

RADx Underserved Populations (RADxSM-UP) Return to School Phase II Kick-off

July 14, 2021



Agenda

Topic	Speaker	Time
Welcome & Introductions	Dr. Eliseo J. Pérez-Stable	3:00pm
Overview of RADx	Dr. Francis Collins	3:10pm
Overview of RADx-UP and the Return to School Initiative	Dr. Eliseo J. Pérez-Stable Dr. Richard Hodes Dr. Alison Cernich	3:20pm
Team Presentations	Dr. Sonia Lee	3:40pm 10 minutes per team
Overview of RADx-UP CDCC	Dr. Beda Jean-Francois Dr. Warren Kibbe	4:30pm
Q&A	Moderated by Dr. Sonia Lee	4:45pm

Agenda Overview, Welcome & Introductions



Eliseo J. Pérez-Stable, M.D.

**Director, National Institute on Minority Health and Health Disparities
(NIMHD)**

WELCOME & INTRODUCTIONS

OVERVIEW OF RADX PROGRAM

Overview of RADx Program



Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health (NIH)

Rapid Acceleration of Diagnostics (RADx) Initiative

RADx Tech – \$908M*

Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Underserved Populations (RADx-UP) – \$533M

Interlinked community-engaged research projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations

RADx Radical (RADx-rad) – \$187M

Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

RADx Advanced Testing Program (RADx-ATP) – \$192M

Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput — create ultra-high throughput laboratories and “mega labs”

Data Management Support – \$70M

Build an infrastructure for and support coordination of the various data management needs of many of the COVID-19 efforts

At-Home Diagnostic Testing– \$20M

Evaluate the effectiveness of existing diagnostic technologies and platforms in at-home environments

* Includes \$185M in BARDA funds for development of RADx tests (funds were not transferred to NIH)

RADx Tech

Overarching Goal

Establish a robust pipeline of innovative diagnostic technologies to **increase national testing capacity**

Innovate Across the Testing Landscape

Expand the number, type, access, and throughput of testing technologies

Optimize Technology Performance

Develop technology for a range of essential “Use Cases”

- At-home
- Point of Care (POC)
- Testing Laboratory
- Testing Products



RADx-Advanced Technology Platforms (RADx-ATP)

Overarching Goal

Increase testing capacity and throughput by identifying existing and late-stage testing platforms to achieve **rapid scale-up or expanded geographical placement**

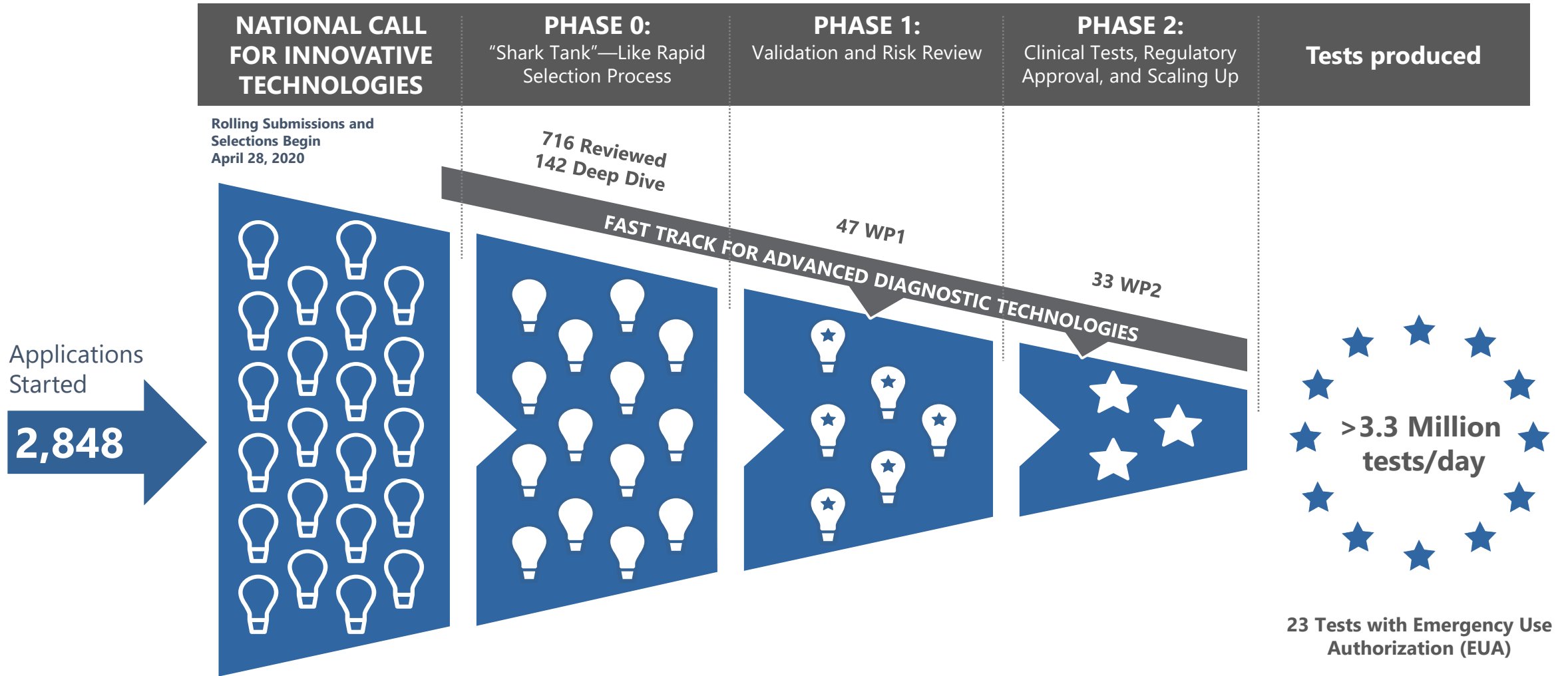
- Emphasize differential POC testing to distinguish SARS-CoV-2 vs. influenza
- Establish rapid collaborations with key industry partners



Scale-up Late-Stage Technologies

Support Scale-Up of High-Throughput Labs to Add Capacity

RADx-Tech “Innovation Funnel” (as of 6/29/21)

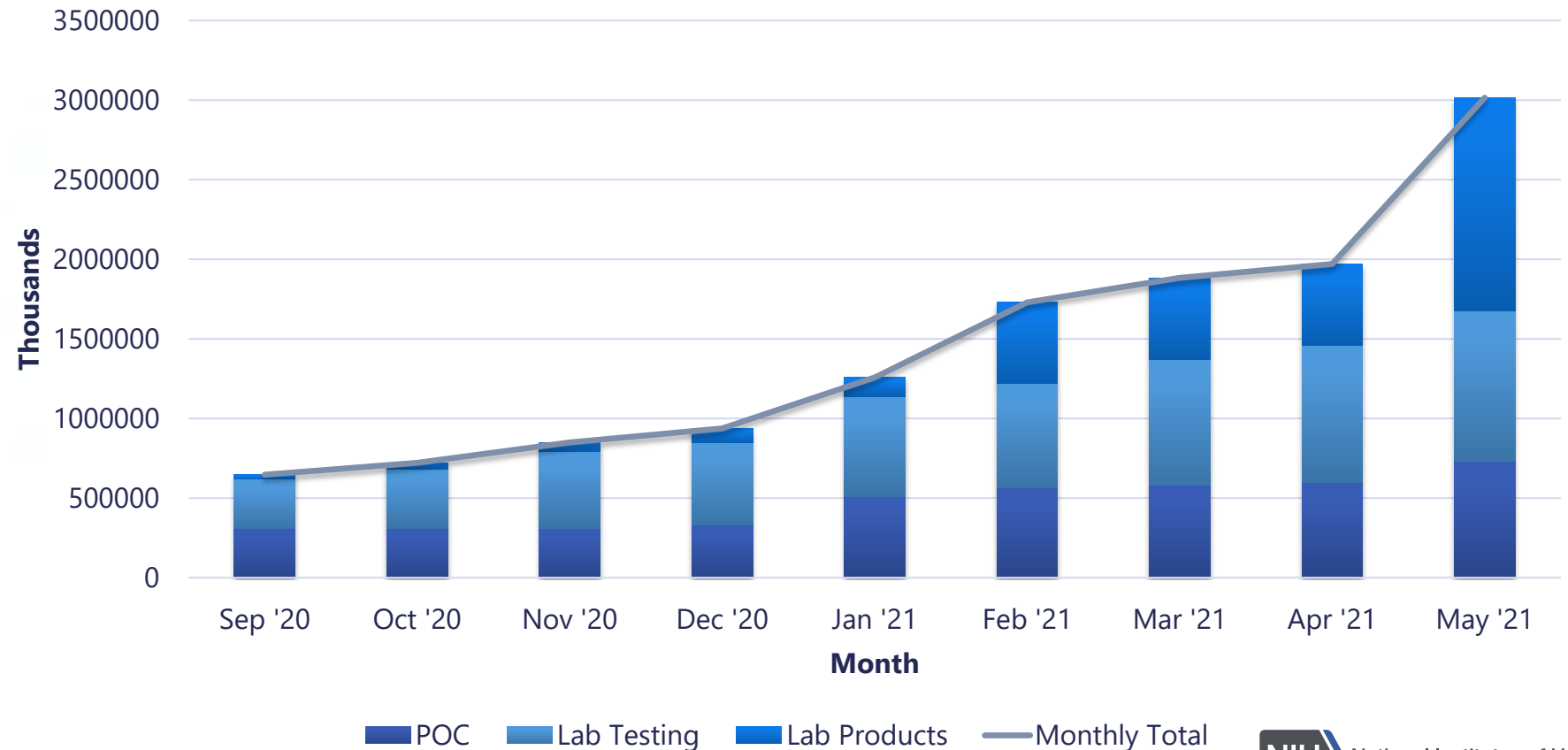


Note: The Innovation Funnel was reopened for a second time between **June 7th – June 28th, 2021** during which **253 applications were received and 97 completed**. Applications will be reviewed over the next few weeks to select 3 to 5 projects.

Contribution of RADx to the National Testing Capacity

RADx awards are contributing over **3 million tests per day** to the National Testing capacity as of May 2021

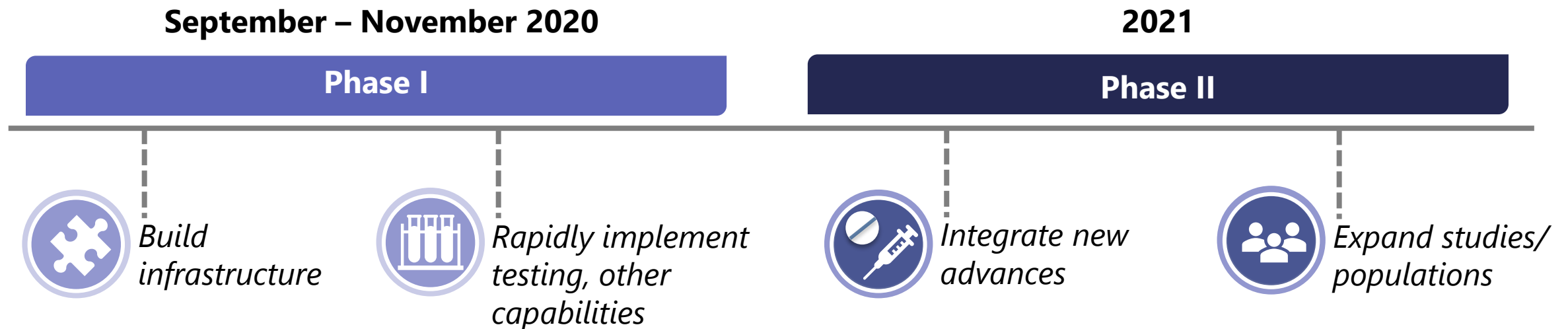
Tests Produced Per Day



RADx-Underserved Populations (RADx-UP)

Overarching Goals

- Enhance COVID-19 testing among **underserved and vulnerable populations** across the US
- Develop/create a **consortium of community-engaged research projects** designed to rapidly implement testing interventions
- **Strengthen the available data** on disparities in infection rates, disease progression and outcomes, and **identify strategies to reduce these disparities** in COVID-19 diagnostics



RADx-Radical (RADx-rad)

Overarching Goal

Support new, **non-traditional approaches** and **new applications of existing tools** that address gaps in COVID-19 testing and develop platforms that can be deployed in future outbreaks of COVID-19 and other, yet unknown, diseases

Example Research Technologies of Interest

- **Novel biosensing and chemosensory testing** for COVID-19 screening
- **Single vesicle, exosome, and exRNA isolation** for the detection of SARS-CoV-2
- **Predicting viral-associated inflammatory disease severity** in children with laboratory diagnostics and artificial intelligence
- **Wastewater-based detection** of SARS-CoV-2
- **Multimodal COVID-19 surveillance** methods for high-risk populations

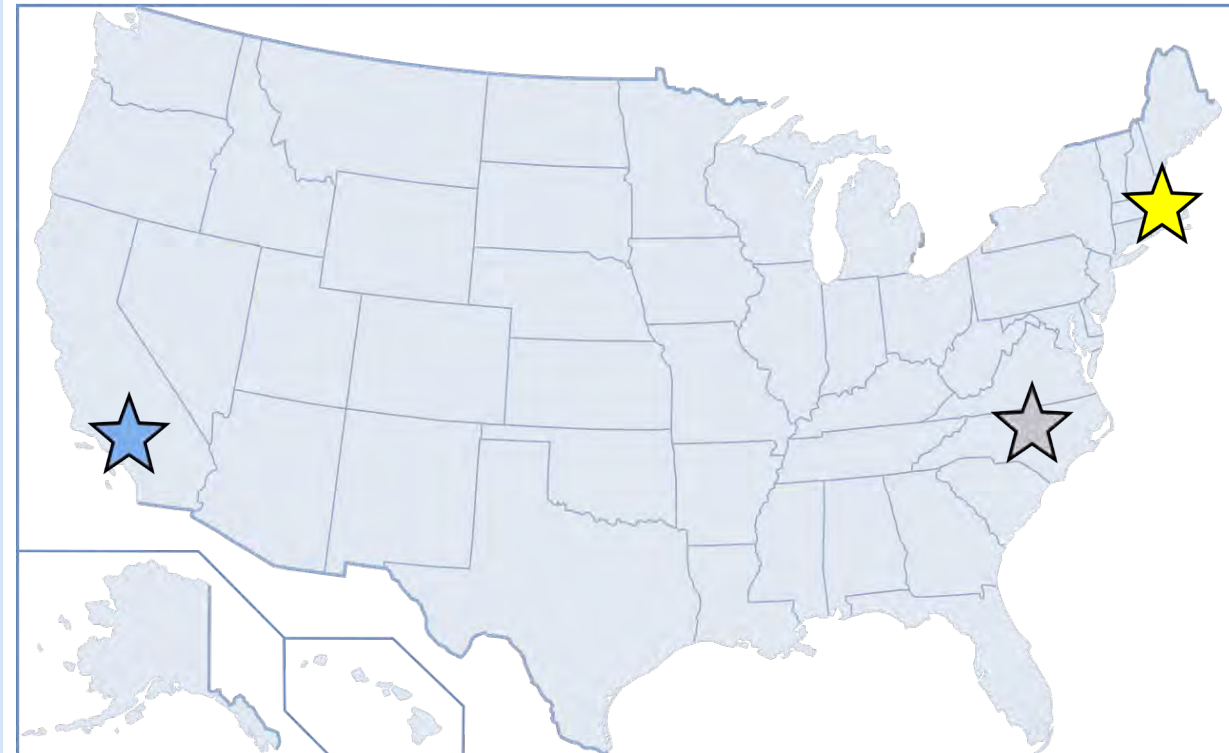


RADx Coordination

RADx is supported by unique coordinating centers that are collaborating with each other to enhance and optimize each program

- ★ **Data Consortium Coordination Center & Program Organization (D-C3PO)** – UCSD, San Diego, CA (RADx-rad)
- ★ **Consortia for Improving Medicine with Innovation & Technology (CIMIT)** – MGH, Boston, MA (RADx Tech/ATP)
- ★ **Coordination & Data Collection Center (CDCC)** – Duke/UNC, Durham, NC (RADx-UP)

U.S. Distribution of RADx Coordination Centers



RADx Data Management

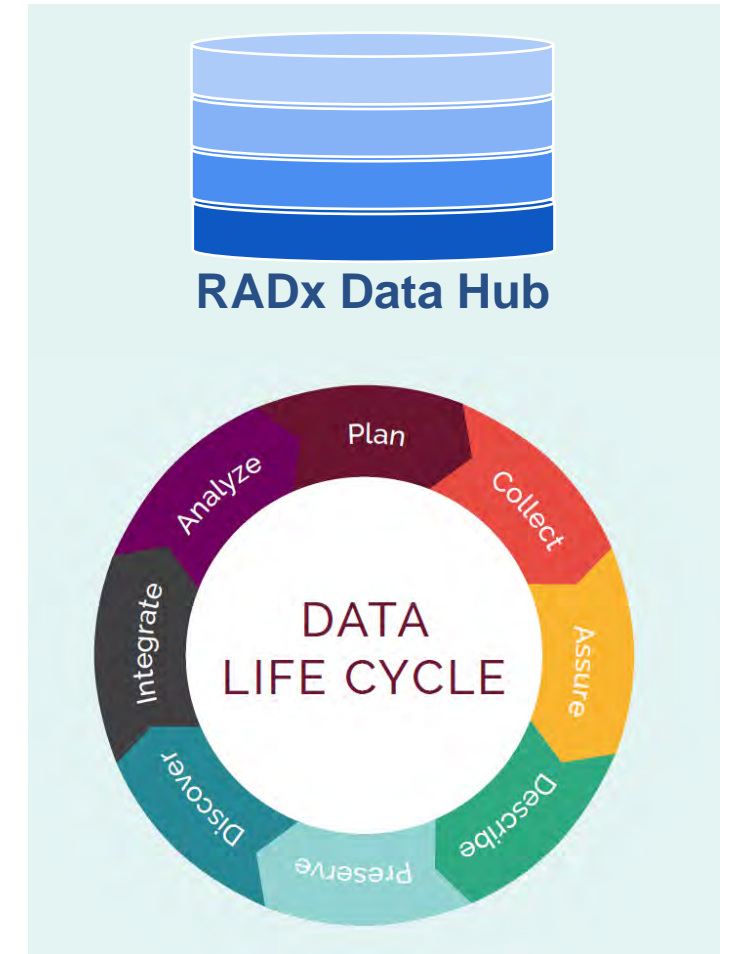


Overarching Goal

Develop platform to integrate data, on individuals and populations, from a variety of sources – including serology and genetic test results, output from smart sensors, self-reported clinical symptoms, and EHR data

- Support Common Data Elements
- Metadata & Data Repository
- Data Management
- Data Curation and Harmonization

Will provide access to deidentified RADx and related data, algorithms, and other capabilities generated by RADx programs and related technologies



INTRODUCTION OF RADX-UP

RADx-UP Program



Richard J. Hodes, M.D.

Director, National Institute on Aging (NIA)



Eliseo J. Pérez-Stable, M.D.

**Director, National Institute on Minority Health and Health Disparities
(NIMHD)**

RADx-UP Strategies

- **Expand capacity to test broadly** for SARS-CoV-2 in highly affected populations, including asymptomatic persons.
- **Deploy validated point of care tests** as available, including self-test and saliva-based methods.
- **Inform implementation of mitigation strategies** based on isolation and contact tracing to limit community transmission.
- **Understand factors** that contribute to COVID-19 disparities and **implement interventions** to reduce these disparities.
- **Establish infrastructure** that could facilitate evaluation and distribution of vaccines and therapeutics.

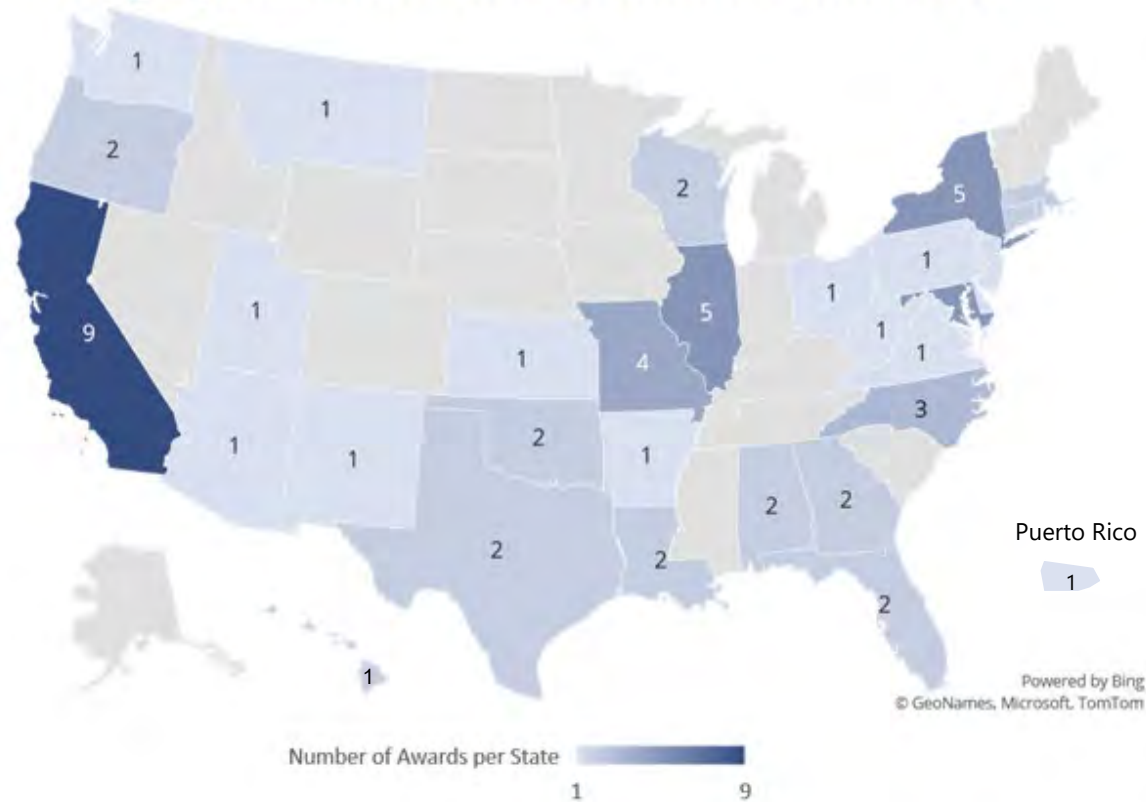
RADx-UP Phase I Snapshot: 69 Funded Research Projects and Coordination and Data Collection Center

NOT-OD-20-121, NOT-OD-20-120, NOT-OD-20-119

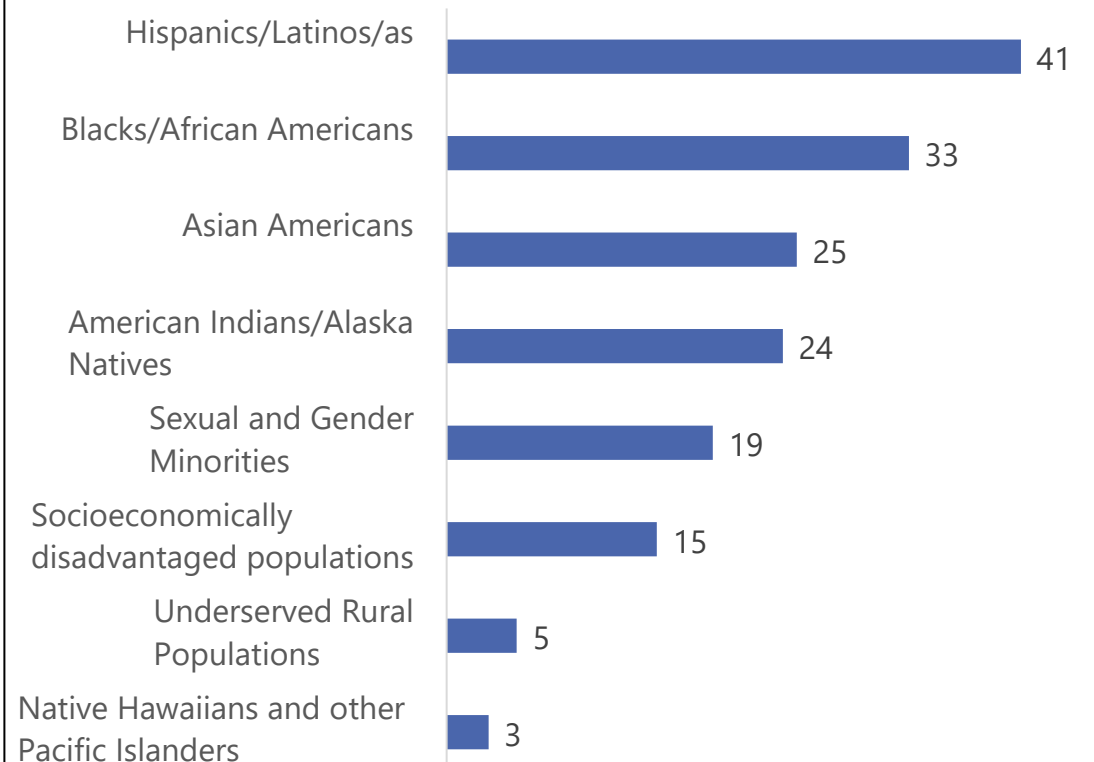
Funded sites and research projects span a total of **31 states** in addition to DC and Puerto Rico and include **55 institutions**.

Projects include diverse health disparity population affected by COVID-19.

Geographic Distribution of Award Institutions



Populations with Health Disparities

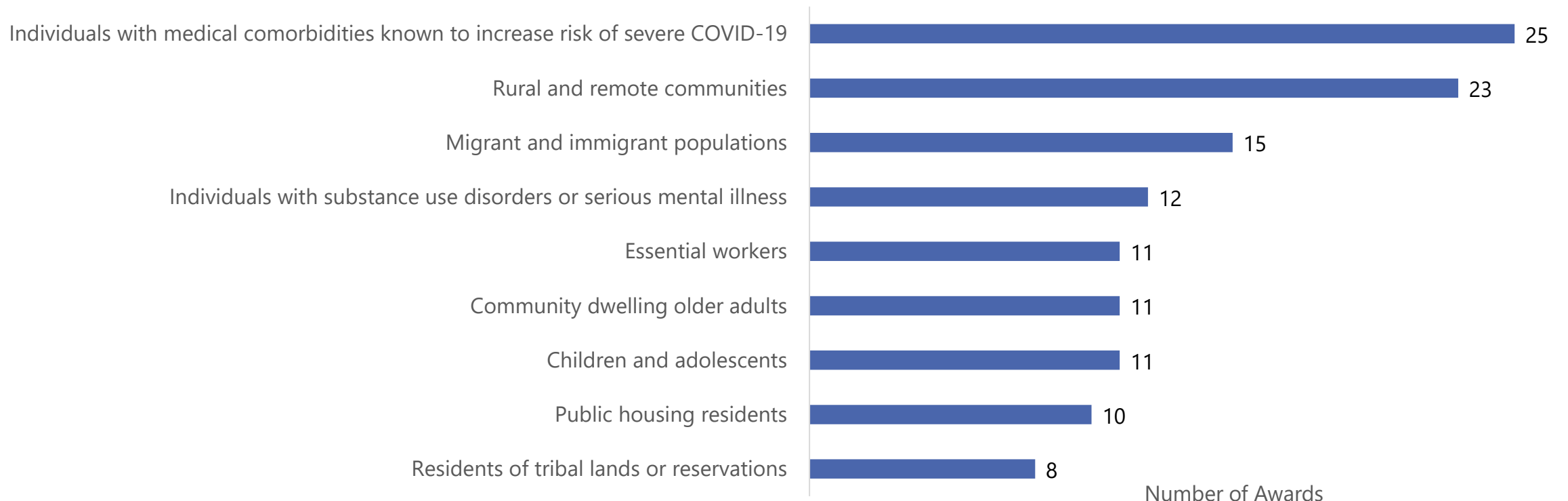


RADx-UP Phase I Snapshot: 70 Funded Sites and Research Projects

NOT-OD-20-121, NOT-OD-20-120, NOT-OD-20-119 & RFA-OD-20-013

Together, funded sites and research projects propose to serve a diverse population set, with many projects serving individuals with medical comorbidities known to increase risk of severe COVID-19, rural and remote communities, and migrant and immigrant populations.

Target Vulnerable Population Projects (1/2)



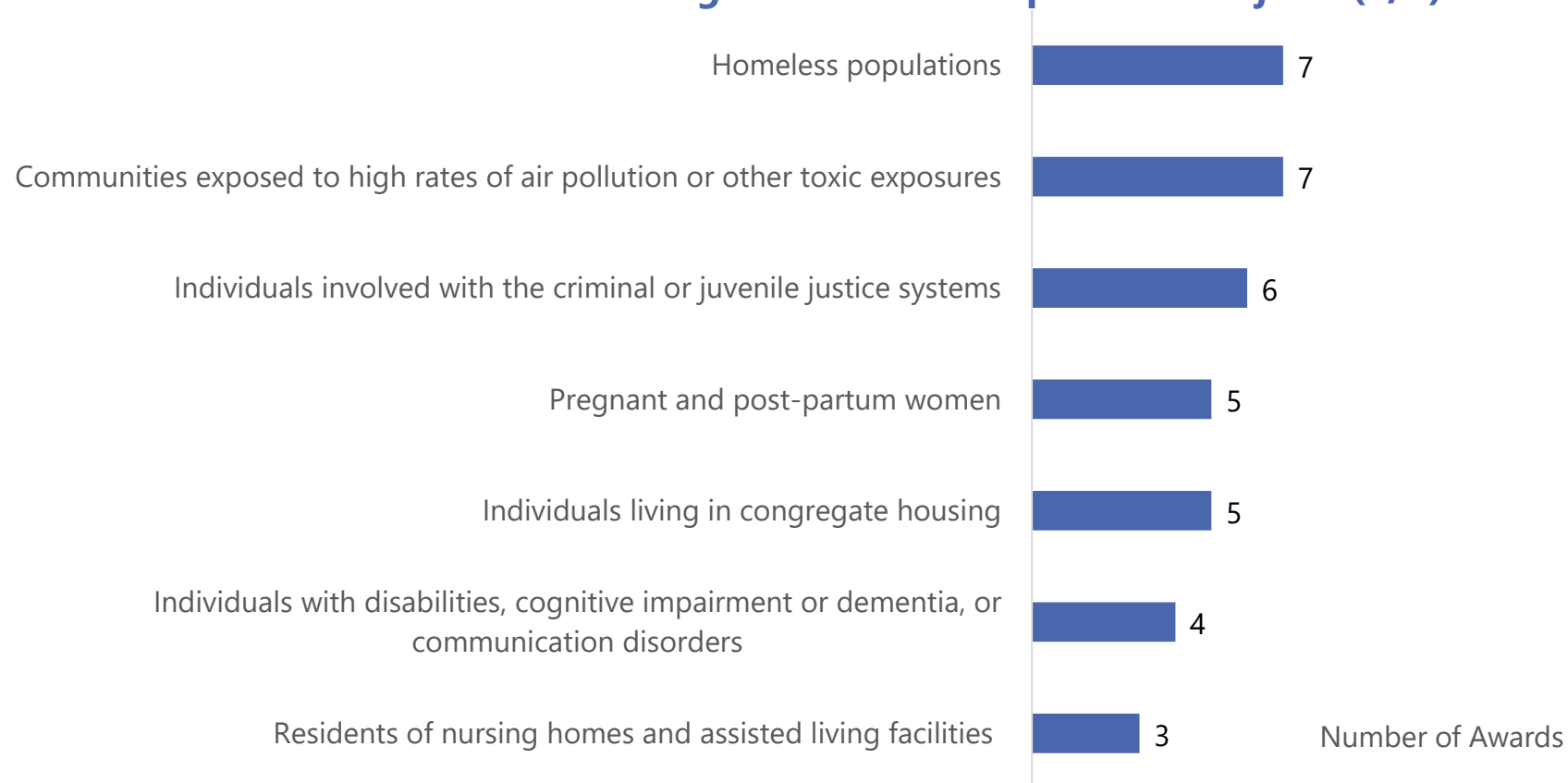
Note: Some projects/sites address multiple target populations.

RADx-UP Phase I Snapshot: 70 Funded Sites and Research Projects

NOT-OD-20-121, NOT-OD-20-120, NOT-OD-20-119 & RFA-OD-20-013

Funded sites and research projects also propose to serve the following additional vulnerable populations.

Target Vulnerable Population Projects (2/2)



Note: Some projects/sites address multiple target populations.

RADx-UP Phase I Awards

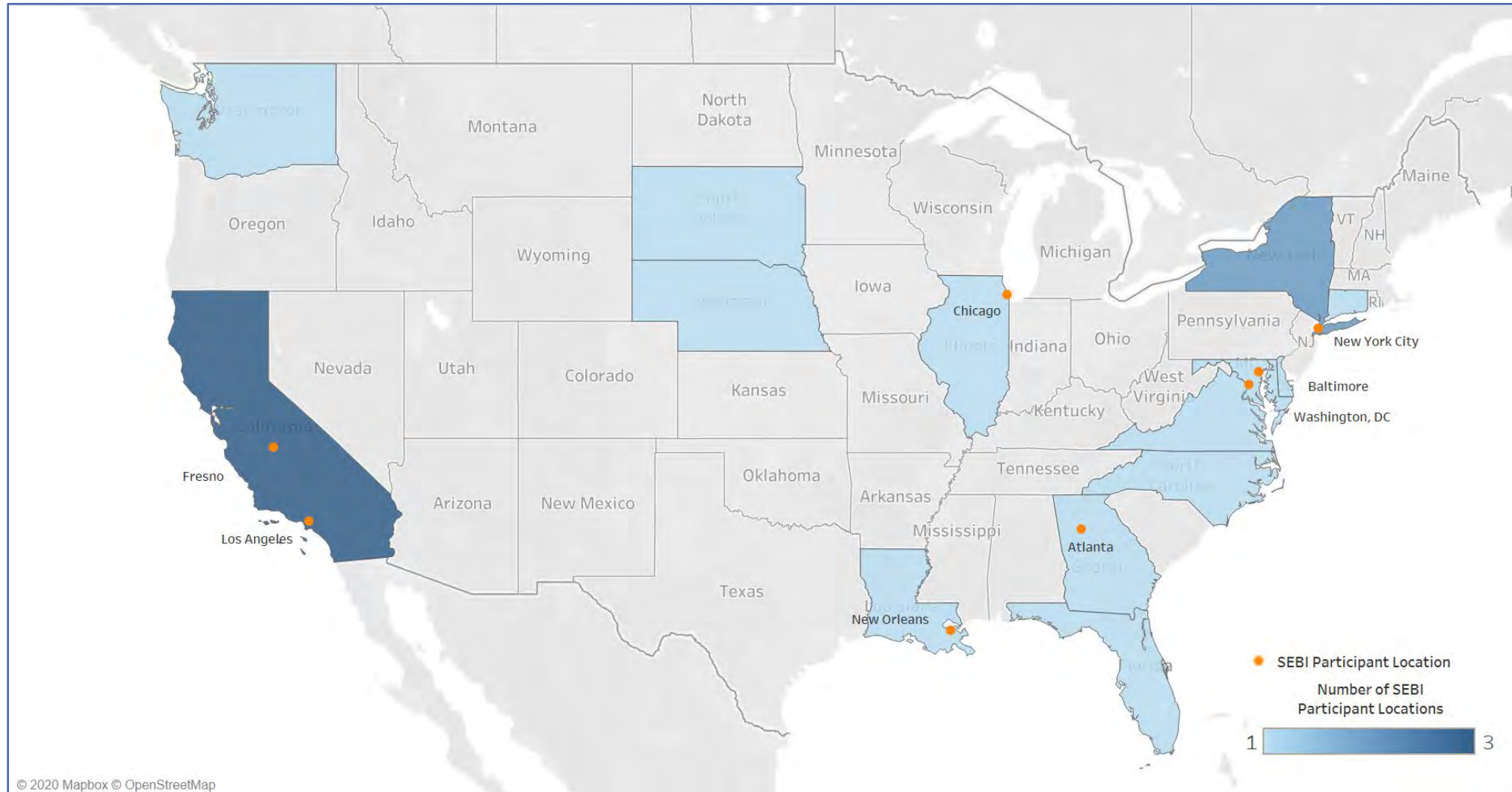
Testing Participant Locations



Note: Cities listed are not exhaustive, as some projects only provided state-level information.

RADx-UP Phase I Awards

Social, Ethical and Behavioral Implications (SEBI) Participant Locations



Note: Cities listed are not exhaustive, as some projects only provided state-level information.

Testing Research Projects: Large Networks, Consortia & Research Centers

NOT-OD-20-121

Program Information: \$5M per site over 2 years; 30 sites

- Understand the factors associated with COVID-19 morbidity and mortality disparities and to lay the foundation to reduce disparities for those underserved and vulnerable populations
- Closely partner with communities to develop and implement interventions to increase access and uptake of testing
- Provide large-scale testing and collaborate across the consortium of projects to serve as a resource for future studies and outreach

Overview

- **Awarded 29 sites in FY20, 1 site in FY21**
 - Approximately 500,000 participants/tests
- **Testing methods include a range of POC, pooled, & lab-based; PCR, antigen, and Ab:**
 - Abbott ID NOW, Roche cabas, Cepheid GeneXpert, Hologic Aptima/Panther Fusion, Advanta Dx, Quest Diagnostics LDT, ThermoFisher, Infinity BiologiX, LabCorp, and custom tests
- **Testing at prisons, mental health programs, in public housing & community centers**
 - Focus on rural and urban, Tribal, and aging communities



Testing Research Projects: Community Collaborations & Partnerships

NOT-OD-20-120

Program Information: \$2M per site over 2 years; 23 sites

- Strengthen available data on disparities in infection rates and disease progression and outcomes among underserved and vulnerable populations across the US
- Understand differences in testing access and uptake patterns
- Partner with communities to build the evidence-base of approaches to identify and address disparities in diagnostic testing uptake and effectiveness

Overview

- **Awarded 4 sites in FY20, 19 in FY21**
- **Testing methods include a range of POC, pooled, & lab-based; PCR, antigen, and Ab:**
 - Abbott ID NOW, Abbott Architect IgG Assay, Applied BioSystems, Cellex Rapid Test, KorvaLabs Curative SARS-Cov-2 Assay, Cepheid GeneXpert, Cellex Rapid Test, Healgen, Quidel Sofia SARS antigen test, ThermoFisher, TaqPath, LabCorp, Inno Diagnostics, and custom tests
- **Testing at mobile-sites, community health centers, in public housing & at home**
 - Focus on individuals with medical comorbidities, substance use disorders or illness, and community dwelling older adults



Social, Ethical and Behavioral Implications

NOT-OD-20-119

Program Information: \$1.2M per site over 2 years; 16 sites

- Assess ethical, historical, healthcare, social, economic, and contextual factors surrounding COVID-19 testing
- Investigate influence of cultural beliefs and attitudes, perceived expectations, and preferences
- Inform development of interventions and tools to increase access to and acceptability of testing

Overview

- **Awarded 5 projects in FY20, 11 in FY21**
- **Research conducted through community health centers, online surveys, public housing developments, and Tribal communities**
 - Focus on individuals with medical comorbidities, migrant and immigrant populations, Tribal populations, and rural and remote communities



RADx-UP Coordinating Center (CDCC)

RFA-OD-20-013

Program Information: \$80M over 4 years

- Serve as a national resource to coordinate across the RADx Consortium
- Provide overarching support and guidance in: (1) Administrative Operations and Logistics, (2) COVID-19 Testing Technology, (3) Community and Health System Engagement and (4) Data Collection, Integration and Sharing
- Support the pilot project programs: (1) Rapid pilot studies, (2) Community collaboration grants

Overview

- **Awarded to Duke/UNC**
- **Innovative ideas for data management, hub and spoke models of networked testing, and outreach to underserved communities**
- **Experience in developing new SARS-CoV-2 testing technologies**
 - Provide strong technical assistance to testing protocols and adoption/distribution of new, emerging technologies



Phase II: New Funding Opportunities

	NOT-OD-21-101	NOT-OD-21-103	RFA-OD-21-008	RFA-OD-21-009
Opportunity Name	Administrative Supplements for RADx-UP	Competitive Revisions for Testing / Vaccination	Testing / Vaccination U01	SEBI U01
Total Direct Costs per year	\$300,000 (total costs)	\$750,000	\$750K-\$1.5M	\$400,000
Application Receipt	May 10	May 28	July 07	July 07
Number of Awards	10 - 15	10 - 15	25-50	16
Eligibility	RADx-UP Phase I	NIH grantees	Open	Open
Scientific Focus	Address vaccine hesitancy within existing RADx-UP projects	Testing interventions in environment of vaccine availability	Testing interventions in environment of vaccine availability	Address SEBI implications of testing

OVERVIEW OF RETURN TO SCHOOL

Overview of RADx-UP Return to School



Alison Cernich Ph.D.
Deputy Director,
***Eunice Kennedy Shriver* National Institute of Child Health and Human
Development (NICHD)**



RADx-UP Return To School Diagnostic Testing Approaches Phase I (OTA-21-004)

Goal

Develop and test COVID-19 diagnostic testing approaches to safely return children and staff to the in-person school setting in underserved and vulnerable communities

Mechanism

Other Transaction Authority to provide flexibility for changing circumstances and funding of non-traditional partners

Budget

\$50 million commitment from the OD congressional appropriation

Return to School Phase I

OTA-21-004

Program Information: ~\$33M awarded in Phase I; 8 sites

- Focus on children and adolescents below the age eligible for vaccination via Emergency Use Authorization (age 16) and all school personnel
- Advance methods to integrate testing in return to or maintenance of in-person instruction
- Identify effective, scalable, and sustainable testing implementation strategies, including in-school testing, in community pediatric primary care clinics, childcare centers, preschool, and school settings serving primarily underserved or disadvantaged children and their families.

Overview

- **Awarded 8 projects** in April FY21
- **Strategies for school-based settings** to combine frequent testing with proven safety measures to reduce the spread of COVID-19



Return to School Phase II

OTA-21-007

Program Information: ~\$15M awarded in Phase II; 5 sites

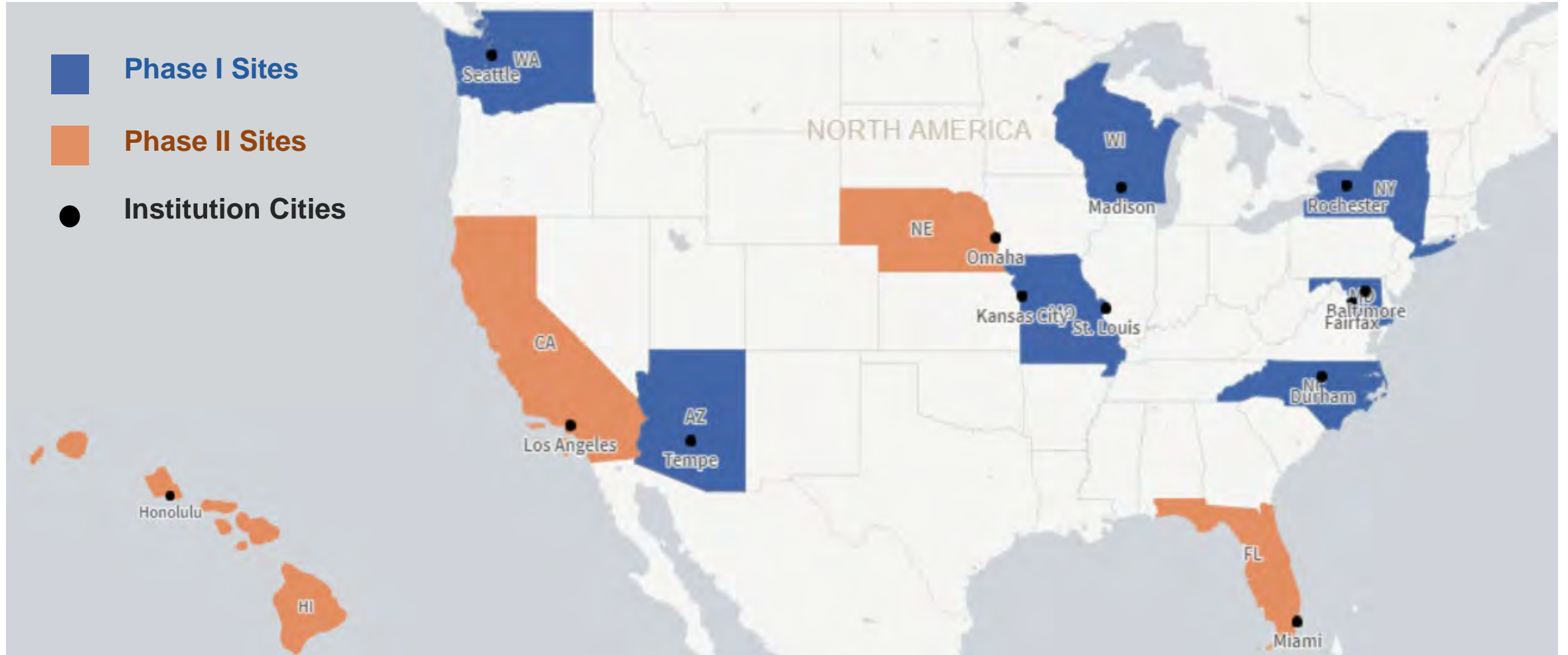
- Focus on children and adolescents below the age eligible for vaccination via Emergency Use Authorization (age 12) and all school personnel
- Advance methods to integrate testing in return to or maintenance of in-person instruction
- Identify effective, scalable, and sustainable testing implementation strategies, including in-school testing, in community pediatric primary care clinics, childcare centers, preschool, and school settings serving primarily underserved or disadvantaged children and their families.



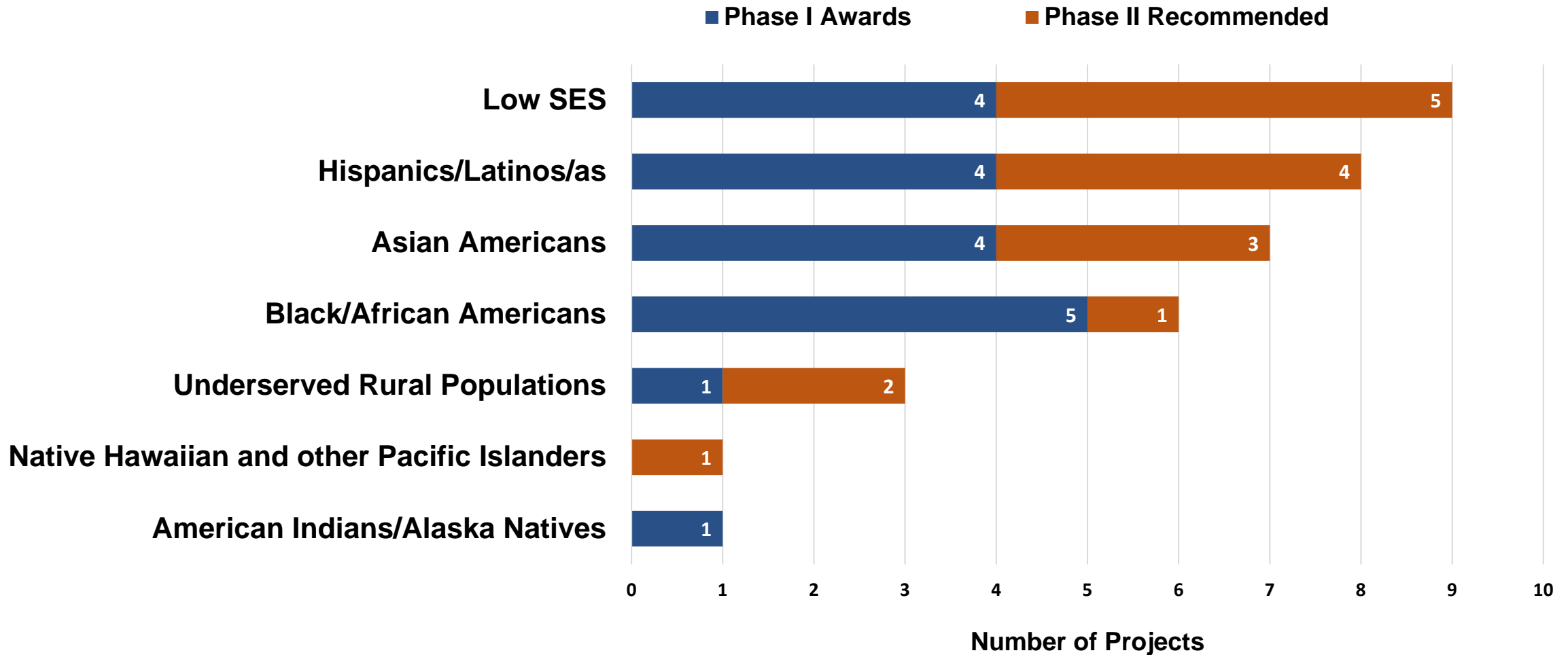
Overview

- **Awarded 5 projects** in June 2021 (3 additional awards in negotiations)
- **Strategies for school-based settings** to combine frequent testing with proven safety measures to reduce the spread of COVID-19

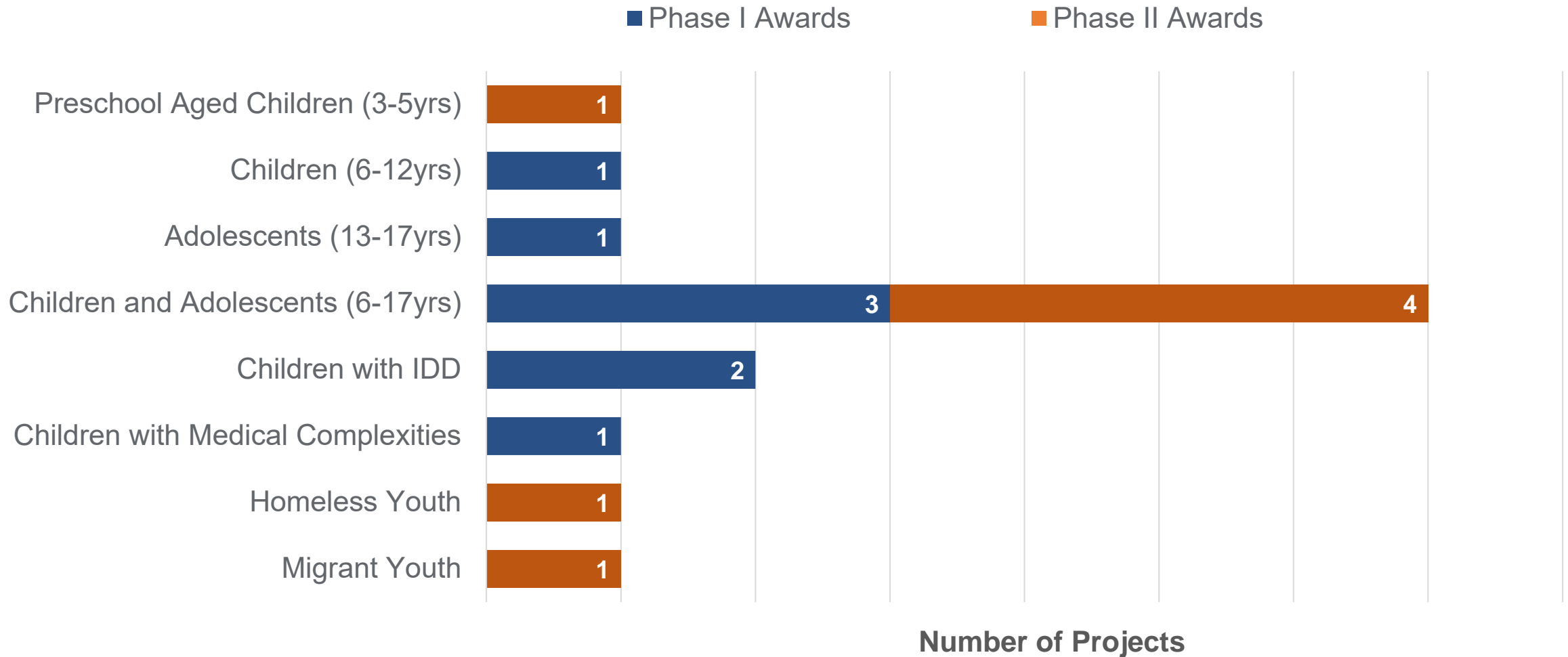
Geographic Distribution of Projects



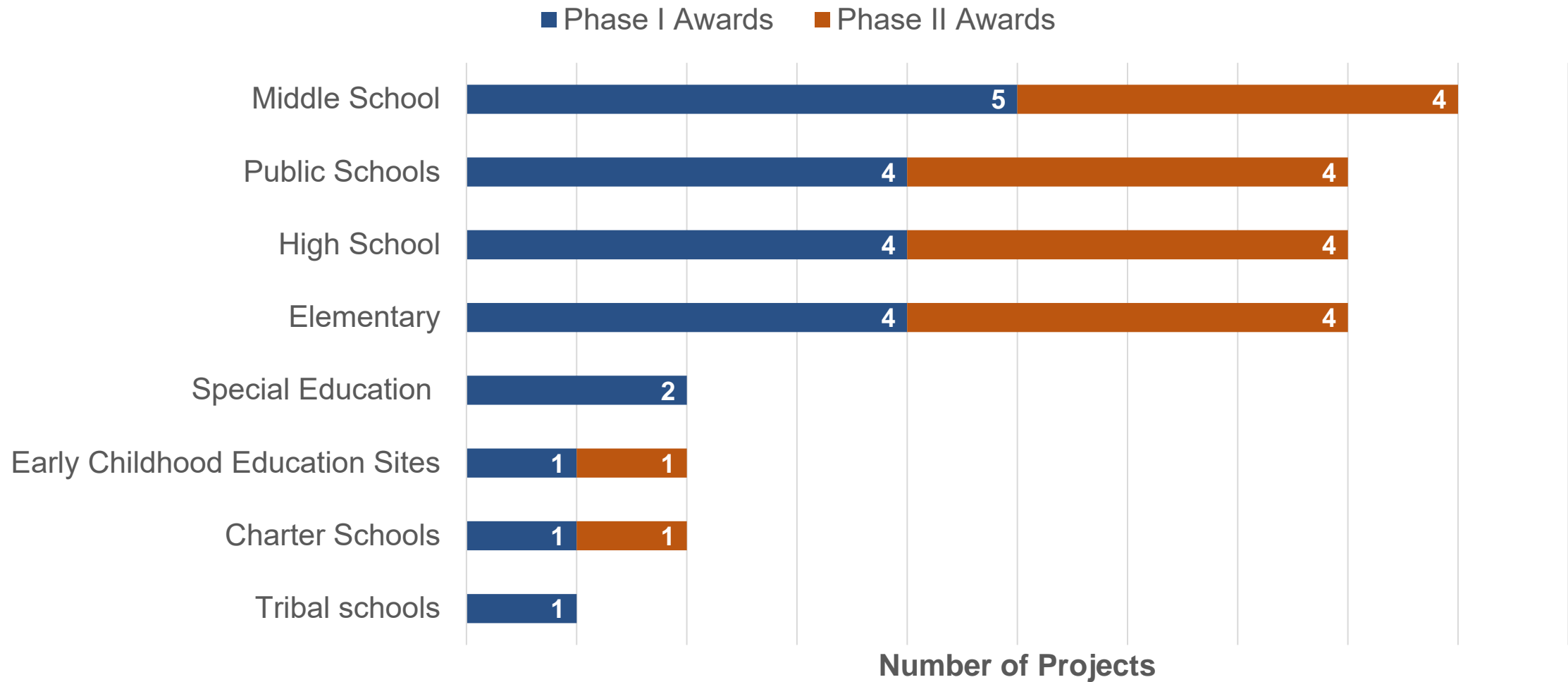
Target Populations with Health Disparities



COVID-19 Vulnerable Populations



Educational Settings



Team Presentations



Sonia Lee Ph.D.
Eunice Kennedy Shriver National Institute of Child Health and Human
Development (NICHD)

TEAM PRESENTATIONS

Speaker



Lisa Gwynn, D.O, MBA

University of Miami School Of Medicine

Maximizing Child Health and Learning Potential Promoting a School Culture of Safety in the Era of COVID-19

University of Miami Miller School of Medicine



Dr. John T. Macdonald
FOUNDATION



Our Team

PI: Lisa Gwynn, DO, MBA, MSPH

Co-PI: Elizabeth Pulgaron, PhD

Co-PI: Viviana Horigian, MD, MHA

Project Manager: Maria Ferraris, MEd, MPM



Our Team

Social Worker

Psychologist

Post-Doctoral Fellows

Interns

Project Manager

Research Assistants



Dr. John T. Macdonald Foundation School Health Initiative

- Miami-Dade County Public Schools (MDCPS) – Largest district in Florida; 4th largest district in the nation
- Established in 2000, provides comprehensive healthcare services in schools in Miami-Dade County.
- Includes 3 High Schools, 2 Middle Schools, 4 Elementary – (all Title 1) 94% qualify for free/reduced lunch.
- Over 10,000 children are enrolled.
- Mixed model of health suites in Elementary, and 1 Middle School, Full-service clinics in all High Schools and 1 Middle School.
- Staffed by Pediatricians and APRN's, along with Pediatric residents, RN's, LPN's.
- Services offered include well visits, sports physicals, immunizations, screenings, mental health, management of chronic health conditions, reproductive health services including STI's and HIV.
- Telehealth equipment connects health suites with doctors at hub clinics.



Community Pediatrics

- **Pediatric Mobile Clinic** – Established in 1992. Travels into underserved neighborhoods and provides comprehensive healthcare services to uninsured children throughout Miami-Dade County.
- **SHOTZ-2-Go!** - Established in 2020 in partnership with the Florida Department of Health (FDOH) to combat the high percentage of unvaccinated children throughout Miami. Provides all vaccinations to children in schools, at health fairs, community events, etc.
- **COVID-19 Testing team** – Funded through philanthropic donations and FDOH in July 2020. Provides testing to children of all ages. Since the program's inception, over 15,000 children have been tested.



RADx-UP Project

- **Study 1**

Elicit input of key stakeholders in creating COVID-19 testing protocols and vaccine confidence initiatives.

- a) Culturally acceptable
- b) Addresses issues of stigma/discrimination
- c) Maximize trust/confidence of the source and format

Aim 1.1 – Conduct cross-sectional assessment of current COVID-19 knowledge and experiences of parents and school staff. Online surveys will measure knowledge and attitudes, health risk beliefs, vaccine confidence, stigma/discrimination, trauma, anxiety. Participants will be incentivized. Information regarding participation in future focus groups will be provided.

Aim 1.2 – Conduct focus groups (two per school level). Youth, parents and school staff will be recruited



RADx-UP Project

Study 1 (cont'd)

Aim 1.3 – Using the quantitative and qualitative data gathered in aims 1.1 and 1.2, we will design COVID-19 testing protocols and COVID-19 health and vaccine confidence initiatives to present to and solicit feedback from our advisory board.

- i. Advisory board – pediatric infectious disease expert, representative from the local health department, MDCPS health services representative, parent representative, school leadership, school champions.
- ii. School champions – will be chosen from each school. Personnel who will assist and advocate for the implementation of the interventions
- iii. Will meet monthly to make revisions and adjustments to protocols as needs emerge
- iv. The COVID-19 health education program will have developmentally appropriate versions, length and duration and formats will be determined by results of aim 1.2



RADx-UP Project

Study 2

Explore the feasibility of strategic COVID-19 testing protocols with goal of increasing sense of safety and creating a protocol which will increase student in-person academic time, and participation in extracurricular activities, including sports.

- i. Protocols expected are for students that are symptomatic, exposed and for higher-risk students (e.g., athletes).
- ii. Non-randomized parallel controlled trial – 4 intervention schools; 5 control schools services as usual.

Aim 2.1 – COVID-19 testing protocols implementation. Data collected will include percent of students quarantined, results of students in protocol, number of missed in-person school days. Comparisons will be made between intervention and control schools.

Aim 2.2 – Pilot testing strategies for athletes.

Testing that will be used: Binax Now rapid tests; confirmatory Cue tests.



Dr. John T. Macdonald
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RADx-UP Project

Study 3

Evaluate the feasibility and impact of a COVID-19 health education and vaccine confidence initiative

Aim 3.1 – Collect process data on success with recruitment and ability to deliver the intervention. Analyze data on acceptability of the intervention from middle and high school students, parents, and school staff using consumer feedback surveys at the end of the intervention.

Aim 3.2 – Evaluate whether the health education and vaccine confidence intervention increased knowledge and effected behavior change for outcomes for students, parents and school staff. It is hypothesized that intervention schools will have increased knowledge and higher vaccination rates.

Aim 3.3 – To assess the feasibility and consumer usage of providing COVID-19 vaccines in school settings in clinics and through mobile units parked at schools. It is hypothesized that intervention schools will have higher vaccination rates among students and staff.



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Thank you!

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Twitter: @lisagwynn



Dr. John T. Macdonald
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Speaker



Moira Inkelas, Ph.D., MPH

University of California, Los Angeles

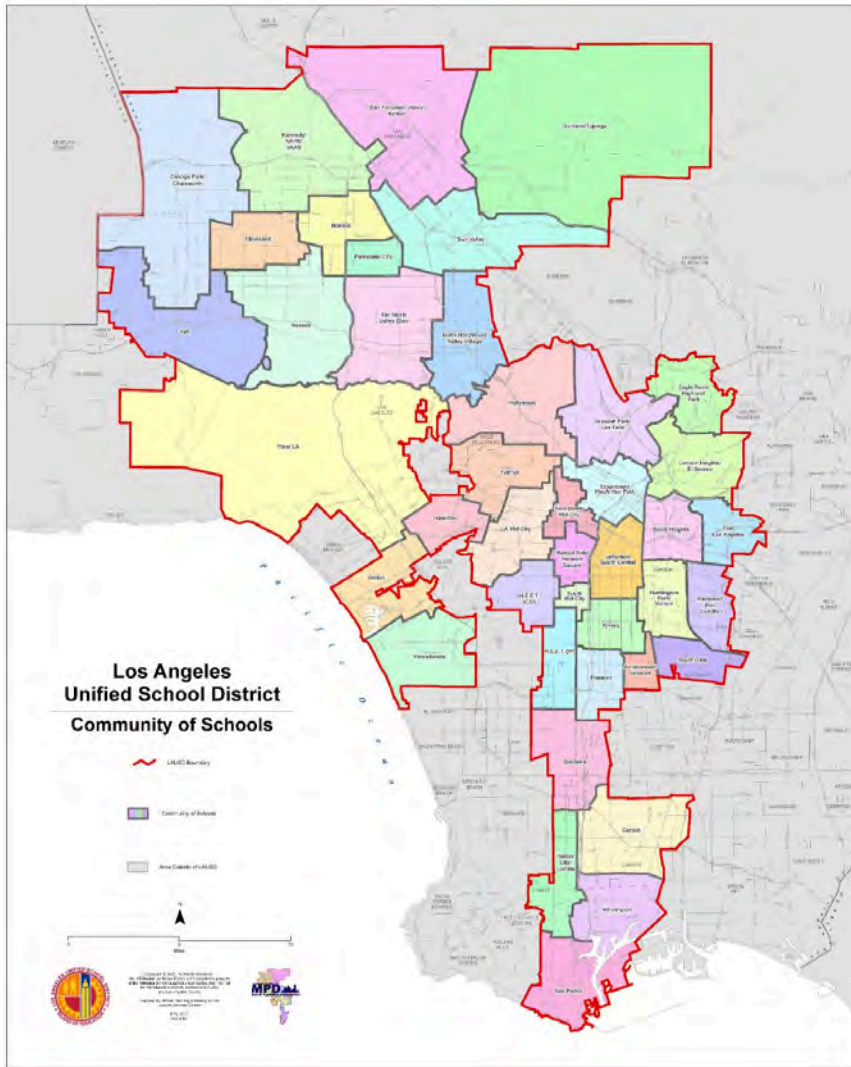


Impact of COVID-19 Testing and Mitigation on Equitable Return-to-School in the Second Largest U.S. School District

RADx Underserved Populations (RADx-UP)
Return to School Diagnostic Testing Approaches
Phase II Kick-Off

July 14, 2021

Population of the Los Angeles Unified School District



- 850 schools across 720 square miles
- Preschool through Grade 12
- Multiple configurations (e.g. K-6, 6-8, K-12)
- About 500,000 students
- 80% economically disadvantaged
- 74% Latino, 8% African-American, 4% Asian, 2% Filipino, 10% White

Collaboration to identify outcomes and program features

Initial population characteristics:

Baseline cumulative incidence of COVID infection among students (%):	4
Baseline cumulative incidence of COVID infection among adults (%):	4
Baseline prevalence of active COVID infection among students (%):	0.6
Baseline prevalence of active COVID infection among adults (%):	0.6
Baseline proportion of adults vaccinated (%):	0
Baseline proportion of students vaccinated (%):	0
Baseline prevalence of COVID safety education (%):	10
Probability of receptiveness to COVID safety outreach (%):	50

Infection time-course:

Days from infection until infectious:	3
Days from infection until no longer infectious:	13
Days from infection until symptomatic:	5
Days from infection until no longer symptomatic:	15
Days from infection until no longer actively infected:	15

Probability of symptoms if infected:

- for adults (%):	70
- for students (%):	50

Test accuracy:

Test specificity (%):	99.9
Test sensitivity on day of infection (%):	0.1
Test sensitivity 1 day after infection (%):	0.1
Test sensitivity 2 days after infection (%):	0.1
Test sensitivity 3 days after infection (%):	50
Test sensitivity 4 days after infection (%):	80
Test sensitivity 5+ days after infection ("peak sensitivity") (%):	95
Days of peak sensitivity:	3
Test positivity at end of active infection (%):	50
Daily decline in test positivity after recovery (%):	10

Exogenous infection risks:

- to students (% per day):	0.04
- to parents (% per day):	0.04

Surveillance testing:

Testing fraction (% of enrolled students tested per testing day): 25

Test on Mondays?

Test on Tuesdays?

Test on Wednesdays?

Test on Thursdays?

Test on Fridays?

Lab turnaround time for surveillance test results (days): 2

Quarantine length after student tests positive (days): 14

Time window for detecting classroom outbreaks (days): 14

Number of recent infections required to declare a classroom outbreak: 3

Quarantine length after classroom cluster detected (days): 14

Self-report attestations:

Attestation sensitivity if infected and symptomatic (%):	90
Attestation sensitivity if infected and presymptomatic/asymptomatic (based on knowledge of exposure) (%):	50
Attestation specificity (%):	80
Quarantine length after positive attestation (days):	3

In-home transmission risks:

- from infectious adult in household to student (% per infection):	16
- from infectious adult in household to partner (% per infection):	40
- from student to adult in household (% per infection):	40

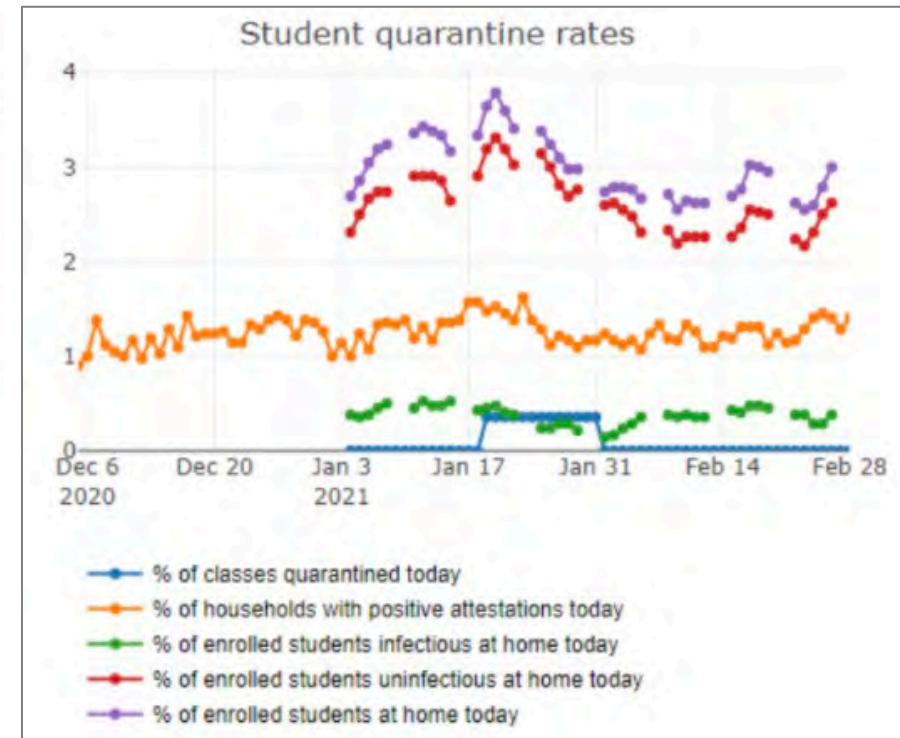
Education and testing after positive attestations:

Response time for contacting households after positive attestations (days):	1
Increase in attestation sensitivity after education (%):	30
Response time from adult attestation followup call until test sample collection (days):	1
Lab turnaround time for attestation-triggered test results (days):	2
Student quarantine length after household adult tests positive (days):	14

At-school transmission risks:

Risk of transmission to close classmates per infectious student (% per day):	0.1
Risk of transmission to distant classmates per infectious student (% per day):	0.05

- Local conditions
- Virus dynamics
- Test accuracy
- Mitigation policies



Modeling infection dynamics and mitigation strategies to support K-6 in-person instruction during the COVID-19 pandemic

<https://agent-based-models.shinyapps.io/RegionalCOVIDSchoolSimulation/>

Features of COVID-19 testing program

- LA Unified secured sufficient capacity to provide periodic asymptomatic and exposure/symptom-based testing.
- Exposure/symptom-based testing available for students, staff, and household members.
- Testing is free.
- RT-PCR SARS-CoV-2 testing, including anterior nasal and saliva, with guaranteed 24 hour turn-around.
- Tracing of school contacts, and collaborative investigation of potential epidemiologically linked cases with Los Angeles County Department of Public Health

Testing program measures



Los Angeles Unified COVID-19 Dashboard

Results Overview: 7/8/2021

Test and Vaccine Capacity - District-Wide

2,190,408	30,390	21,432	49,886	382	0
Total Tests w/valid results	Tests w/results, last 7 day:	Test Capacity, next 7 days	Total vaccines given	Vaccines given, last 7 days	Vaccine capacity, next 7 days

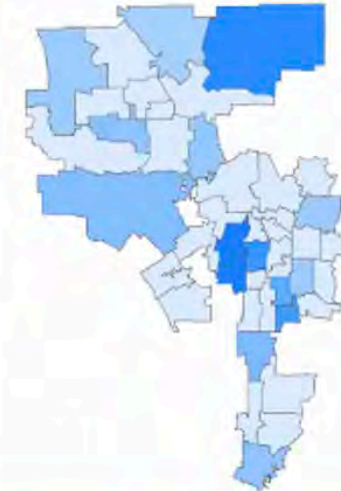
Result Summary - District-Wide

0.14%	66	0	82,757
Positive Test Rate, last 7 days	Number of cases, last 7 days	School-associated Cases, last 7 days	Daily passes, last 7 days

Community Case Rates

LA County Testing

LAUSD Testing



No reported symptoms or exposures

Reported symptoms or exposures

Person Type	Number of tests, last 7 days	Positive test rate, last 7 days	Number of tests, last 7 days	Positive test rate, last 7 days
<input checked="" type="checkbox"/> Community Members - Adults	4,960	0.40%	17	0.00%
<input checked="" type="checkbox"/> Community Members - Children	257	0.39%	0	0.00%
<input checked="" type="checkbox"/> Staff reporting to worksite	7,450	0.11%	21	0.00%
<input checked="" type="checkbox"/> Staff Working Remotely	122	0.00%	0	0.00%
<input checked="" type="checkbox"/> Student	17,542	0.07%	21	0.00%
	23	0.00%	0	0.00%
Adult Ed	40	2.50%	0	0.00%
Early Ed	901	0.22%	4	0.00%
Elementary	10,356	0.05%	14	0.00%
Total	30,331	0.14%	59	0.00%

Tests Overview

Tests Weekly/Daily

Testing Capacity Utilization

Daily Health Pass

Community Engagement

LAUSD Vaccination

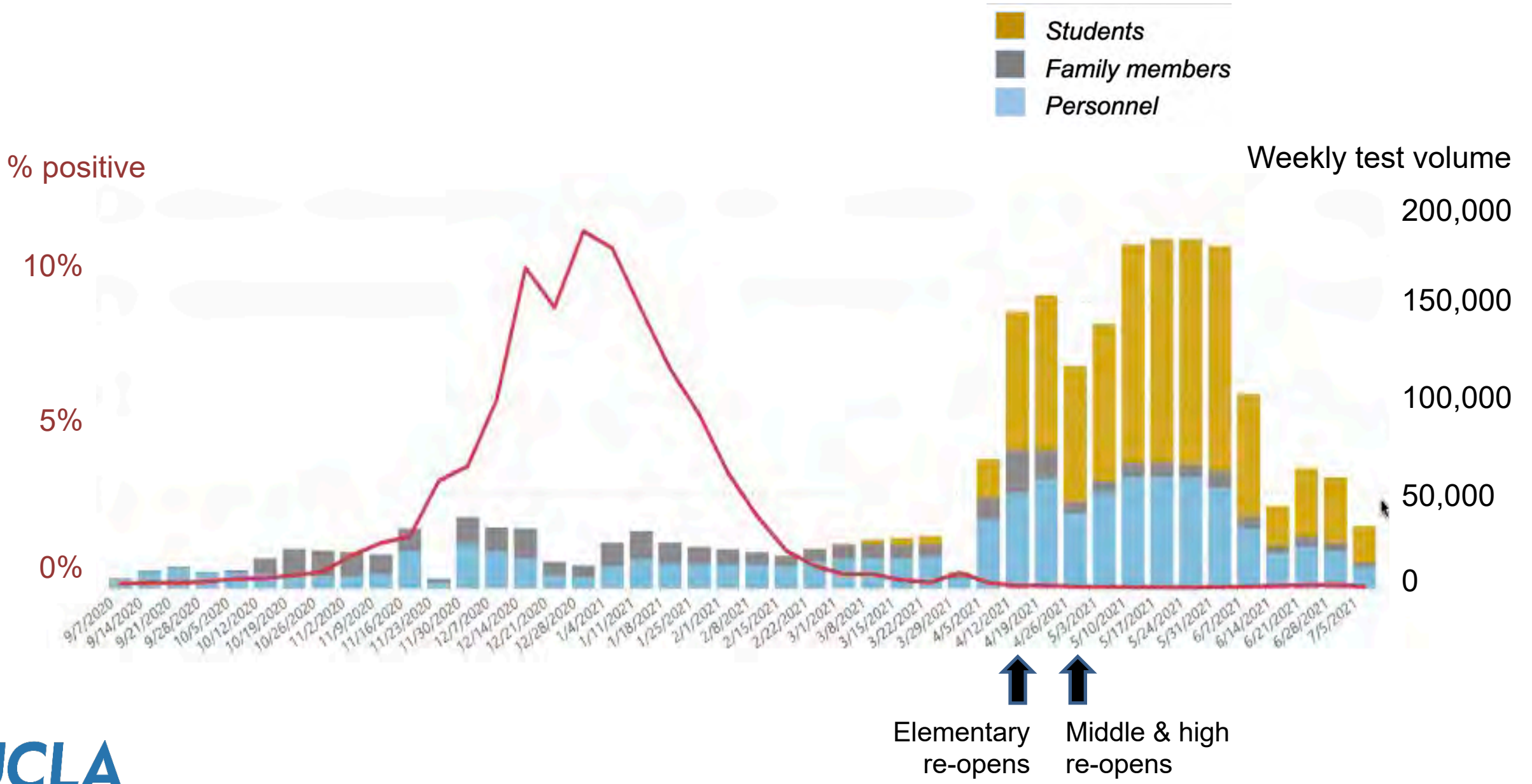
Daily Pass Report

Testing Report

People Tested

Vaccination Report

Periodic and exposure/symptom-based testing in 2020-21



Research aims

Aim 1. Study how COVID-19 surveillance testing influences secondary infection and school attendance and how it influences disparities in these outcomes associated with student characteristics, including poverty.

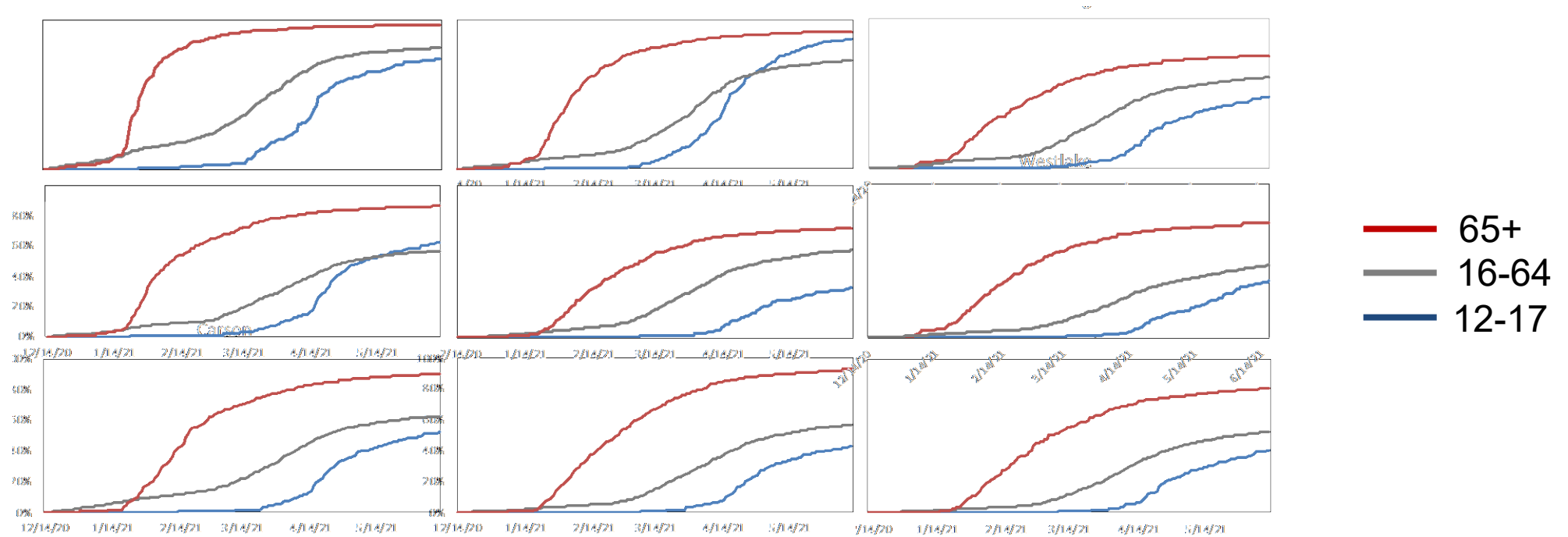
Aim 2. Study how surveillance testing influences overall, and disparities in, parent perception of safety, decision to return in-person, and daily attendance.

Aim 3. Explore use of targeted, responsive health education to address identified parent information gaps linked with disparities.

Outcomes: Cases, school-based secondary infection, decision to return, attendance, and missed school days due to isolation or quarantine

COVID-19 impact and variation in LA Unified cities/neighborhoods

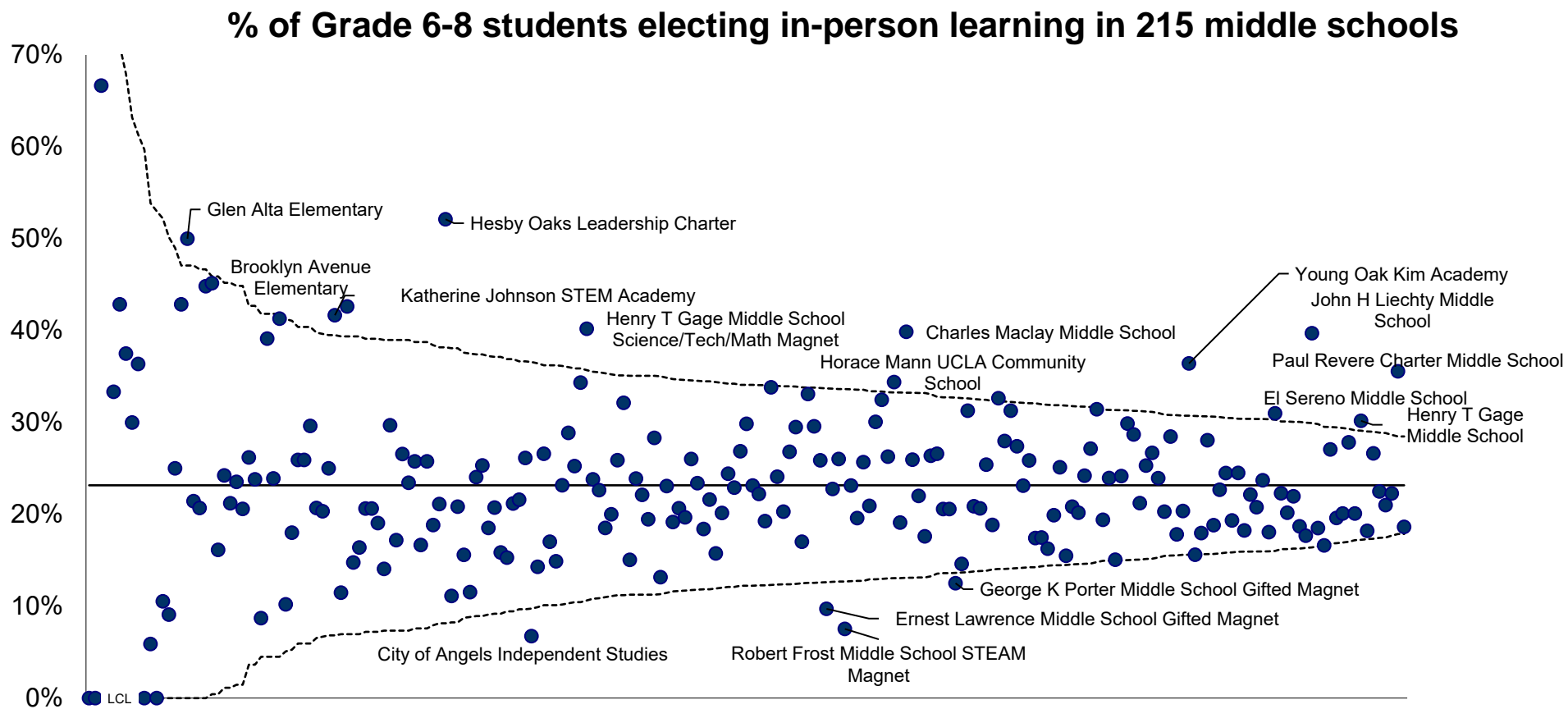
- Cases per 100,000 range from 4,461 (4%) to 2,288 (22%)
- Deaths per 100,000 range from 41 (0.04%) to 554 (0.5%)
- Variation in vaccination coverage



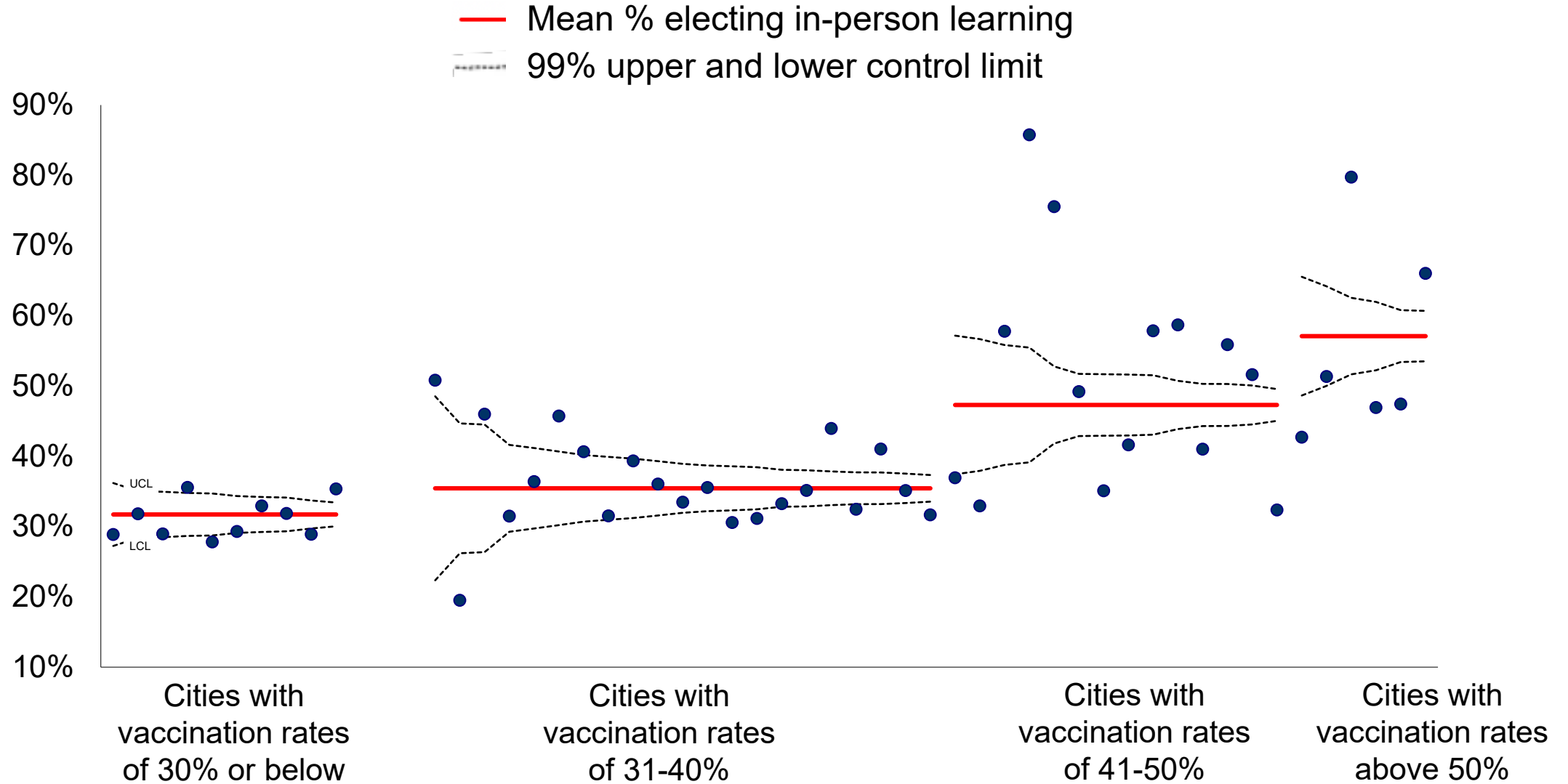
Return to in-person learning – Example of learning from variation

As of April 21:

- 38% for elementary, 25% for middle, and 17% high school
- Elementary return range from 23% to 95% across schools



% of elementary students electing in-person learning in 51 cities



Understanding parent safety concerns and decision-making

- Adding content to Autumn survey of parents, staff, students on academics, school climate, and social and emotional learning
- Parent interviews on safety concerns, perceived risks, perceived burdens of mitigation measures, and decision-making

LAUSD SCHOOL EXPERIENCE SURVEY RESULTS 2020-21



Responsive communications

Instructions

Submit photos and videos at today's vaccination site. Grab photos or videos of people checking in, getting their shots, and so forth.

134/1200

Tips

- Keep 6 feet distance at least
- Hold the camera steady

56/300

Additional Context (Optional) ⓘ

Select content ▾ **Browse**

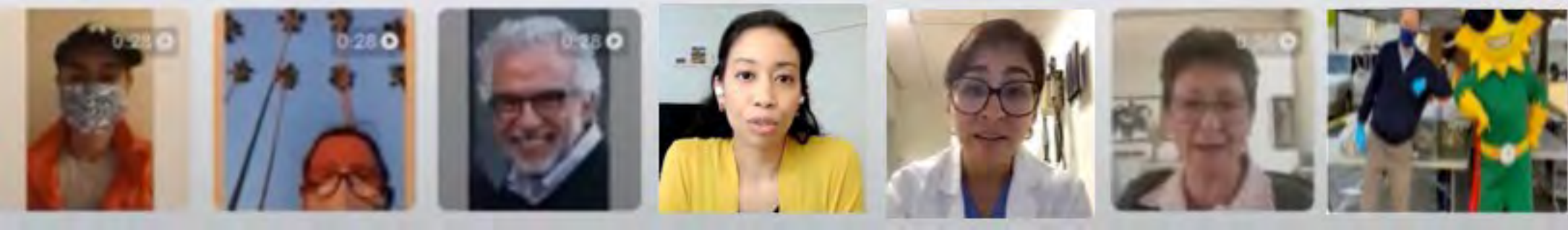
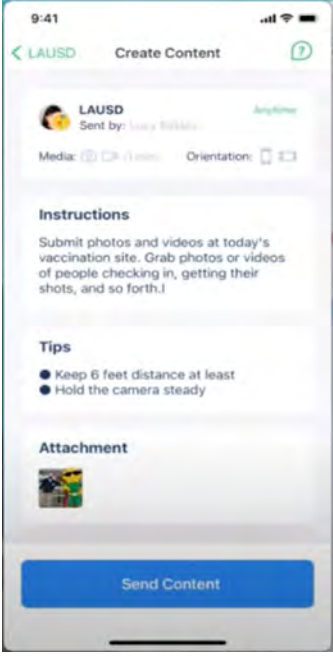
Select content
Upload content
Enter link

Any Orientation ▾ 15 secs ▾

Send Now ▾

Deadline ⓘ

Time Period ▾ 24 hours ▾



Research team

Moira Inkelas
Public Health



Mitch Wong
Internal Medicine



Onyi Arah
Epidemiology



Kim Gomez
Education



Annabelle De St
Maurice
Infectious Disease



David Goodman Meza
Infectious Disease



Vladimir Manuel
Family Medicine



Tony Kuo
Epidemiology



Dan Cooper
Pediatrics



Rebecca Dudovitz
Pediatrics



Whit Hayslip
Consultant



Maryjane Puffer
LA Trust for
Children's Health



Speaker



Rebecca Lee, Ph. D.

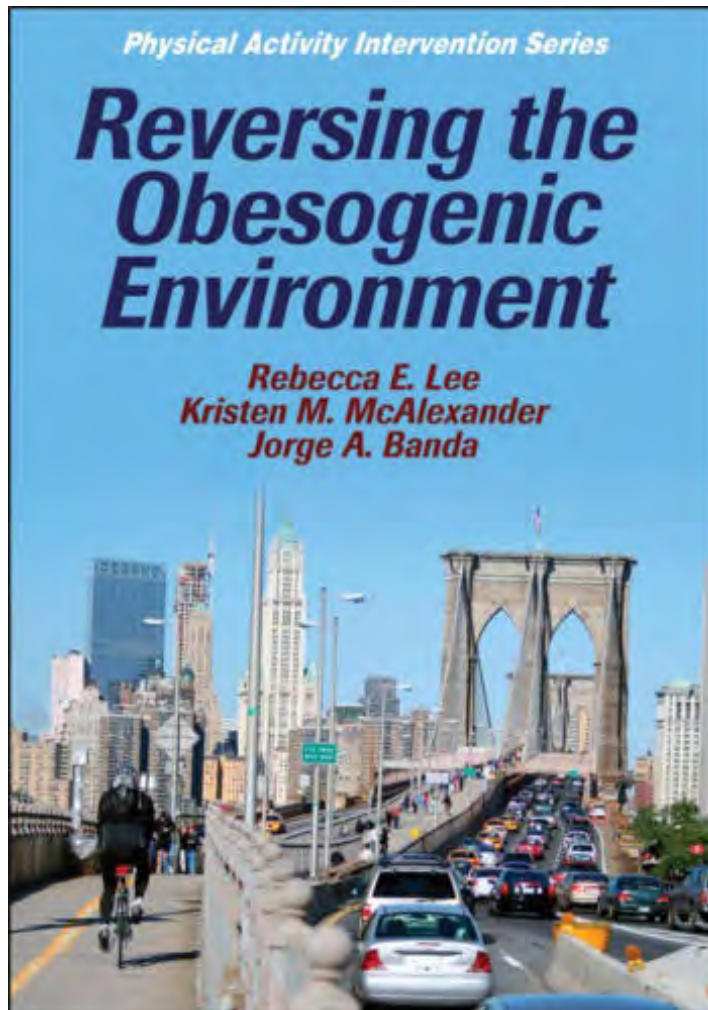
Arizona State University

Back to School Safely with SAGE:
BE SAGE
10T2HD108101-01

Rebecca E. Lee, PhD (Principal)

Center for Health Promotion and Disease Prevention
Edson College of Nursing and Health Innovation





Rebecca E. Lee, PhD

Professor, Center for Health Promotion and Disease Prevention, Edson College of Nursing and Health Innovation

Senior Sustainability Scientist, Julie Ann Wrigley Global Institute of Sustainability, Arizona State University
Fulbright-García Robles Core Scholar, Mexico, 2011-2012; 2019-2020

Author, *Reversing the Obesogenic Environment* (Human Kinetics, 2011)

<http://rebeccaelee.weebly.com/>

releephd@yahoo.com

@doctorlee



History

- 1/2010-12/2012 Science and Community: Ending obesity improving health (NIH 1R13CA162816)
- 7/2012-6/2015 Science and Community: Partnering to prevent early childhood obesity (NIH 1R21HD073685)
- 4/2016-12/2021 Partnering for PA in Early Childhood: Sustainability via Active Garden Education (SAGE) (NIH U01 MD010667)



Study Team

Rebecca Lee, PhD, PI, Community health psychologist, Physical activity research

Meredith (Meg) Bruening, PhD, Public health nutrition, Maternal and child health

Michael Todd, PhD, Biostatistics, Research methodology

SeungYong Han, PhD, REDCap administration, Data management

Hector Valdez, MA, Program Manager, Bilingual/bicultural community embedded management

Robert Santana, Health innovation

Hyunsung Oh, PhD, Social work

Vel Murugan, PhD, Molecular biology, Lab operations

Michelle Villegas-Gold, PhD, Public health, Global health

Joanna Kramer, MD, Pediatrics, Phx Children's Hospital

Tomás León, Equality Health Foundation, CHWs



Research Questions

- **RQ 1.** How acceptable, feasible, efficacious, and scalable is back-to-early care and education (ECE) testing of **young children** (3-5 years)?
- **RQ 2.** What is the acceptability and feasibility of routine ECE screening of **ECE personnel** (teachers and aides) who have direct contact with children?
- **RQ 3.** What is the additive efficacy of routine ECE screening of personnel (teachers and aides) who have direct contact with children on **attendance**?
- **RQ 4.** Leveraging SAGE, can enhanced outdoor learning opportunities using garden-based education help to mitigate risk of COVID-19 transmission (open air ventilation) as measured by **attendance** and **parent reports of transmission**?
- **RQ 5.** Can SAGE contribute as a best practice to help close gaps created by the lack of classroom-based ECE on **motor development** and **eating in the absence of hunger** in 3- to 5-year olds?

What is the ASU Biodesign COVID-19 Saliva Test?



- Parent coaching
- Short straw
- Vivid imagery

What is SAGE?



Lee RE, et al. Design and methodology of a cluster-randomized trial in early care and education centers to meet physical activity guidelines: Sustainability via Active Garden Education (SAGE). *Contemporary Clinical Trials*. 2019 Feb 1;77:8-18. DOI: <https://doi.org/10.1016/j.cct.2018.12.003>.

Possible Timeline

- Fall 2021 – July/August/September
 - Child saliva testing at 40 ECE sites
 - Teacher saliva testing at 20 ECE sites (half of the 40)
- Fall 2021 – Oct/Nov (through the AY)
 - Install gardens 20 ECE sites (of those above)
 - Measure child motor development, eating in the absence of hunger
- Spring 2022
 - Measure changes in child motor development, eating in the absence of hunger



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<http://sageasu.weebly.com/>

<http://rebeccaelee.weebly.com/>

Speaker



Russell McCulloh, M.D.

University of Nebraska Medical Center

Mobile Health-Targeted SARS-CoV-2 Testing and Community Interventions to Maximize Migrant Children's School Attendance During the COVID-19 Pandemic

Russell J. McCulloh, MD (Contact PI)

University of Nebraska Medical Center

Children's Hospital & Medical Center



Our Team (most of them)



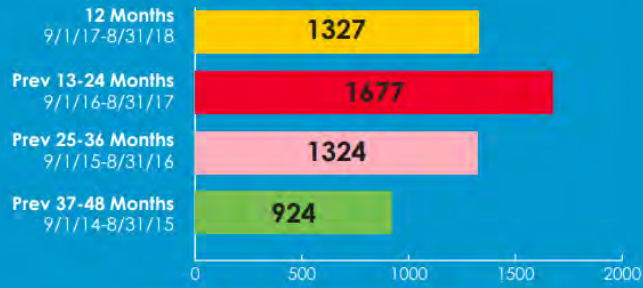
Project Overview

- Enroll 800 total participants in integrated screening and SARS-CoV-2 testing program
- Source: Families in the Nebraska Migrant Education Program
 - ~400 students
 - ~400 caregivers
- **Interventions:**
 - Daily symptom screening via mHealth tool for household risk of SARS-CoV-2 infection
 - Positive screens recommended to perform salivary SARS-CoV-2 testing
 - Weekly social determinants of health screening
 - Positive screens offered community navigator services
 - Interviews of participants regarding use of the program, reasons for testing or declining to test
 - Measurement of school attendance, positive tests, mHealth tool use
- **Rationale:** Successful implementation of our program will provide valuable insight into the feasibility and scalability of mHealth-targeted at-home salivary SARS-CoV-2 testing in migrant households.

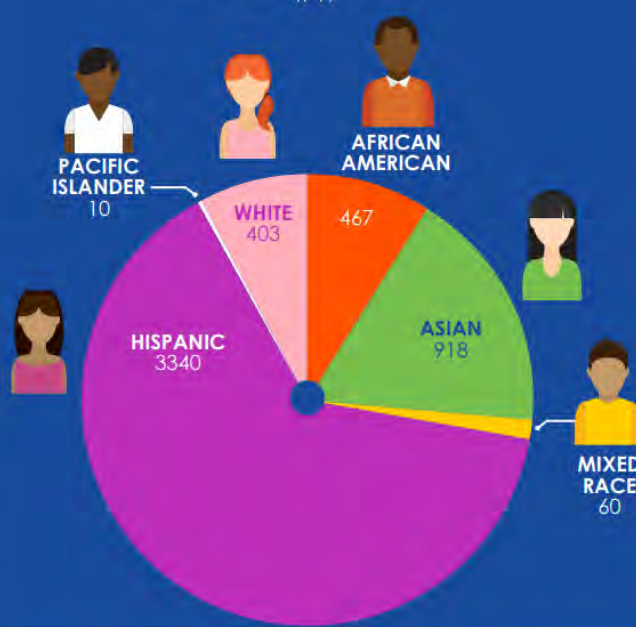
Questions to answer

- What is the feasibility of mHealth-targeted at-home salivary SARS-CoV-2 testing among migrant children and their families?
- What is the impact of mHealth-targeted at-home salivary SARS-CoV-2 testing on school absenteeism among migrant children?
- What is the feasibility of mHealth screening and response for socioeconomic challenges among migrant households?
- What is the impact of mHealth-targeted public aid and community assistance among migrant families reporting need?
- What socioeconomic challenges negatively impact the ability and willingness of migrant families to safeguard their health and wellbeing during COVID-19?
- What changes (e.g., public aid, legal protections, community programs, etc.) do migrant families believe are necessary to enhance their ability and willingness to safeguard their health and well-being during COVID-19 and similar future events?

MOBILITY



RACE/ETHNICITY



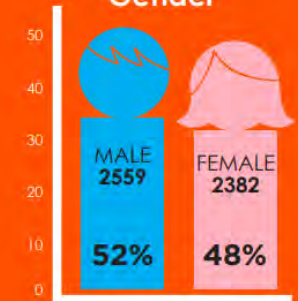
WHO WE SERVE



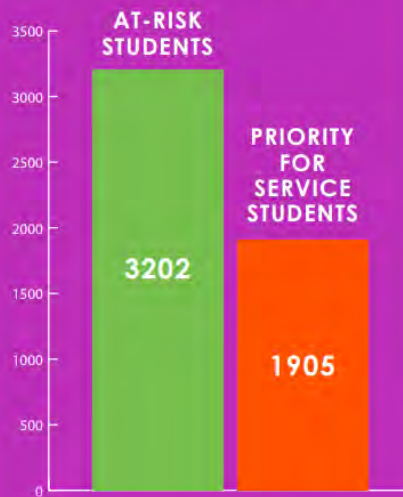
Total Child Count
(2017-2018)

4941

Gender



AT-RISK AND PFS STUDENTS

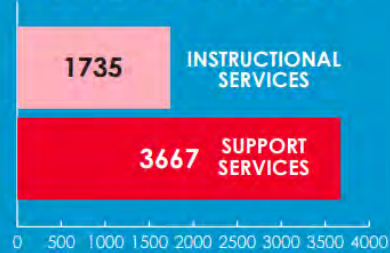


GRADUATION RATE

2017-2018

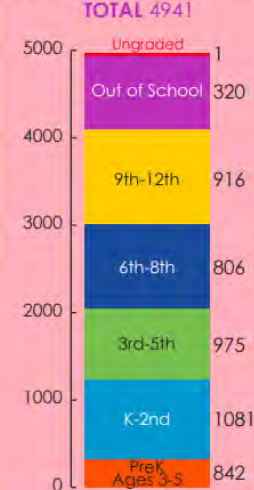


TYPE OF SERVICES

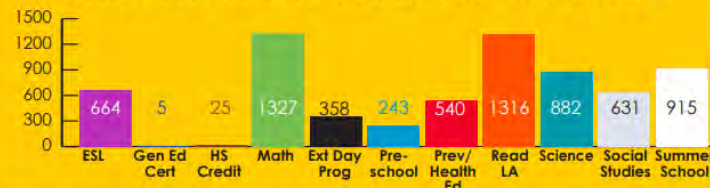


ELIGIBLE CHILDREN

TOTAL 4941



INSTRUCTIONAL SERVICES PROVIDED



For more information on the Migrant Education Program
please visit: www.education.ne.gov/Migrant



100%

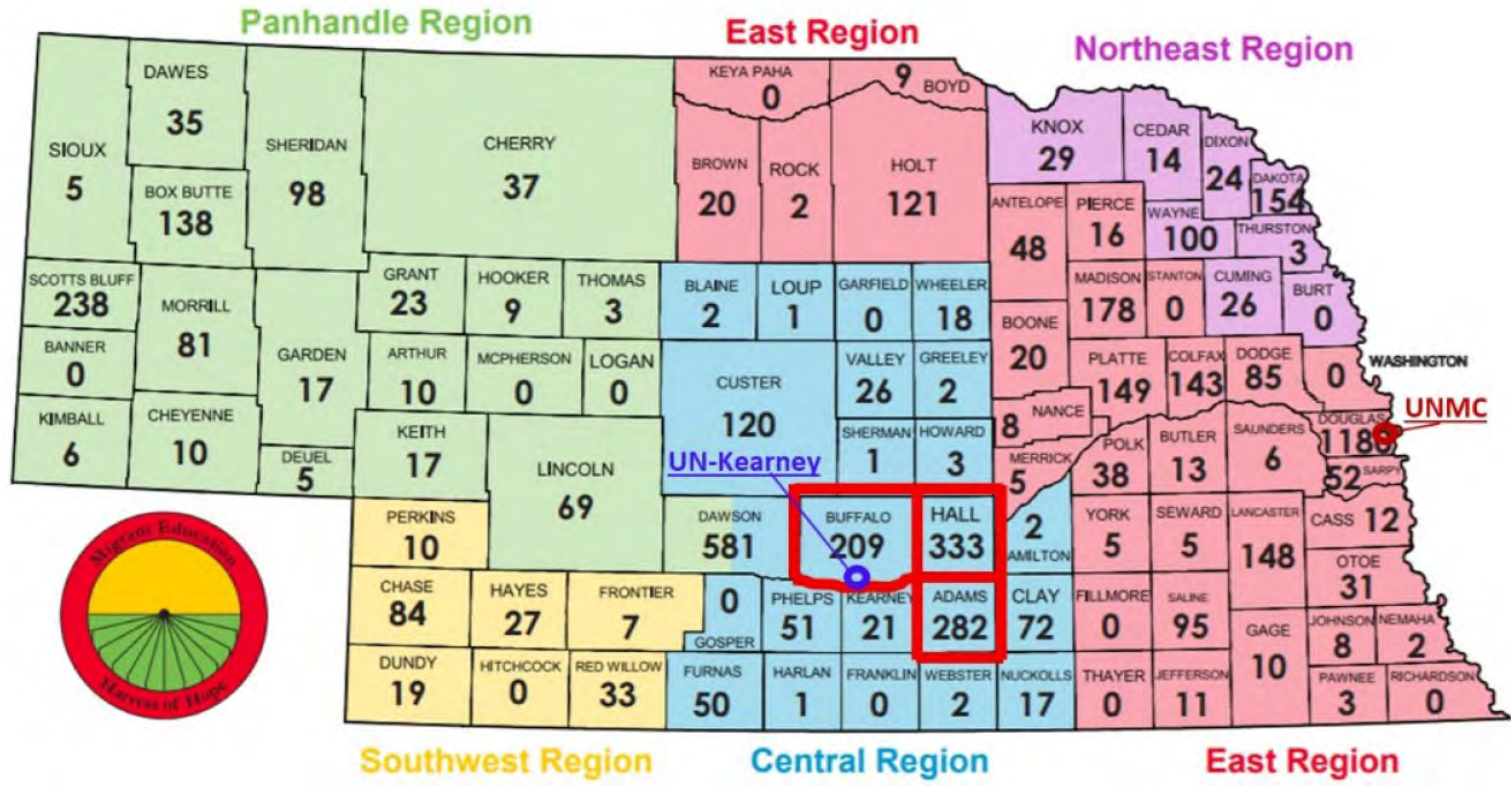
Categorically eligible
for free lunch



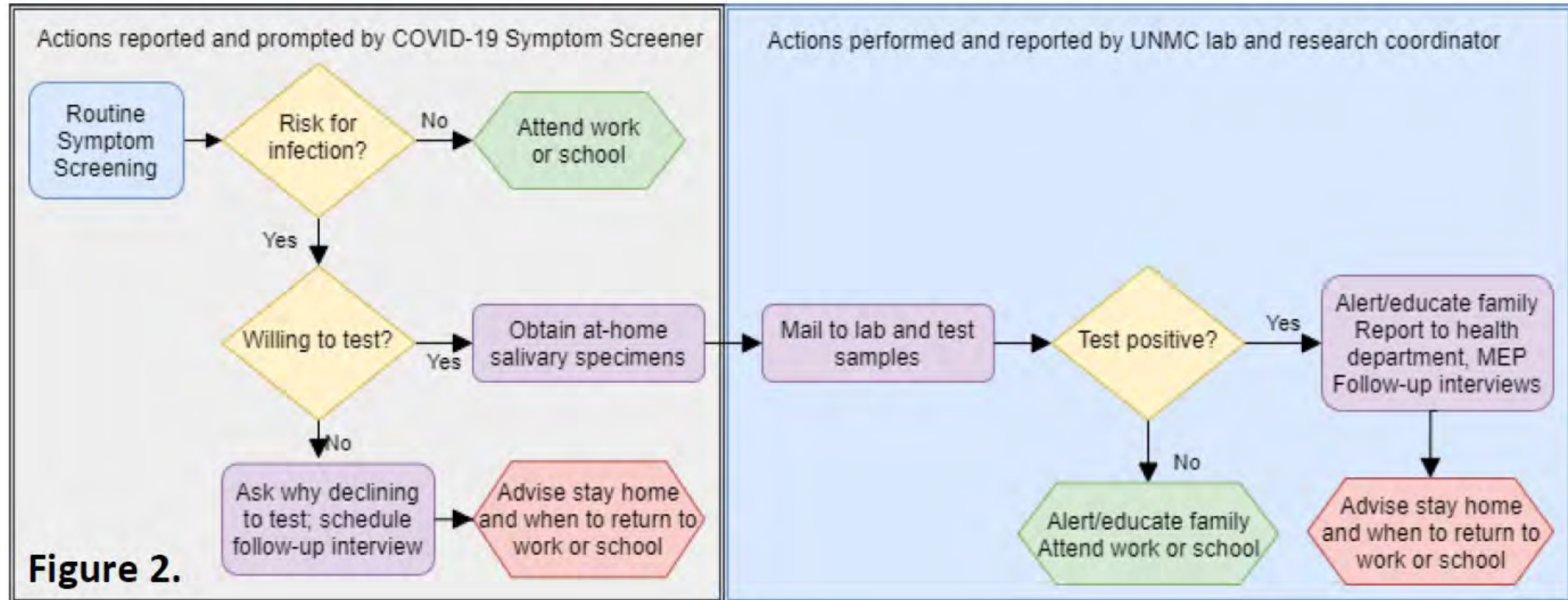
2,149
Limited
English
Proficient

245 Verified for
Special Education

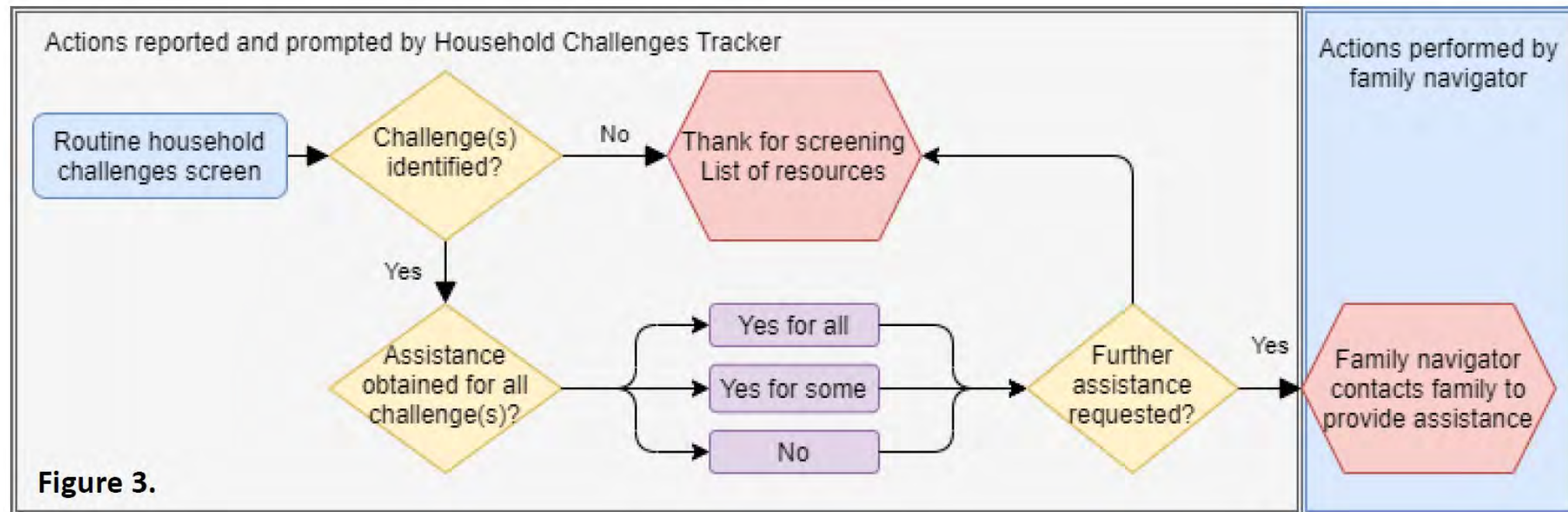
Counties of Focus



Testing approach



Social Determinants of Health



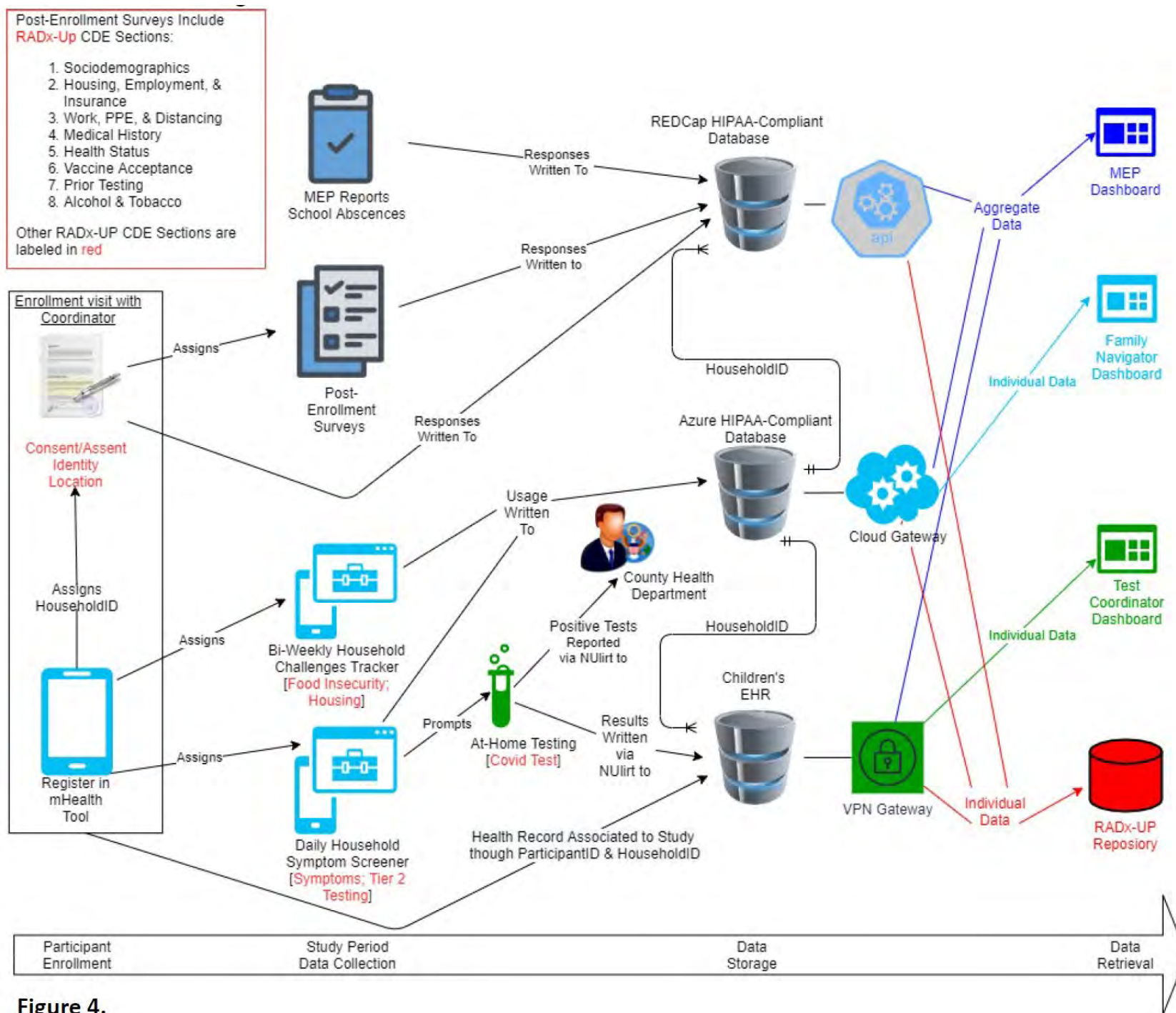


Figure 4.

How our project addresses the RADx-UP program

- Collaboration with school organizations that serve exceptionally at-risk communities speaking various languages
- Builds on community partnerships in rural Nebraska
- Implementation of testing strategy that builds on learned experience in mHealth and salivary testing strategies
- Has potential to scale to other programs and communities nationally

Community/school engagement plans

- Initial community consultation already has resulted in modification of the protocol prior to submission
- Annual report and review via external advisory board
 - Will also communicate with IDeA-CTR CAB
- Community consultation meetings twice annually
 - Buffalo County Community Partners (CAB)
 - Nebraska Migrant Education Program
 - Individual consultation/interviews with migrant families (minimum 3 families)

Speaker



May Michiko Okihiro, M.D.

University of Hawaii at Manoa

Empowering Schools as Community Assets to Mitigate the Adverse Impacts of COVID-19

University of Hawai'i
Investigators:

Dr. May Okihiro

Dr. Alike Maunakea

Dr. Ruben Juarez



www.PAAC.info





Pacific Alliance Against COVID-19



- Ruben Juarez, PhD (Economics)
 - UH Economic Research Organization (UHERO)
- Alike Maunakea PhD (Epigeneticist)
 - UH John A. Burn School of Medicine, Dept. of Anatomy and Physiology
- May Okihiro, MD (Pediatrician)
 - UH John A. Burns School of Medicine, Dept. of Pediatrics

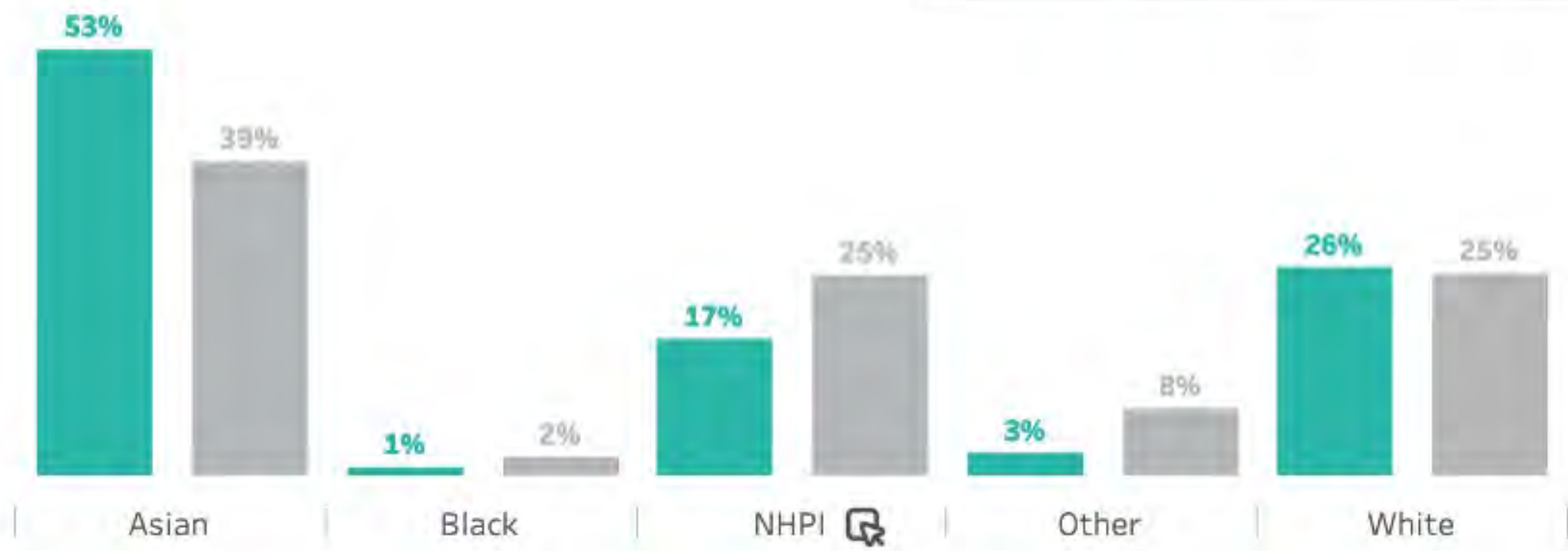


	% Population	07/11/21 Cases (26,827)	07/11/2021 Deaths (502 total)
Pacific Islander	4%	19%	21%
Filipino	16%	20%	23%
Hawaiian	21%	21%	13%
White	25%	19%	8%
Japanese	15%	7%	20%
Chinese	4%	2%	6%
Other	8%	6%	6%

All

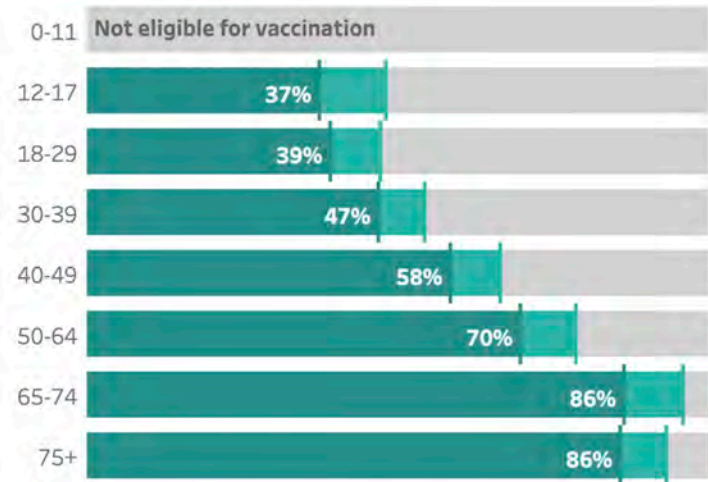
Unknown 19%

Percent of Vaccine Recipient Population Compared to State Population

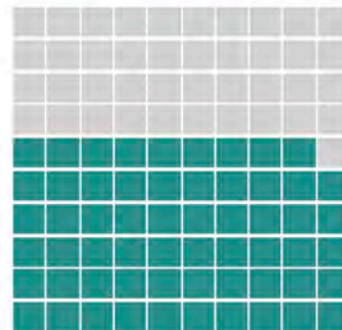


These figures do **NOT** include doses from Federal Pharmacy Program or Federal Agency Doses

These percentages represent the known race/ethnicity as reported in VAMS | ** Applies only to the subgroup of NHPI persons vaccinated after March 23

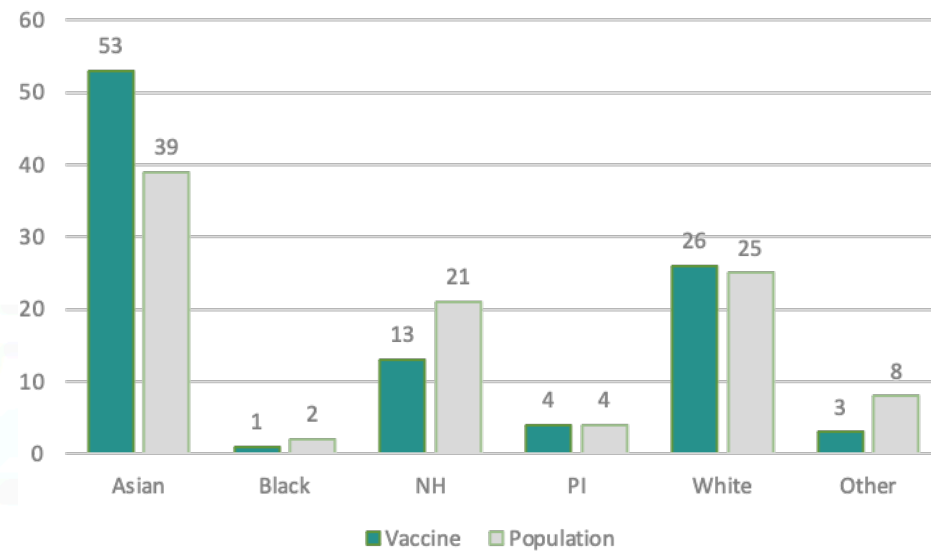


**60%
COMPLETED**



12yrs and older
(percent of 12+ pop)

% Vaccination vs % Population

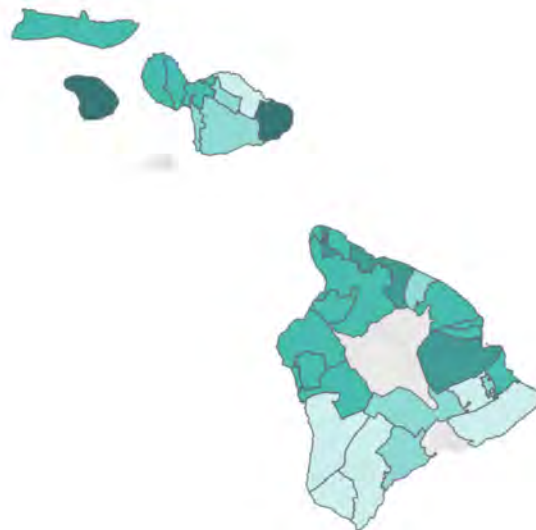


*These figures do **NOT** include Federal Agency doses.



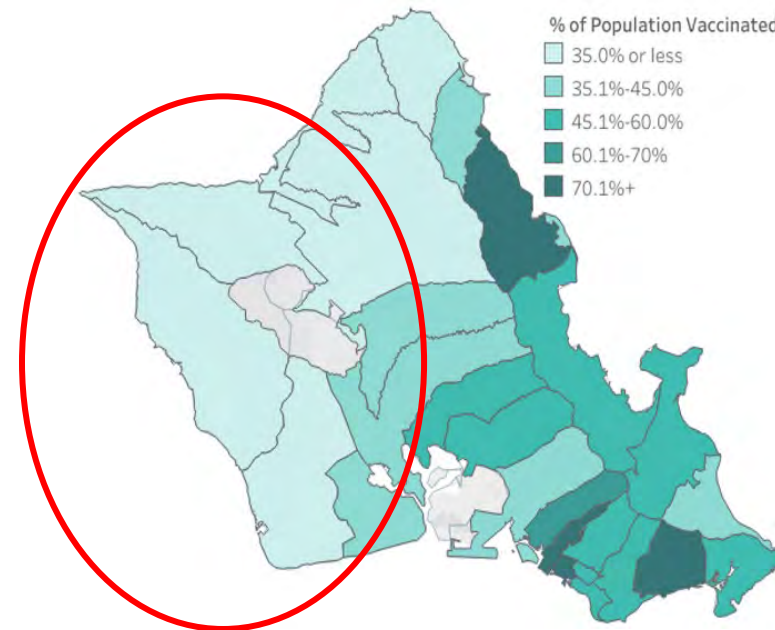
% of Population Vaccinated

- 35.0% or less
- 35.1%-45.0%
- 45.1%-60.0%
- 60.1%-70%
- 70.1%+

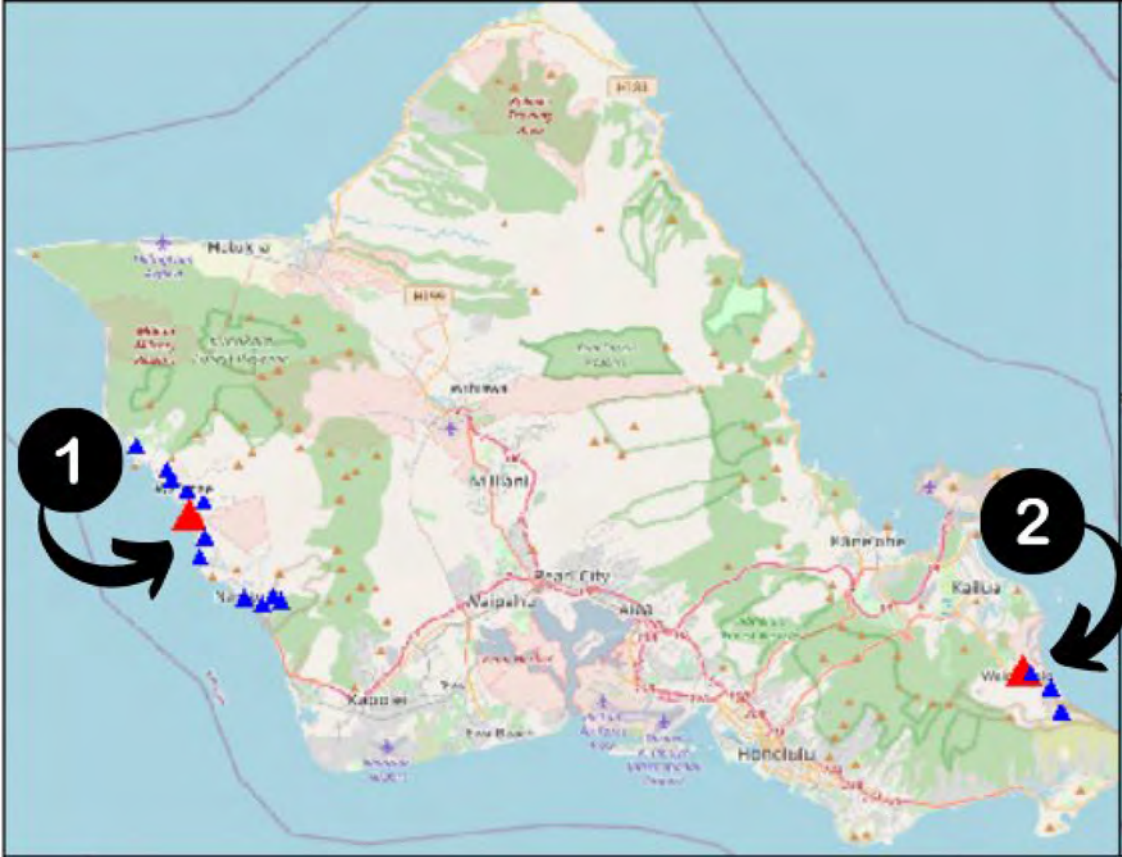


% of Population Vaccinated

- 35.0% or less
- 35.1%-45.0%
- 45.1%-60.0%
- 60.1%-70%
- 70.1%+



AHARO Health Centers



1

Waianae Coast Comprehensive Health Center

Wai'anae, O'ahu, Hawai'i

2

Waimanalo Health Center

Waimanalo, O'ahu, Hawai'i

3

Molokai Community Health Center

Kaunakakai, Moloka'i, Hawai'i

4

Hamakua-Kohala Health



Honoka'a, Hawai'i Island, Hawai'i

5

Bay Clinic

Hilo, Hawai'i Island, Hawai'i

Map Key

-  Health Centers
-  Schools in Health Center's catchment

Burbio's K-12 School Opening Tracker

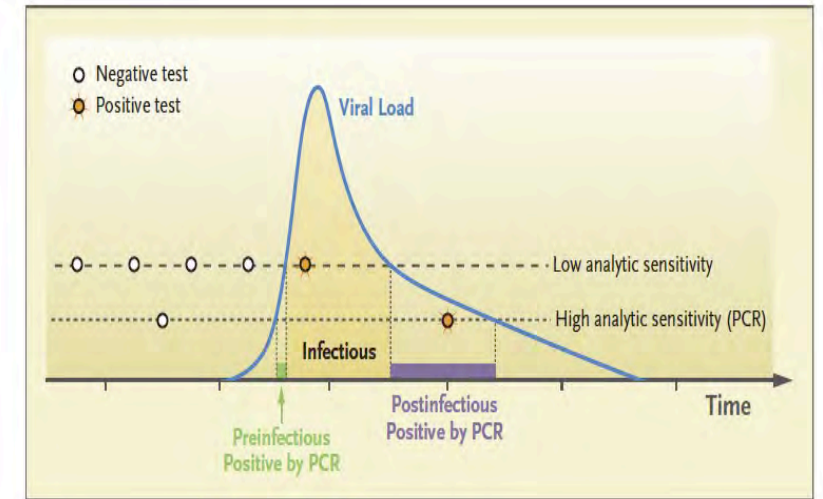
In-Person Index for K-12 Public Schools

June 29, 2021



Community SARS-CoV-2 Testing Rapid Antigen Testing

- Antigen tests
 - Detect viral proteins as they rise
 - Done in 15 minutes
 - Highly specific
 - Less sensitive
 - Less important for surveillance
- Partnership with Hawaii Department of Health



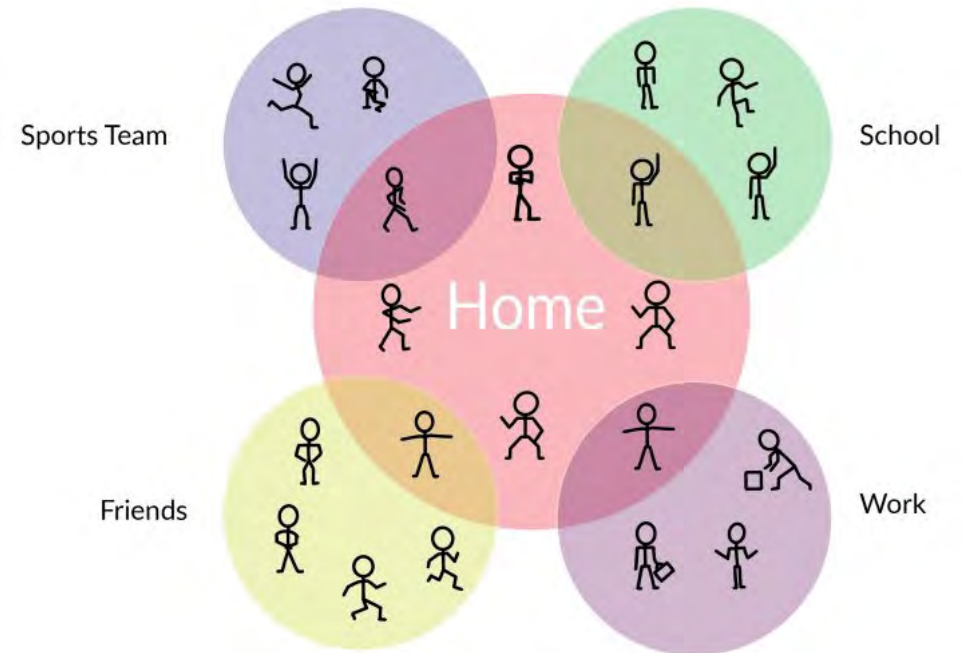
School Ohana (Family) Bubble Program

- Eligibility:

- Adults
- Adolescents: 12-17 years

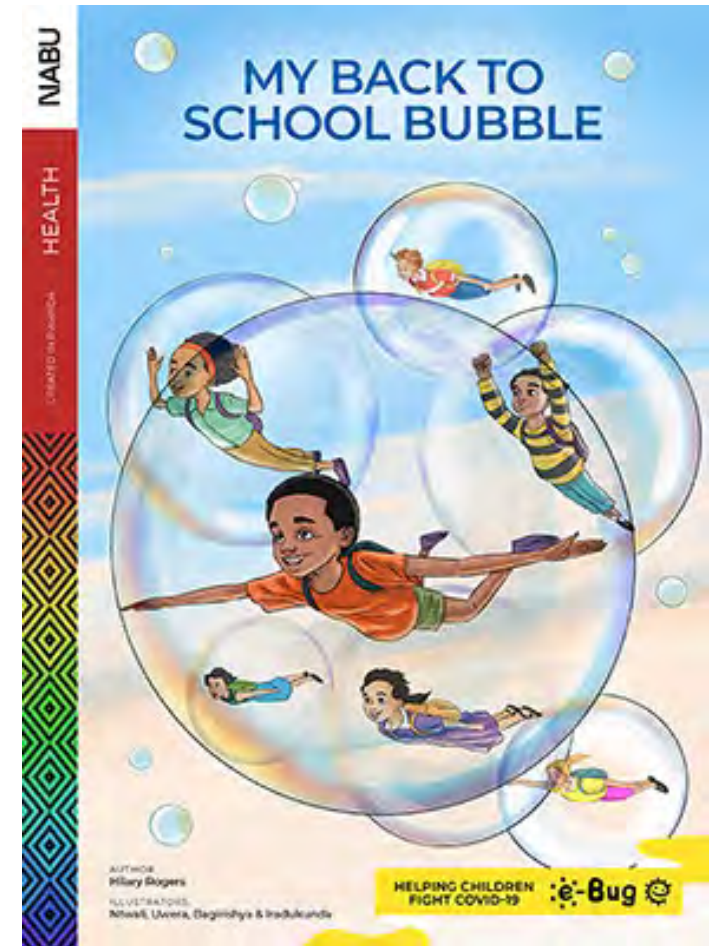
- Start:

- Consent and assent
- Survey – demographics, risks (age, chronic conditions, housing), knowledge about COVID-19
- Antibody serology testing – pin prick
- Rapid antigen test – 15 to 30 min.



School Ohana Bubble

- POSITIVE Antigen Test → confirmatory PCR
 - Must quarantine until result is available
 - Results - same day to 1-2 days.
- Frequency
 - *Once a week or more often as needed*
- Results and all data: Qualtrics-based
- Data:
 - Effectiveness - # tested, # of tests, # positive, attitudes and activities
 - Vaccinations
 - Costs



PAAC Testing Team



Kamaile Academy Results

- Over 80% of teachers and staff participate in the pilot at Kamaile Academy, with more than half of them more than once
- 61% of participants report feeling safer at schools
- 51% report being more likely to be vaccinated



Kamaile Academy Results

- 82% are more likely to get tested next time that they show symptoms
- 87% would refer their family to a similar testing program



“It’s a preventative measure. We can come and gauge, how are we doing in our own communities and with our own families. Are we keeping safe? It’s a good way to monitor and that’s why I keep doing it.”

Kamaile Principal Paul Kepka

- *“The data helps us make decisions so students can keep safe and focus on learning...Staff feel comfortable so they can focus on learning.”*



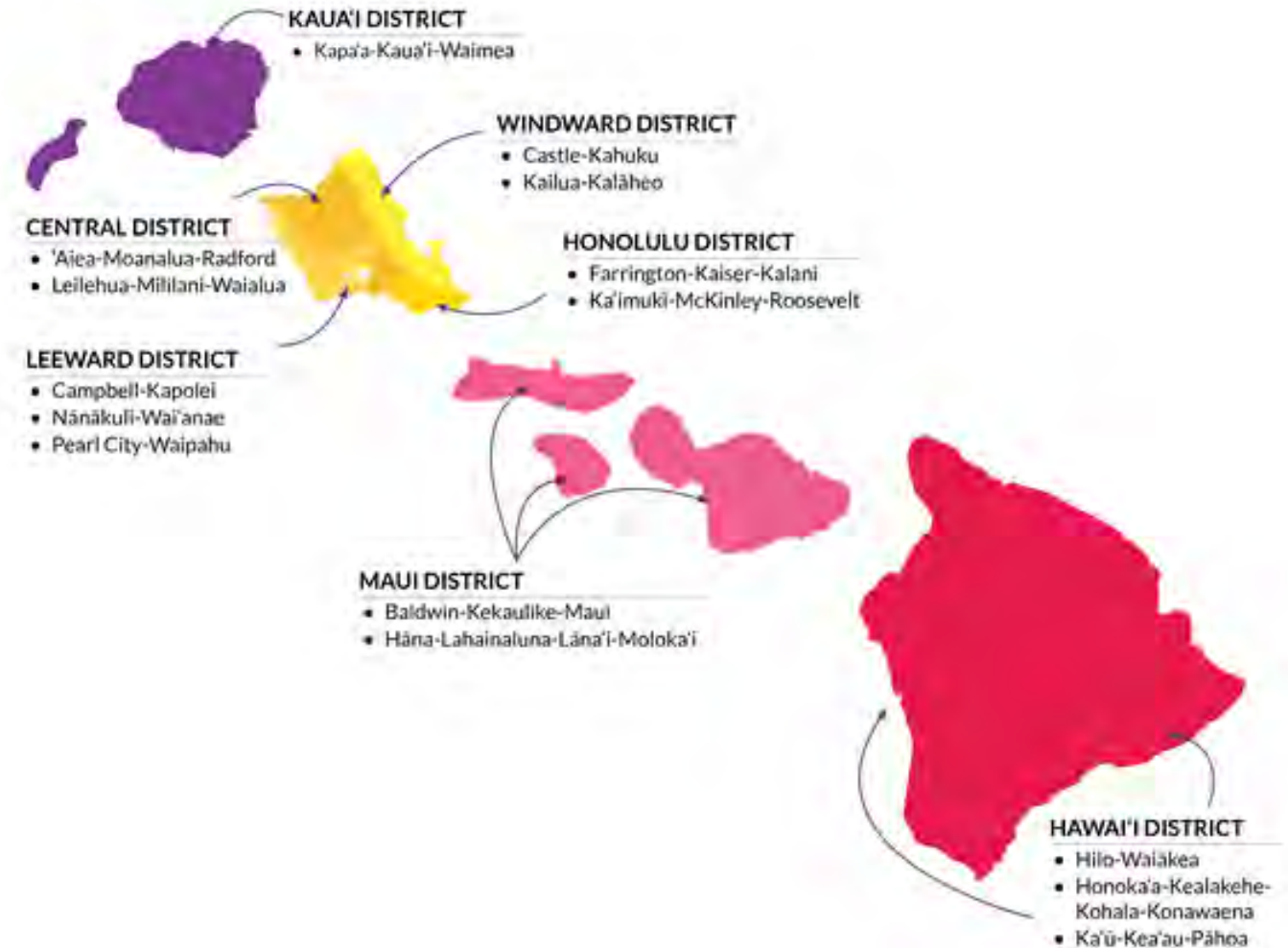
PAAC School Ohana Bubble Toolkit

- Disseminating lessons learned
- Community Health Centers support community schools
- Contents
 - Training
 - Equipment and supplies
 - Agreements
 - Procedures and Policies
 - Checklists



PAAC School Testing Program

- Each site will work with their school district complex.
- Frequency of testing
 - Start with weekly
 - Tiered system
 - To be determined with DOH/CDC (e.g. regional vaccination rate & so vulnerability index)
 - Low prevalence → test less often
 - Rising prevalence → increase frequency



School Testing Teams and Strengthening the Healthcare 'auwai (“stream”)

- Community Health Workers
 - Enriched with underrepresented minorities
- Students - college & high school
 - COVID-19 PAAC Curriculum/Certification
 - Learn about community-based research
 - Build new skills and practice safe protocols
 - *e.g.* Safely perform COVID-19 testing
 - Learn about healthcare and other research activities
 - *e.g.* Data entry, dissemination of results, laboratory procedures, other healthcare jobs





Mahalo!



To learn more:
www.PAAC.info

OVERVIEW OF RADX-UP CDCC

CDCC Program Officer



Beda Jean-Francois, Ph.D.

National Institute on Minority Health and Health Disparities (NIMHD)

Welcome from the RADx-UP CDCC

Principal Investigators



**Michael Cohen-
Wolkowicz,
MD, PhD**

*Duke Clinical Research
Institute (DCRI)*



**Giselle Corbie, MD,
MSc**

*UNC Center for Health
Equity Research*



**Warren A. Kibbe,
PhD, FACMI**

*Duke Department of
Biostatistics and
Bioinformatics*



Al Richmond, MSW

*Community-Campus
Partnerships for
Health (CCPH)*



Susan Knox, MBA

*Duke Clinical
Research Institute*



Chris Woods, MD

*Durham VA
Medical Center;
Duke University*



Krista Perreira, PhD

*UNC Center for
Health Equity
Research*



Duke Clinical Research Institute



SCHOOL OF MEDICINE

Center for Health Equity Research



**Renee Levery, BSN,
MA**

*Duke Clinical
Research Institute*



Keith Marsolo, PhD

Duke University



Lisa Wruck, PhD

*Duke Clinical
Research Institute*



**Bhargav Adagarla,
MS**

*Duke Clinical
Research Institute*



National Institutes of Health
Turning Discovery into Health®



RADx-UP Coordination and Data Collection Center (CDCC)

July 14, 2021

The RADx-UP CDCC is funded through NIH emergency cooperative agreement 1U24MD016258

RADx-UP CDCC Goals

Accelerate COVID-19 community implementation science via an agile, flexible, participatory, transparent and sustainable CDCC.

Amplify and disseminate community best practices for successful implementation of COVID-19 testing strategies and vaccines.

Support data collection, integration, and sharing while preserving necessary data protections.

Utilize RADx-UP infrastructure to support COVID-19 research.

RADx-UP CDCC Guiding Principles

Communities are at the center of our work.

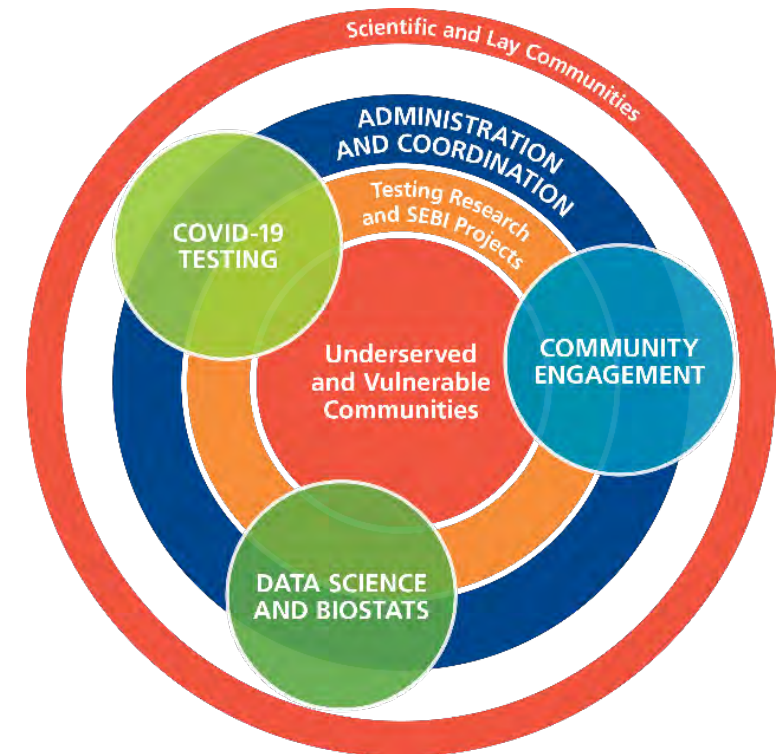
Data sovereignty protections and sharing with communities and participants are essential in building trust and being trustworthy.

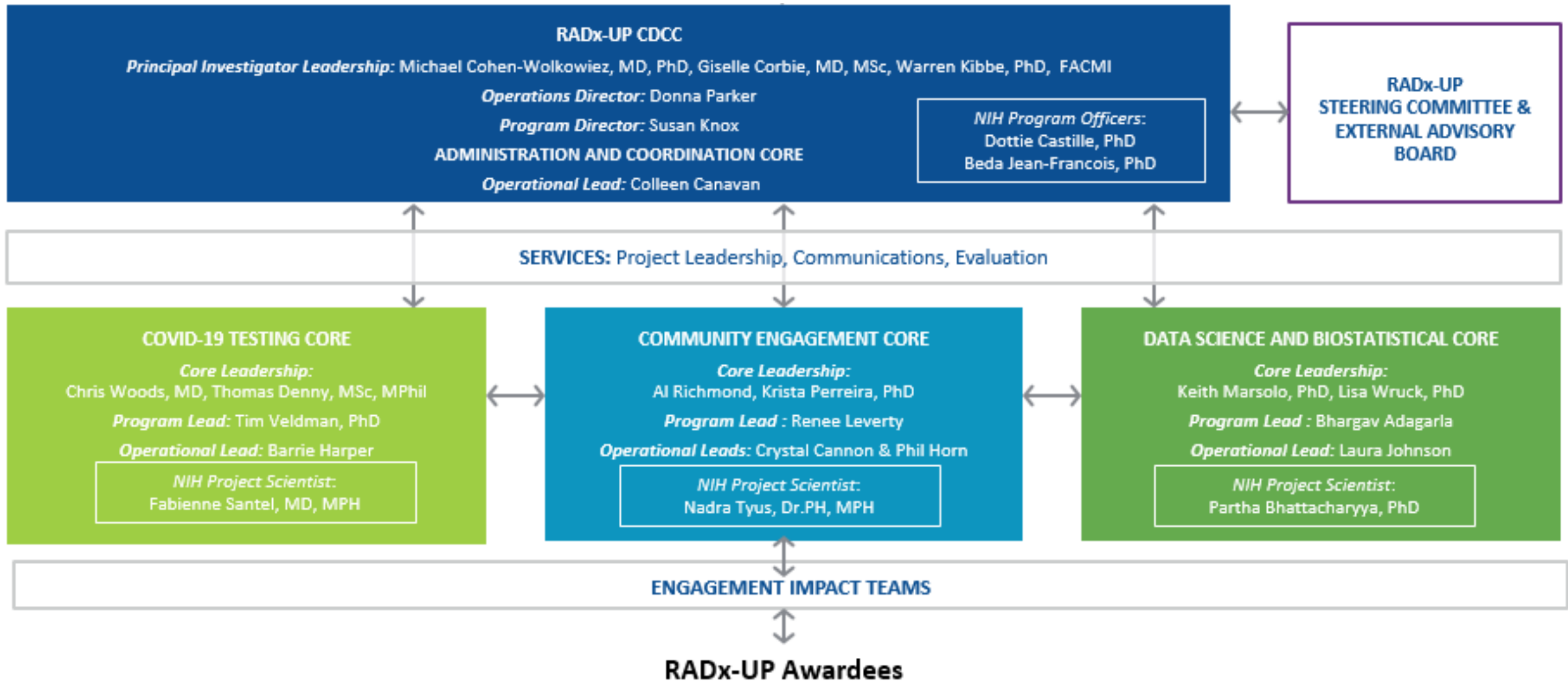
Intentional support of study teams is critical to streamline results and troubleshoot.

Broad dissemination of program activities, data, and best practices are key.

Strategic partnerships will augment community benefits from the program.

Impact will be broad and will inform national guidance, strategy, and response to COVID-19.





RADx-UP CDCC Cores

Administration & Coordination

- Communication
- Committee oversight
- Processes, policies, procedures
- Partnerships
- Evaluation

Community Engagement

- Best practices
- Engagement Resource Library
- COVID-19 Equity Evidence Academy
- Community of Practice
- Community Collaboration Mini-Grants

COVID-19 Testing

- Technical support
- Repository of emerging technologies
- Testing selection & implementation
- Rapid Research Pilot Program

Data Science & Statistics

- Data harmonization
- Security, privacy, and protections
- Data exchange
- Data representation and visualization

ENGAGEMENT IMPACT TEAMS

RADx-UP CDCC Engagement Impact Teams

- Single point-of-contact between CDCC and project teams with project management & community engagement support
 - Coordinating testing, community engagement, and data collection and sharing resources
 - Identifying challenges, collaboratively generating solutions, sharing best practices
 - Collecting required forms (data use agreements, IRB-approved Informed Consent Forms, etc.)
 - Connecting projects with translation services
 - Monitoring progress



RADx-UP CDCC Communications

Provide regular updates to RADx-UP awarded projects to:

- Support engagement, testing, and data collection/integration
- Promote co-learning between and among projects and communities that we serve

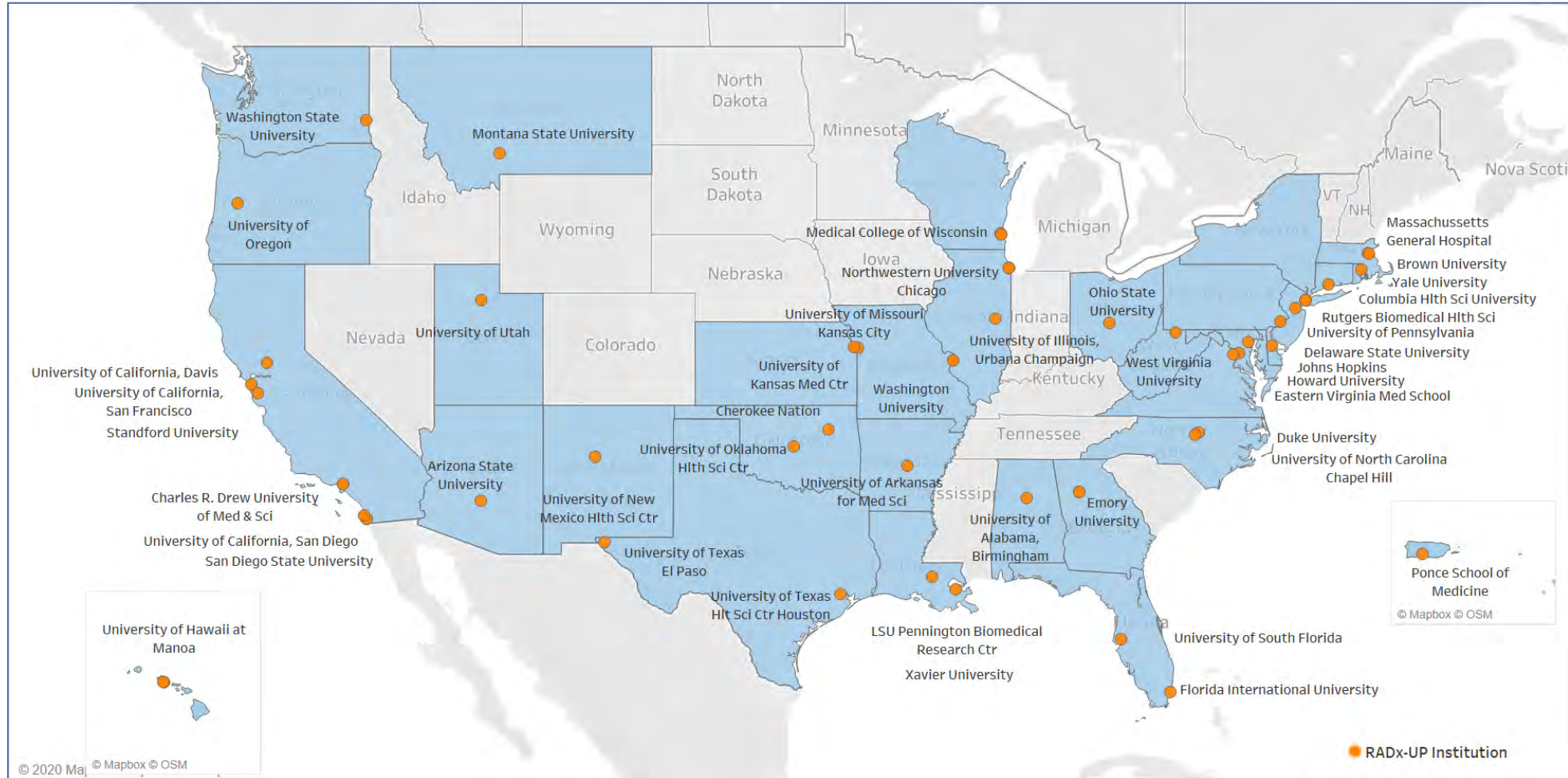


QUESTIONS & ANSWERS

APPENDIX

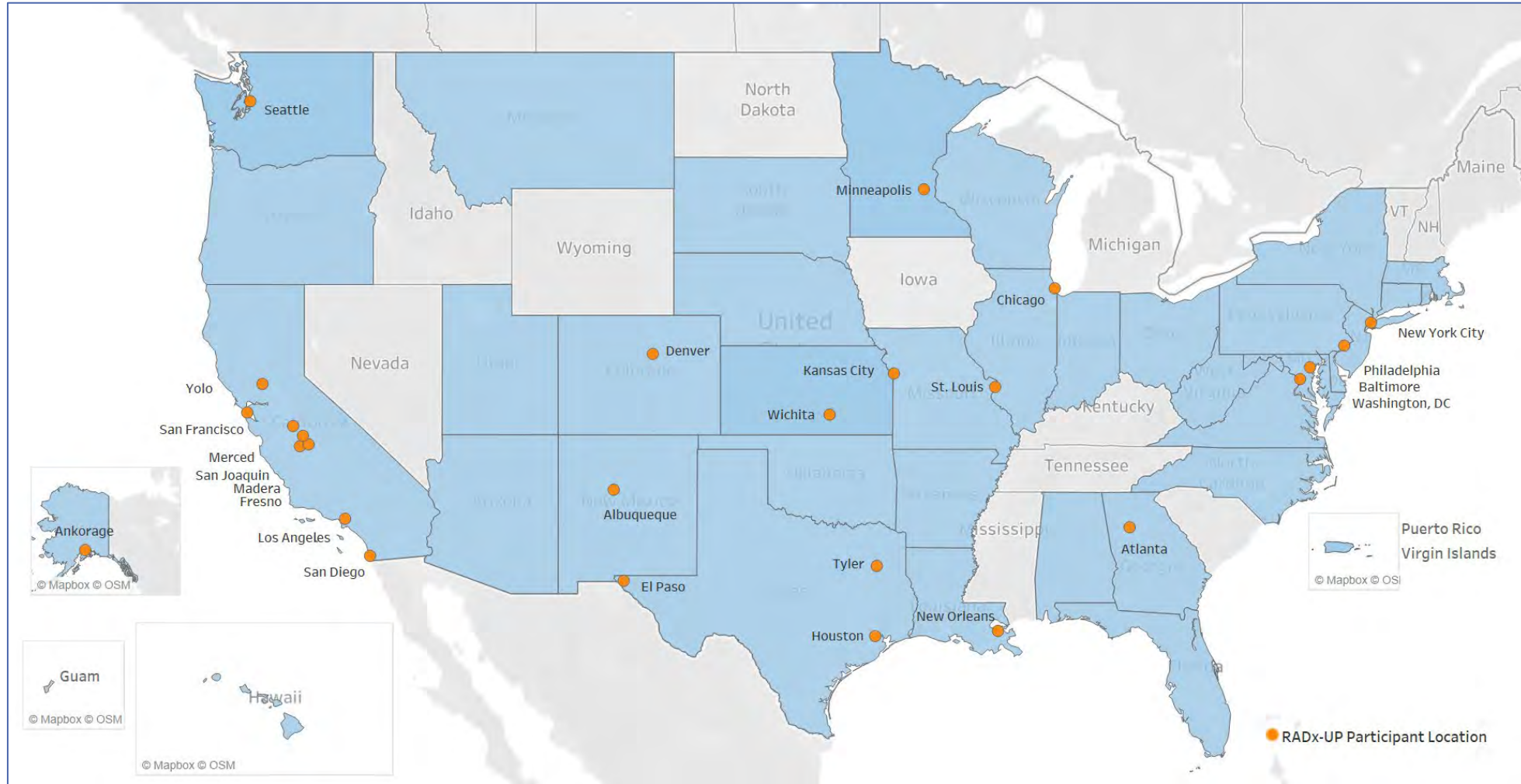
RADx-UP Phase I Award Institution Locations

NOT-OD-20-121, NOT-OD-20-120 & NOT-OD-20-119



RADx-UP Phase I Award Participant Locations

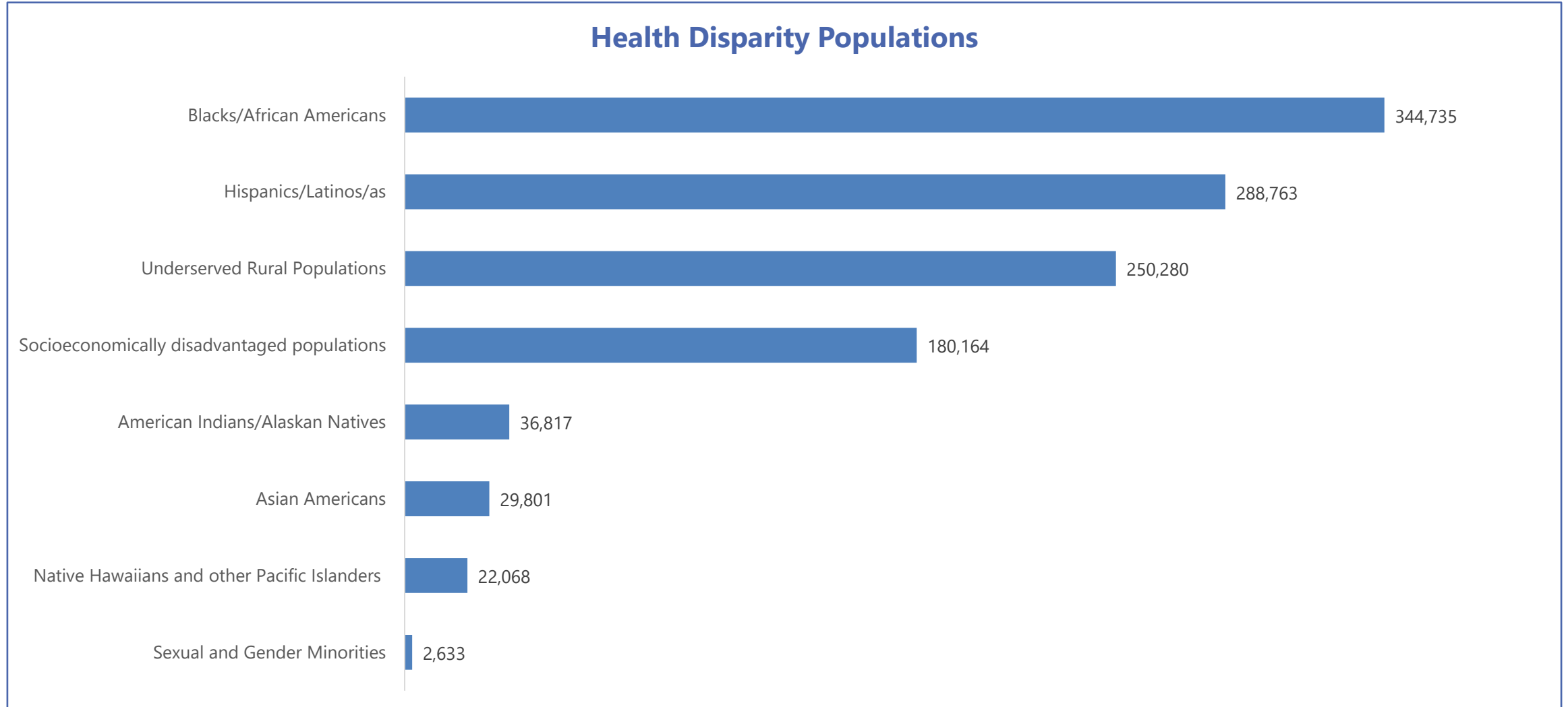
NOT-OD-20-121, NOT-OD-20-120 & NOT-OD-20-119



Note: Cities listed are not exhaustive, as some projects only provided state-level information.

RADx-UP Phase I Award Sample Size Estimates

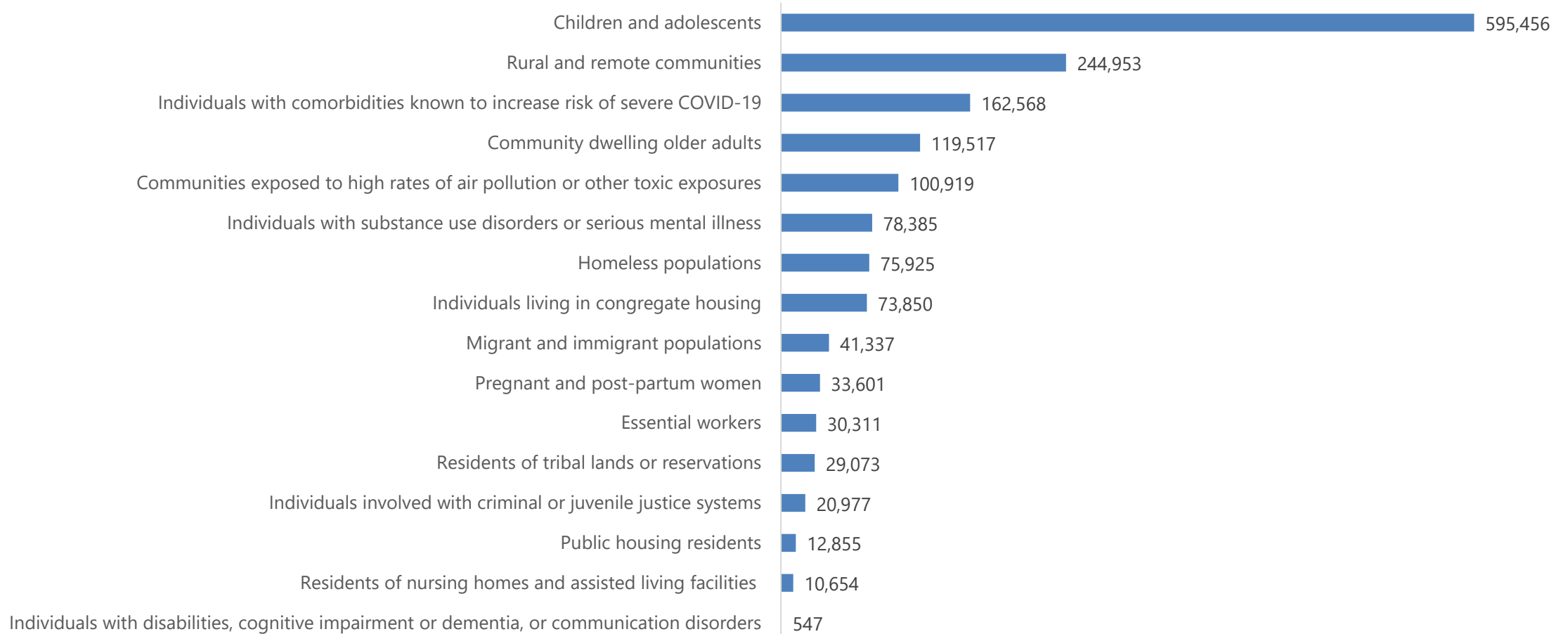
NOT-OD-20-121, NOT-OD-20-120 & NOT-OD-20-119



RADx-UP Phase I Award Sample Size Estimates

NOT-OD-20-121, NOT-OD-20-120 & NOT-OD-20-119

Vulnerable Populations



RADx Point-of-Care Testing Technologies

Organization	Sample Type(s)	Type of Test	Turnaround Time
Ellume	Nasal swab	Antigen	<15 mins
Luminostics	Nasal swab	Antigen	<30 mins
MatMaCorp	Nasal swab, Oral swab, Saliva	Nucleic acid, RT-PCR	70 mins
Maxim Biomedical	Nasal swab	Antigen	15 mins
Mesa Biotech	Nasal swab	Nucleic acid, RT-PCR	30 mins
MicroGEM International	Nasal swab, Saliva, Sputum	Nucleic acid, RT-PCR	15 mins
Quidel	Nasal swab, Other	Antigen, lateral flow assay (LFA)	15 mins
Talis Biomedical	Nasal swab, Oral swab	Nucleic acid; Reverse transcription loop-mediated isothermal amplification (RT-LAMP)	20 mins
Visby Medical	Nasal swab	Nucleic acid, RT-PCR	30 mins
Ubiquitome	Nasal swab	Nucleic acid, RT-PCR	40 mins

RADx High-Throughput Laboratory Testing Technologies

Organization	Sample Type(s)	Type of Test	Turnaround Time
Aegis Sciences	Nasal Swab, Oral Swab	Nucleic acid, RT-PCR	16-24 hours
Broad Institute	Nasal Swab	Nucleic acid, RT-PCR	24 hours
Ceres Nanosciences	Nasal Swab, Oral swab, Saliva	Other	30 mins
Flambeau Diagnostics	Saliva	RT-LAMP	1 hour
Fluidigm	Nasal swab, Saliva	Nucleic acid, RT-PCR	2.5 hours
Helix OpCo	Nasal swab, Oral swab	Nucleic acid, next generation sequencing	<24 hours
Mammoth BioSciences	Nasal swab	Nucleic acid, CRISPR, RT-LAMP	40 mins
Path Group	Nasal swab, Oral swab, Saliva, Other	Nucleic acid, RT-PCR	24 hours
Sonic Healthcare	Nasal swab, Oral swab, Sputum, Other	Nucleic acid, RT-PCR	24 hours
Quanterix	Blood, Nasal swab, Saliva, Sputum	Antigen	24-48 hours