
- RADx-UP project teams have distributed and/or conducted millions of COVID-19 tests and transferred CDEs data collected from participants reporting on more than 447,000 tests.
- As of December 2023, 1,384 RADx-UP unique research project authors have published more than [270 research articles](#) in 112 academic journals. These publications include two special supplements to *Pediatrics* and a special issue of the *American Journal of Public Health* (November 2022). There will also be a second *AJPH* supplement to be released in spring 2024.
- Of 142 awarded projects, 101 projects have completed CDE data collection and are in or entering the final stages of depositing data with the RADx-UP CDCC and transfer of the data to the RADx Data Hub.



Community Engagement

Engagement with community partners has been critical to understanding and integrating strategies to mitigate health inequities. RADx-UP has strengthened existing relationships between academic researchers and their community partners which facilitated the rapid mobilization needed to implement interventions, enhance acceptance, and communicate the importance of COVID-19 testing. These partnerships have also strengthened community infrastructure to be better prepared for future public health emergencies.

Two examples of projects, among many similar successes, are described below:

- Led by the University of Oregon, the Oregon [*Saludable: Juntos Podemos* project](#) has focused its efforts on increasing COVID-19 testing and other COVID-19 transmission prevention behaviors among Latino community members across 11 counties in Oregon. Using *promotores de salud*, an individual level intervention, the researchers have determined that culturally informed outreach can increase community engagement and participation. The *promotores*, bilingual and bicultural health outreach workers, has successfully delivered culturally tailored health education to the Latino communities and have increased COVID-19 testing by nearly four times per testing event compared to sites with outreach as usual. Further, the researchers have determined that those who were vaccine hesitant had concerns about side effects and had not been given sufficient information about vaccine efficacy. This has provided a better understanding of how to reduce disparities in health care among these communities.
- The RADx-UP Safe Return to School Diagnostic Testing Initiative has aimed to build the evidence base for safely returning students, teachers, and staff members to in-person school settings in areas with underserved and vulnerable populations. Researchers have sought to understand the motivators and barriers to testing from different perspectives to increase participation in school-based testing programs. Key motivators of COVID-19 testing in school have included the convenience of testing in schools as well as the desire to keep oneself and others safe from COVID-19; however, some have been concerned about the implications of receiving a positive test result. By establishing COVID-19



testing protocols for schools in vulnerable communities, these projects have helped inform policy and decision-makers on the best strategies to support students, teachers, and staff members in a safe return to school during the COVID-19 pandemic and which can be applied to future pandemics and public health emergencies.

- With a special issue published in the journal *Pediatrics*, studies conducted by the [ABC Science Collaborative](#) concluded that offering in-school testing increased the testing of close contacts of positive students and allowed for shortened quarantine durations; nursing staff were critical to the success; and where resources were limited, testing was more difficult.

In addition to supporting individual projects, the RADx-UP community of practice has produced lessons learned and other resources to aid in community engagement.

- The annual [RADx-UP Scientific Meeting](#) featured the data results and lessons learned from dozens of RADx-UP projects. In addition to academic researchers, community partners presented findings and valuable insights, highlighting RADx-UP's dedication to authentic, sustainable community partnership.
- The bilingual [RADx-UP Community Health Worker Symposium](#), in English and Spanish, highlighted the essential role of Community Health Workers (CHWs) in promoting health equity. Presenters included CHWs who shared their experiences in the field and suggestions for improvements.
- The [Engagement Resource Library](#) contains some 300 tools for researchers and communities on areas such as community engagement best practices, research study recruitment and participation, health equity, and more.
- The figure below provides a graphic representation of the many resources developed by the projects in the [RADx-UP Community of Practice](#) that are now publicly available for adaptation in use in other contexts.



A functional RADx-UP Community of Practice



Impact and the Path Moving Forward

The RADx-UP program has brought together academic researchers and community members from across the U.S. to develop innovative approaches to expanding COVID-19 testing for underserved and vulnerable populations. RADx-UP has gathered insights about promising testing and vaccination approaches that can translate research into sustainable programs, practices, and policies.

Testing and vaccine implementation in underserved and vulnerable populations should take the following into account:

- The importance of identifying and implementing CDEs early and carefully:
 - Community partners must be active participants and co-creators; this requires bidirectionality in communication and full and equal collaboration
 - Language adaptations need to go beyond word-for-word translation because cultural considerations are critical to inclusivity as well as reliability and validity of research results



- Scientific and community benefits are possible by measuring standard demographic factors, social determinants of health, and COVID-19-related variables using standardized questions (i.e., NIH RADx-UP CDEs) that permit cross-site analysis and consortium-level findings
- Privacy, transparency, security, and data sovereignty are critical to building community trust in the research process and with researchers
- Community engagement is most effective when given appropriate time and attention, adequate compensation for community collaborators, and full partnership among researchers, community participants, and NIH scientific staff
- Developing culturally appropriate testing and vaccination strategies requires knowledge of the social context and lived experience within each community

The outcomes from the RADx-UP program have provided valuable information and resources to reduce disparities for those who are disproportionately affected by, have the highest infection rates, and are at risk for complications or poor outcomes from the COVID-19 pandemic.

Conclusion

In summary, RADx-UP has provided a timely, responsive mechanism to support innovative research projects seeking to understand testing patterns of COVID-19 and the implementation of strategies to rapidly increase reach and access to approved diagnostics among populations experiencing health disparities or are otherwise underserved. The impact of RADx-UP community engagement has allowed for a wide breadth of populations to connect with COVID-19 mitigation resources.

RADx-UP can continue to inform efforts to alleviate barriers to testing for the most vulnerable populations and reduce health disparities by:

- Fostering stronger community collaborations with academic researchers and extending community-directed research through published research results including cross-consortium analyses of aggregated RADx-UP data, findings shared at the [2023 Equity Evidence Academy](#), and additional dissemination activities.



- Informing public health policy decisions at local, state, and federal levels and implementing effective strategies for reducing disparities in future pandemics. Examples of RADx-UP outputs to support this include the [Health Equity Framework](#), the [Opportunities to Enhance Health Equity by Integrating Community Health Workers into Payment and Care Delivery Reforms](#).
- Evaluating intervention approaches across cultural groups and environments and assessing the impacts on reducing health disparities.
- Understanding the mental health effects and substance misuse associated with COVID-19, social isolation, and the overall impacts on health and health care access for non-respiratory acute illness due to fear of exposure to COVID-19 in healthcare facilities.
- Understanding the effects of health care on persons with chronic medical conditions requiring ongoing monitoring.
- Evaluating the impact of forced social isolation at all ages and environments, including students required to attend remote education.
- Building and maintaining important relationships to allow lasting impact on underserved and vulnerable populations.

The knowledge gained through the RADx-UP program, and the strategies that the community-engaged research teams developed throughout all phases of the program, can be used to address future public health crises in vulnerable communities. This program has an expansive footprint across the U.S. and its affiliated territories that reaches underserved and vulnerable populations to mitigate the health disparities of COVID-19. It represents only the beginning of the impact that the NIH and its research partners can have on the health of the nation.