

# RADx-UP Coordination and Data Collection: An Infrastructure for COVID-19 Testing Disparities Research

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The COVID-19 pandemic has further exposed structural racism, inequalities, and other forms of systemic oppression that have limited opportunities for health equity and community well-being.<sup>1-4</sup> Research in geographic areas with a high percentage of COVID-19 morbidity and mortality provides evidence for the importance of setting and community when evaluating the differential effects of the pandemic on medically underserved populations.<sup>3,5</sup> Communities with high rates of COVID-19 infections and deaths often also disproportionately suffer from the economic ill effects of the pandemic, including job loss, loss of income, disruptions in schooling and childcare, loss of housing, and accompanying stress and anxiety.<sup>3,6-9</sup>

COVID-19 has perpetuated health disparities among racial and ethnic minorities, with higher prevalence and mortality rates in communities that face barriers to health care, employment, and health insurance coverage, as well as other social and structural inequities.<sup>10,11</sup>

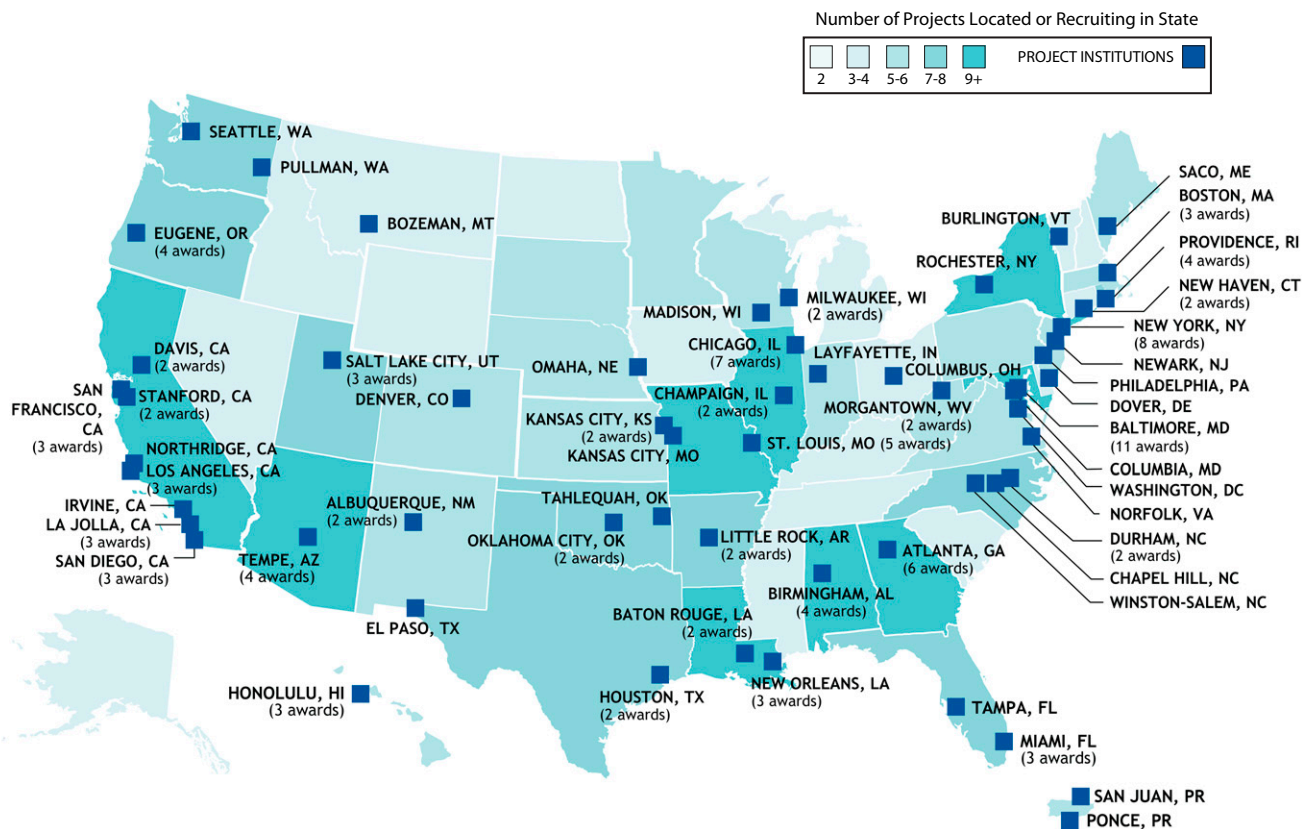
Built environment and neighborhood determinants affect the spread of infectious disease. Social and structural factors such as inequitable access to testing and preventive services, a higher proportion of essential workers in a given community, and lack of trust in health care providers further aggravate unequal disease burden.<sup>12-14</sup> These persistent disparities underscore the need for additional research into the effects of location on COVID-19 risk to develop successful

mitigation strategies. Underserved populations need enhanced care and improved resources, education, and stakeholder-informed solutions to mitigate the spread of COVID-19, including timely access to testing and vaccination. Addressing and eliminating COVID-19 disparities calls for novel approaches that engage stakeholders from underserved communities.<sup>15,16</sup> The pandemic has created an opportunity to test the effects of wide-scale community-engaged research in addressing these disparities.

## THE RADx-UP PROGRAM

Funded by the National Institutes of Health (NIH), the Rapid Acceleration of Diagnostics-Underserved Populations (RADx-UP) program is a consortium of research projects throughout the United States. The RADx-UP program aims to understand factors that led to the disproportionate burden of the pandemic on underserved populations and implement interventions to mitigate these disparities.<sup>17</sup> To our knowledge, RADx-UP is the single largest health disparities research investment in the history of the NIH. As of July 2022, more than 125 projects have been funded through RADx-UP in all US states as well as American Samoa, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, and the US Virgin Islands, serving historically marginalized and medically vulnerable populations (Figure 1).<sup>18</sup> All RADx-UP projects are grounded in the principles of community-engaged research, with research and testing implemented in partnership with community leaders and organizations.

The Duke Clinical Research Institute (Durham, NC) and the University of North Carolina Center for Health Equity Research (Chapel Hill, NC) jointly lead



**FIGURE 1— RADx-UP Project Map: United States**

Note. RADx-UP = Rapid Acceleration of Diagnostics-Underserved Populations.

the RADx-UP Coordination and Data Collection Center (CDCC) in partnership with Community-Campus Partnerships for Health (Raleigh, NC). The CDCC supports the RADx-UP consortium of funded projects in community engagement, testing strategies, data collection and integration, and colearning between the projects and the communities they serve. The CDCC comprises three connected pillars: a community engagement core, a testing core, and a data science and biostatistics core.

The CDCC’s governance framework ensures that the direction and key initiatives of the RADx-UP program are responsive to community needs and priorities. The CDCC includes an external advisory board; data stewardship,

publications, and steering committees; working groups; and community and health system stakeholders and partners. Addressing COVID-19 disparities in underserved populations calls for solutions that include the involvement of community partners and stakeholders. The CDCC community engagement approach is consistent with Public Health 3.0, a framework that prescribes collaboration among health care researchers and nontraditional partners.<sup>19</sup> According to this framework, research targeting health equity promotion must be done in partnership with community leaders and trusted representatives, community organizations, and local stakeholders so that the current research infrastructure is strengthened. The CDCC is assembling evidence

from all projects on how to best nurture and strengthen relationships between communities and academic institutions to enhance our ability to serve as critical partners in health disparities research.

The goals of the CDCC are the following:

1. to accelerate COVID-19 community implementation science via an agile, flexible, participatory, transparent, and sustainable infrastructure;
2. to amplify and disseminate community best practices for successful COVID-19 testing and vaccines;
3. to support data collection, integration, and sharing while preserving necessary data protections;
4. to use the RADx-UP infrastructure to support COVID-19 research; and

5. to evaluate the impact of the RADx-UP program to update and increase access and sustainability of COVID-19 testing in underserved populations.

The composition of the CDCC is intended to reflect the historically marginalized communities that RADx-UP serves. The CDCC also performs systematic tracking and evaluation that draw from existing data to monitor systems across sites, develop novel assessment methods, and provide a platform for dialogue and decision-making. The Translational Science Benefits Model (TSBM)<sup>20</sup> and the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework<sup>21</sup> guide RADx-UP tracking and evaluation. TSBM provides measurable clinical and translational science research indicators to support patient, community, and policy outcomes. The RE-AIM framework addresses the interactions at the individual, clinic or organization, and community levels that affect the population-based health outcomes of programs or policy. These efforts serve to gauge the impact of the CDCC and RADx-UP projects, assess the extent of stakeholder engagement, and inform the direction and focus of the RADx-UP consortium to address health disparities.

## Community Engagement Core

The CDCC community engagement core identifies and strengthens strategic partnerships across the RADx-UP projects to address the needs and interests of communities that disproportionately bear the burden of illness and disease<sup>22</sup> and to speed the translation of innovation into practice. The community

engagement core's engagement impact teams provide a conduit between projects and the CDCC components, including direct technical assistance in identifying and addressing barriers to equity in COVID-19 testing and facilitating strong community involvement and impact.

These teams bring together researchers, health system leaders, health care professionals, community members, and policymakers to discuss high-impact, life-saving study results ready for translation using an equity perspective. In the setting of a highly politicized pandemic where misinformation has been rampant,<sup>23</sup> demonstrating the trustworthiness of the scientific, medical, and research enterprise is of paramount importance.

Community stakeholders are essential to ensuring that testing meets their needs.<sup>24</sup> To this end, the core's Engagement Resource Center offers a publicly available knowledge repository of RADx-UP resources.<sup>25</sup> The core has also established workgroups to provide alignment, engage with community partners, and support projects serving particular populations (e.g., tribal nations, children) with shared common goals. The RADx-UP Community Collaboration Mini-Grant Program provides funding to community-serving groups and faith-based organizations, as well as tribal nations, to help mitigate the COVID-19 spread. In addition, considering the need for rapid acceleration of this process and the urgency in developing a research-ready system during times of public health crisis, the CDCC adopts innovative approaches to stay true to community-engaged research practices. In particular, we have observed a tension between generating much-needed information quickly and nurturing trust through thoughtful and deliberate engagement.<sup>26</sup> The

community engagement core ensures that community partners play a critical role in the development, design, prioritization, implementation, and evaluation of research initiatives that are culturally and contextually appropriate.

## Testing Core

The CDCC testing core provides technical assistance and scientific guidance on existing and emerging COVID-19 diagnostics, testing supply management, and implementation by developing, curating, and maintaining a repository of emerging technologies and disseminating diagnostic technology assessments. The testing core specifically provides technical expertise to support project teams in conducting studies or evaluations using diagnostic tests for COVID-19. This support includes (1) reviewing the protocol to match testing methods with specific project study designs and unique needs of the communities served; (2) promoting reach and access to testing sites (particularly for underserved populations); (3) navigating cost and supply chain challenges for reagents, sample collection devices, and kits; and (4) advancing and fast-tracking resources for at-home collection and shipping to increase reach to underserved communities. The core also supports a partnership with Arizona State University that offers access to an online repository (<https://radx-up.org/covid-19-testing-commons>) of existing and emerging COVID-19 testing technologies to help match appropriate test procedures with target populations.

Like the community engagement core, the testing core faced challenges and gained insights during start-up. These include training by faculty and staff to remain current with updated

federal guidelines and newly approved test methods as regulations change. The core is particularly sensitive to the history of unethical and inappropriate research involving underserved populations; accordingly, the CDCC has committed to an assessment of diagnostic technologies that have completed appropriate regulatory approvals. The progression of the pandemic and the development of vaccines have expanded the focus of testing to include serological assessments of disease- and vaccine-induced antibodies. As a result, vaccine availability, distribution, and associated hesitancy has shifted popular sentiment regarding testing for active viral infection, which has required deliberate messaging about why such testing remains essential.<sup>27</sup> This shift may affect whether projects can fully execute their testing plans, given that vaccines are available to participants and may affect future testing uptake. The community engagement and testing cores work together to foster uptake of testing in sexual and gender minority populations, communities of essential and service workers, and those facing environmental exposures.

## Data Science and Biostatistics Core

The CDCC's data science and biostatistics core supports awardees' data collection, data integration into a public repository, and data-sharing activities. The core employs standardized terminology for health data domains and draws from a set of NIH-approved common data elements (CDEs)<sup>28</sup> that are recommended for use in clinical research to enhance data quality and support aggregated data analysis across sites and over time. This ambitious NIH effort aims to collect CDEs

across a consortium of diverse projects in underserved populations. The CDCC will develop a research infrastructure to knit projects together into a unified network to facilitate data sharing and the reporting of results across projects. The data science and biostatistics core established data-sharing informed consent documents and data use agreements as research infrastructure elements to create a network with unified approaches. The core combines project data sets to create the RADx-UP data warehouse and links program data and external data sets (e.g., the American Community Survey, US Census) in an integrated data repository available to investigators, community members, and the public through a data-sharing and visualization portal. The portal enables the rapid sharing of data, collaboration, and identification of best practices and strategies for overcoming barriers across projects.

This infrastructure addresses an essential and urgent need of communities served by RADx-UP: community-level data on testing to craft appropriate policy responses to the pandemic. At the same time, community leaders and investigators have raised concerns about data sharing because of the potential for group harm inherent in research with underserved populations.<sup>29</sup> To promote transparency while maintaining data security, the core has implemented an innovative, cloud-based platform developed in collaboration with Microsoft (Redmond, WA) using the Azure cloud. The core also is creating processes, communications, and dissemination methods to ensure that national leaders can learn from communities and that communities in RADx-UP can learn from each other. The data collected by the RADx-UP projects and sent to the data science and biostatistics core includes CDEs from

study participants, interviews, and focus groups. The core also collects process data (e.g., collected during engagement impact team and working group sessions) for the evaluation team. The core has organized and convened a data stewardship committee to (1) review the ethical and practical tensions inherent in data use, (2) ensure respect for data sovereignty with tribal nations, (3) communicate the need for standardized data at the community level, and (4) determine the best practices for sharing information back with projects and communities.

This approach fosters trust in COVID-19 research by addressing community-driven research questions, improving the quality of research by streamlining processes, and providing community members with the data they need to foster advocacy and inform future research valuable to communities. The core establishes policies for privacy, security, access, release, and publication to enable the sharing of RADx-UP data and knowledge assets to reduce the impact of COVID-19. The core complements these efforts with continued education about the benefits of CDEs and the need to collect identifiers to support data linkage with external data sets. This approach balances the selection of CDEs and the ability to generate shared data, evidence, and new knowledge with the burden on projects and participants.

## EARLY INSIGHTS FROM RADx-UP

The RADx-UP CDCC's goal is to deliver a research-ready system responsive to questions that communities are asking, move evidence to action, and reduce health inequalities related to COVID-19

and beyond. Fast-moving projects share a robust and preexisting relationship with community partners and tailored community engagement strategies to ensure access for the communities served. These strategies include the following:

1. testing that is inclusive, community-centered, and accessible (i.e., convenient locations and times, particularly for rural and minority communities);
2. programming that is culturally and linguistically responsive;
3. friendly messaging;
4. diverse and bilingual leadership and staff who reflect the communities served with access to accurate materials and information; and
5. resources and services made available mainly to underserved families.

To overcome barriers to testing, RADx-UP projects also provide rapid testing; locate testing sites in communities; share recommendations from family, friends, or trusted community members about testing sites; and offer linkages to services and support for those who test positive. Projects also strive to mitigate COVID-19 disparities, including networking with community pharmacy partners, providing significant numbers of testing personnel to ensure an efficient and nondisruptive process, offering special support for the elderly, and countering misinformation regarding test accuracy with community education. Key lessons have included ensuring that the informed consent acknowledges equity, does not ask for identification (to avoid reduced utilization among undocumented immigrants), and allows opt outs for saving specimens for future research. In addition, projects have found that a flexible approach allowing iterative adaptation incorporating community feedback (e.g., through bilingual

coalitions) has the greatest potential to promote project success. These observations exemplify the ultimate purpose of RADx-UP to engage with community partners to successfully reduce COVID-19 disparities and address the social determinants of health for long-term health equity.

## CONCLUSIONS

The CDCC has adopted an infrastructure that aims to center the needs and interests of underserved populations. Consistent with a precision public health approach, the RADx-UP program aims to create the foundation to minimize health inequalities and advance health equity effectively through tailored interventions in communities.<sup>30</sup> Furthermore, RADx-UP will highlight how community engagement approaches may vary for different populations and how understanding this may increase access to COVID-19 testing and vaccines. RADx-UP will gather and aggregate context-specific data from different communities to address questions about health disparities relevant in the heterogeneous landscape of underserved populations, while applying a framework that acknowledges social and structural factors as key drivers of health inequalities and involves collaboration with community members. *AJPH*

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## CONTRIBUTORS

G. Corbie, E. M. D'Agostino, W. A. Kibbe, and M. Cohen-Wolkowicz conceptualized and wrote the original draft of the editorial. G. Corbie, E. M. D'Agostino, C. W. Woods, G. Dave, K. Marsolo, L. M. Wruck, W. A. Kibbe, and M. Cohen-Wolkowicz developed the study methodology. G. Corbie, A. Richmond, C. W. Woods, G. Dave, W. A. Kibbe, and M. Cohen-Wolkowicz acquired funding. G. Corbie, S. Knox, C. W. Woods, G. Dave, K. M. Perreira, L. M. Wruck, W. A. Kibbe, and M. Cohen-Wolkowicz supervised the study. E. M. D'Agostino, C. W. Woods, G. Dave, K. Marsolo, and L. M. Wruck performed the investigation. E. M. D'Agostino, C. W. Woods, G. Dave, K. Marsolo, and L. M. Wruck performed study visualization. S. Knox, A. Richmond, and K. M. Perreira were responsible for administration. A. Richmond, C. W. Woods, G. Dave, K. Marsolo, and L. M. Wruck performed data curation. K. Marsolo and G. Dave performed formal analyses. All authors reviewed and edited the editorial.

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## HUMAN PARTICIPANT PROTECTION

The RADx-UP program was approved by the Duke University institutional review board.

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