

# RADx Underserved Populations (RADx<sup>SM</sup>-UP) Return to School Phase I Kick-off

April 16, 2021



# WELCOME & INTRODUCTIONS

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# Agenda Overview, Welcome & Introductions



**Eliseo J. Pérez-Stable, M.D.**

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

# Agenda

Topic	Speaker	Time
Welcome & Introductions	Dr. Eliseo Pérez-Stable	9:00am
Overview of RADx	Dr. Francis Collins	9:05am
Overview of RADx-UP and the Return to School Initiative	Dr. Eliseo Perez-Stable Dr. Richard Hodes Dr. Alison Cernich	9:15
Team Presentations	Dr. Sonia Lee	9:25am 15 minutes per team
Overview of RADx-UP CDCC	Dr. Beda Jean-Francois Dr. Michael Cohen-Wolkowicz	11:45am
Q&A	All Attendees	12:00pm

*For webinar technical support, please contact Gifty Murray at +1 571 455 8199*

# OVERVIEW OF RADX PROGRAM

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# 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 – \$845M\***

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) – \$512M**

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) – \$230M**

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

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

## Innovate Across the Testing Landscape

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

## Optimize Technology Performance

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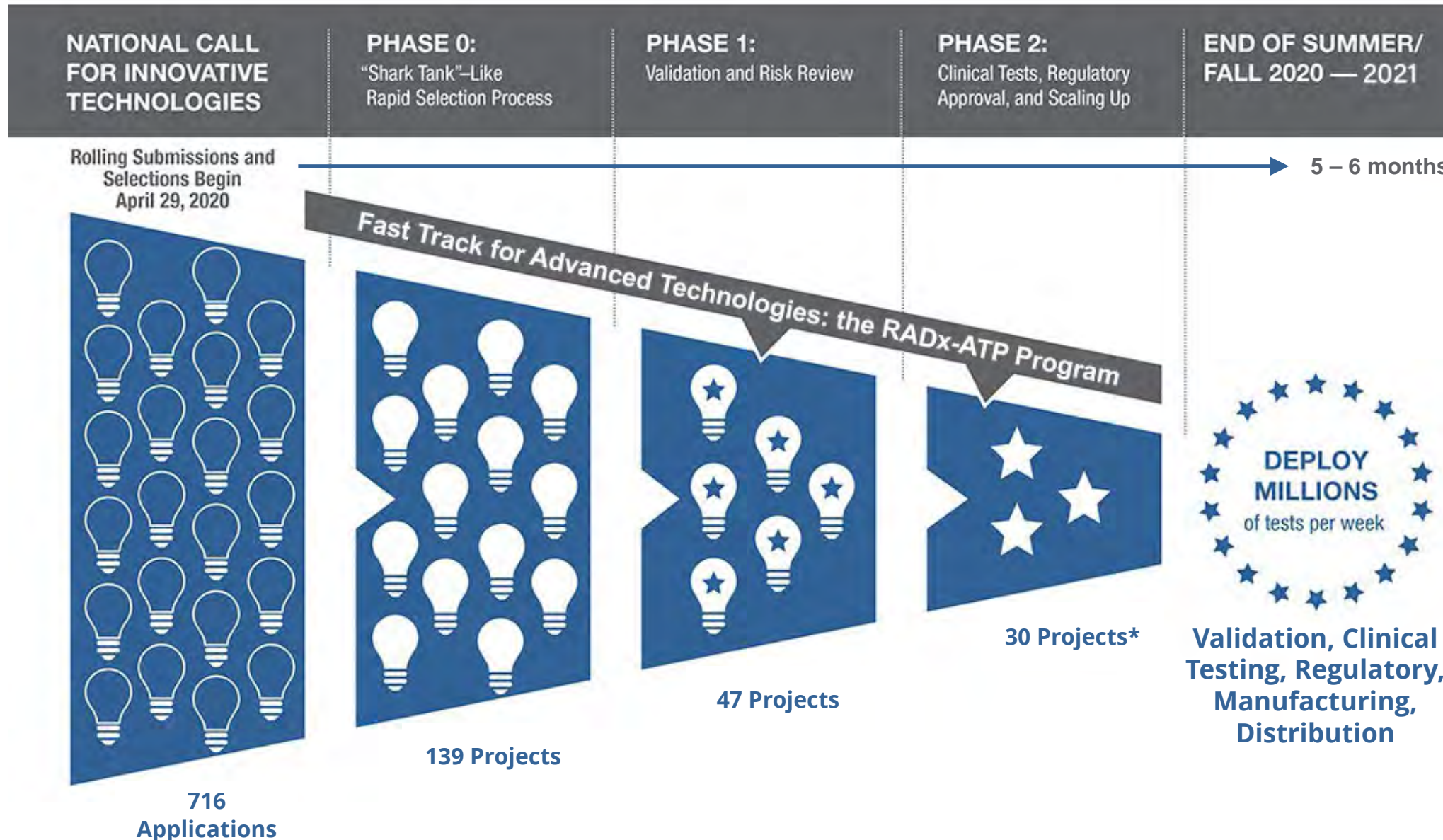
Develop technology for a range of essential “Use Cases”

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





# RADx Tech “Shark Tank”



**Note:** \*17 Tech/ATP projects have EUA, including the first at home testing kit (Ellume test)

# RADx-Advanced Technology Platforms (RADx-ATP)

## Overarching Goal

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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

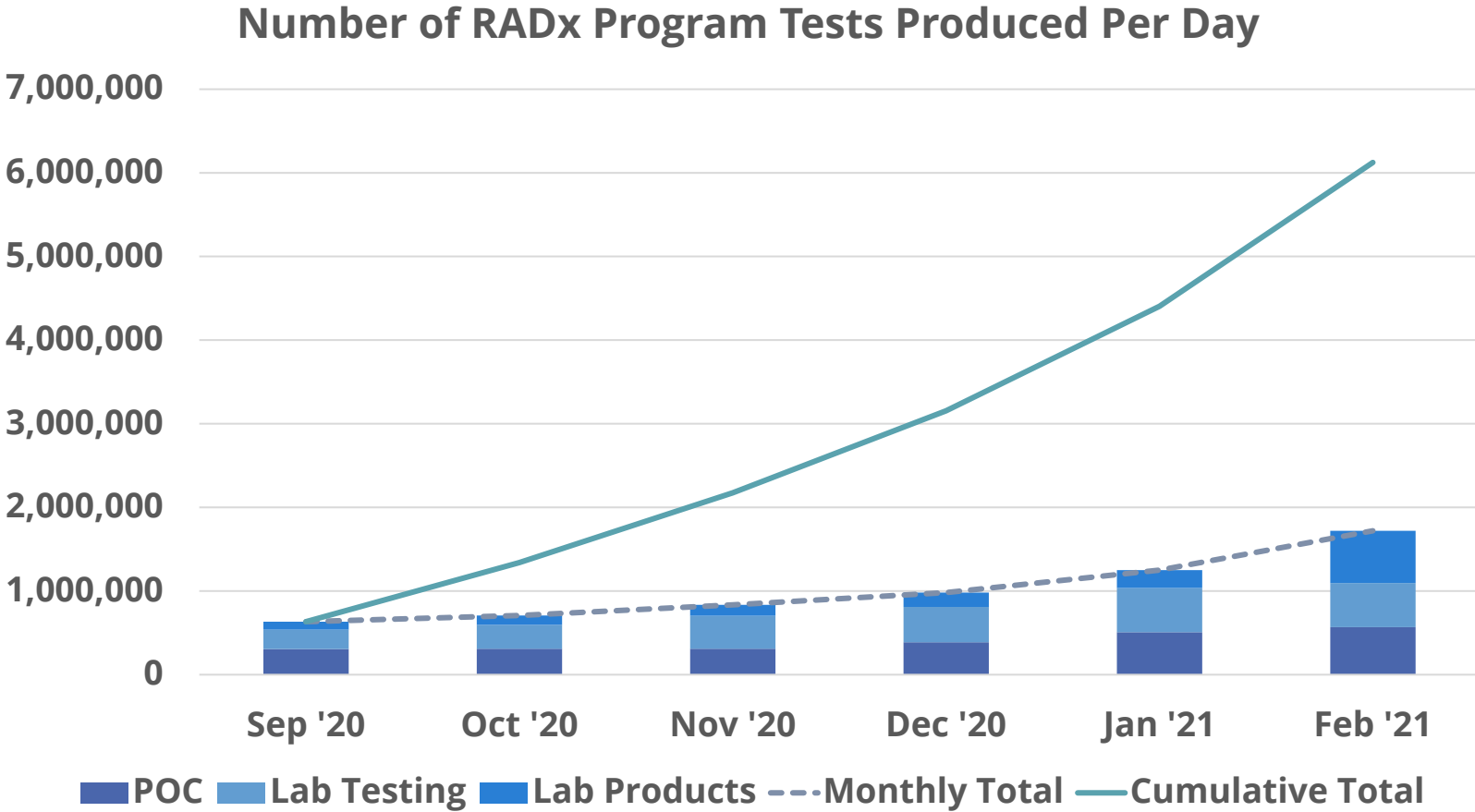


Scale-up Late-Stage Technologies

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

# Contribution of RADx to the National Testing Capacity

RADx awards contributed a cumulative **6.1M tests per day** to the National Testing capacity as of February 2021



**Note:** \*Cumulative total of 94 million tests per day produced between Sept and Dec 2020

# 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

September – November 2020

2021

Phase I

Phase II



*Build infrastructure*



*Rapidly implement testing, other capabilities*



*Integrate new advances*



*Expand studies/populations*

# RADx-Radical (RADx-rad)

## Overarching Goal

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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

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- **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

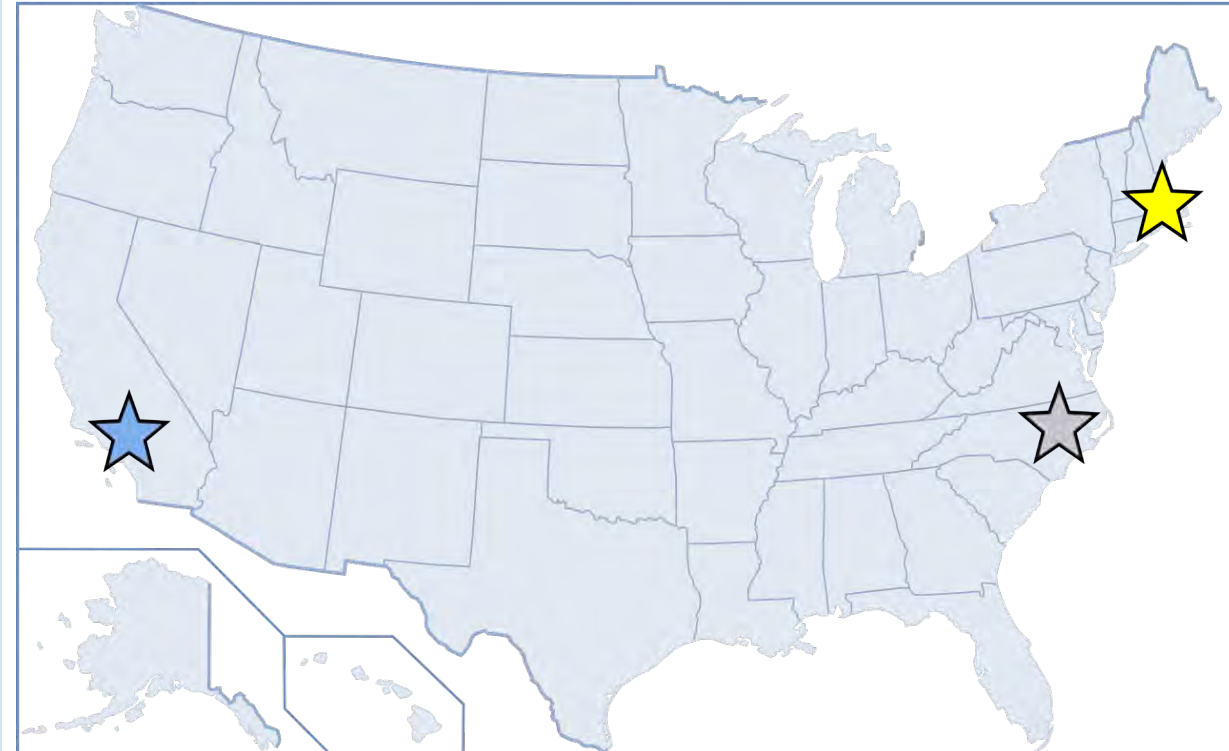


# RADx Coordination

**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



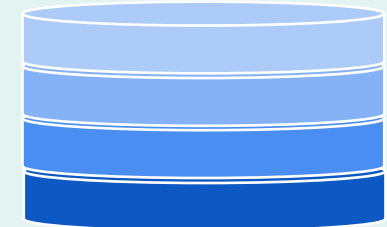
## Overarching Goal

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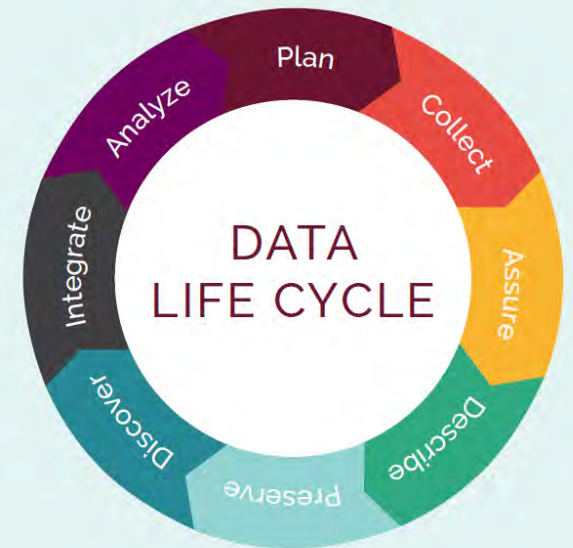
Develop platform to integrate data, on individuals and populations, from a variety of sources – including serology and genetic test results, output from smart sensors, self-reported clinical symptoms, and EHR data

- 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



**RADx Data Hub**



# INTRODUCTION OF RADX-UP

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# 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)**

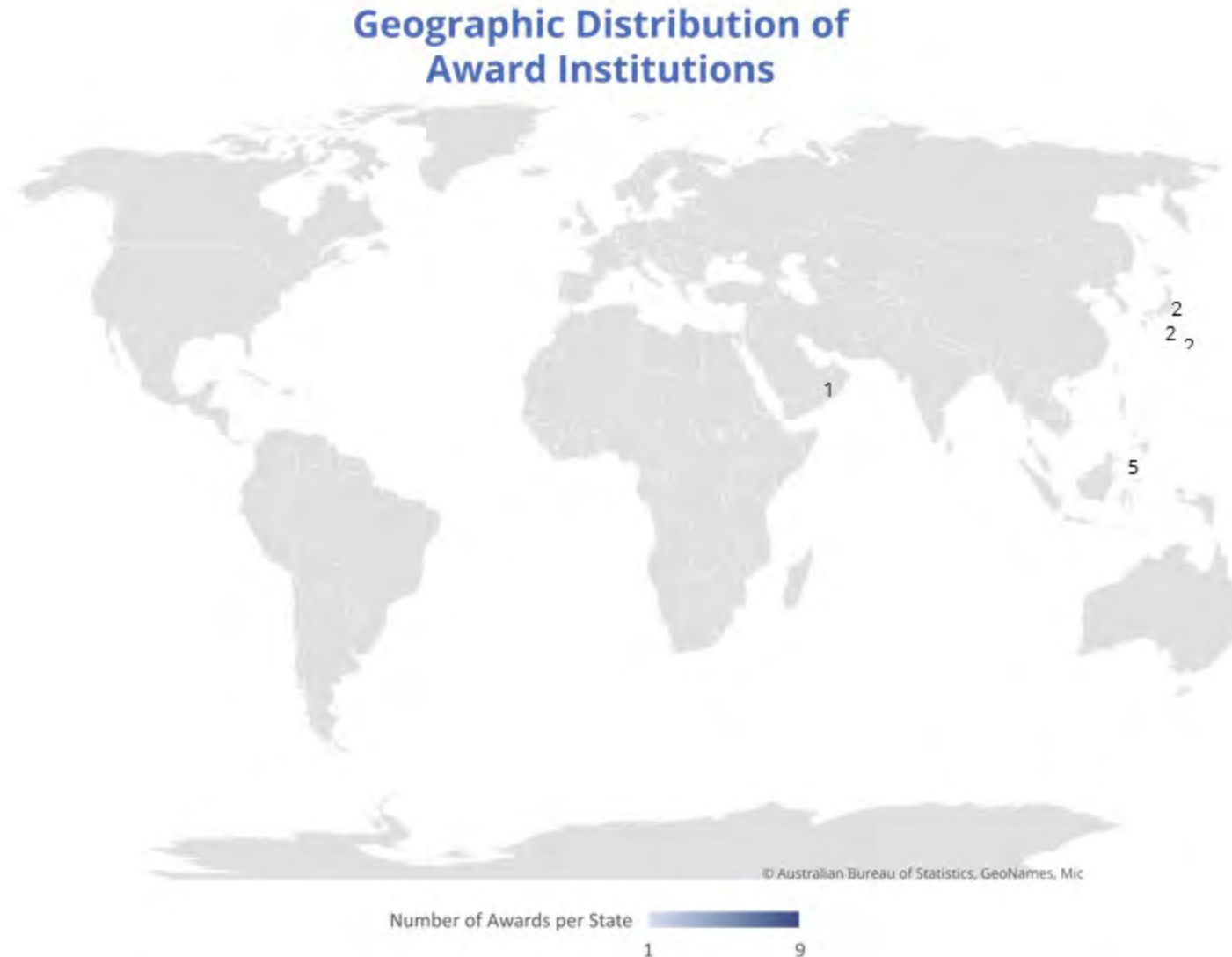
# RADx-UP Strategies

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- **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: 70 Funded Sites and Research Projects

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



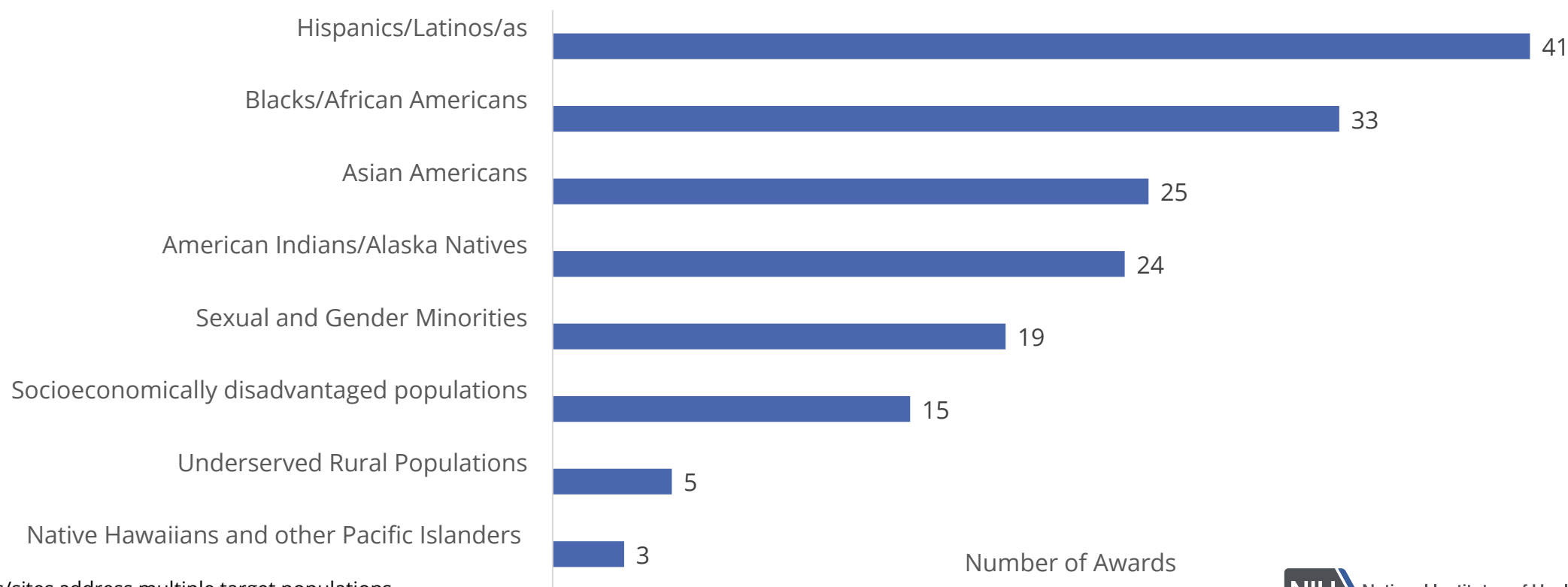
Funded sites and research projects span a total of **31 states** in addition to DC and Puerto Rico and include **54 institutions**.

# 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 Hispanic/Latino and African American populations, as well as Asian Americans and American Indians/Alaska Natives.

### Target Health Disparity Population Projects



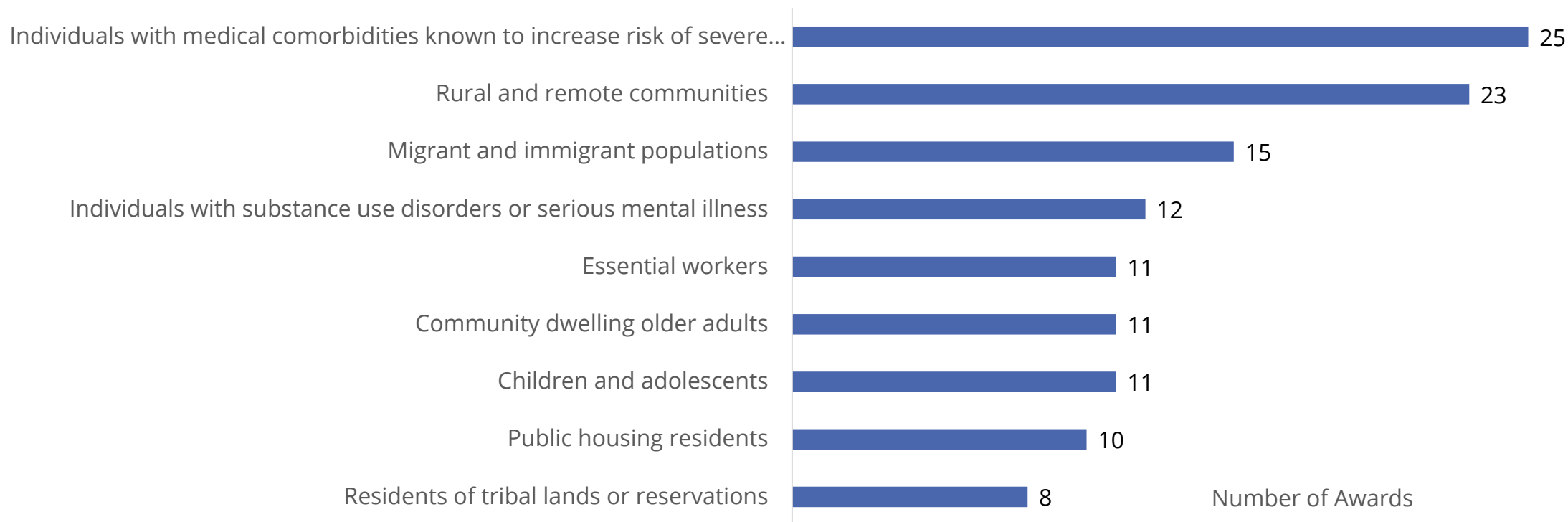
**Note:** Some projects/sites address multiple target populations.

# 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

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)



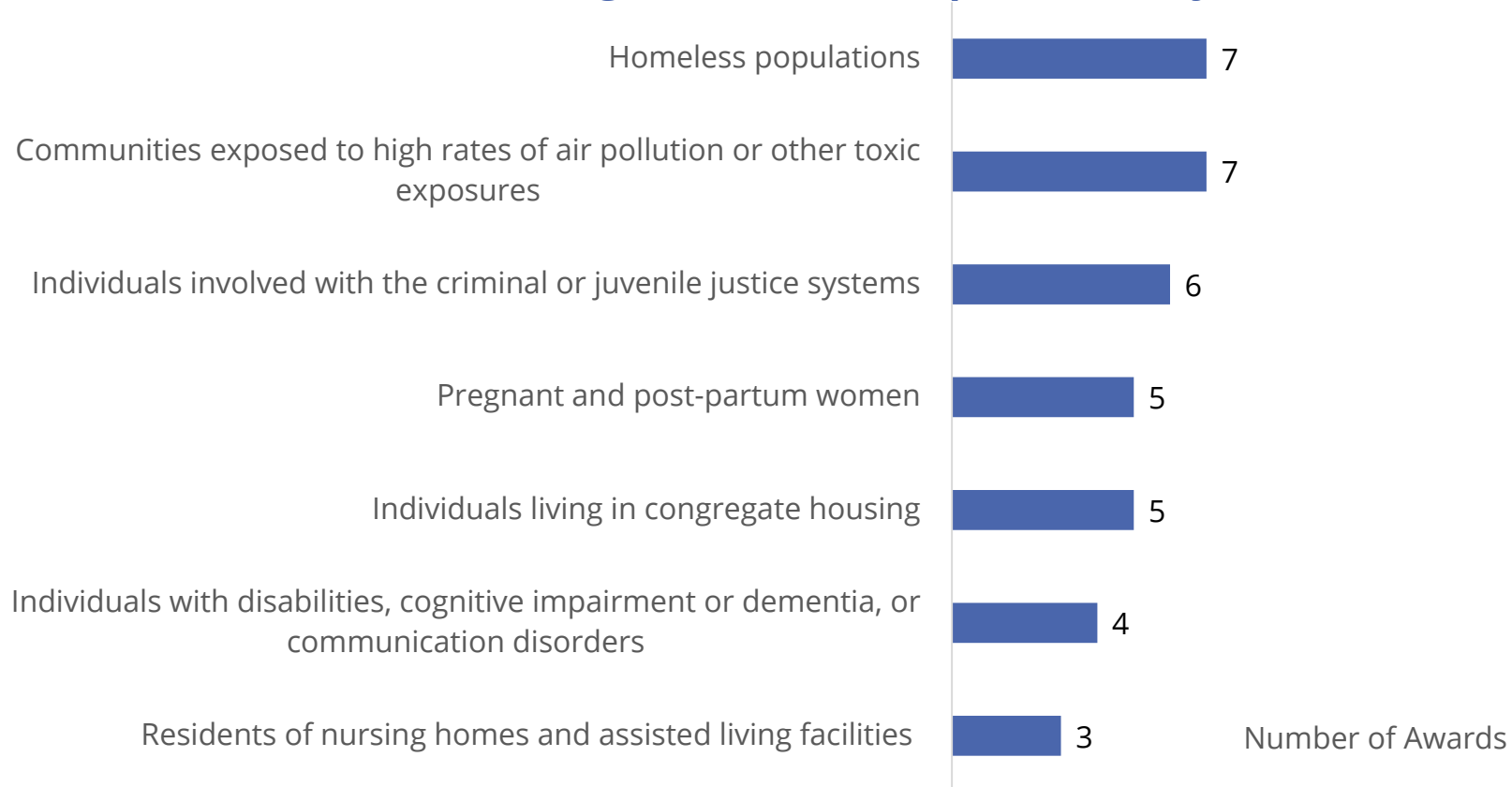
**Note:** Some projects/sites address multiple target populations.

# 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

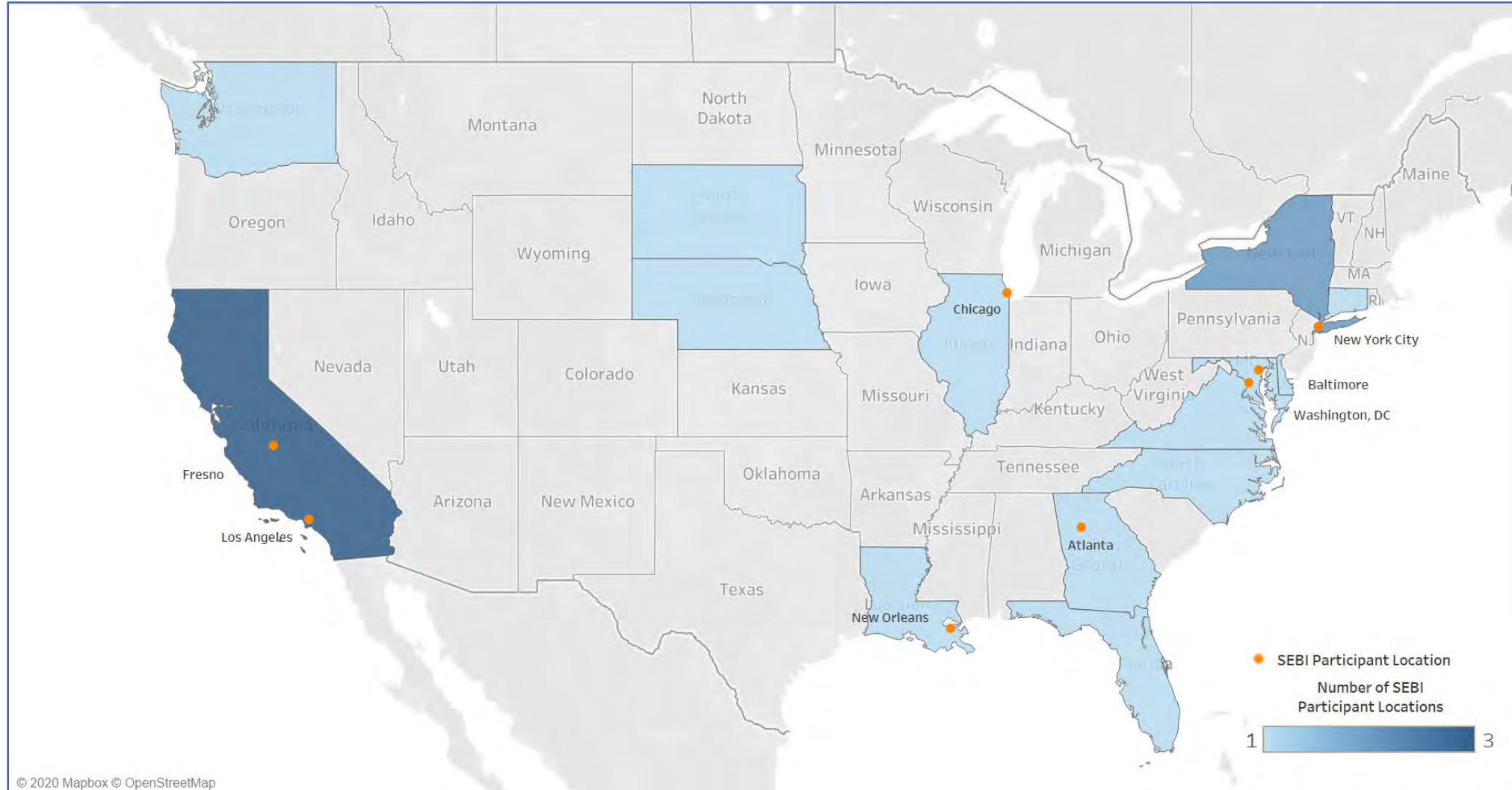
## Testing Participant Locations



**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 mental 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



# OVERVIEW OF RETURN TO SCHOOL

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# 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 (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

## 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
- **Phase II Awards** projected for the summer of FY21





# Return to School

## Institution Locations: Awarded Projects



### Cities Represented

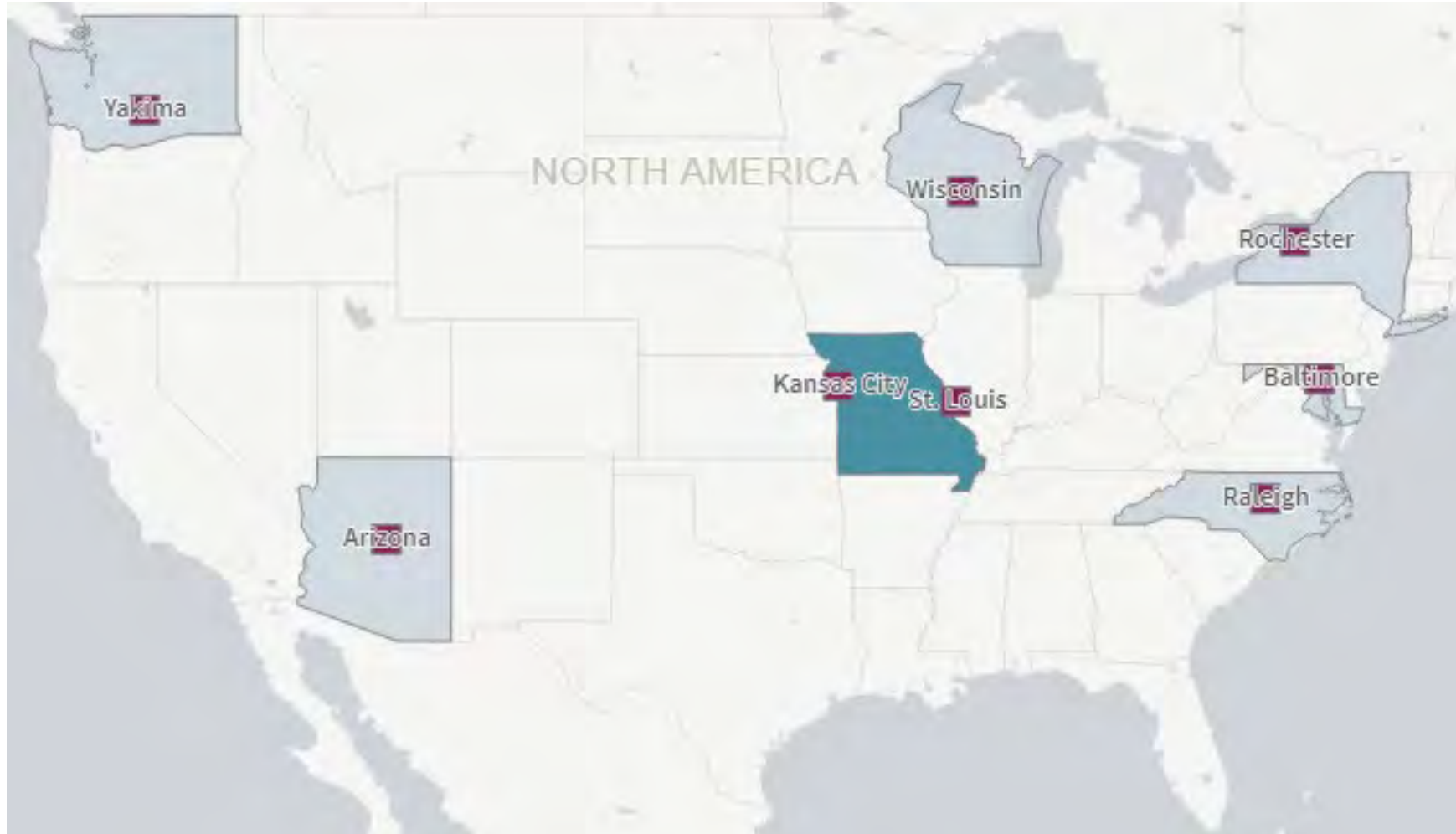
- Baltimore, MD x2
- Durham, NC
- Fairfax, VA (not listed on map)
- Kansas City, MO
- Madison, WI
- Rochester, NY
- Seattle, WA
- St. Louis, MO

Number of Projects



# Return to School

## Study Locations: Awarded Projects



Number of Projects



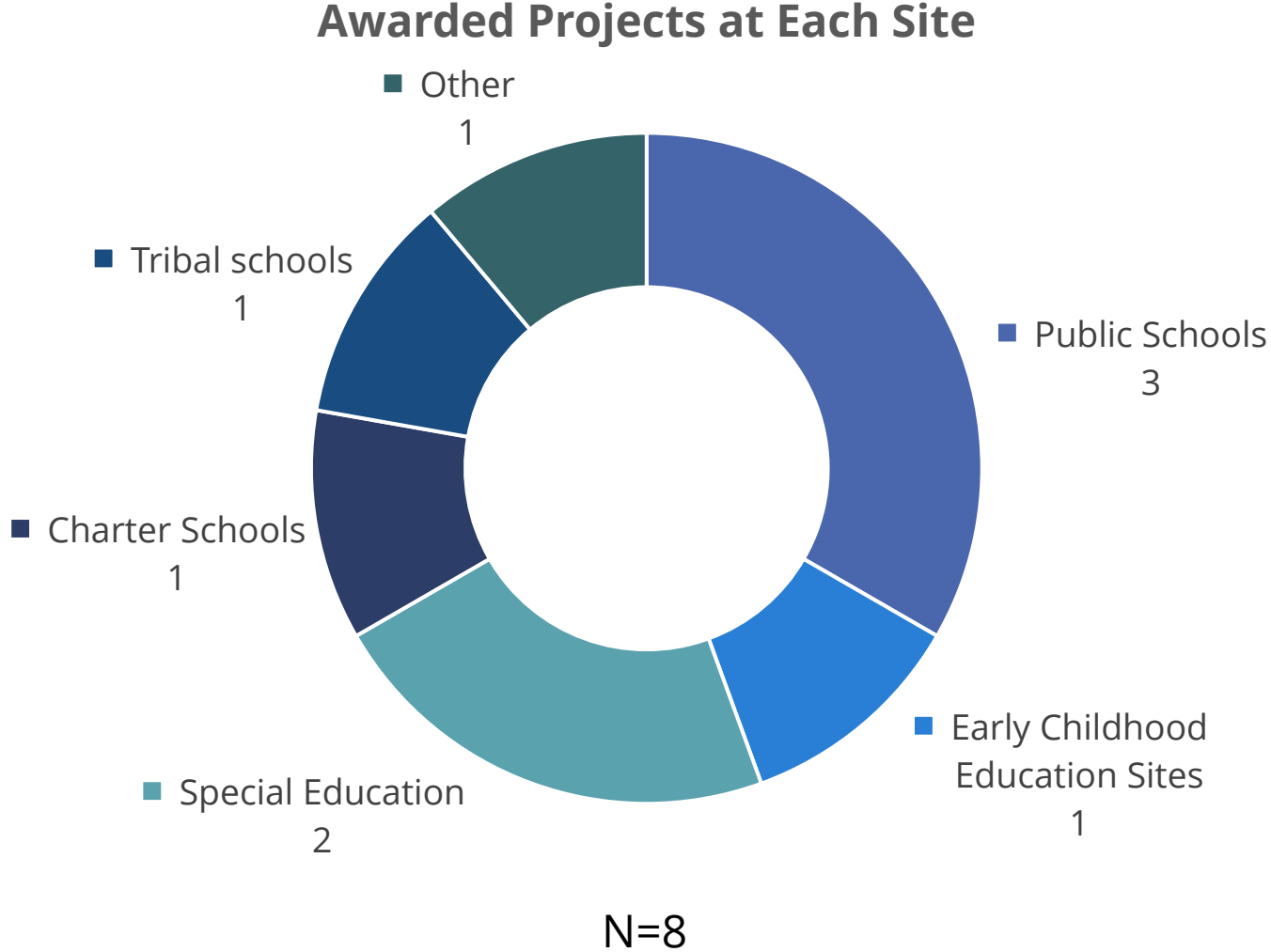
Note: Geographic areas listed are not exhaustive, as some applicants only provided state-level information

### Geographic Areas

- White Mountain Apache and Navajo Nation, AZ
- Baltimore, MD
- Kansas City, MO
- Madison, WI
- Raleigh, NC
- Rochester, NY
- St. Louis, MO
- Yakima Valley, WA

# Return to School

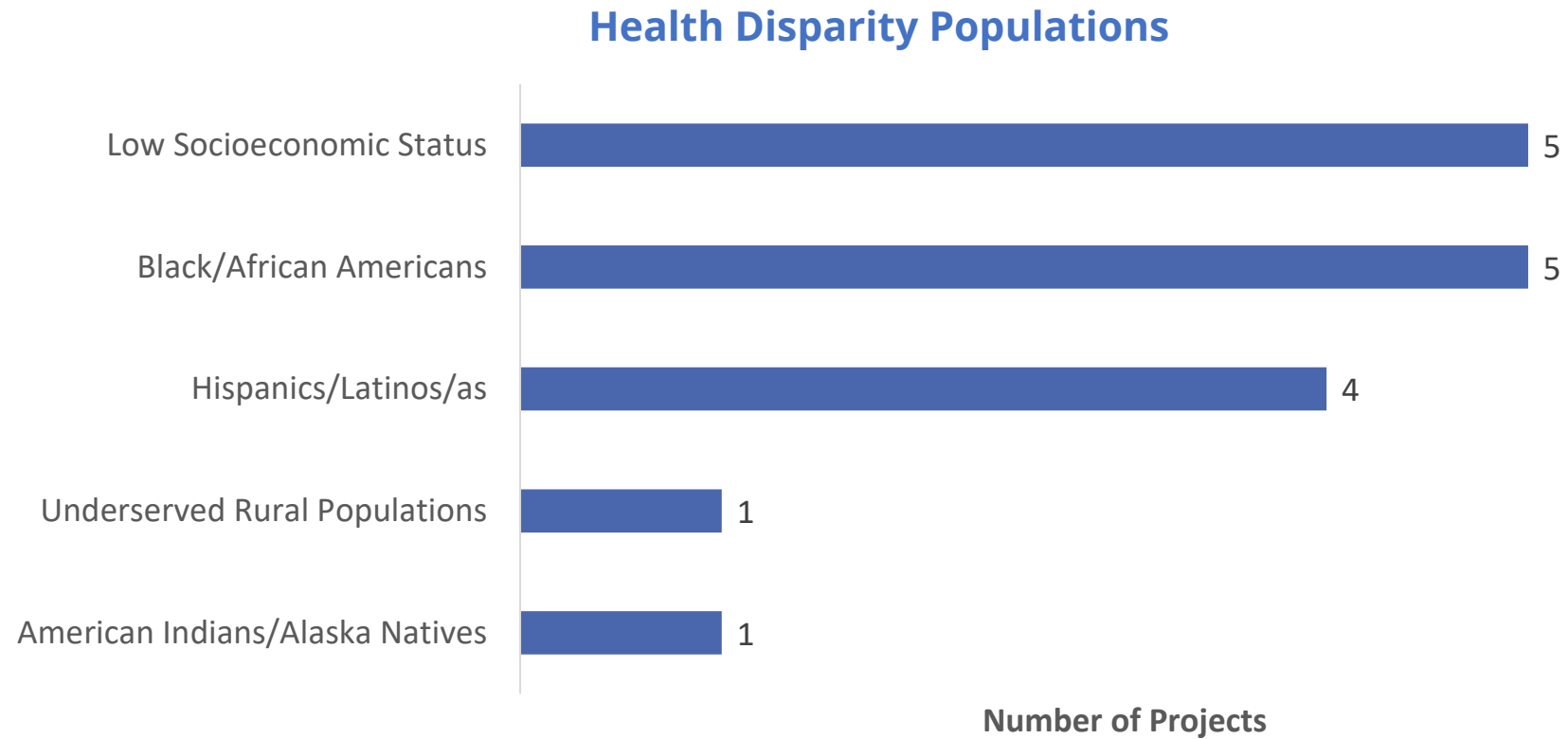
## Project Settings – Awarded Projects



Note: other refers to a Pediatric Complex Care Program (1)  
Note: The breakdown of sites is not additive; some projects work in multiple settings

# Return to School Phase I

## Target Health Disparity Populations

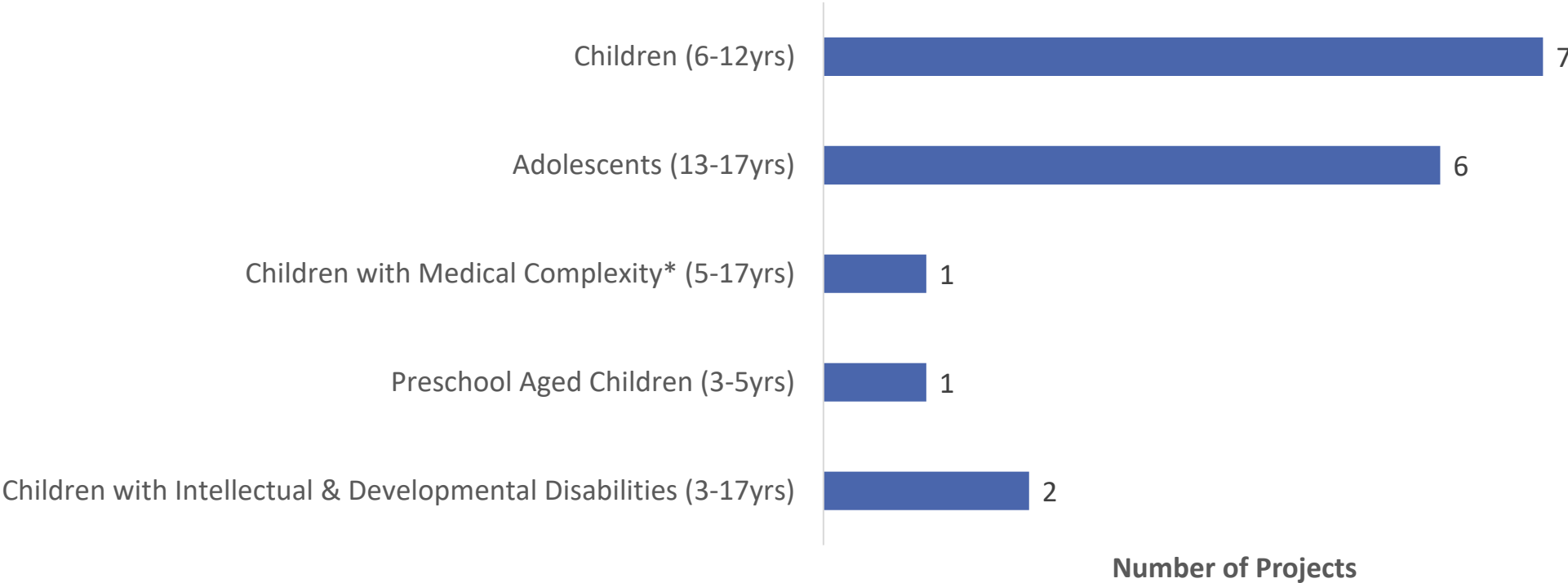


# Return to School

## Vulnerable Populations



### Vulnerable Populations



\*Children with medical complexity include children who have substantial family-identified health care service needs, such as medical care, specialized therapy, and educational needs; children with chronic medical conditions; children with functional limitations; and correspondingly have high utilization of healthcare resources. See slide notes for full definition.

# TEAM PRESENTATIONS

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# Introduction of Project Teams



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

# Investigator



**John Foxe, Ph.D.**

**NICHD, University of Rochester**



# COV-IDD: Testing for COVID-19 in children with intellectual and developmental disabilities



John Foxe, Martin Zand, Stephen Dewhurst

University of Rochester Intellectual & Developmental Disabilities Research Center (UR-IDDRC)

## Five Major Goals:

- 1) Virological Testing:** We will establish a nasal-swab FDA-approved testing regimen to monitor and identify disease outbreaks in a school setting at ultra-high risk for COVID-19 disease transmission. We will rapidly identify infections and develop approaches for isolating and contact-tracing to stem virus spread.
- 2) Serological Testing:** Serology will establish background immunity levels in students and staff, from infection or vaccination, following those who are antibody-positive longitudinally to quantify temporal decay of IgG and neutralizing antibody levels. We will determine whether protective immunity in children with IDD, a population with prevalent immunological dysfunction, wanes at accelerated rates compared to the population-at-large.
- 3) Modeling to Optimize Testing:** We will use agent-based simulation models to guide testing strategies and interventions in this specialized population. Simulations will be conducted interactively and iteratively, to assist in planning and implementation of testing procedures.
- 4) Mobile Unit Testing:** We will deploy a customized, disability-enabled, mobile testing unit to directly deliver rapid flexible testing wherever need arises.
- 5) Overcoming Testing & Vaccine Anxiety/Hesitancy:** We will conduct focus groups to identify community concerns, myths and misconceptions about testing and vaccination, and create a multimodal educational campaign that addresses and mitigates these concerns.



*Transforming lives of people with disabilities*

Mary Cariola Center (**MCC**) serves moderate-to-severe IDD children (**N=450**) via a large professional support staff (**N=500**). 70% of MCC students live in poverty, and 54% are from under-represented minority backgrounds. 100% are on federal food assistance programs.



## The Mobile Testing Unit

We will staff, equip and deploy a customized, disability-enabled, mobile unit (*UR Health in Testing - HIT Mobile*) to bring testing directly to the MCC community.



# Testing at the URM Central Laboratories

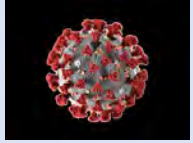


Table 1: URM COVID-19 Testing Capacity and Modalities

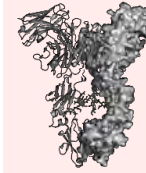
Platform	Capacity: Tests/Day	Certification
Roche 8800	2000	FDA-EUA
Cepheid	500	FDA-EUA
Hologic	500-1000	FDA-EUA
TF Amplitude	3000-6000	FDA-EUA



RADx-UP samples will be tested on the **Thermo-Fisher Amplitude** molecular (RT-PCR) system:

- Extremely high throughput; readily available testing reagents
- Three targets for robust detection of multiple lineages
- 3.5 hour run time

The URM Central Laboratory has tested over 500,000 respiratory specimens for SARS-CoV-2 since the beginning of the pandemic with an average TAT of 24 hours



## Abbott Architect platform

Measures IgG against the SARS-CoV-2 nucleocapsid protein

FDA EUA

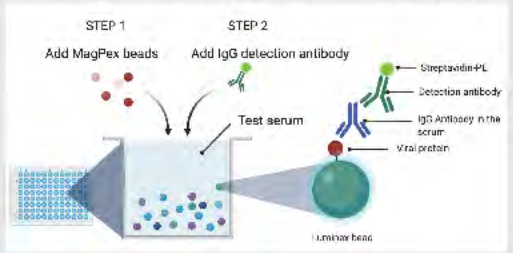
High throughput (500-800 per day)

High sensitivity and specificity

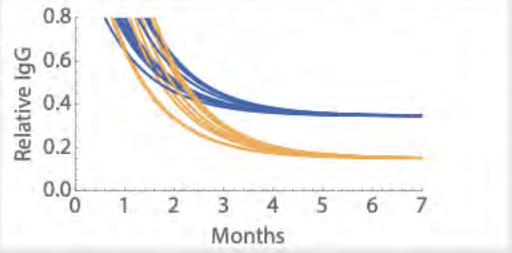
**Volumetric Micro Sampling**



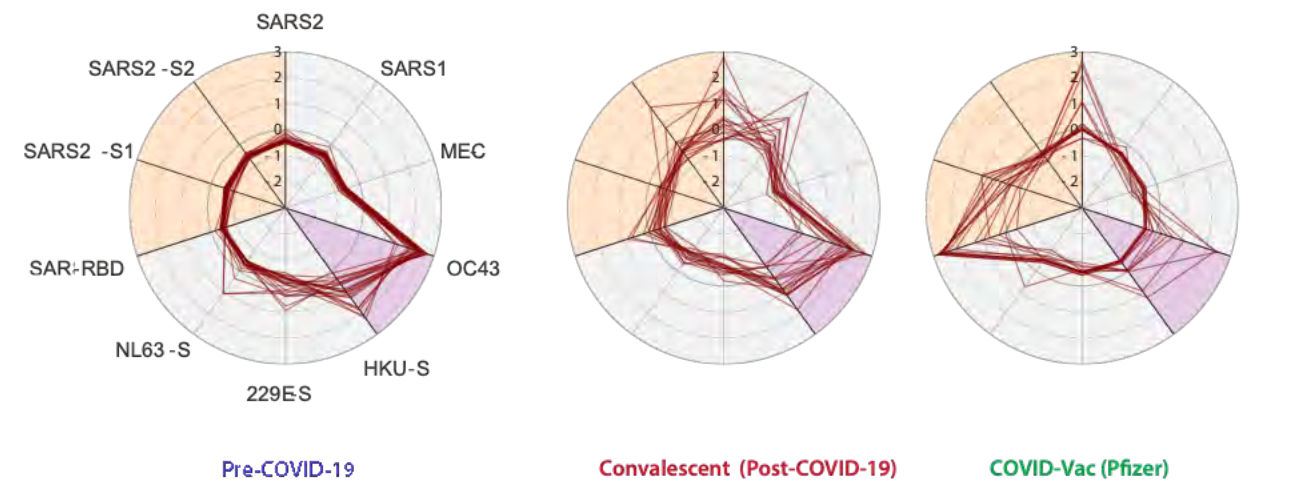
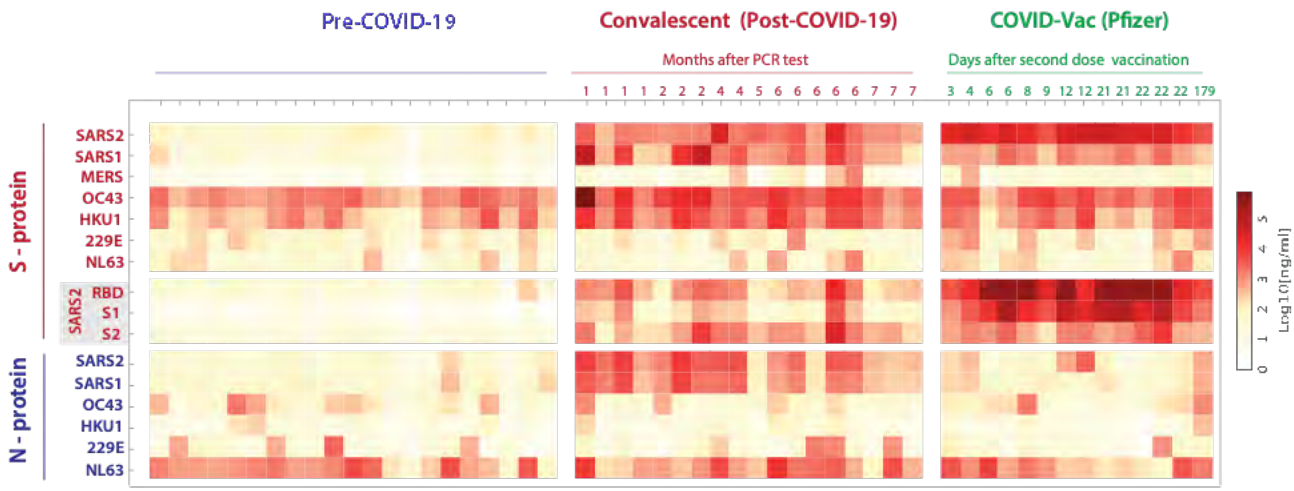
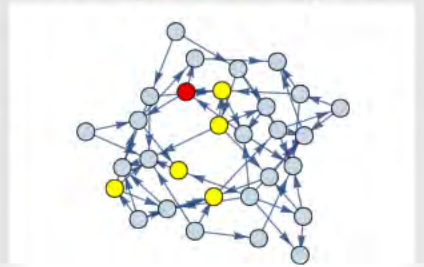
**Multiplex Analysis (mPLEX-CoV)**



**Anti-SARS-CoV-2 RBD Levels**



**Modeling of immunity levels**



**Scientific Questions:**

How does IgG antibody reactivity against SARS-CoV-2 change over time in teachers, staff, and IDD students?

What are the patterns of IgG cross-reactivity to circulating coronavirus strains?

What are the rates of asymptomatic transmission in vaccinated staff and IDD students?

## Contact Data



## Serology



## Virologic Testing



## Scientific Questions:

What testing patterns and frequency are needed to:

- Detect asymptomatic SARS-CoV-2
- Minimize risk of transmission of SARS-CoV-2
- Monitor classroom immunity

What changes in contact, immunity, and classroom structure maximize student and staff attendance?

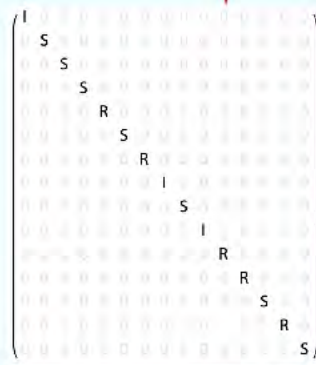
- Class size
- Contact patterns
- Community prevalence of viral variants

## General Deliverables:

- Flexible models that could be adapted to different school staff and student configurations allowing "what if?" scenario modeling



Contact Matrix



Immunity



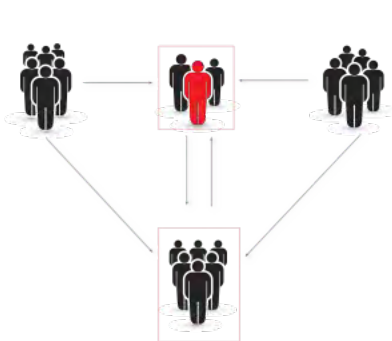
Infectivity

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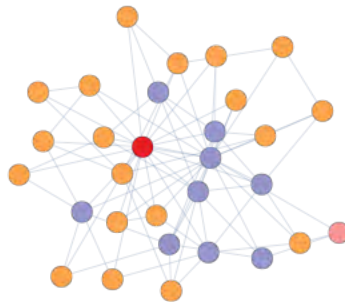


Exposure

**Susceptible**  
**Exposed**  
**Infected**  
**Recovered**



Agent Based Models



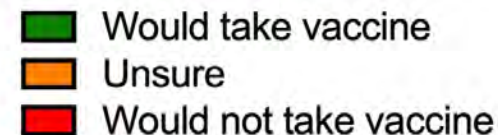
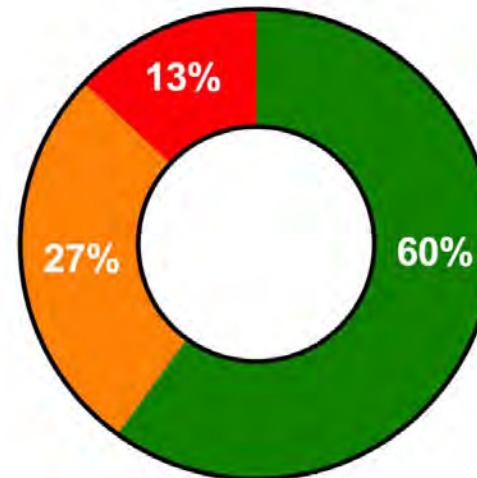
Stochastic Mobility Models

# Overcoming Testing & Vaccine Hesitancy; Measuring Impact

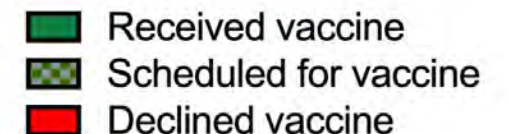
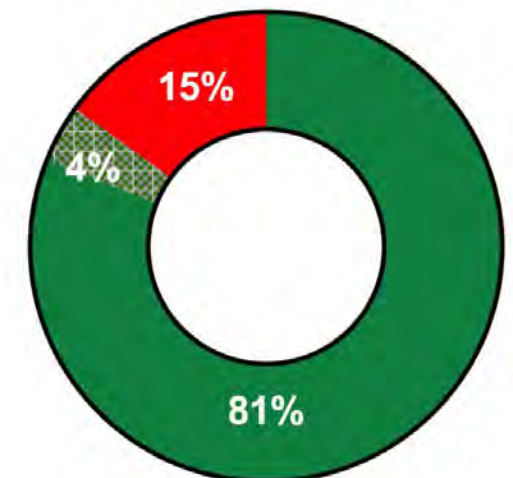
1. **Focus group interviews** with priority populations
2. **Targeted strategies to increase understanding** of the COVID-19 vaccine
3. **Effective communication tools/media** (social/digital, web, PR, testimonials)
4. **On-the-ground education** (speakers' bureau; "table talk")
5. **Graphic medicine** (innovative visual media and art)

## Overcoming URMC Workforce Hesitancy

Initial Survey Data



Employee Vaccination





# PROMIS: Patient-Reported Outcome Measurement Information System

## NIH Roadmap for Medical Research initiative produced the **PROMIS**

- ▶ Efficient, precise, responsive and validated patient-reported outcome measure (PROM)
- ▶ Produce comparable domain-focused, PROM of health across patient subgroups and therapies
  - ▶ 11-year, \$100 million effort by NIH
  - ▶ Produces validated data quickly
    - ▶ Item Response Theory
    - ▶ Computer Adaptive Testing (CAT)



## PROMIS based on the Biopsychosocial Model

### Physical Health

Physical Function

Upper Extremity Mobility  
Physical Function

Physical Symptoms

Fatigue  
Itch  
Pain

### Mental Health

Emotional Distress

Anxiety  
Depression

Psychological Function

Self-Efficacy

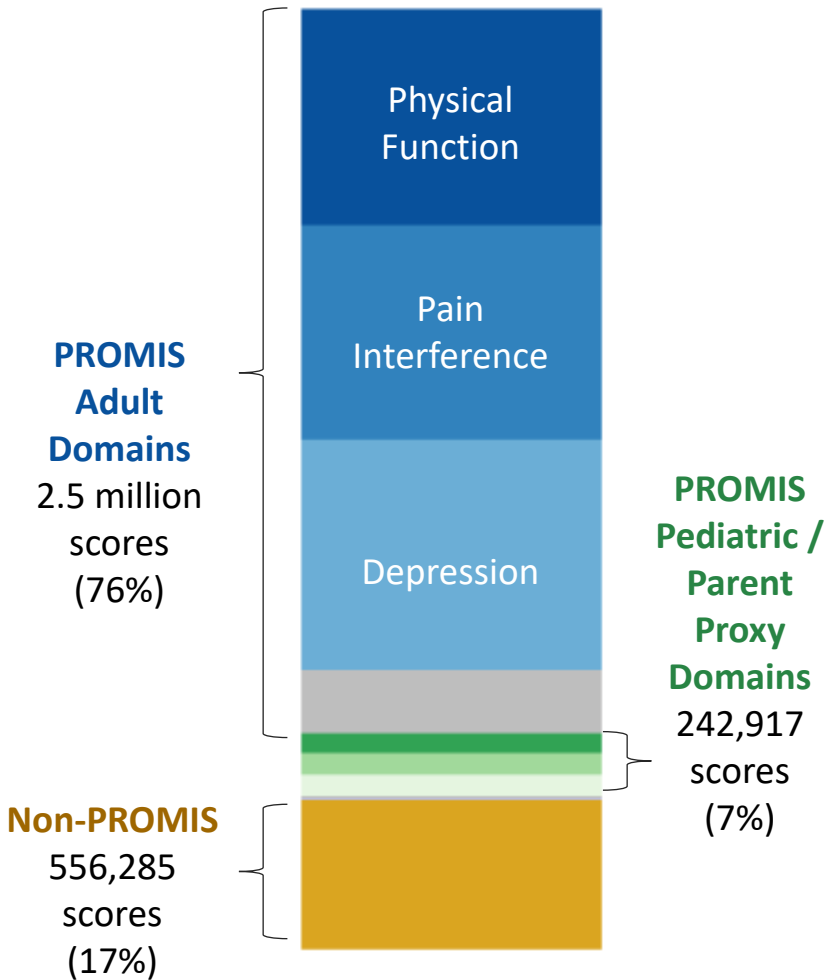
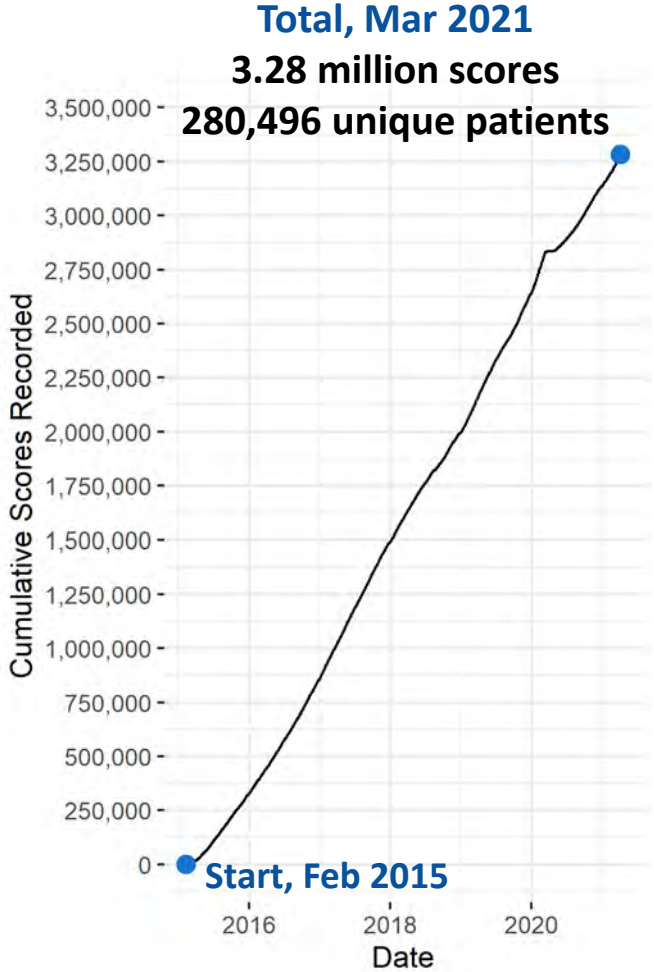
### Social Health

Social Function

Ability to Participate in Social Roles and Activities

Social Relationships

# UR Voice: Data Collection



## PROMIS CATs

**44 seconds**  
Median time to complete assessment

**4 items**  
Median items answered per assessment

**98.2% completed**

# Key Innovations

1. **Highly Significant Population** – kids with IDD
2. **Longitudinal Serology** – assess durability of immunity in kids with IDD
3. **Mobile Testing Unit** – to reach kids at home
4. **Use of PROMIS** – to measure impact rapidly (and scalably); opportunities for machine learning

**MAR 23 2021**  
As I dropped off my sandals for repair, Rochester's #1 cobbler tells me: My wife won't get the vaccine. They used fetuses for Moderna and Pfizer but old ones from the 60's. We looked it up and it's true. She might get the Johnson & Johnson because they don't use fetuses. It's her choice. We're Catholic. I HAD to get the Moderna because I'm immunocompromised

The J&J vaccine was developed, and is produced, in a proprietary fetal cell line that J&J owns, called PER.C6. A fetal cell line is not fetal tissue. These are immortal cell lines that grow forever, and are currently over 30 years old. PER.C6 originated from a single elective abortion in the Netherlands in 1985. The J&J vaccine contains no fetal cells.

United States Conference of the Catholic Bishops: "Receiving a Covid-19 vaccine ought to be understood as an act of charity toward the other members of our community. In this way vaccinated safely against Covid 19 should be considered an act of love of our neighbor and part of our moral responsibility for the common good."  
(Dec. 11, 2020)

The Moderna and Pfizer vaccines were developed and produced without use of a fetal cell line or any cells at all.

There have never been so many vaccines for a single infectious pathogen.

We have 4 licensed vaccines.

Stephen Dewhurst, Ph.D.  
Virologist  
Vice Dean for Research  
Professor and Chair Microbiology & Immunology  
University of Rochester School of Medicine & Dentistry

CHARMAINE

# Investigator



**Kanecia Zimmerman, M.D.**

**NICHD, Duke University**

# SARS-COV-2 Surveillance and Diagnostic testing for return to K-12 schools

*Kanecia Zimmerman, MD MPH and Danny Benjamin, MD PhD*

*April 16, 2021*



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# Schools are opening, but not everyone is returning

## The Statistics...

- Black and Latino students have been more likely to choose remote options
  - **New York City**: enrolled students of color far outnumber white students, but white students returning outnumber black students by 12,000
  - **Some NC districts**: Black students comprise >60% of enrolled students, but only 20% of those returning
  - **Mississippi**: 50% of enrolled white students accounted for nearly 70% of returning students
- Multiple potential reasons, but current narrative is limited
  - **Fear**: >85% of Black parents believed that children are “at serious risk of health effects from COVID-19”
  - **Mistrust of school** to keep children and families safe: >95% were concerned about their child contracting COVID-19 at school, and >90% were concerned about their child bringing COVID-19 home from school
  - **Racism**: enforcement of mitigation measures at school may provide further opportunity for asymmetrical discipline practices based on race
  - **A new opportunity**: remote learning is a welcome relief from within-school racism and bullying

# Prolonged quarantines limit in-person time for those who choose to return to school buildings

- Quarantine Durations:
  - 7-14 days required for those exposed to students/staff with COVID-19
  - 7 day quarantines with negative test at 5-7 days (CDC guidance)
- Testing ACCESS is:
  - Necessary to limit quarantines
  - Limited for Black and Latino families
- Black and Latino children who are exposed to COVID-19 in school will have disproportionate access to in-person learning

**Given limited transmission in the school setting with strict adherence to mitigation measures, Black and Latino students assume multiple short- and long-term risks from quarantine without substantial benefit to them, their families, or their communities.**

# Surveillance and exposure testing may help demonstrate school safety and improve testing access

- **AIM 1: Assess the effectiveness of rapid, school-based SARS-CoV-2 **surveillance** in reducing within-school transmission and restoring trust among Black and Latino families.**  
**Hypothesis 1:** School-based SARS-CoV-2 surveillance testing will result in similar incidence of within-school transmission, but increased trust as measured by  $\geq 30\%$  increase in the proportion of Black and  $\geq 20\%$  Latino children returning to in-person education, compared to schools without testing.
- **AIM 2: Assess uptake of school-based testing and time to safe school return after **exposure****  
**Hypothesis 2:** School-based testing will improve testing uptake in underserved children ( $>50\%$  increase (95% CI 0.4, 0.6)) and decrease time-to-return to school by 7 days (95% CI, 3, 11) without increased incidence of within-school transmission, compared to schools that do not provide testing.
- **AIM 3: Identify the **perceived benefits, concerns, and barriers** to school-based SARS-CoV-2 testing and in-person learning among Black and Latino families.**  
**Hypothesis 3:** Barriers to school-based testing will include perceived repercussions for working family members; barriers to in-person learning will extend beyond concerns about risks of SARS-CoV-2.



# Against a backbone of engagement and education: The ABC Science Collaborative

## What Is the ABC Science Collaborative?

A program that pairs scientists and physicians with school and community leaders to help understand the most current and relevant information about COVID-19.

- -Biweekly meetings with schools/districts
- -Educational webinars for teachers and staff (COVID-19, vaccines)
- -Community meetings
- -Student science lessons



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## The Team

Public health scientists and physicians affiliated with the Duke School of Medicine, the Duke Clinical Research Institute, and the University of North Carolina School of Medicine.



# Implementation

## Surveillance Cohort

- Weekly testing to include:
  - 10-20% consented students
  - 100% of consented staff (non-vaccinate)
- Charter schools in Durham, NC
- Heterogeneous population
- Similar return to in-person school among children of color

## Exposure cohort

- Testing of students exposed to COVID-19
  - At the time of exposure
  - At 5-7 days post exposure
- Iredell-Statesville Schools
- High incidence of SARS-CoV-2 throughout the pandemic
- Prior collaboration for ABC-11
  - interest in changing policy

# Facilitators

- Surveillance testing in traditional public schools (Durham) – w/o careful communication and engagement from ABC
- New law in NC (SB220) requiring reporting to ABCs about within school transmission, mitigation measures, quarantine, etc.
- Ready comparison to RTS data to establish impact of testing

# Feedback and dissemination

Community Advisory Board	National Advisory Committee
Latin-19	Dan Cooper, MD: UC Irvine
Black-19	Kimberly Monroe, MD: University of Michigan
PAC-4	Donna Tyungu, MD: University of Oklahoma
Checks and Balances for study procedures	Florence Burgeois, MD MPH: Harvard University
Continuous Feedback (Qualitative AIM) and Improvement for 3 Testing Cycles: Dissemination via community meetings	Andi Shane, MD MPH MSc: Emory University
	Charlotte Hobbs, MD: University of Mississippi
	Vanessa Maier, MD MPH: MetroHealth
	Dawn Nolt, MD MPH: Oregon Health and Science University

# Thank you.



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# Investigator



**Dana Keener Mast, Ph.D.**

**CDC, ICF, INC.; CHILDREN'S MERCY HOSPITAL**

# School TLC Study

## Support for Safe Return to In-Person School: COVID-19 Testing, Learning, and Consultation



### Co-Principal Investigators

Dana Keener Mast, PhD  
ICF

Jennifer Goldman, MD  
Children's Mercy Kansas City

Jennifer Schuster, MD  
Children's Mercy Kansas City



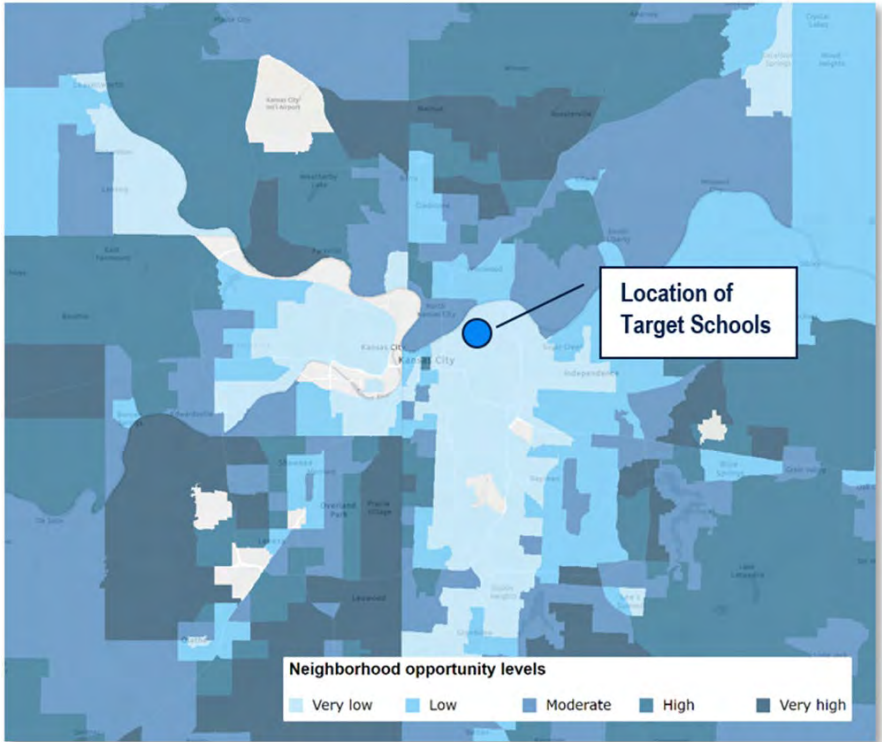
## School TLC Study Highlights

- Targets highly disadvantaged schools in urban setting
- Multi-phase study
- Testing preference study
- Formative needs assessment
- Proactive medical consultation and tailored communication strategies
- Plan for year 2 (pending): Project ECHO to expand reach





	<b>Rogers Elementary School</b>	<b>Northeast Middle School</b>	<b>East High School</b>
Number of staff	<b>489</b>	<b>686</b>	<b>1,075</b>
Number of students	<b>67</b>	<b>85</b>	<b>112</b>
Percent free and reduce lunch	<b>100</b>	<b>100</b>	<b>100</b>
Percent Black/AA	<b>42.6</b>	<b>42.8</b>	<b>46.7</b>
Percent Hispanic	<b>45.3</b>	<b>38.3</b>	<b>40.3</b>
Returned to in-person school (hybrid)	<b>03/15/2021</b>	<b>03/22/2021</b>	<b>04/05/2021</b>



Targeted schools are located in zip codes rated as very low opportunity areas (Childhood Opportunity Index)

➔ **School Population Demographics**

Enter chart data sources here.

**Phase 1: April – July 2021**

**Study Aim: Determine preferred COVID-19 testing strategies and identify factors that influence choice to test and return to school in disadvantaged school settings.**

**Targets 3 schools**

---

## **Testing Preference Study**

**What testing strategies are preferred by students, staff, and parents?**

- Offer surveillance testing to all students and staff
- Collect nasal and saliva specimens followed by Testing Preference Assessment “Which test did you like better?”

## **Formative Needs Assessment**

**What attitudes, knowledge, and barriers among students, staff, and parents influence choice and ability to test and return to in-person learning?**

- Survey parents of all enrolled students
- Interview parents, nurses, school staff, principals, community stakeholders, and a health department official

Phase 2: August – December 2021

**Study Aim: Augment COVID-19 testing with tailored medical consultation and communication strategies and evaluate impact on in-person schooling.**

**Targets 3 original schools for testing with medical consult and communication strategies  
+ 3 new schools to receive testing only**

---

## **Tailored Medical Consultation and Communication Strategies and Comparative Outcomes Study**

**Was COVID-19 testing combined with tailored medical consultation and communication strategies more effective in supporting in-person schooling than COVID-19 testing services alone?**

- Refine testing strategy based on testing preference study and continue diagnostic testing for students, staff, and family members of exposed students (offer to 3 original schools and 3 new schools)
- Augment testing with tailored medical consultation and communication strategies in 3 original schools (intervention schools)
- Track and compare in-person schooling metrics between three intervention schools, three testing-only schools, and synthetic controls from remaining schools
- Survey parents and conduct focus groups with parents and staff in each group

**Phase 3: January 2022 – April 2023 (pending)**

**Study Aim: Determine whether a statewide telehealth network is an effective strategy for disseminating tools to support schools for continued in-person learning.**

**Targets additional school districts (TBD)**

---

## **Project ECHO and Evaluation**

**How did participating school nurses and school administrators use the tools and information shared on Project ECHO to assess and address the needs of their communities for safe return and sustainability of in-person learning?**

- Continue to offer diagnostic testing as needed within KCPS district
- Use an existing ECHO platform to implement a train-the-trainer model with school staff across Missouri
- Conduct Post ECHO survey and interview participants

# Investigator



**Jason Newland, M.D., M. Ed.**

**NICHD, Washington University**



# Assessing Testing Strategies in K-12 schools



**Jason G. Newland MD, MEd**  
**@JasonGNewland**  
**April 16, 2021**





## Delmar Divide

- North of Delmar Boulevard
- Predominantly African-American
- Indexes of Social Well-Being worse
  - Childhood Asthma
  - Life expectancy less
  - Level of education

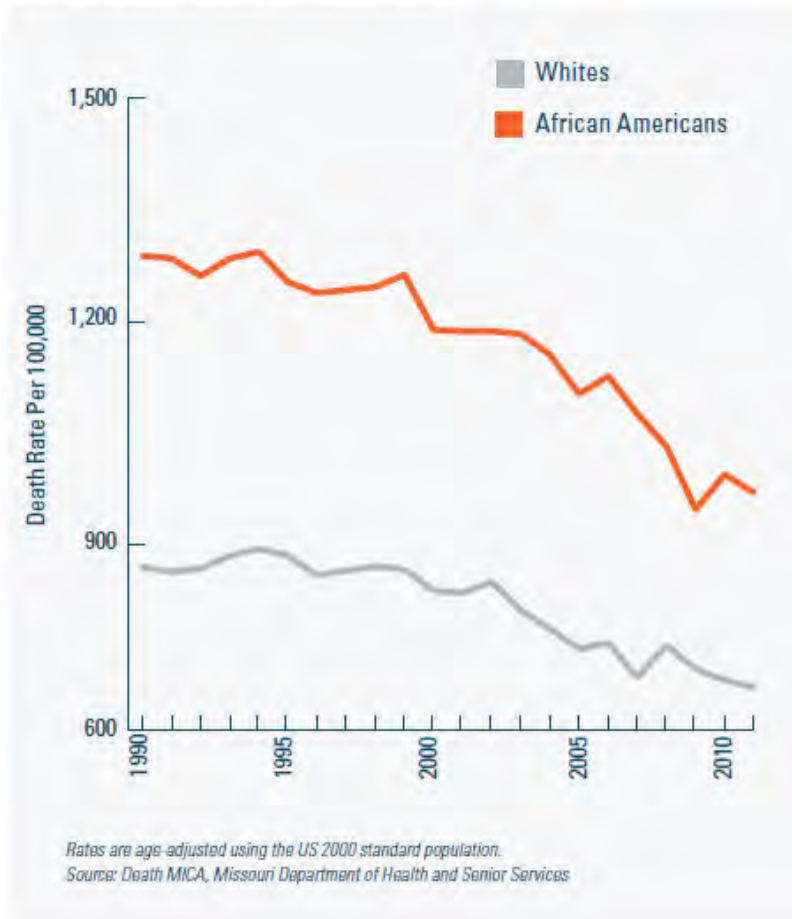
### COVID-19

- Most heavily impacted
  - More cases early
  - More deaths

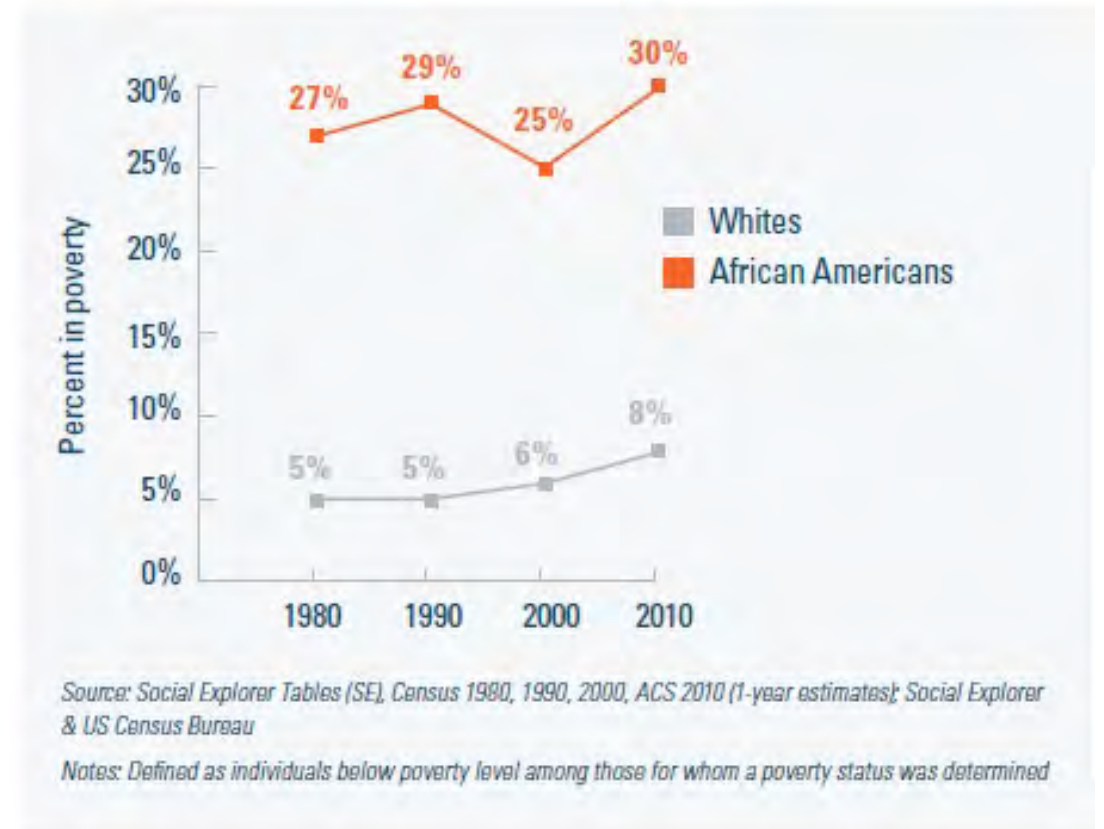
Purnell J. et al "For The Sake of All" 2015

# St. Louis- For The Sake of All

**Figure 2.** Death rates among St. Louis County and St. Louis City residents of all ages

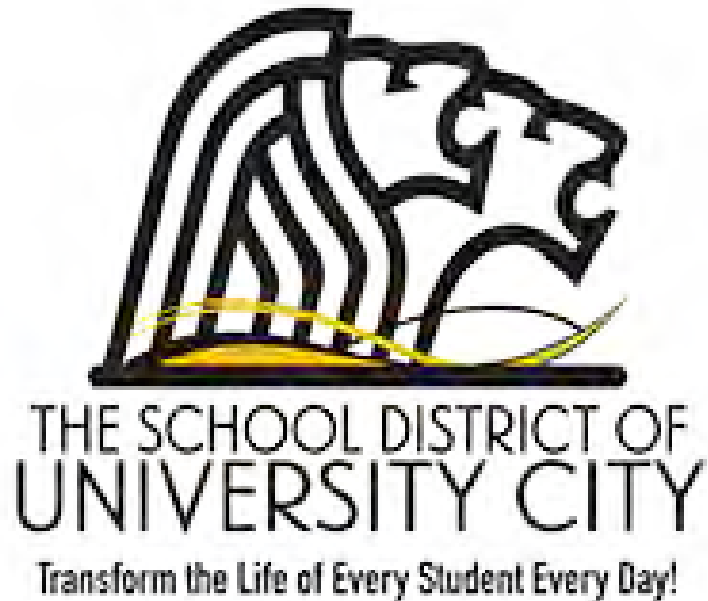


**Figure 8.** Poverty in St. Louis County and St. Louis City, 1980 – 2010



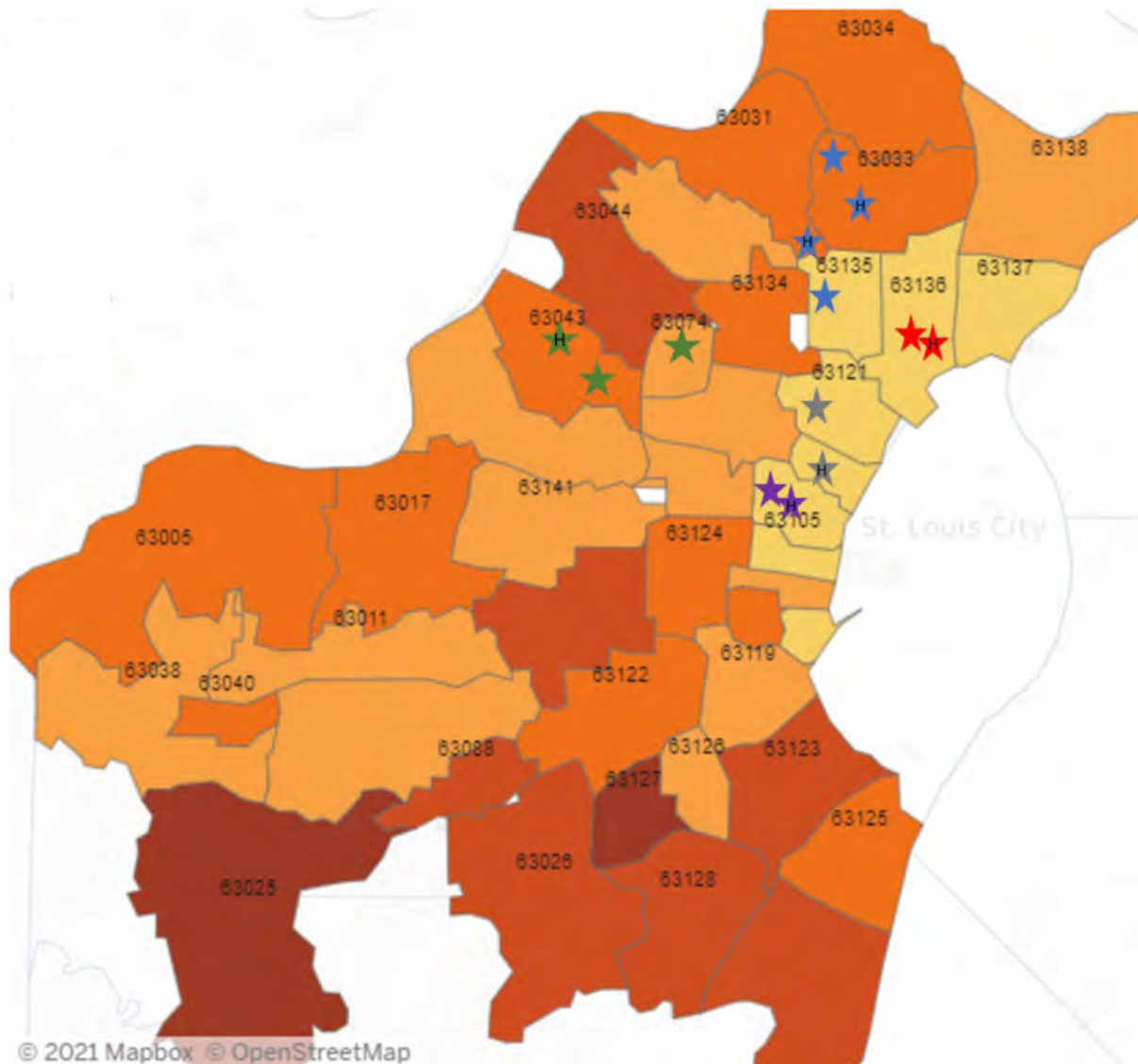
Purnell J. et al "For The Sake of All" 2015





# North County Schools

- Predominantly African-American
- All receive Title 1 funding
- 100% free or reduced lunch
- In-person attendance 30-40%



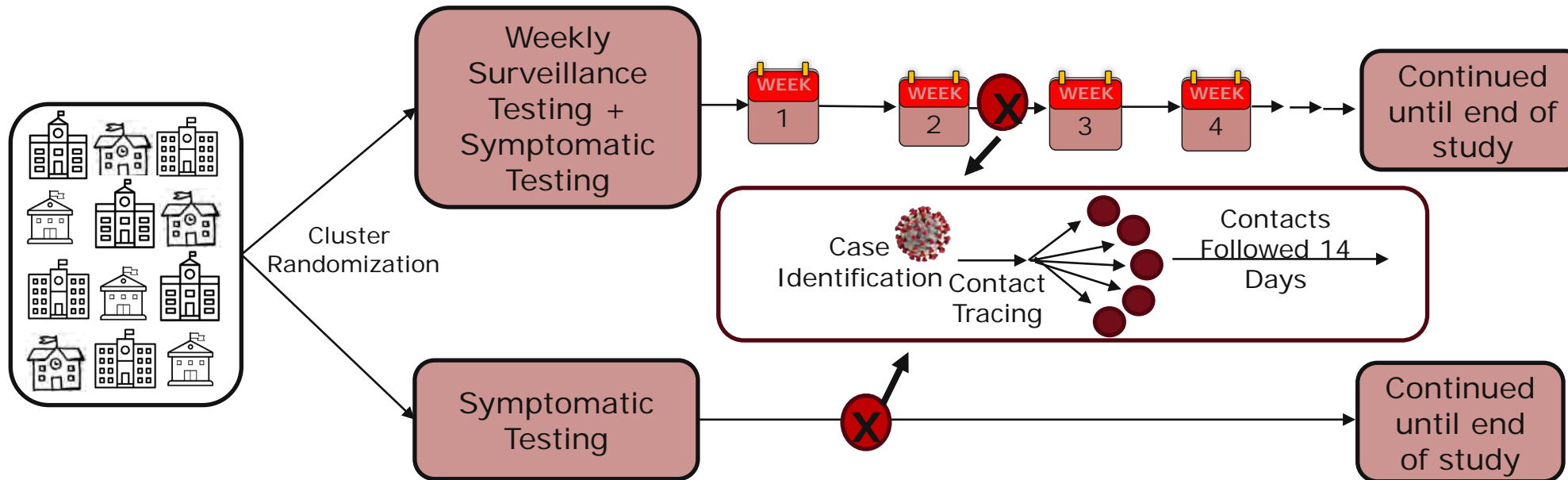
Which SARS-CoV-2 testing strategy limits SARS-CoV-2 transmission in middle and high schools?

# Washington University Genome Center

- Developed a saliva-based SARS-CoV-2 PCR test in collaboration with Fluidigm that received Emergency Use Authorization by the FDA on Aug 26, 2020
- This test has been used with Special School District project, CDC school transmission project, and WashU undergraduates
- Test accuracy is similar to nasopharyngeal sample collection



# Best Testing Strategy



# Community Engagement

# WEPOWER



# Community Engagement

- Community advisory board (CAB) will be established to guide testing messaging, listening sessions, and ongoing concerns:
  - Members from each school district
  - Community partners
  - Study staff
  - Compensation for being on CAB will be provided
- Community Partners will assist in recruitment and development of the listening sessions and help with testing

# Social, Behavioral, and Ethical Implications

- Listening sessions will be conducted with students, family members, teachers, and administrators
- Will assess concerns regarding COVID-19 and:
  - In-person school
  - SARS-CoV-2 testing
  - Vaccination



# Washington University in St. Louis Study Team

## **Pediatric Infectious Diseases**

- Brittany Bonty
- Brock Montgomery
- Jason Newland
- Stephanie Fritz
- Sara Malone
- Cindy Terrill
- Esther Lu

## **Occupational Therapy**

- Kelly Harris

## **Brown School of Social Work**

- Nancy Mueller
- Myisha Wilcher-Roberts
- Sheretta Barnes
- Cynthia Williams
- Charlene Caburnay

## **Pathology and Informatics**

- Julie Neidich
- Albert Lai
- Brett Maricque

So I say to you, walk with the wind,  
brothers & sisters, and let the spirit of  
peace and the power of everlasting  
love be your guide.



John Lewis  
July 17, 2020  
NY Times

**BREAK 10:30 - 10:45 AM**

---

# Investigator



**Ryan Coller, M.D., MPH**

**NICHD, University of Wisconsin-Madison**

An aerial photograph of Madison, Wisconsin, taken at sunset. The sun is low on the horizon, casting a warm, golden glow over the city and the water. The Monona Reservoir is in the foreground, with several sailboats scattered across its surface. The city buildings are visible in the background, with some lights beginning to glow. The overall scene is peaceful and scenic.

# ReSET: Restarting Safe Education and Testing for Children with Medical Complexity

University of Wisconsin-Madison



RADx-UP Kickoff - 4/16/2021

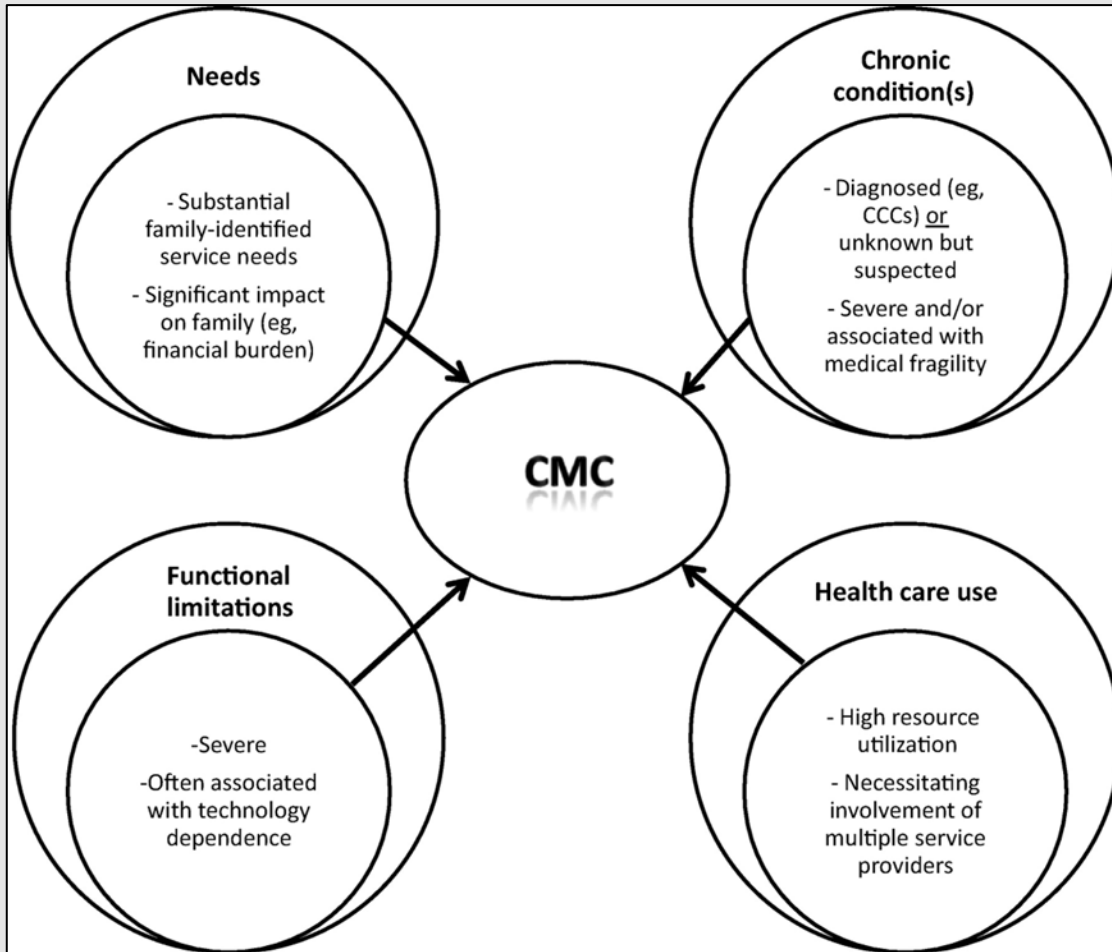
# Wisconsin Team



- Investigators (PIs: Ryan Coller and Greg DeMuri)
  - Infectious Diseases – DeMuri, McBride, O’Connors, Wald
  - Complex Care – Coller, Ehlenbach
  - Human Factors – Kelly, Werner
- School engagement – Butteris, DeMuri, Koval
- Family engagement – Burns (WI DHS Statewide Coordinator for CYSHCN), Katz (Director of Family Voices of WI), Kelly
- Statewide Data Collection – UW Survey Center
- Project Management: Warner



# Medical Complexity and RADx-UP



Children with Medical Complexity = CMC

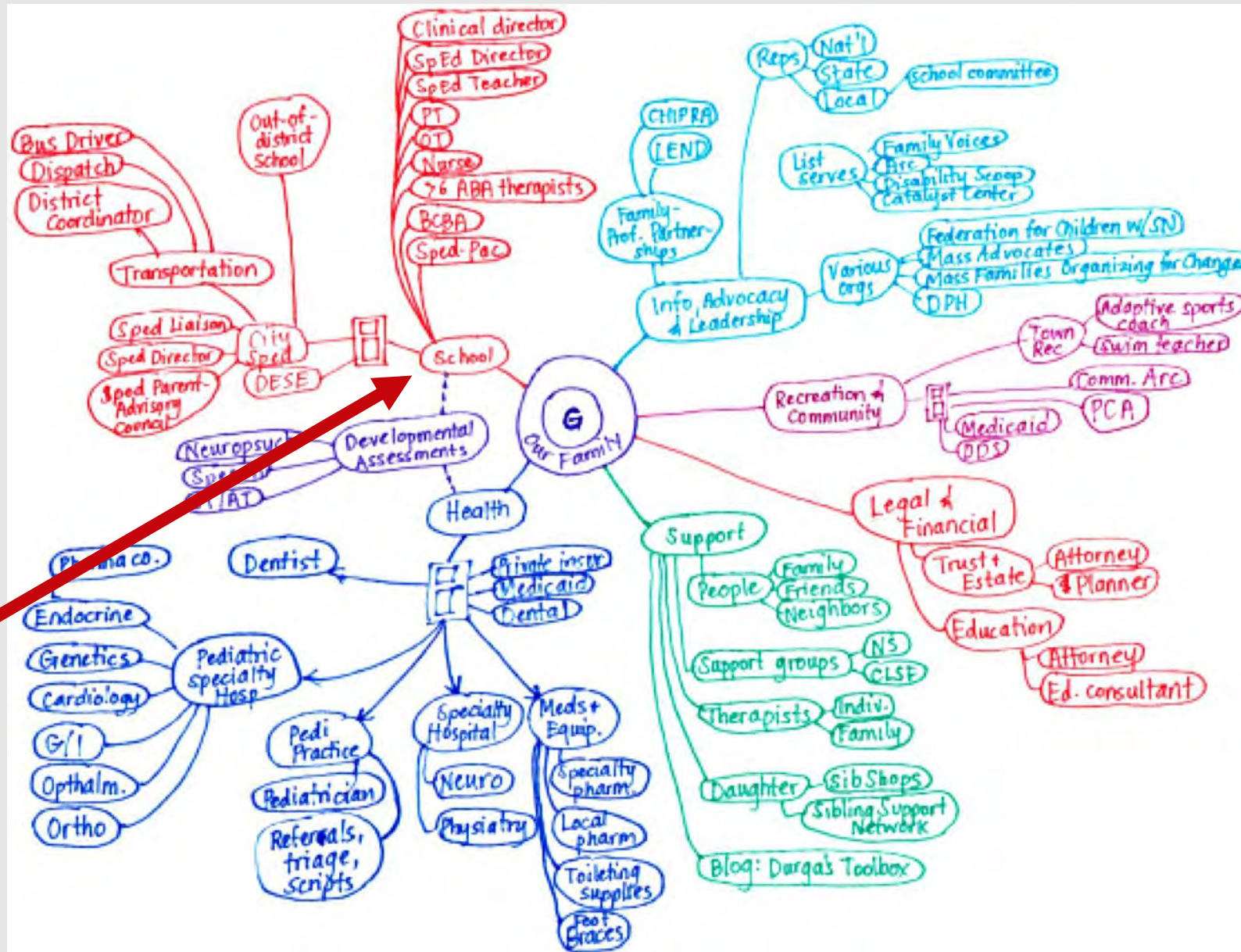
- ***Medically Vulnerable Population***

- 1-5% US children yet 33% spending
- > 50 hours / week direct care needs
- Risk for severe COVID-19 disease

- ***Socially Vulnerable Population***

- >50% live in poverty
- Disproportionately from communities of color

# Medical Complexity and School







# Unique School Challenges

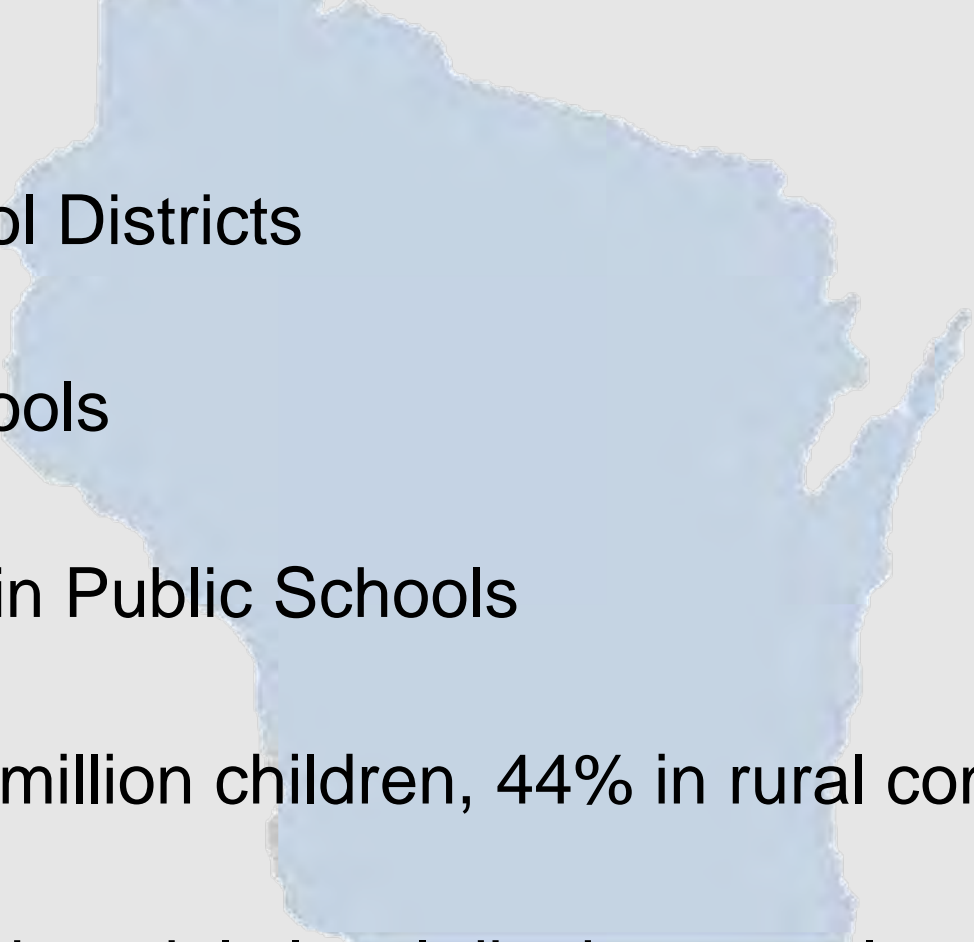
- Virtual platforms, therapies, parent employment
- Physical distancing, mask wearing is difficult or impossible
  - Many need aerosol generating procedures in routine daily care
    - Physical and intellectual dependence → # personnel exposed / day is high
- Require substantial local education resources
  - WI districts contribute \$1B not covered by state (majority of spend)
- Diffuse → any given school may have relatively few children

**School attendance = unique risk to child AND school AND other children**

- **Parents opting out, some have no option**
- **Schools, by law and necessity, must figure out how to do this safely**



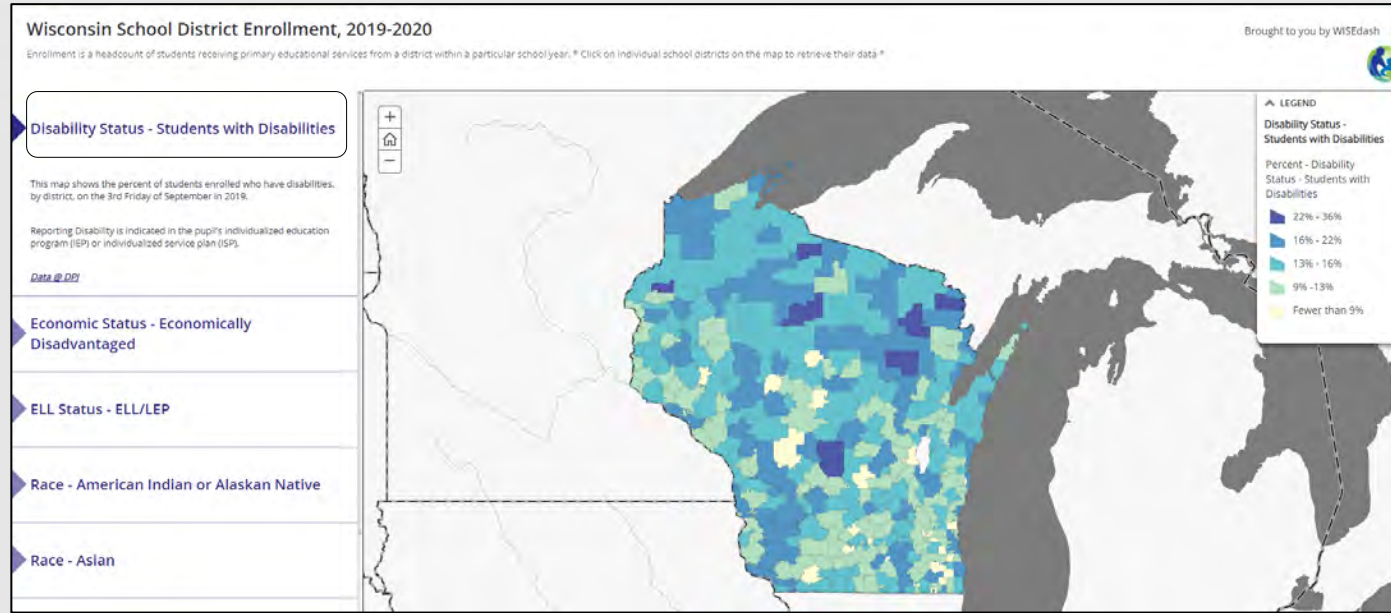
# Wisconsin School System

- 72 Counties
  - 421 Public School Districts
  - 2190 Public Schools
  - 86% Enrollment in Public Schools
  - Approximately 1 million children, 44% in rural communities
  - Decentralized with mainly local district control
- 
- A light blue map of the state of Wisconsin, showing its outline and internal county boundaries. The map is positioned in the center-right of the slide, partially overlapping the list of statistics.

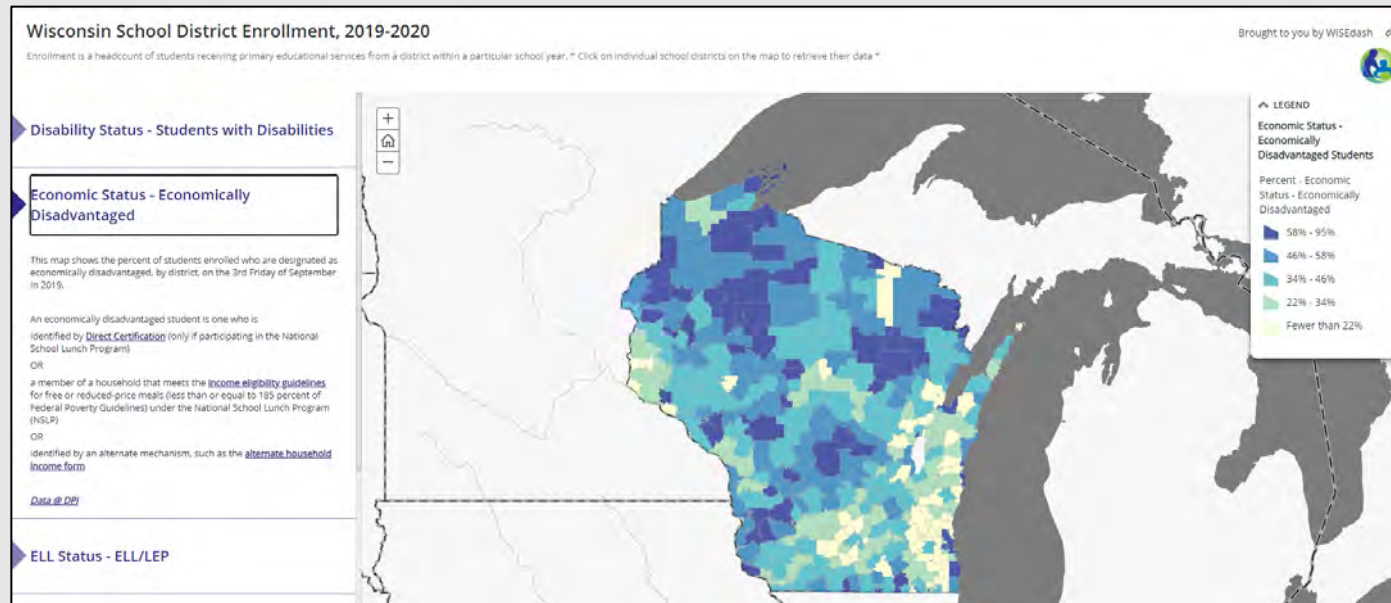
# Variation across WI Districts



## Disability Status



## Economic Disadvantage



# Research Objective



***Increase safe return to school for children with medical complexity (CMC) and school personnel through 3 complementary approaches:***

**Establish feasibility of home and school-based testing strategies (Aim 1)**

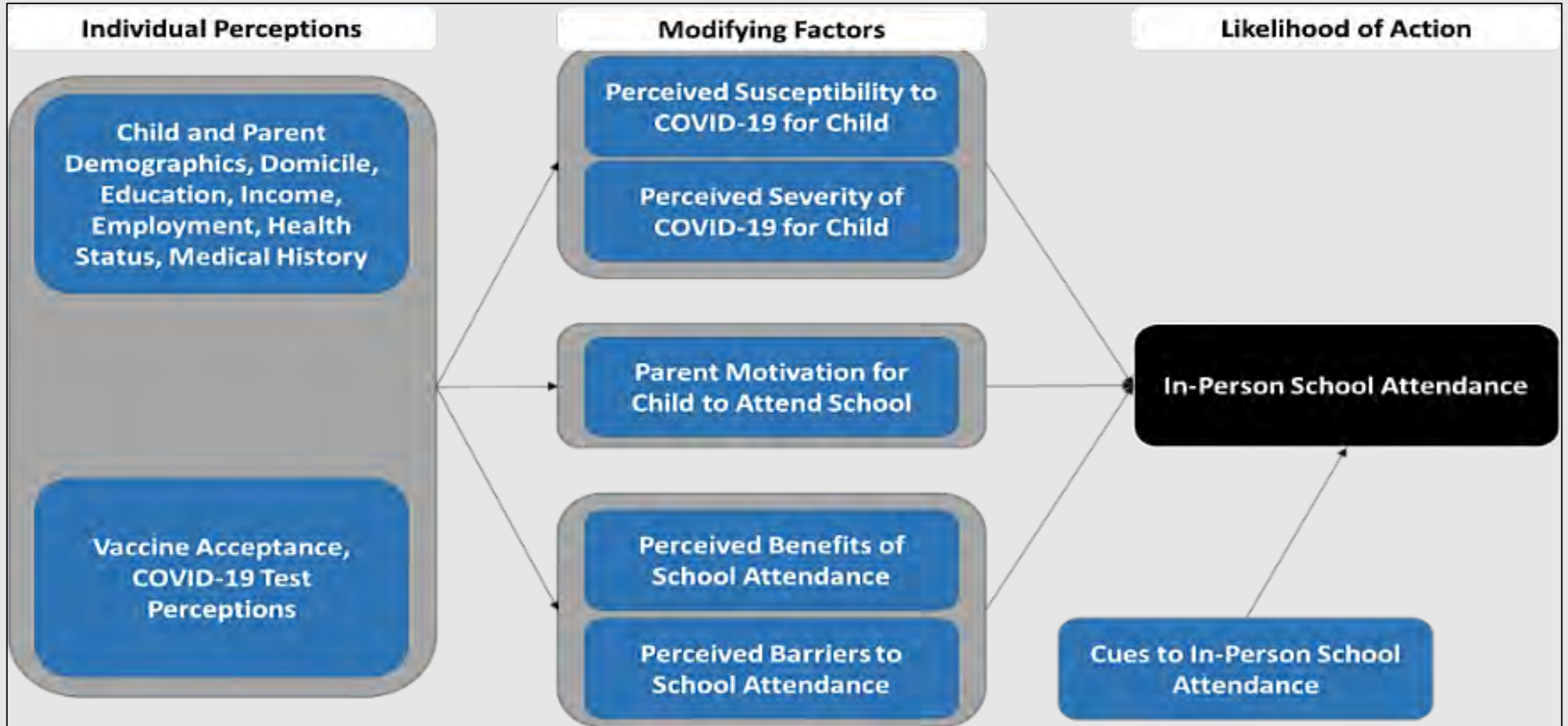


**Establish stakeholder consensus priorities for safe school attendance (Aim 3)**



**Identify predictors of parents choosing in-person school (Aim 2)**

# Parent Perceptions of School Safety



27 novel questions, designed by our team and UWSC, pilot tested with parents

# Aim 1 – Home and School Testing Feasibility



***Determine feasibility of in-home (Aim 1a) and school-based (Aim 1b) SARS-CoV-2 testing strategies, and associations with CMC parent perceptions about in-person school attendance.***

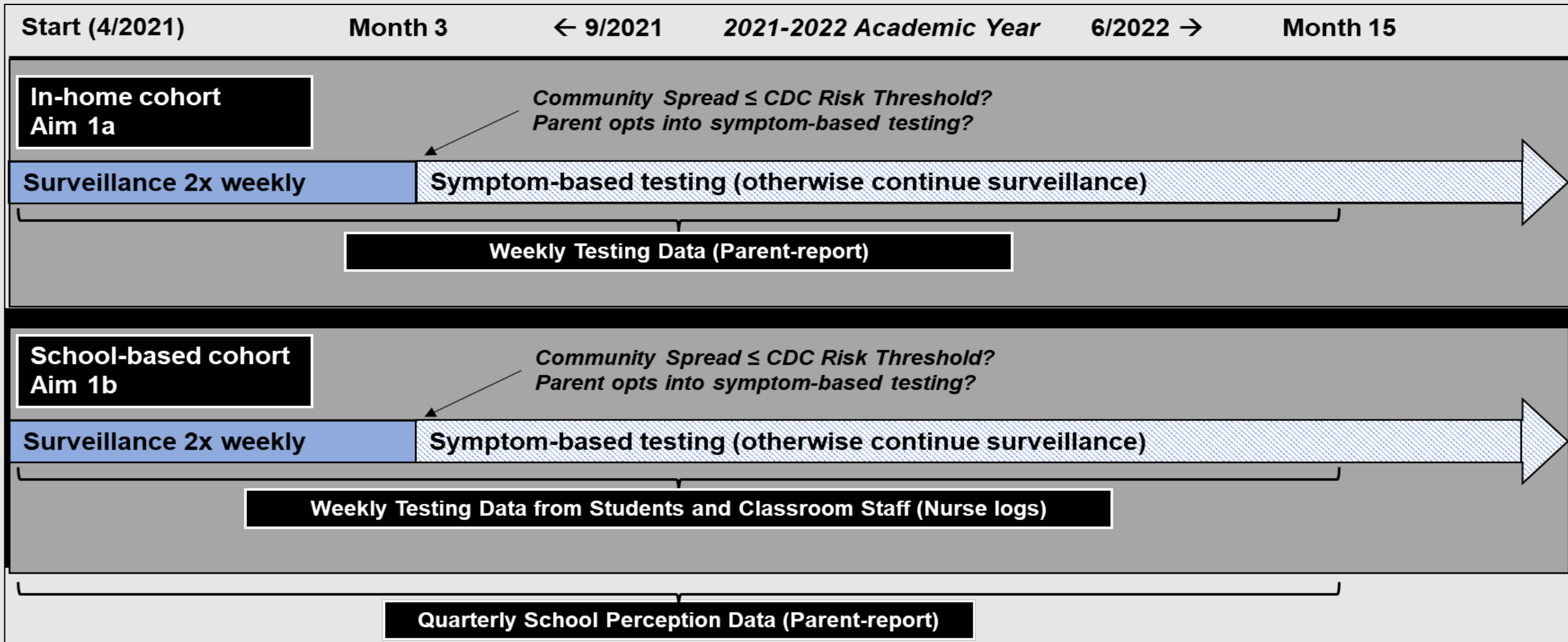
## **In-Home Cohort**

- Recruited from UW Pediatric Complex Care Program

## **School Cohort**

- Recruited from Waisman Early Childhood Program
- 30% have developmental disabilities

# Aim 1 – Adaptive Design





# Aim 1 – Analysis Goals

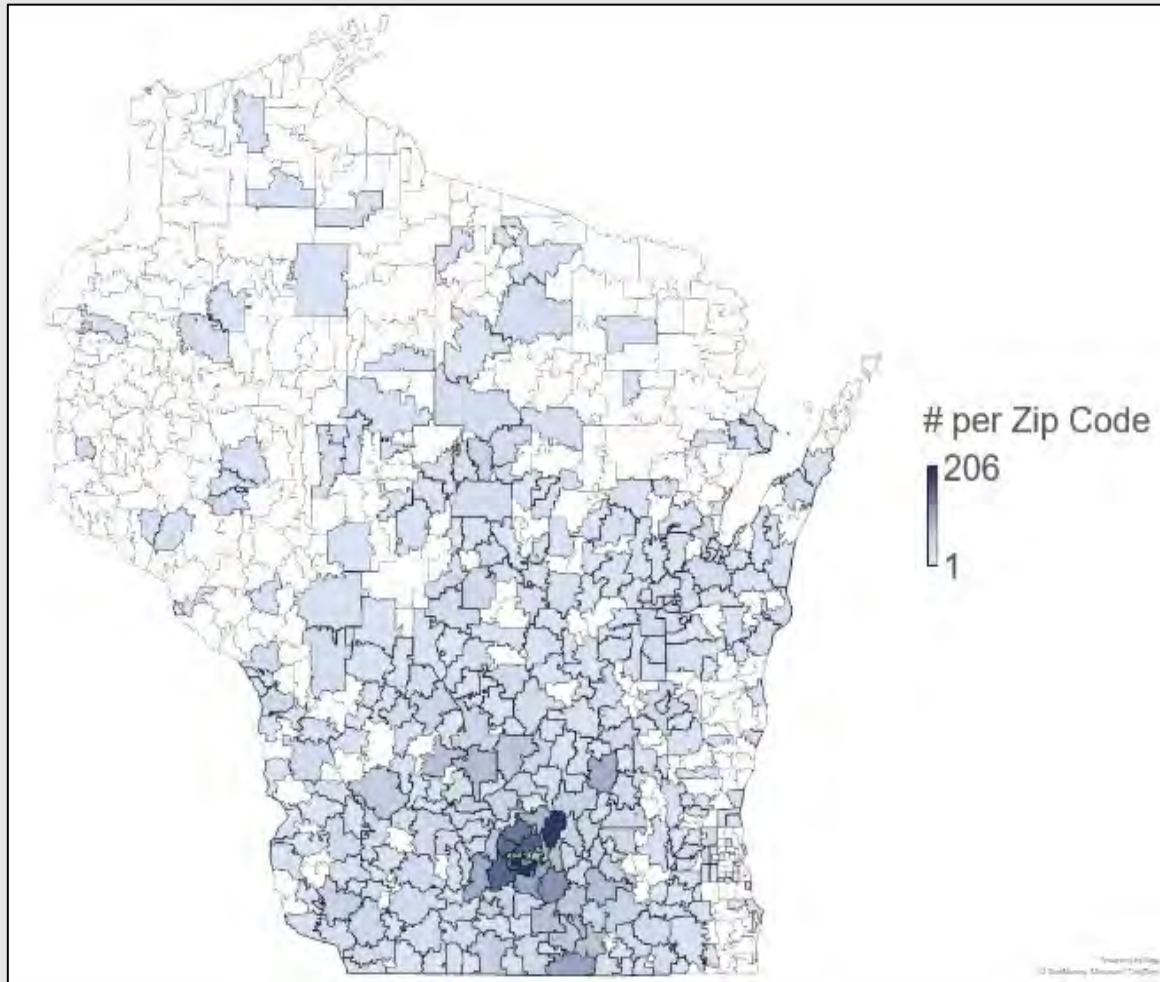
- 1<sup>o</sup>: Feasibility and Parent Perceptions of School Safety
  - Complementary human factors contextual inquiry for in-home testing
- 2<sup>o</sup>: Predictors of opting into continued surveillance
- 2<sup>o</sup>:  $\Delta$  School perceptions associated with  $\Delta$  from surveillance to symptom testing



# Aim 2 – Return to School Decisions



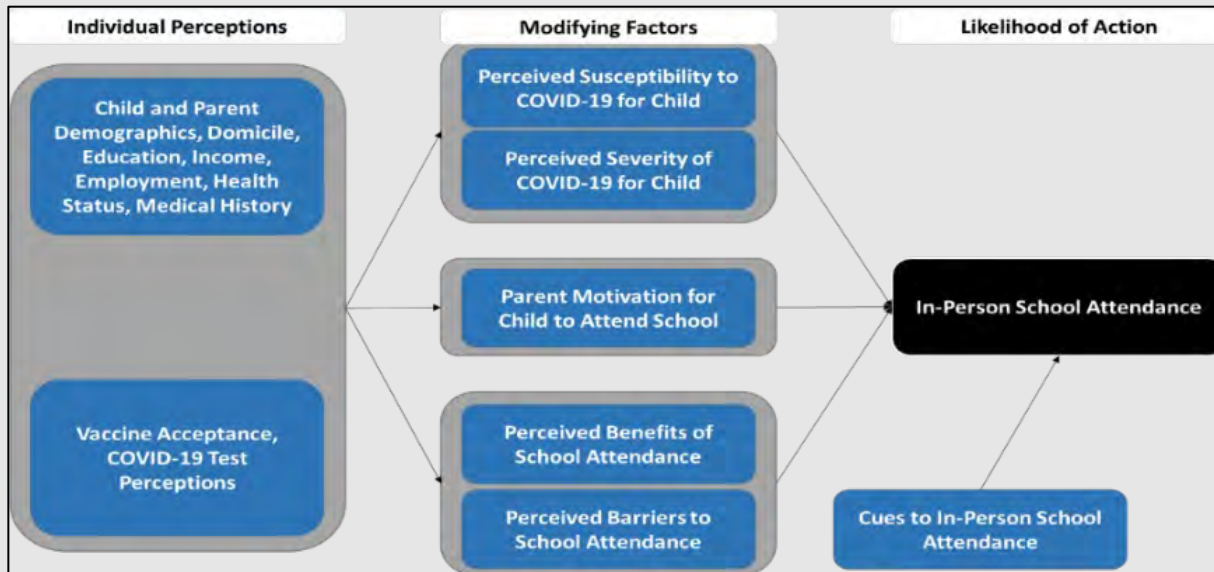
***Identify parent perceptions predicting school attendance for WI CMC in 2021 and 2022***



## Design

- Prospective cohort study, UW
  - N=parents of ~4000 CMC
    - Ages 5-17 years
- Surveyed at 3 points
- Questionnaire emphasis
  - Parent perceptions
  - School attendance practices
  - Demographics and health

# Aim 2 – Return to School Decisions



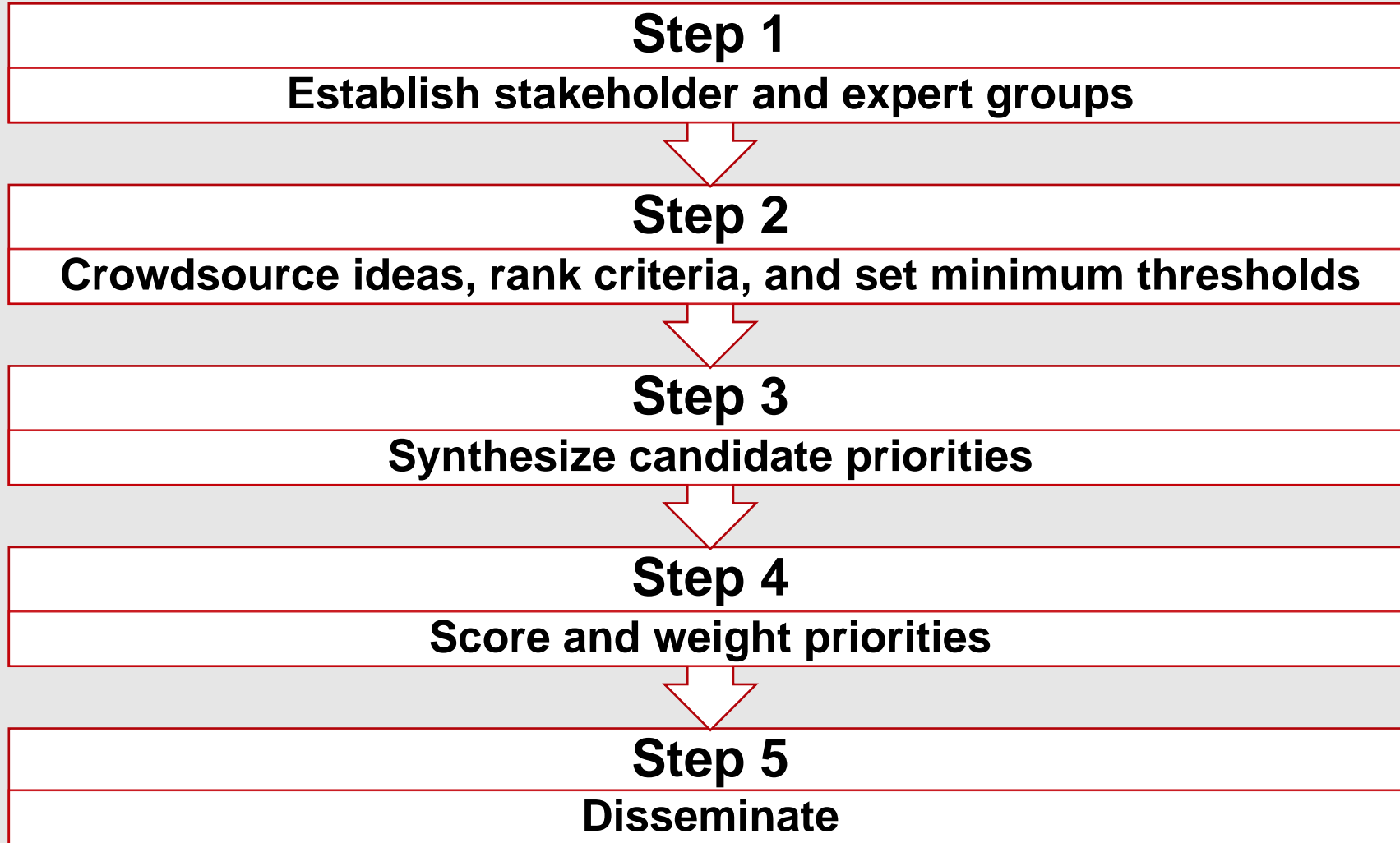
## Analysis Goals

- Predictors of school attendance
  - Highlight disparities
  - Final model = SEM path model
    - Intervention / policy targets
- Explore changes over time



# Aim 3 – Consensus Priorities

***Establish statewide stakeholder consensus priorities for safe in-person school for CMC.***



# Additional Dissemination Plans



## Communication

- ReSET Website
- Social Media
- Virtual Forums
  - School
  - Family
- WI ReSET CMC Implementation Team

## Written Products

- State Superintendent Report
  - Consensus priorities blueprint
- Manuscripts

## Relationships

- Partnership with RADx-UP, teamed sites, ABC Science Collaborative
- National network relationships



# Thank you!

Ryan Coller ([rcoller@pediatrics.wisc.edu](mailto:rcoller@pediatrics.wisc.edu))

Greg DeMuri ([demuri@pediatrics.wisc.edu](mailto:demuri@pediatrics.wisc.edu))

Gemma Warner ([gwaner@pediatrics.wisc.edu](mailto:gwaner@pediatrics.wisc.edu))



# Investigator



**Christina Gurnett, M.D., Ph.D.**

**NICHD, Washington University; Kennedy Krieger Institute**

**Washington University Intellectual and Developmental  
Disabilities Research Center and Kennedy Krieger Institute  
Safe Return to School  
(1OT2HD107556-01)**

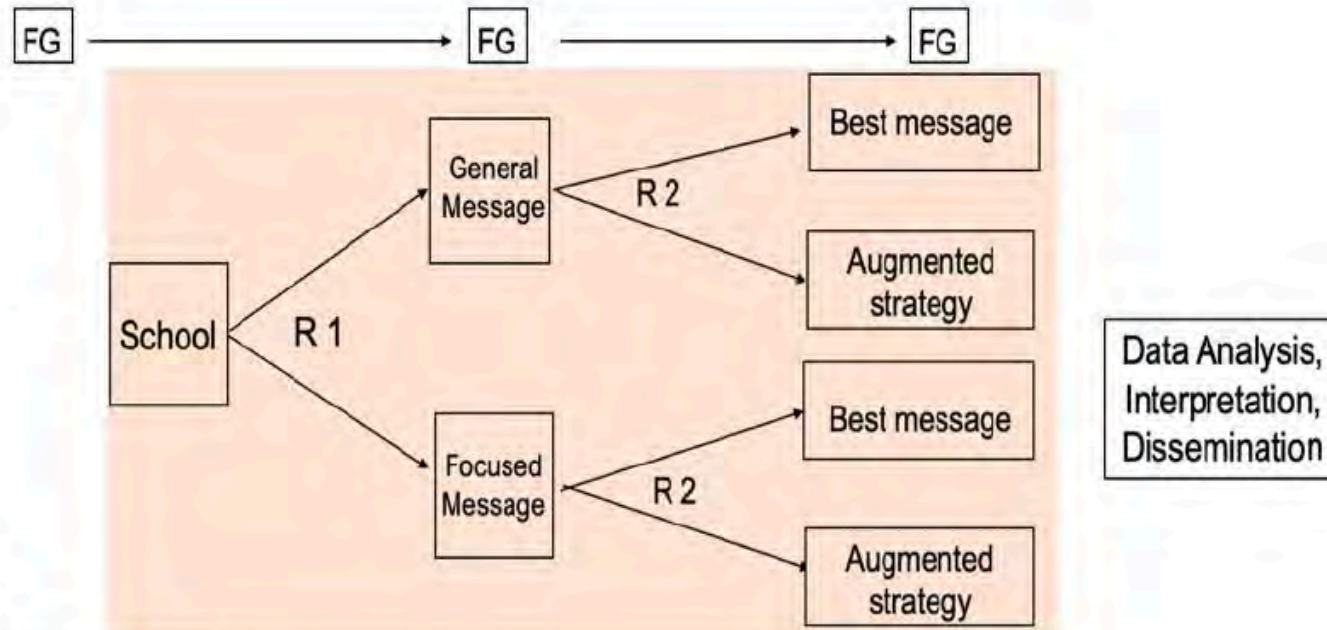
Christina A Gurnett, MD, PhD  
Head, Division of Pediatric and Developmental Neurology  
Co-Director, Intellectual and Developmental Disabilities Research Center  
Washington University in St Louis

Jason Newland, MD  
Professor of Pediatrics, Division of Infectious Disease  
Washington University in St Louis

Luther G Kalb, PhD, MHS  
Center for Autism and Related Disorders, Kennedy Krieger Institute  
Department of Mental Health, Johns Hopkins Bloomberg School of Public Health

# COVID-19 Messaging for SPeciAl School DiStrict Testing

Aim 1

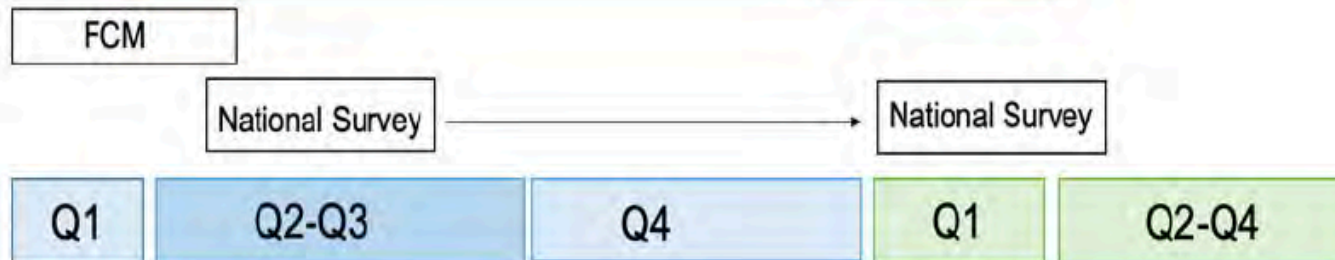


Special School District of St Louis County



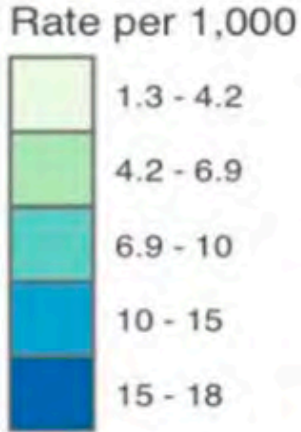
Special School District of St Louis County  
Kennedy Krieger Institute Schools  
University of Missouri Kansas City

Aim 2





# COVID-19 Messaging for SPecial School DiStrict Testing

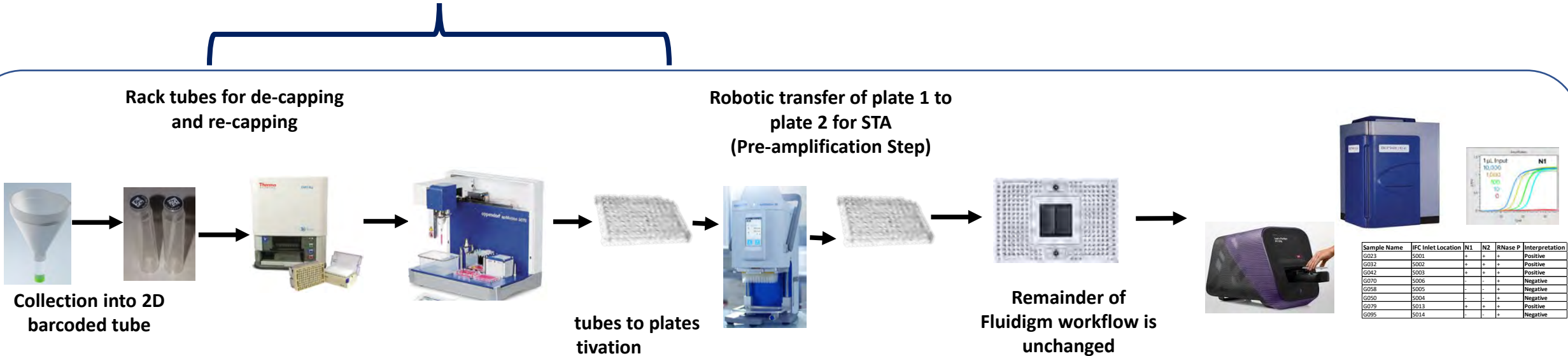


**Table 1: Racial demographics of students in Special School District of St Louis schools**

	Number (%)
Black	440 (48.4%)
White	403 (44.3%)
Asian	18 (4.4%)
Multiracial	27 (2.9%)
Hispanic	20 (2.2%)
<b>Total</b>	<b>909</b>

# SARS-CoV-2 diagnostic test developed at Washington University

BSL2 Environment

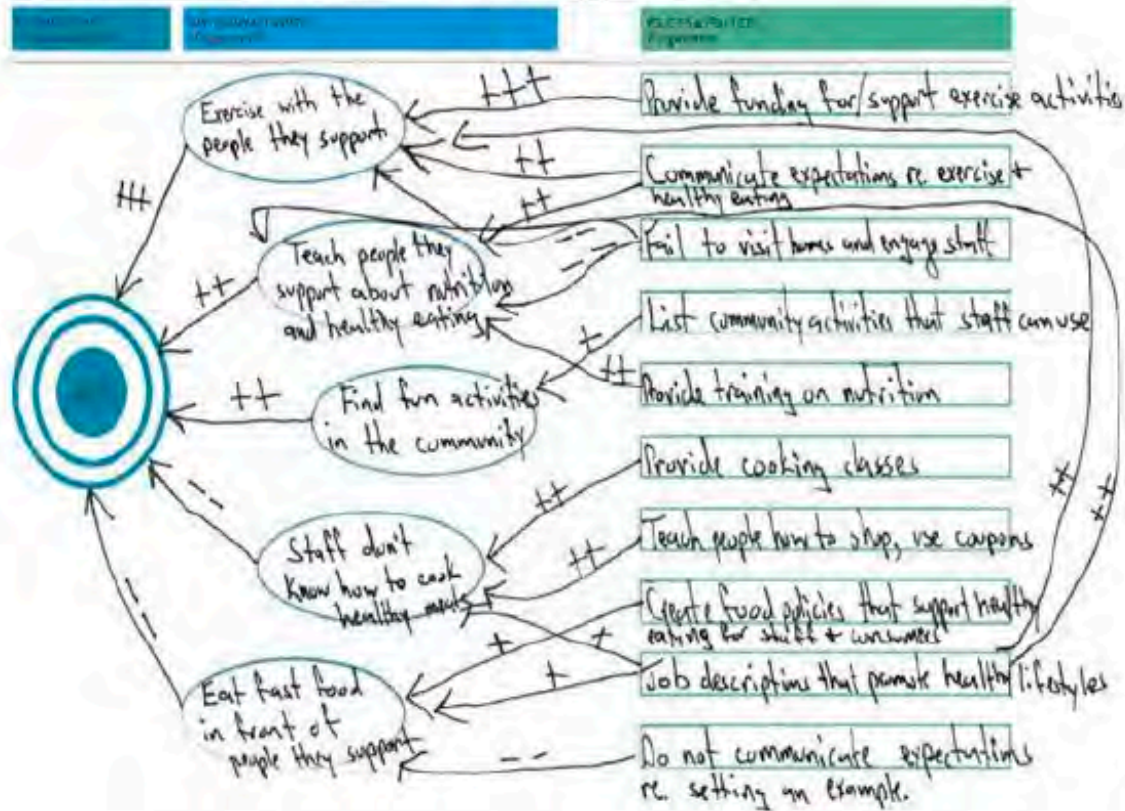


- No RNA extraction step (eliminates need for “reagents” )
- Saliva-based diagnostic test (50ul)
- Uses Fluidigm Advanta DX SARS-CoV-2 assay
- Highly sensitive and specific
- Rapid 3 hour test results
- Scaling to 50K/week; cost \$26.07/test
- Development to EUA submission- 4wks

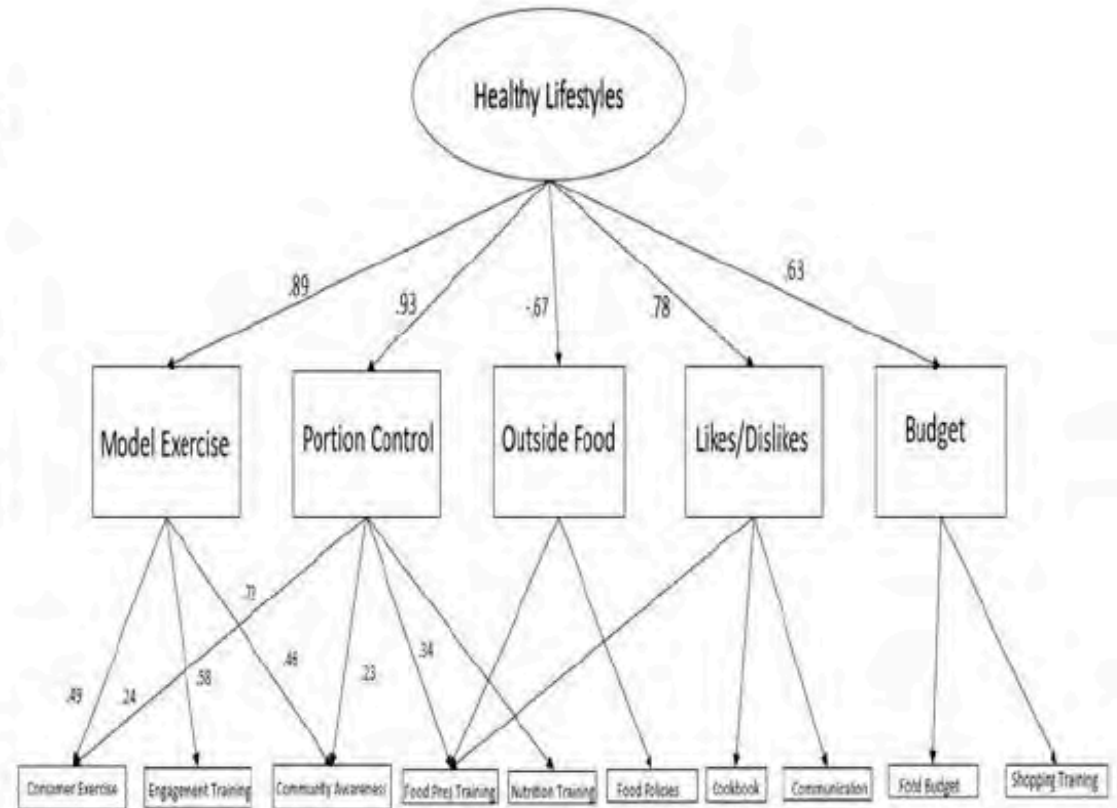
# Fuzzy cognitive mapping of COVID-19 decision-making

A

DEVELOPMENTAL DISABILITIES HEALTH INITIATIVE | HEALTHY LIFESTYLES MAP



B



# National Survey to Assess COVID-19 Impact and Mitigation Strategies

<b>Stakeholder</b>	<b>Description</b>
Association of University Centers for Disability (AUCD)	AUCD is national network of interdisciplinary centers that advance policy and practice for and with individuals IDD, their families, and communities.
Council of Parent Attorneys and Advocates (COPAA)	COPAA's mission is to protect and enforce the legal and civil rights of students with disabilities and their families.
National Community of Practice for Supporting Families with IDD	The Community of Practice for Supporting Families of Individuals is a national network that works towards developing systems of support for families supporting individuals with IDD throughout the lifespan.
Parents' Place of Maryland	The Parents' Place of Maryland is a state-wide, grass-roots effort of families, professionals, and community leaders determined to provide resources, support, and information to parents of children special health care needs.
Maryland Developmental Disabilities Council	The Maryland Developmental Disabilities Council is an independent, self-governing organization dedicated to advancing the inclusion of Marylanders with developmental disabilities in all facets of community life. The Council is 100% federally funded.
Community Advisory Council for the Maryland Center for Developmental Disabilities (MCDD)	The Community Advisory Council for the MCDD is federally required under the Developmental Disabilities Act. The CAC is comprised of a diverse group of stakeholders including self-advocates, family members, representatives from local and state agencies and organizations, and MCDD staff.
Maryland's Community of Practice for Supporting Families	The Maryland Community of Practice for Supporting Families is our statewide network that works toward developing systems of support for supporting individuals with IDD throughout the lifespan. It is housed within the Maryland Developmental Disabilities Administration within the Maryland Department of Health.
People on the Go	People on the Go are self-advocates with IDD that pattern with KKI and the MCEDD.

# COMPASS-T Discussion Sessions: Findings from Families and Staff

MARCH 2021

Session participants

**29** Families

**57** School Staff

## Top benefits for children with special needs

- 1** Increased access to educational opportunities, care, and therapies
- 2** Development of trusting relationships between staff and students/families
- 3** Increased social and emotional benefits

## Top risks for children with special needs

- 1** Challenges implementing social hygiene or prevention strategies
- 2** Challenges implementing quarantining and/or isolation practices
- 3** At higher risk of having severe complications

## Who are trusted sources of information?

**District policies :** School nurses, teachers, case managers, and principals

**General COVID info:** CDC, primary care physicians, and health professionals

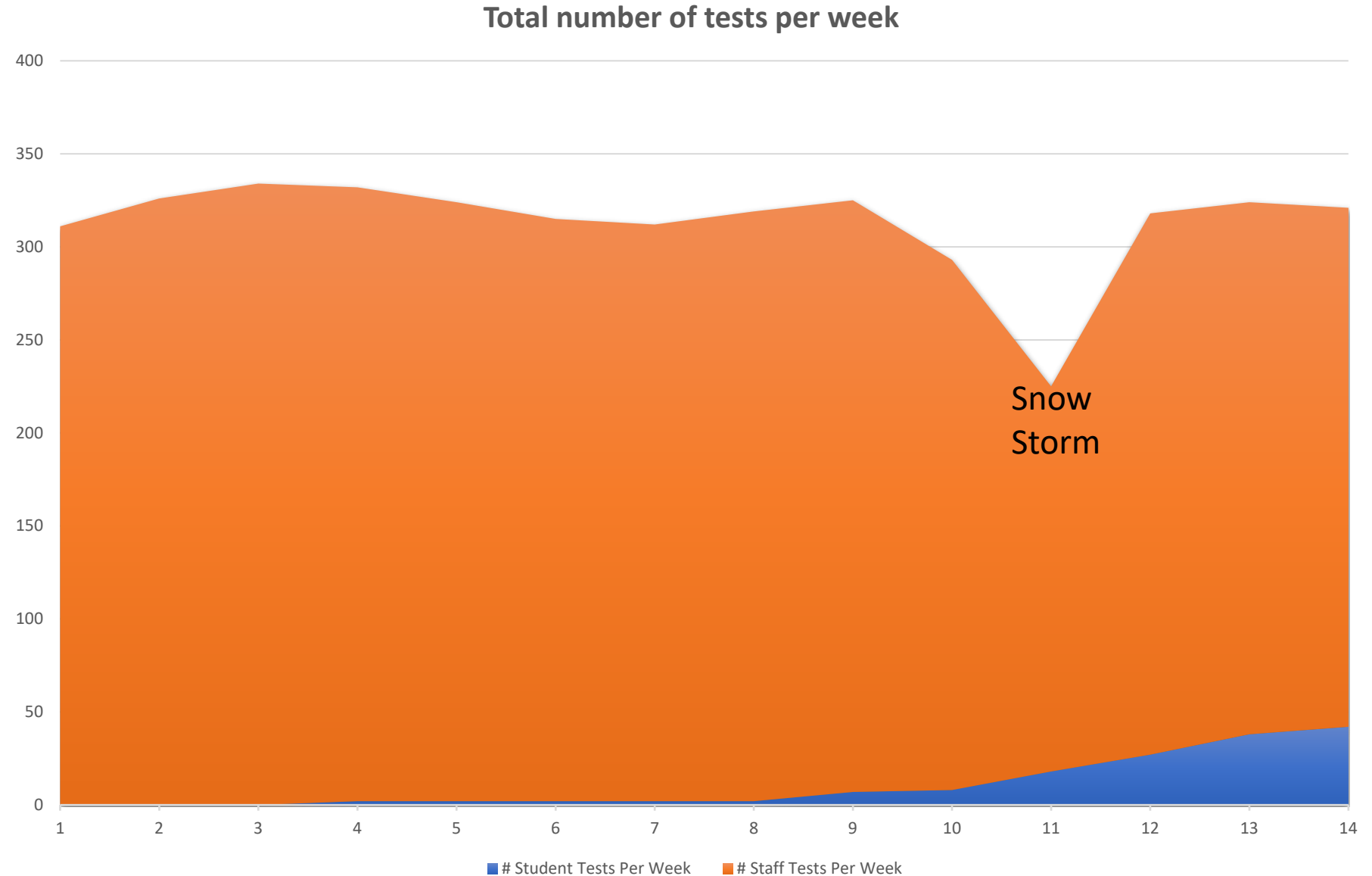
**COVID test results:** Washington University research team

Most to Least Preferred Modes		
Communication Mode	Staff Preference	Parent Preference
Email	High	High
Phone Call	Medium	Medium
Text Message	Medium	Medium
Messaging App (Class Dojo, Remind)	Low	Medium
SSD Website	Low	Medium
Letter from SSD	Low	Low

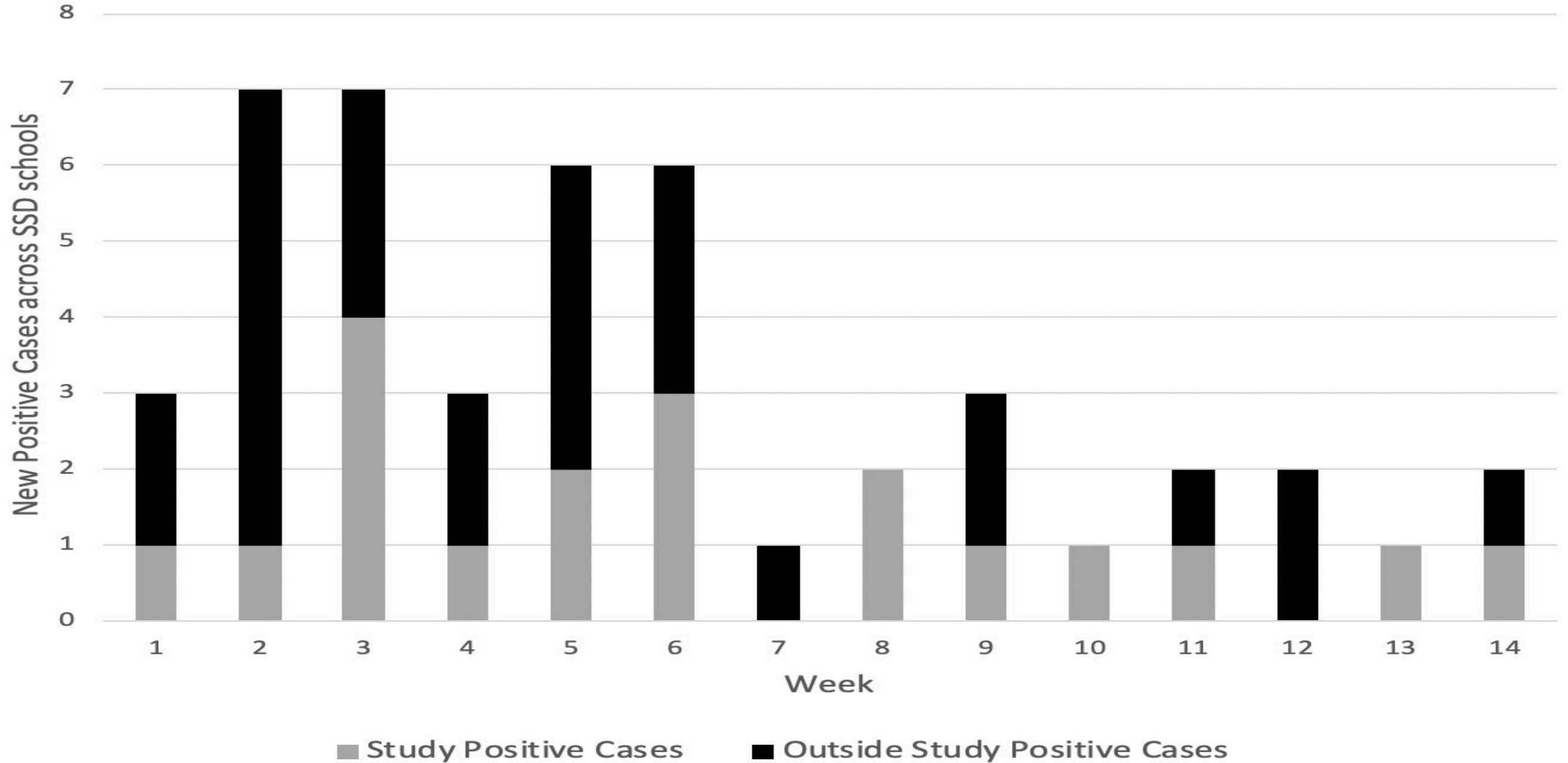
# Staff and student SARS-CoV-2 surveillance testing volume

- 452 participants

- N=4,379 total saliva tests
  - N=4,229 Faculty and staff tests
  - N=150 student tests



# SARS-CoV-2 test positivity among school staff participants





# Conclusions from 14 weeks of staff surveillance testing in 6 Special School District of St Louis County schools

- Staff positivity was not higher than community rates
- In-school transmission was rare (2 out of 97 quarantined for in-school exposure became positive and were likely due to in-school exposure)
- Mitigation strategies were effective
  - Children with disabilities wore mask 70% of the time
  - Reduced classroom capacity/ phased reopening
  - Staff wore face shields when masking and social distancing were not possible
  - Constant commitment of administration and staff

# Dissemination Plan: Return to school for children with disabilities

## Ways for children with disabilities to safely return to in-person school during COVID-19

Children with intellectual and developmental disabilities have a higher risk of severe COVID-19 infection but a greater benefit from in-person schooling.

Based on data from the Special School District of St. Louis County schools, schools can take these steps to help prevent the spread of COVID-19 and keep schools safe when returning in-person:

### Practice safe social distancing (allow at least 6 feet of space between people)

- Have fewer students and staff in the classroom to allow social distancing – for example, reduce classroom size to 50-75% of normal
- Move some students to new spaces to lower the number within classrooms

### Use classroom routines that limit student contact

- Begin with a phased re-entry to allow staff to work through issues and practice safety measures with fewer students. For example, split students into 2 groups with:
  - One group in person on Monday-Tuesday, and the other group in person on Thursday-Friday
  - Both groups virtual on Wednesday to allow for classroom cleaning
- Reduce movement of students to prevent contact outside the classroom:
  - Keep students in small groups in one classroom. These groups should stay together during the day
  - As much as possible, avoid mixing students from different groups. At gym and recess, xxx
  - Have teachers move between rooms instead of having students fill the hallways



Tips for staff to get students to wear masks correctly

**Students have done much better than expected with correct masking. But some students may have trouble, especially those with special needs. Staff should:**

- Model correct mask wearing
- Check often and remind students to keep their masks over their noses – with practice they get better. You can try using a visual cue to remind students to pull up their mask, such as pointing at the tip of your nose
- Praise and reinforce good mask wearers, such as with extra breaks or computer time
- Keep working on mask wearing – do not give up on students who have trouble

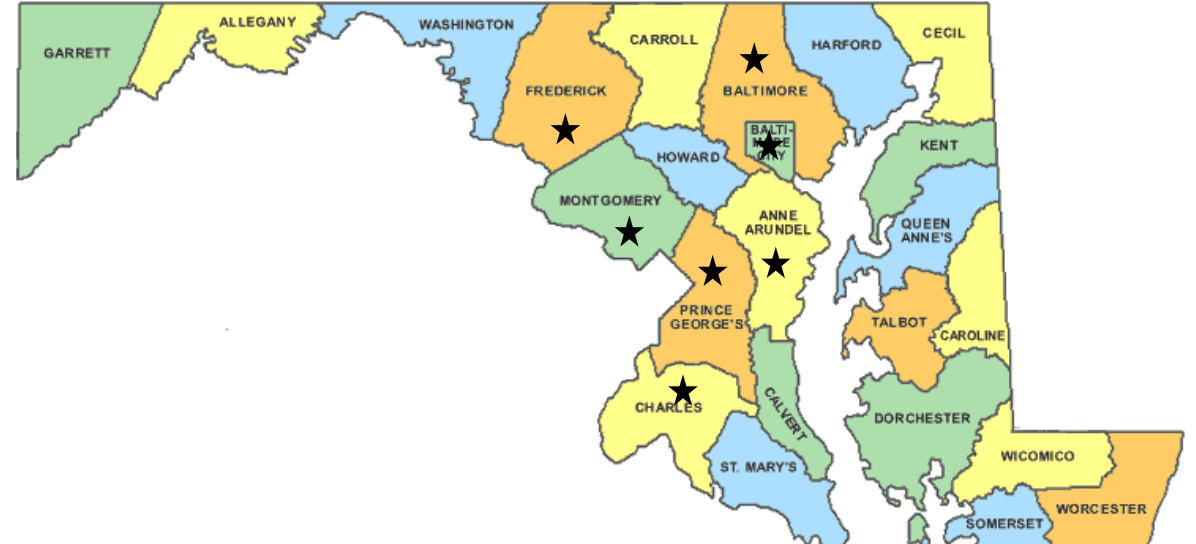


# Safe return to school for all



# Next Steps

- Expansion of voluntary weekly surveillance testing of staff and students to Kennedy Krieger Schools
- Four schools (K-12) in Baltimore, MD. Children are bussed in from across the state
- Highly diverse IDD population (50% Non-White, 50% Autism)
- N=500 saliva-based COVID-19 tests per week
- Qualitative (FCM) and quantitative (survey) data will be used to understand barriers to in-person school attendance at three sites and nationwide
- Testing begins May 2021



# Goals of our study:

- How readily can we translate what we have learned about surveillance testing in schools for children with disabilities to another site?
- Are there regional differences in testing uptake, mitigation methods, vaccine hesitancy, return to school?
- What are the best communication strategies to reach staff and parents?
- What are the barriers to return to school? How do these differ across schools and communities?

# Acknowledgements



## The COMPASS-T Study Team:

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Kennedy Krieger Institute



Intellectual and Developmental Disabilities Research Center



# Investigator



**Emily Haroz, M.A., Ph.D.**  
**NIMH, Johns Hopkins University**



# Safe Schools Project

Re-opening schools serving Native children and adolescents **SAFELY**



*This research was, in part, funded by the National Institutes of Health (NIH) Agreement No. 1 OT2 HD107543-01. The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressed or implied, of the NIH.*





# Significance

1. Native Americans face the highest COVID related health disparities of any racial or ethnic group.
2. Most schools serving Native American youth were closed until March and April or 2021.
3. School attendance and attachment are protective for physical and mental health concerns.

# Weaving a basket to keep our schools safe



Mask Usage

Social Distancing

Frequent Hand-washing

Cleaning and Disinfecting

Contact Tracing

Frequent Testing



# Frequent testing to facilitate a safer return to in-person learning



# Research Questions

1. What are the barriers and facilitators to school re-openings and COVID-19 testing from the perspective of multiple stakeholders involved in schools that serve Native American youth ages 3-16 years?
2. How acceptable and feasible are various COVID-19 testing strategies for schools? And what is their impact on in-person attendance rates, children's learning, and quality of teaching from the perspective of families, teachers, administrators and staff?
3. What are the educational, social, emotional, physical and mental health impacts of returning to in-person learning for Native American youth ages 3-16 years?

# History of Johns Hopkins Center for American Indian Health

- Founded in 1991 by Dr. Mathuram Santosham following a decade of infectious disease research in partnership with White Mountain Apache and Navajo communities.
- In the Johns Hopkins Bloomberg School of Public Health, Department of International Health
- To work in partnership with American Indian and Alaska Native communities to raise the **health status, self-sufficiency and health leadership** of Native peoples to the highest possible level.
  - Infectious Disease
  - Behavioral/Mental Health
  - Training



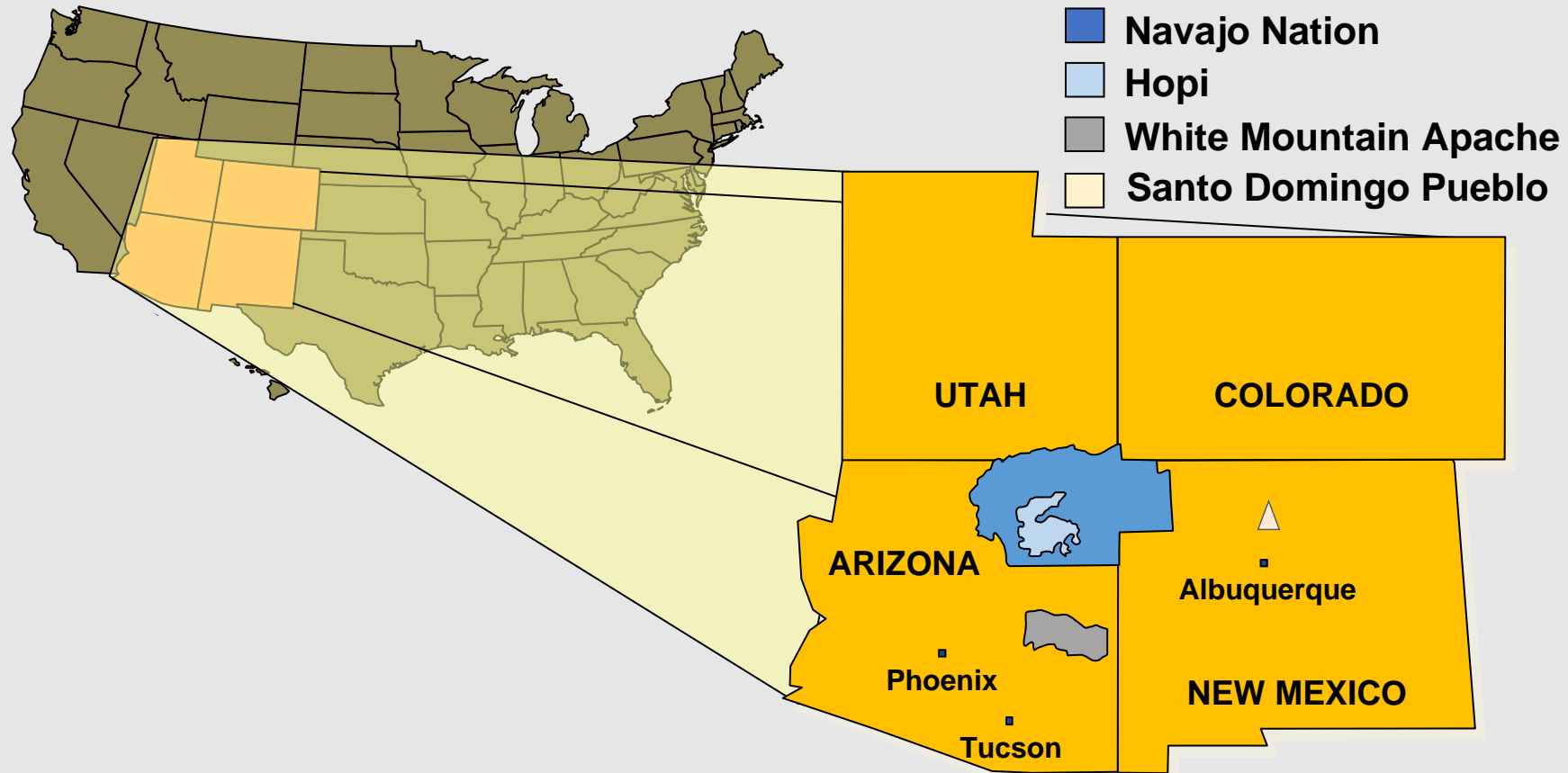
# JHCAIH Offices Serving Reservation Communities

## Arizona

- Chinle
- Fort Defiance
- Tuba City
- Whiteriver
- Fort Apache

## New Mexico

- Albuquerque
- Gallup
- Shiprock



# Project Sites



- White Mountain Apache Tribe
  - Pilot project activities began in January 2021 with three schools
  - Expansion to 16 other schools



- Navajo Nation
  - Shiprock Area Schools
  - Tuba City Area Schools
  - Chinle Area Schools

# Community & school engagement processes

- Build on our 40+ year trust-relationship with tribes
- Ongoing and intensive COVID response including
- MOU with Indian Health Service
- Community Advisory Boards (CABs) in each site
- Local approvals
- Participatory research approaches
- Partnering research with public health practice





# Safe Schools Testing Approaches

	Screening Tests		Surveillance Testing
	Rapid Antigen Tests At Schools	Rapid Antigen Tests at Home	Front End Pooling
What tests?	Abbot Binax Now Ellume Home Test Kits	Abbot Binax Now Ellume Home Test Kits	Concentric by Gingko
Turn around time?	15 minutes	15 minutes	24 hours for pooled test results
Subsequent diagnostic test to confirm?	Yes, particularly if used with asymptomatic individuals	Yes	Yes
Cost?	\$5/test	\$30/test	\$6 per pool (up to 25 individuals)
Sensitivity/Specificity (asymptomatic)	Binax: 70.2/99.6 Ellume: 91/96	Binax: 70.2/99.6 Ellume: 91/96	96/100

# Investigator



**Linda Ko, Ph.D., MPH**

**NIMHD, University of Washington**

**ROSEY**

**ReOpening Schools Safely and Educating  
Youth**

---

University of Washington  
April 16, 2021



# Collaborators

- Community Advisory Board (CAB): 6 members of the community representing three school districts, Yakima Department of Health, and Yakima Valley Farmworkers' Clinic
- Fred Hutchinson Cancer Research Center
- Seattle Flu Study
- Institute for Translational Health Sciences (University of Washington CTSA)

# Purpose

- To test the effectiveness of a testing program for COVID-19 on increasing students' participation in onsite learning using community-based participatory research (CBPR) approach.
- The testing program includes weekly SARS-CoV-2 testing and risk communication.

# Background

- Latinos living in rural agricultural communities were hit hard during the pandemic, exacerbating disparities that existed prior to the pandemic.
- While school closure helped mitigate the spread of COVID-19, Latino children from rural agricultural communities are experiencing learning gaps due to disproportionate access to resources.
- SARS-CoV-2 testing of students and staff, combined with risk communication can help identify outbreaks early, stop transmission and provide reassurance to families and to staff about the safety of on-site instruction.

# Study Aims

**Aim 1.** Identify rural Latino community's social, ethical, behavioral needs and resources for students to return to school and maintain onsite learning using qualitative assessments with school stakeholders, parents, and students.

**Aim 2.** Evaluate the effectiveness of a testing program (SARS-CoV-2 testing and risk communication) on student attendance using a cluster randomized controlled trial (RCT) with two intervention arms: current learning model (comparison) and testing program (SARS-CoV-2 testing + risk communication).

**Aim 3.** Assess implementation outcomes of the testing program with school stakeholders, parents, and children guided by the RE-AIM framework.

# How ROSEY Addresses the RADx-UP Program

By partnering with schools, ROSEY will

1. increase access to SARS-CoV-2 testing to Latino students in rural agricultural communities
2. develop a manual on social, ethical and behavioral concerns and mitigation strategies for students safe return to school, COVID-19 testing hesitancy, and vaccination
3. produce a safety-focused and community-driven manual describing implementation strategies to institute testing and risk communication strategies in schools.

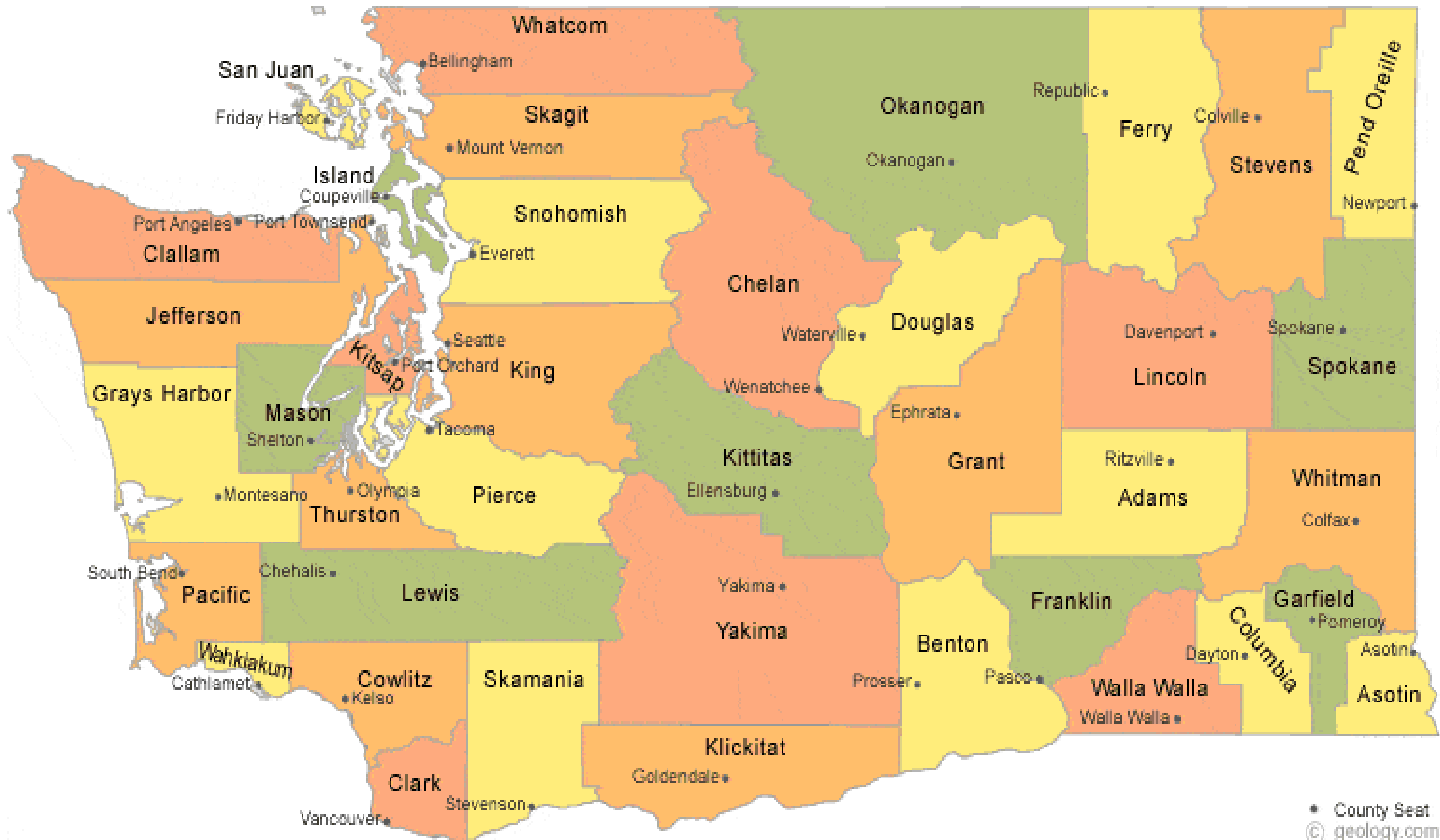


# Community/School Engagement

- CBPR – equal partnership between community and researchers
- CAB meets bimonthly (3/03/21; 3/31/21)
  - **Kickoff**, the CAB reviewed all the materials for district and school leadership to ensure its cultural appropriateness to the school; materials for parents, and students will be reviewed as they get ready.
  - **Recruitment**, the CAB will advise the research team on strategies to recruit parents.
  - **Intervention**, the CAB will review intervention materials and procedures to ensure the information considers school operation and is culturally relevant.
  - **Retention**, the CAB will connect with community leaders to emphasize the importance of research and encourage continued participation in the study.
  - **Dissemination**, the CAB will provide critical input in the manuals and protocols developed for dissemination.

# Community/School Engagement

- Two **community investigators** join the investigators' team
- Both have collaborated on multiple projects with the academic team, co-published papers, and grant submissions.
- Review all study materials and provide input in all aspects of the study in real time.



• County Seat  
 © geology.com

# Lower Yakima Valley

- Small agricultural communities (apples, pears, peaches, cherries, grapes, and hops).
- Census 2011: Lower Valley has a population of about 100,000
  - ~65% of them are of Hispanic origin.
  - 95% are Mexican-American



# OVERVIEW OF RADX-UP CDCC

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# CDCC Overview



**Beda Jean-Francois, Ph.D.**

**CDCC Program Officer, National Institute on Minority Health and Health Disparities (NIMHD)**



**Michael Cohen-Wolkowicz, M.D., Ph.D.**

**CDCC, Duke University**



# RADx-UP Coordination and Data Collection Center (CDCC)

April 2021

# RADx-UP is Part of a \$1.4 Billion NIH Initiative



## RADx Tech

Speed innovative point-of-care, home-based, and clinical laboratory tests for COVID-19

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**BUDGET**  
\$500 Million



## RADx Advanced Technology Platforms (RADx-ATP)

Identify testing platforms that are far enough advanced for rapid scale-up or expanded geographical placement

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**BUDGET**  
\$230 Million



## RADx Underserved Populations (RADx-UP)

Understand and reduce the disparities in COVID-19 morbidity and mortality for those disproportionately affected by COVID-19

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**BUDGET**  
\$500 Million



## RADx Radical (RADx-rad)

Support new, non-traditional approaches to address current testing gaps, and non-traditional applications of existing approaches

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**BUDGET**  
\$200 Million

**This is us**





# 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 Leaders

## Principal Investigators



**Michael Cohen-Wolkowicz, MD, PhD**  
*Duke Clinical Research Institute (DCRI)*



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*UNC Center for Health Equity Research*



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**Chris Woods, MD**  
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**Krista Perreira, PhD**  
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**Keith Marsolo, PhD**  
*Duke University*



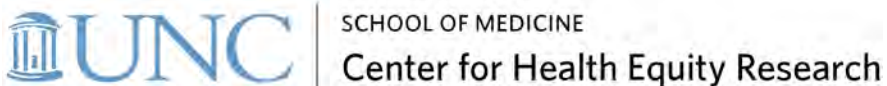
**Lisa Wruck, PhD**  
*Duke Clinical Research Institute*



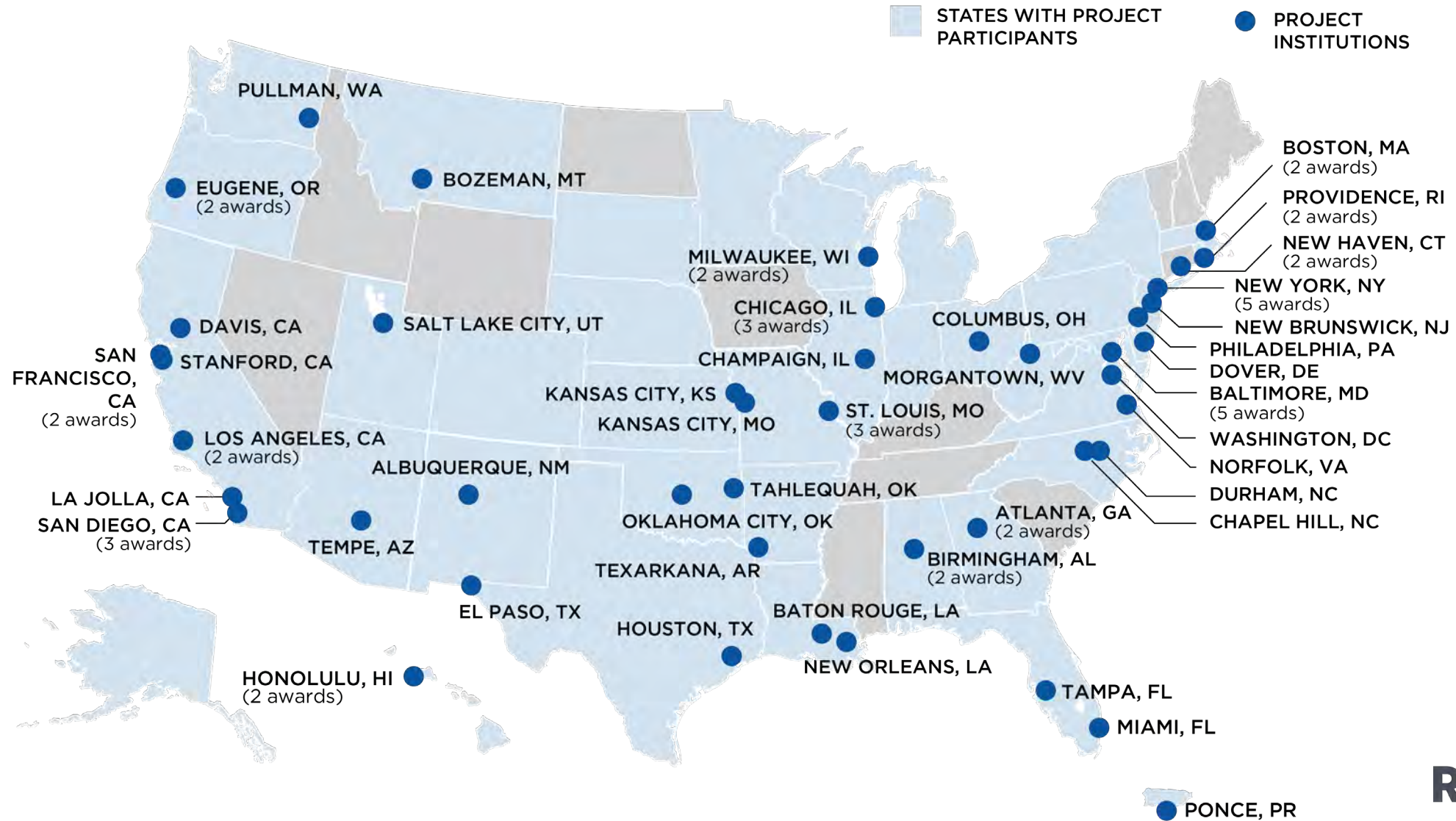
**Bhargav Adagarla, MS**  
*Duke Clinical Research Institute*

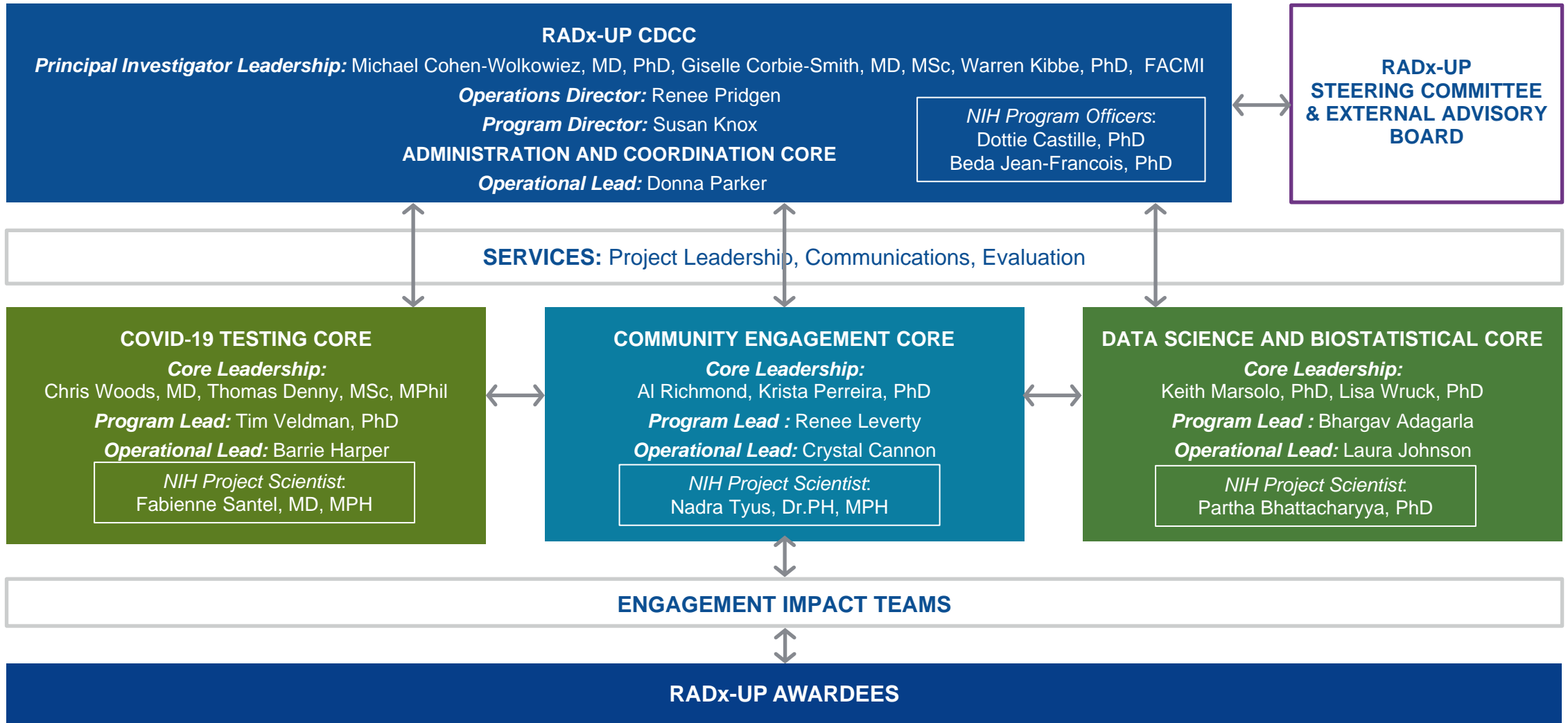


**Erich Huang, MD, PhD**  
*Duke University*



# Organizations Participating in RADx-UP





# CDCC Engagement Impact Teams



## COMMUNITY ENGAGEMENT

- **Project management + community engagement**
- **Single point of contact** for RADx-UP project teams
- **Support RADx-UP project teams**
  - Coordination, testing, community engagement, and data collection and sharing
  - Identify challenges and collaboratively generate solutions
  - Testing and supplies, timeline management, community access and engagement, recruitment and retention challenges, and data use limitations, etc.
- **Assist with troubleshooting**
- **Monitor progress**

# How the CDCC Is Supporting the Projects



## ADMINISTRATION AND COORDINATION

- Communication
- Committees
- Processes, policies, procedures
- Partnerships
- Evaluation



## TESTING RESEARCH AND SEBI PROJECTS



## COVID-19 TESTING

- Technical support
- Emerging technologies
- Research pilot studies



## COMMUNITY ENGAGEMENT

- Best practices
- Engagement Resource Library
- Equity Evidence Academy
- Community of Practice
- Community Collaboration Grants
- Working groups



## DATA SCIENCE & BIostatISTICS

- Data harmonization, sharing
- Security, privacy, and protections
- Data visualization
- DSMBs

# Data Flow

## DATA SOURCES

### RADx-UP Projects

- Individual-level data
- NIH Common data elements

### External data sets

- Individual-level data
- U.S. Census data, American Community Survey data, and electronic health records, National Death Index

## LINKAGES



## DATA REPOSITORIES



### CDCC participant re-contact repository

- Identifiable individual-level demographic data



### CDCC data repository

- Participant data is coded
- De-identified individual-level data



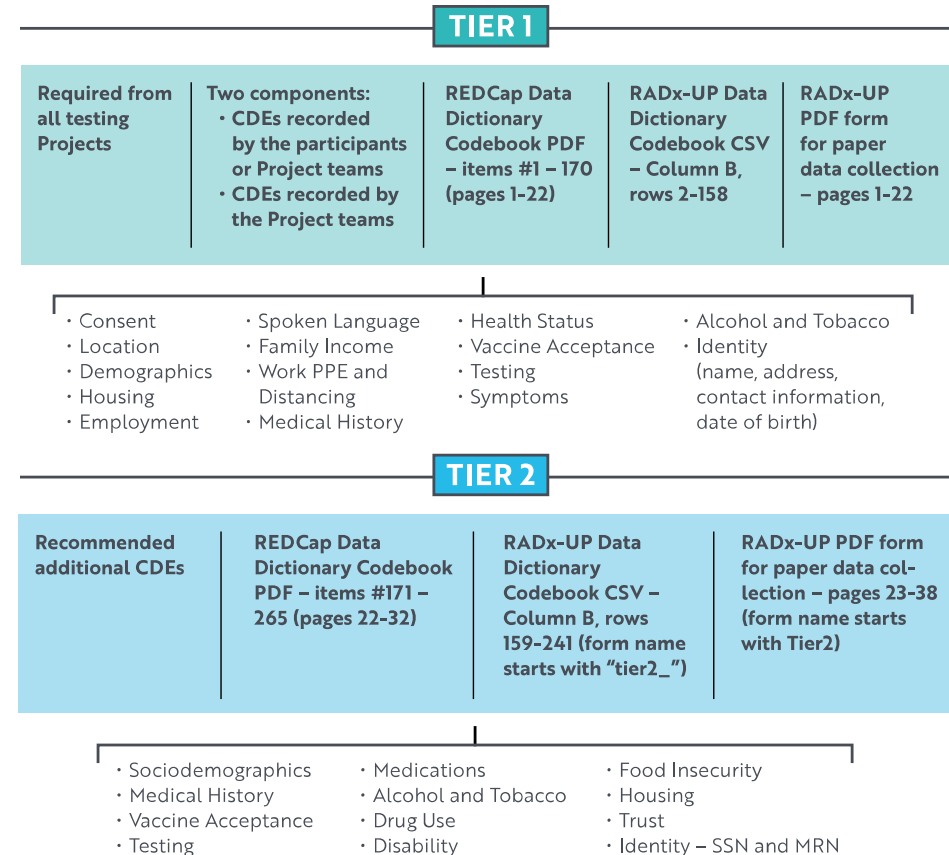
### NIH data repository

- De-identified individual-level data

# NIH Common Data Elements

- The consistent use of the NIH Common Data Elements (CDEs) & ICF data sharing language allows RADx-UP to aggregate data from across the populations and communities that projects study & engage.
- Tier 1 CDEs are required (optional for Pilot Projects). Tier 2 CDEs are recommended additions.
- In development: New Tier 2 NIH CDEs for pediatrics and vaccines

## CDE EXPLAINER - TIER 1 VS. TIER 2





# Typical RADx-UP Onboarding Timeline

## Day 1

- Email from RADx-UP Coordination and Data Collection Center (CDCC) leadership welcoming you to the program.

WEEK 1

## Days 1–3

- A CDCC Engagement Impact Team member (EIT) will reach out to introduce themselves and request updated contact information.

## Days 8–14

- EITs will reach out with Intake Survey due date reminders and information on how to register for CDCC Orientation sessions.

WEEK 2

## Day 8

- An invitation to complete the CDCC Intake Survey will be sent out through REDCap

WEEK 3

## Day 15

- CDCC Intake Surveys are due.

## Weeks 3–5

- CDCC will hold Orientation Sessions for new projects
- EITs will reach out to schedule initial meetings with new projects:
  - Initial Meetings serve to introduce CDCC to project team and project to EIT
  - These meetings will also be opportunity to address any core requests for information and begin discussion of NIH Common Data Elements (CDEs) and CDCC template consent language

WEEK 4

## Week 5

- EITs will begin holding initial meetings with new projects.

WEEK 5

# Thank you.



Please contact us with your  
questions and ideas:

[RADx-UP-CDCC@duke.edu](mailto:RADx-UP-CDCC@duke.edu)

[radx-up.org](https://radx-up.org)

# QUESTIONS & ANSWERS

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# Q&A / Discussion



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

**THANK YOU!**

