RADx Underserved Populations (RADx^{SM}-UP) Return to School Phase I Kick-off

April 16, 2021

National Institutes of Health
Turning Discovery into Health®

WELCOME & INTRODUCTIONS

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-Wolkowiez	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

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 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"

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

Data Management Support – $70M

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

RADx Radical (RADx-rad) – $187M

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

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

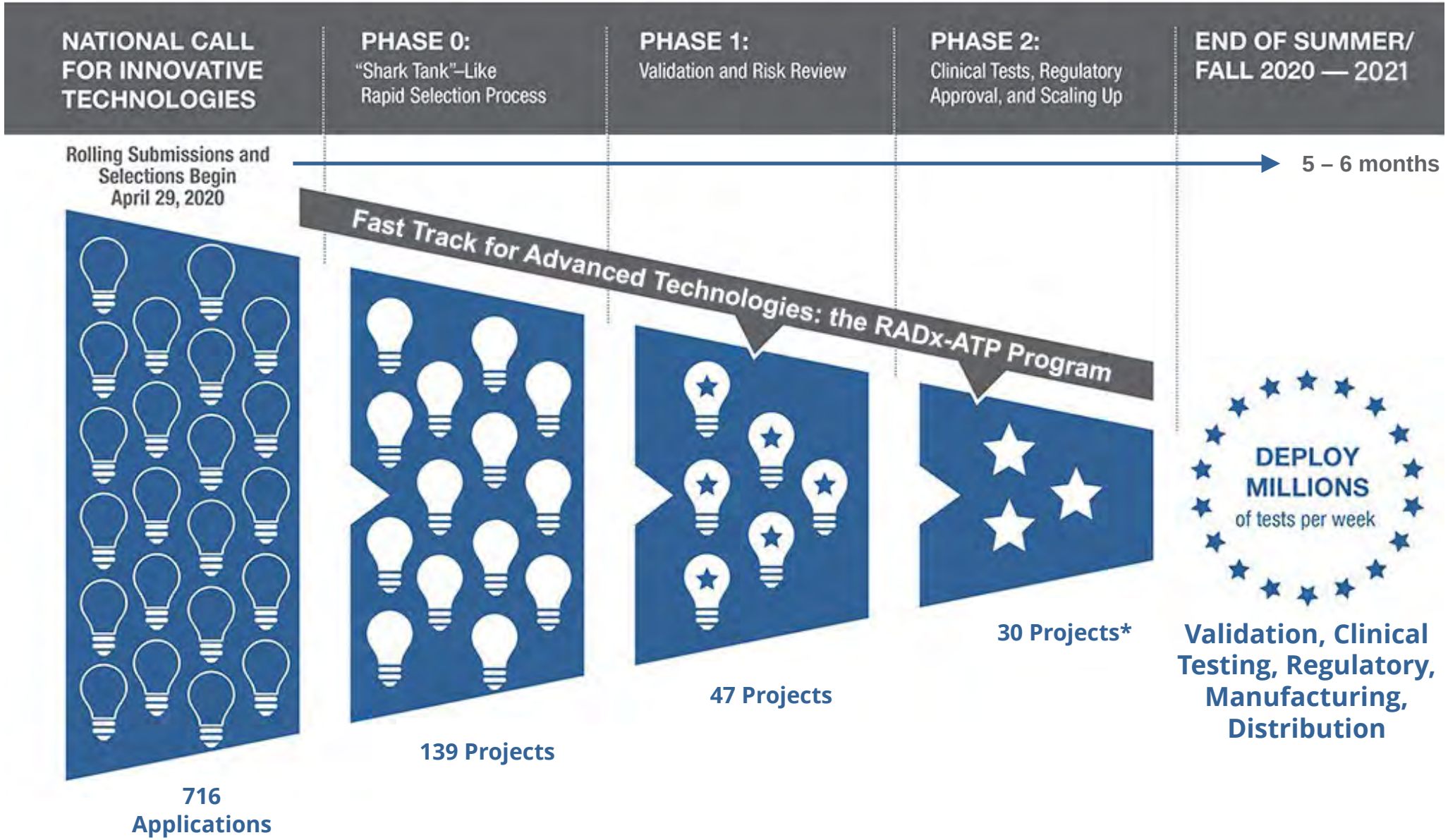
Expand the number, type, access, and throughput of testing technologies

Optimize Technology Performance

Develop technology for a range of essential “Use Cases”

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

RADx 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

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

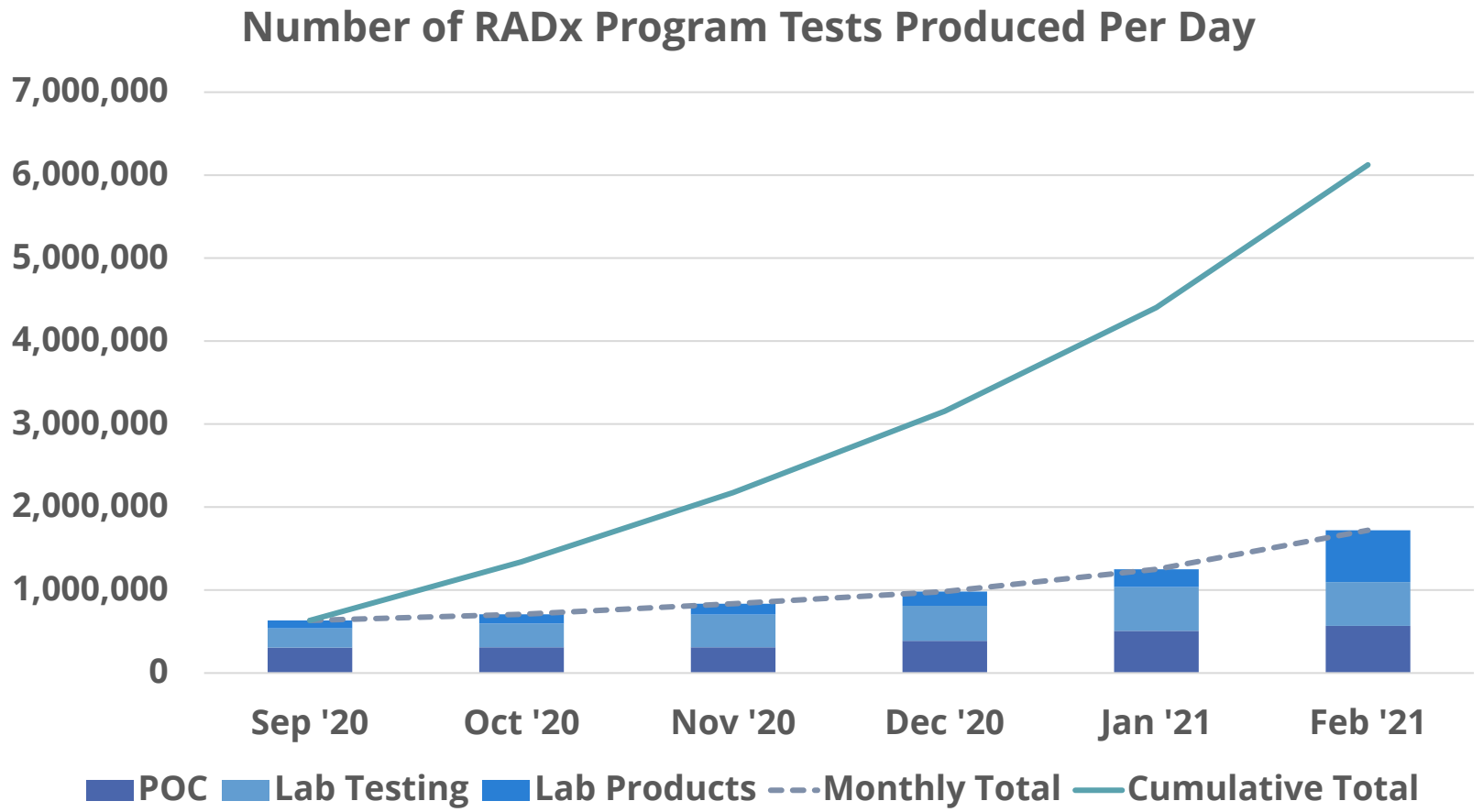
- Emphasize differential POC testing to distinguish SARS-CoV-2 vs. influenza
- Establish rapid collaborations with key industry partners

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

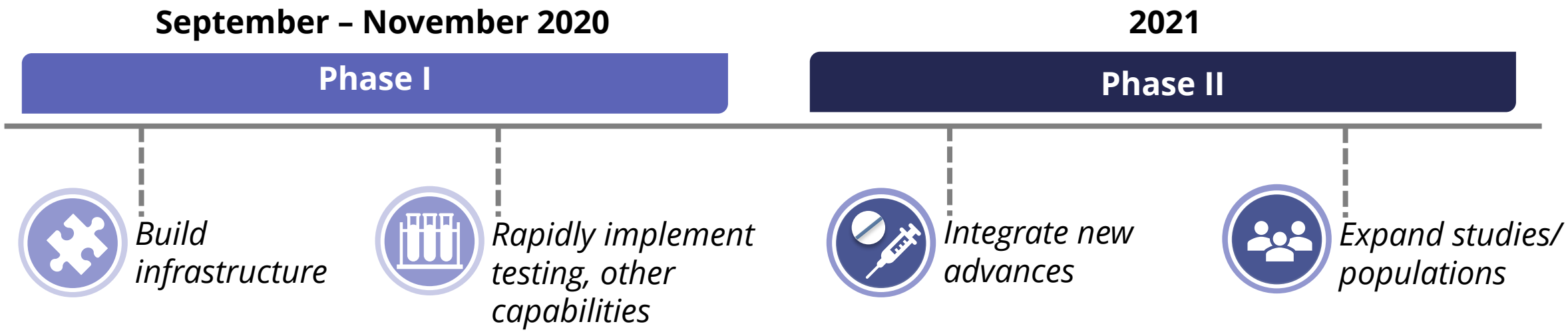


Note: *Cumulative total of 94 million tests per day produced between Sept and Dec 2020

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



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

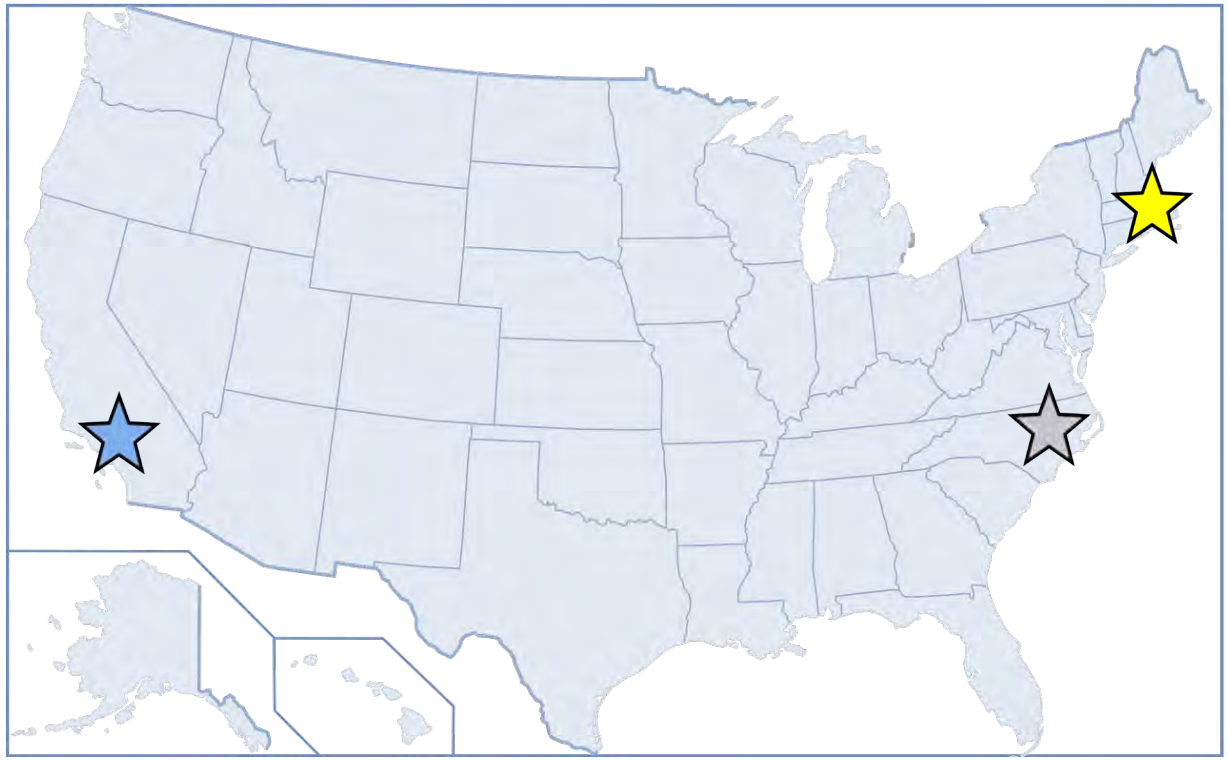
- **Novel biosensing and chemosensory testing** for COVID-19 screening
- **Single vesicle, exosome, and exRNA isolation** for the detection of SARS-CoV-2
- **Predicting viral-associated inflammatory disease severity** in children with laboratory diagnostics and artificial intelligence
- **Wastewater-based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



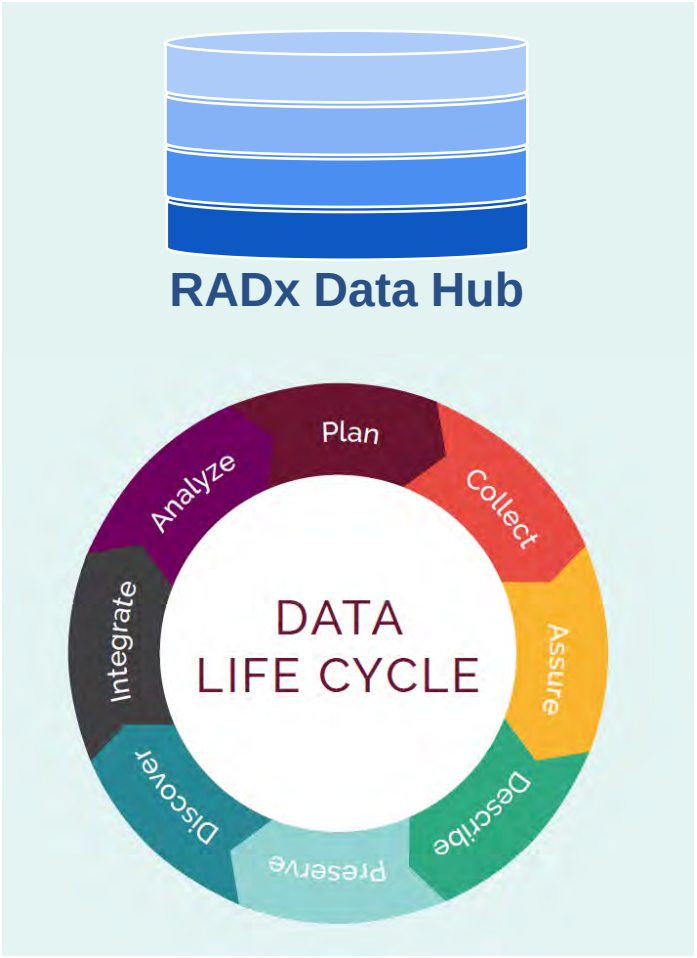
RADx Data Management

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.

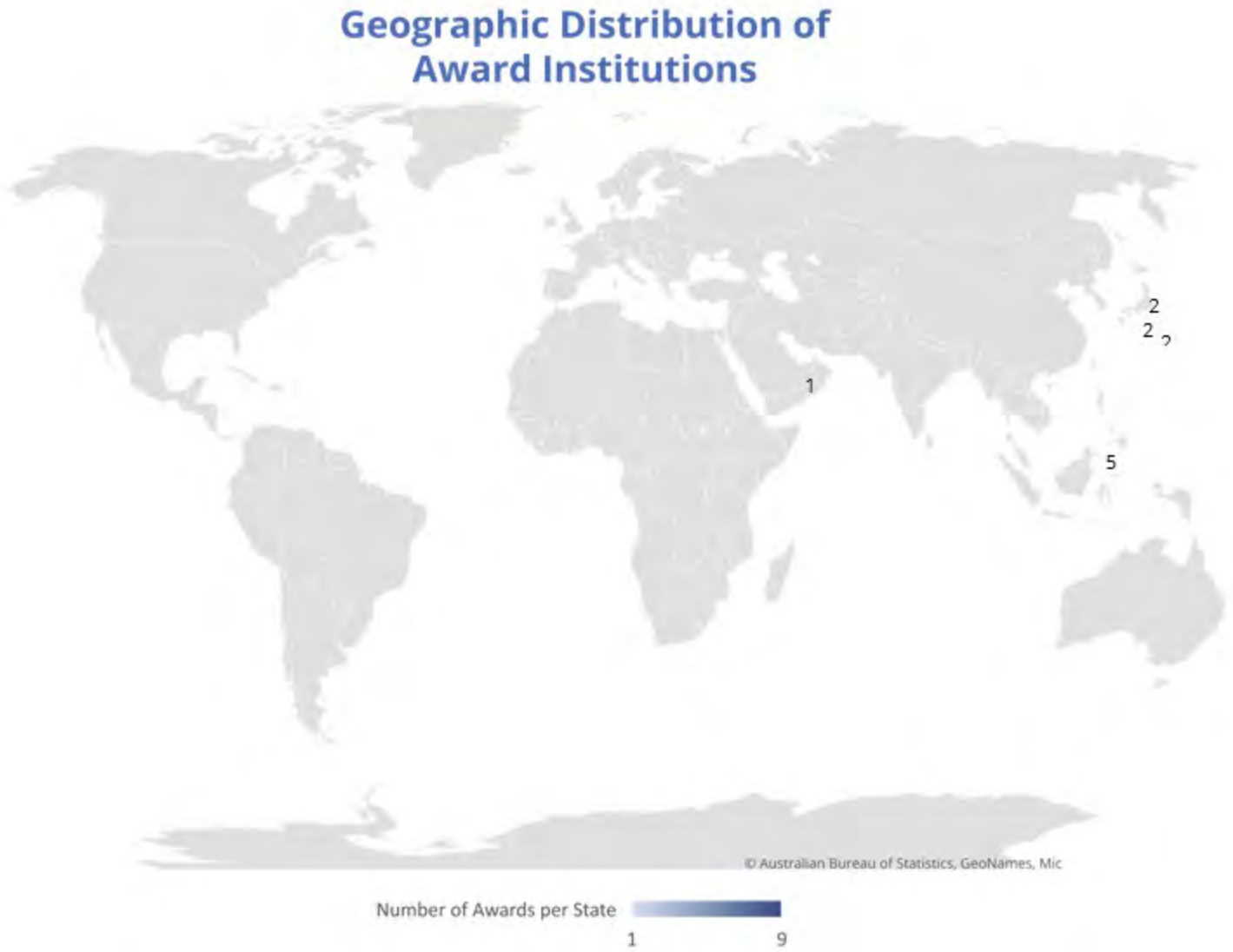
Director, National Institute on Minority Health and Health Disparities (NIMHD)

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: 70 Funded Sites and Research Projects

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

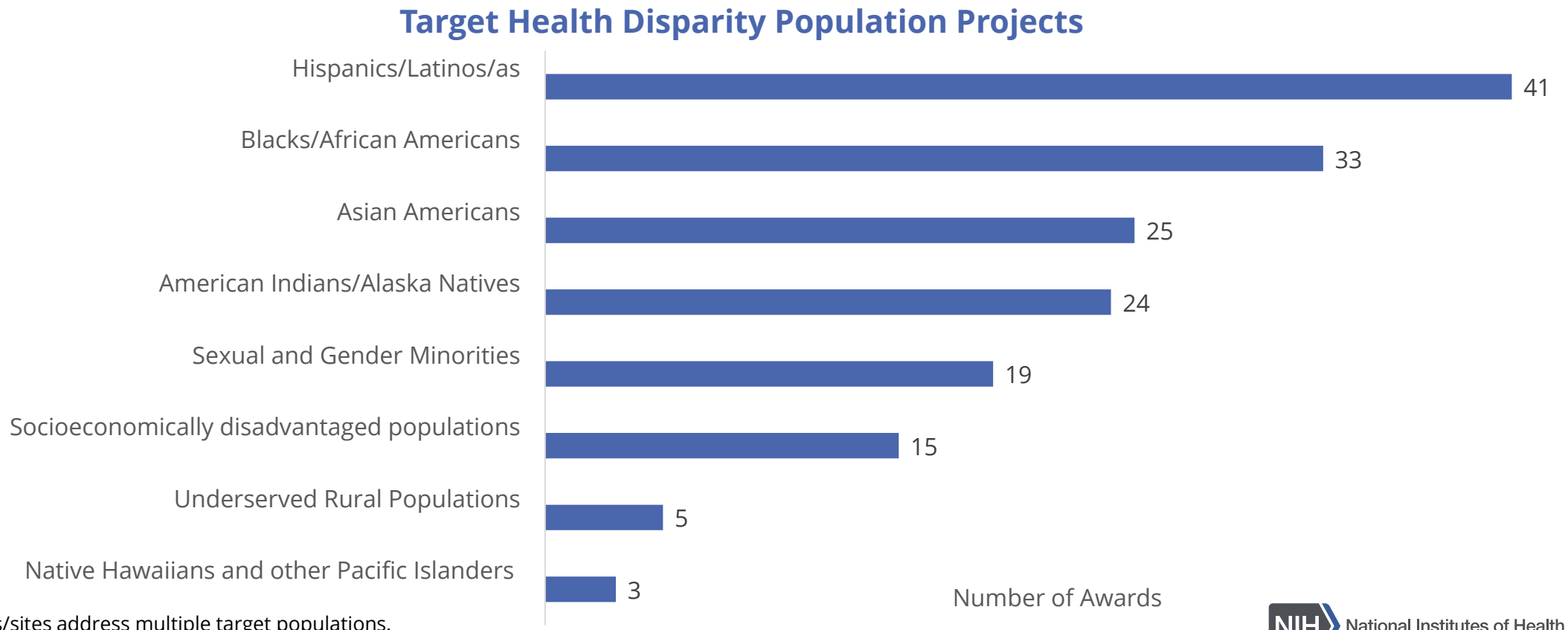


Funded sites and research projects span a total of **31 states** in addition to DC and Puerto Rico and include **54 institutions**.

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.



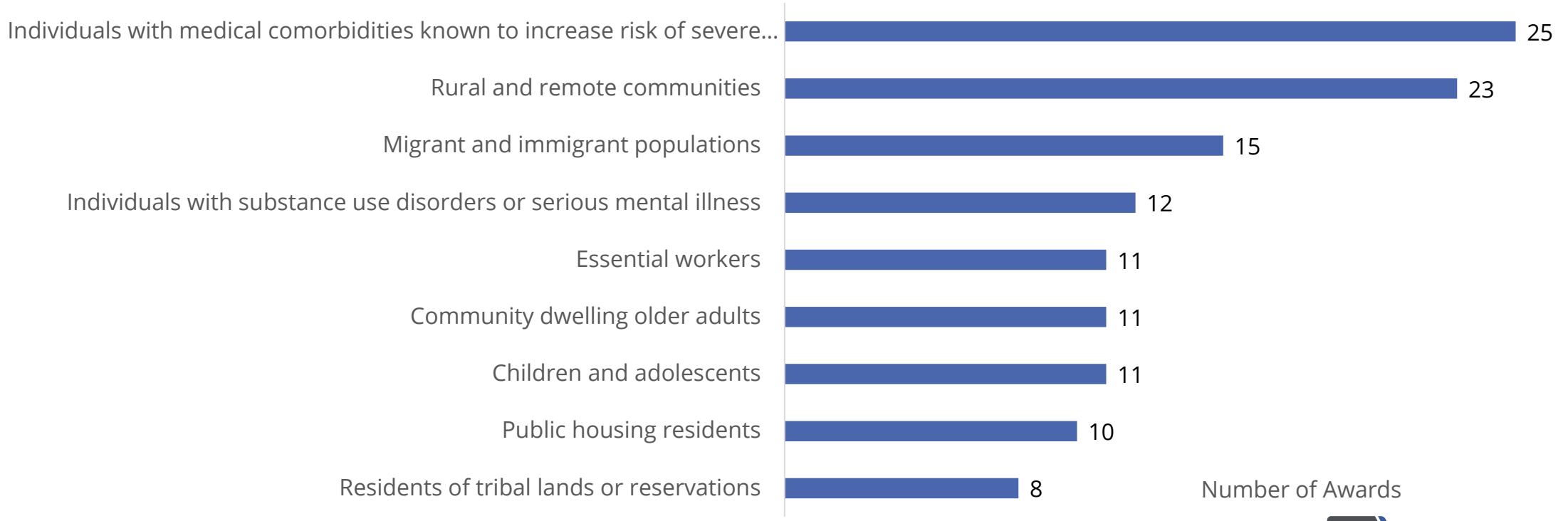
Note: Some projects/sites address multiple target populations.

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)



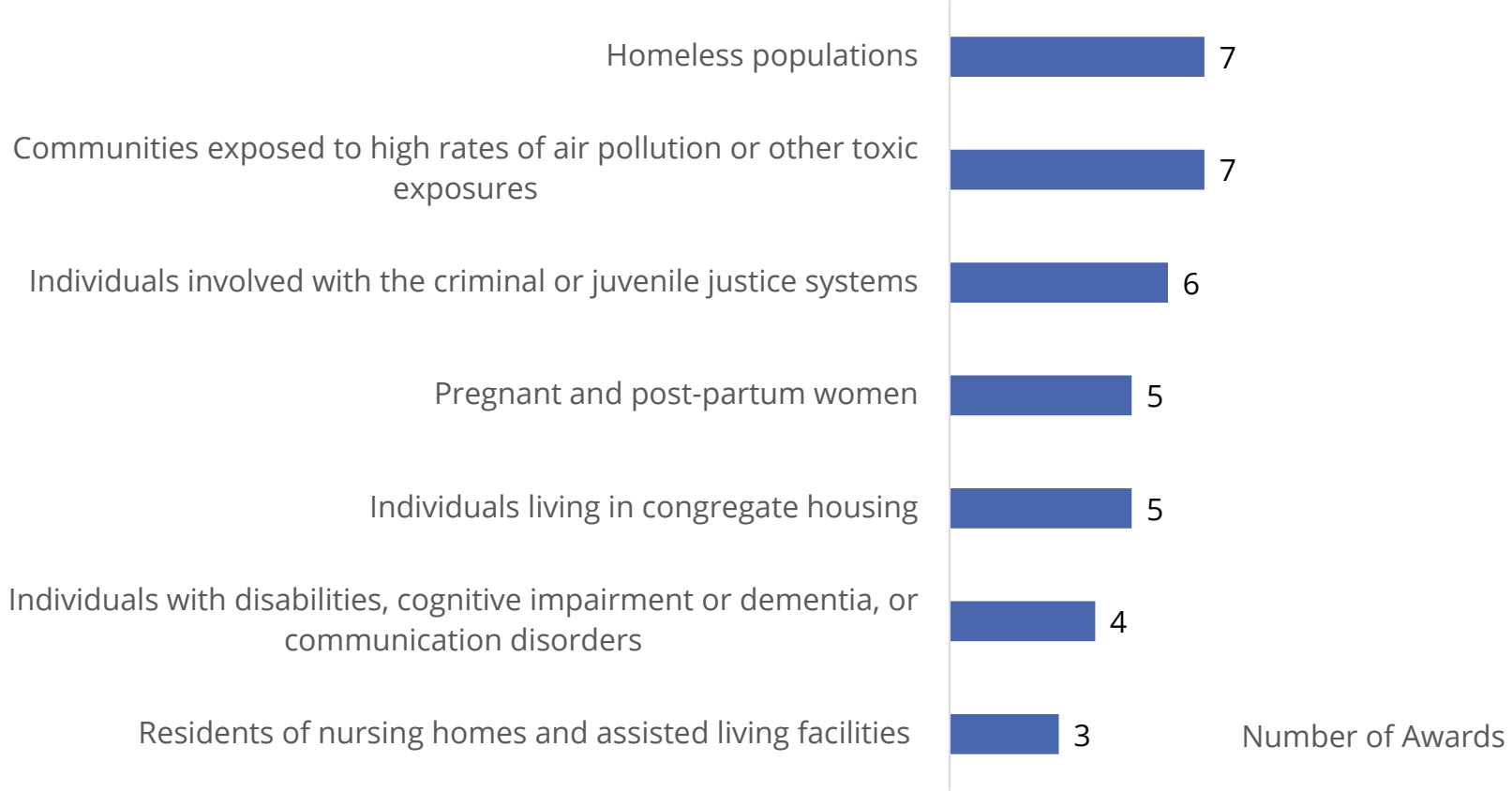
Note: Some projects/sites address multiple target populations.

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.

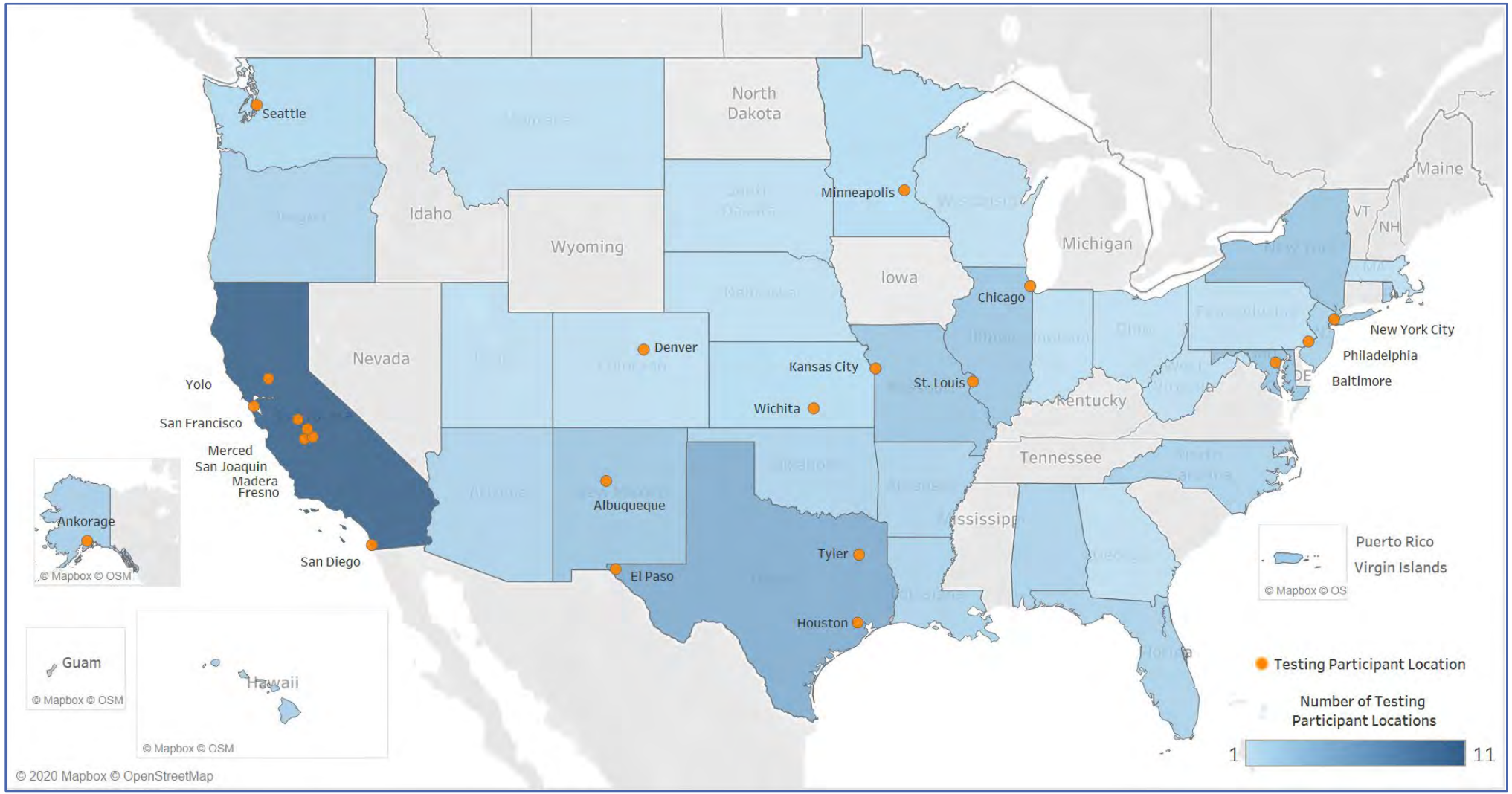
Target Vulnerable Population Projects (2/2)



Note: Some projects/sites address multiple target populations.

RADx-UP Phase I Awards

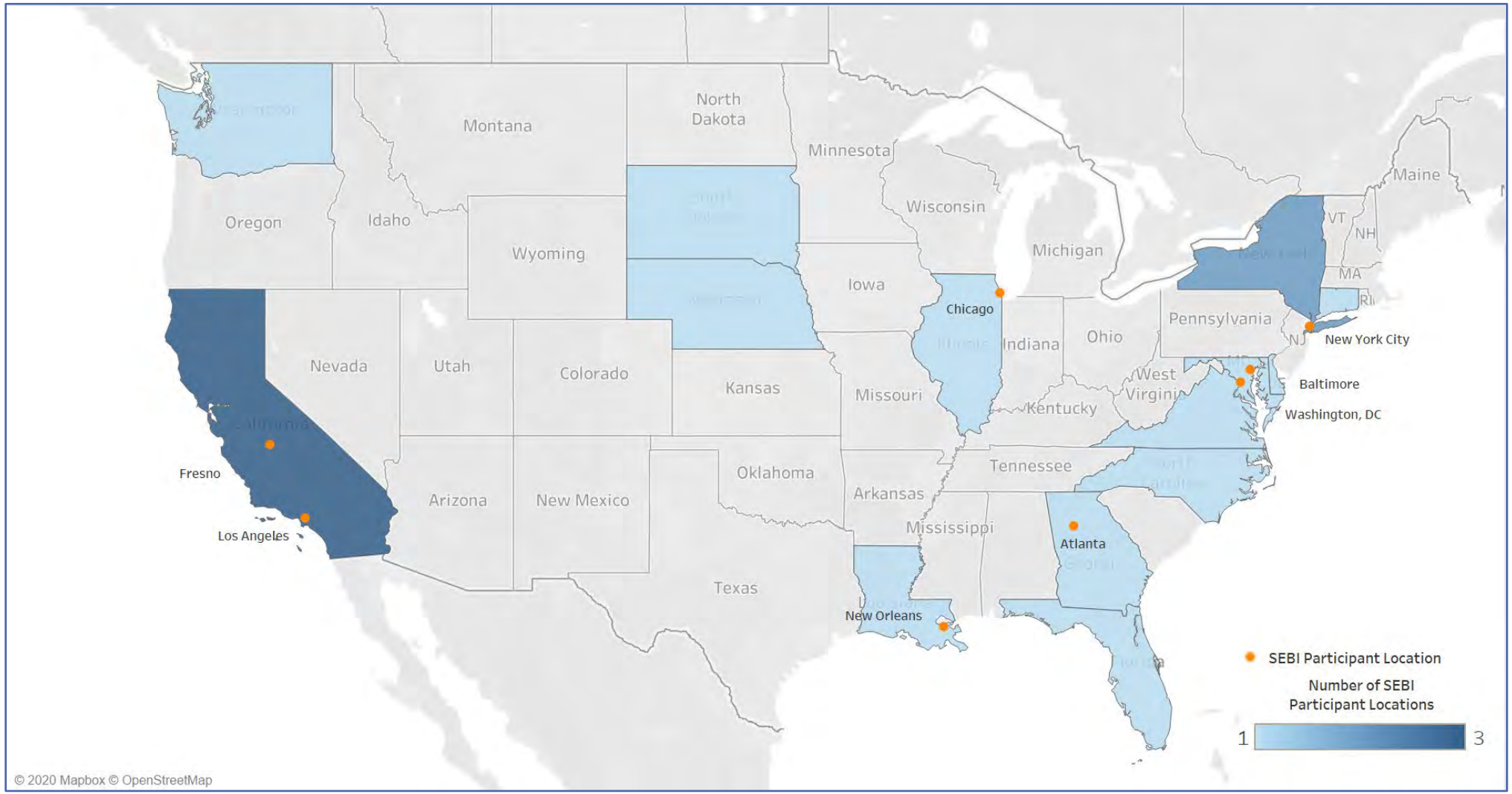
Testing Participant Locations



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

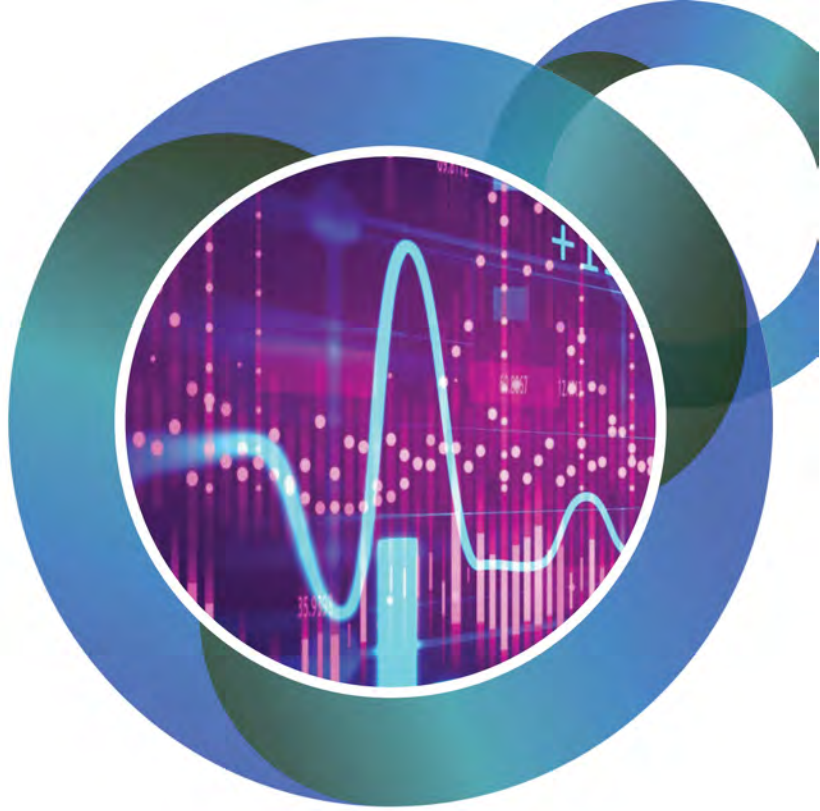
Program Information: $1.2M per site over 2 years; 16 sites

- 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

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

NIH National Institutes of Health
Turning Discovery into Health®

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

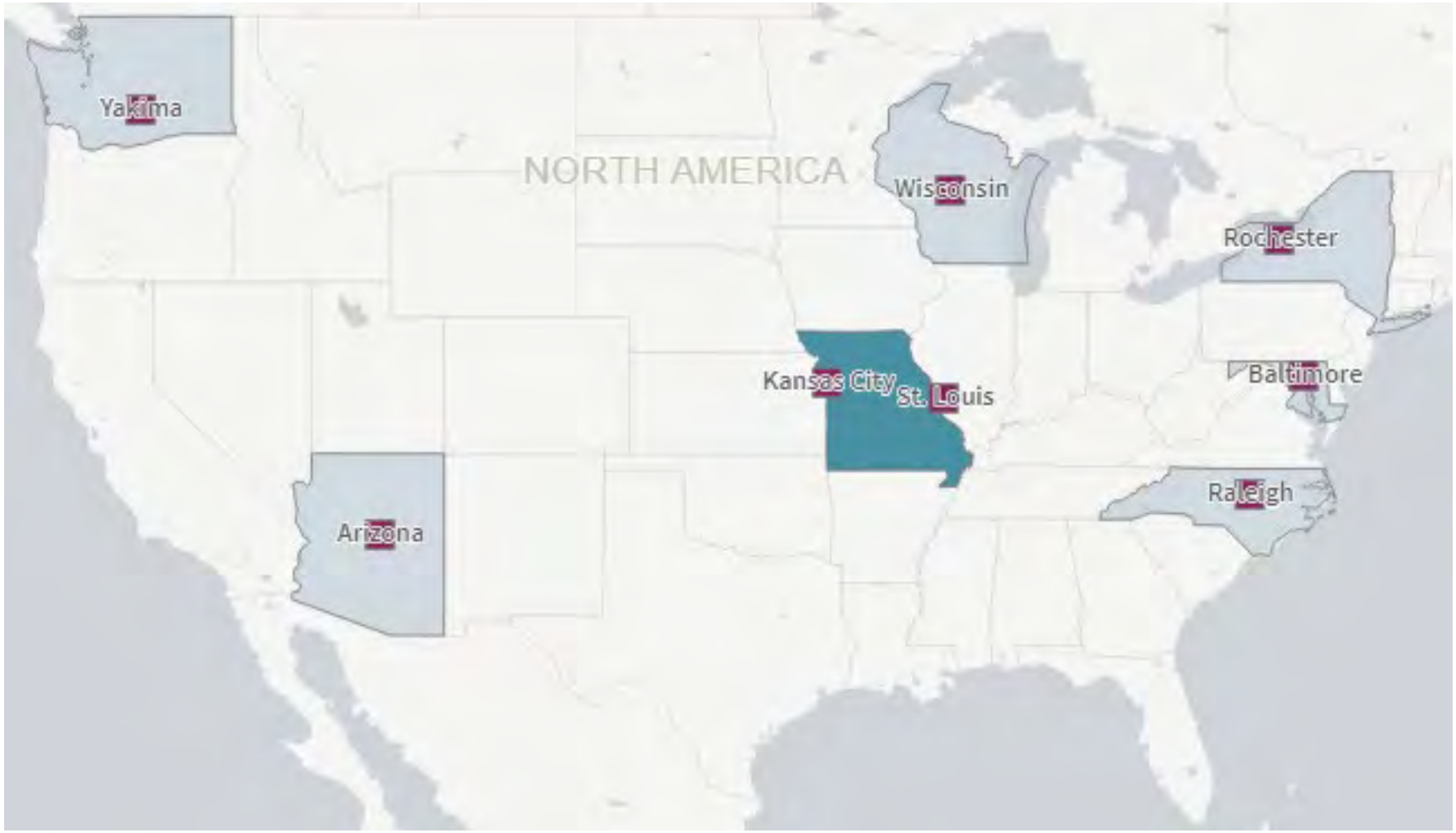
Institution Locations: Awarded Projects

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

Return to School

Study Locations: Awarded Projects



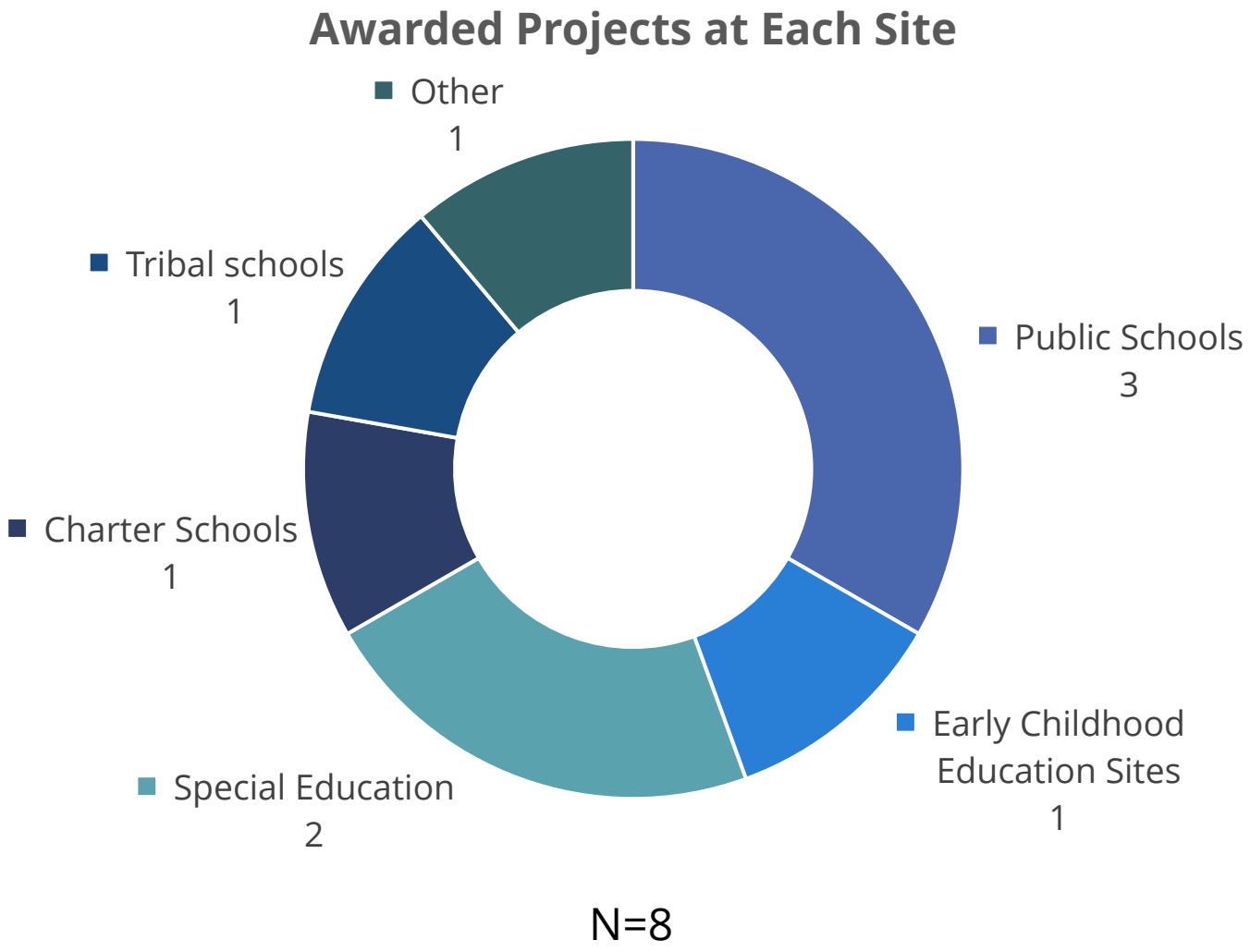
Geographic Areas

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

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

Return to School

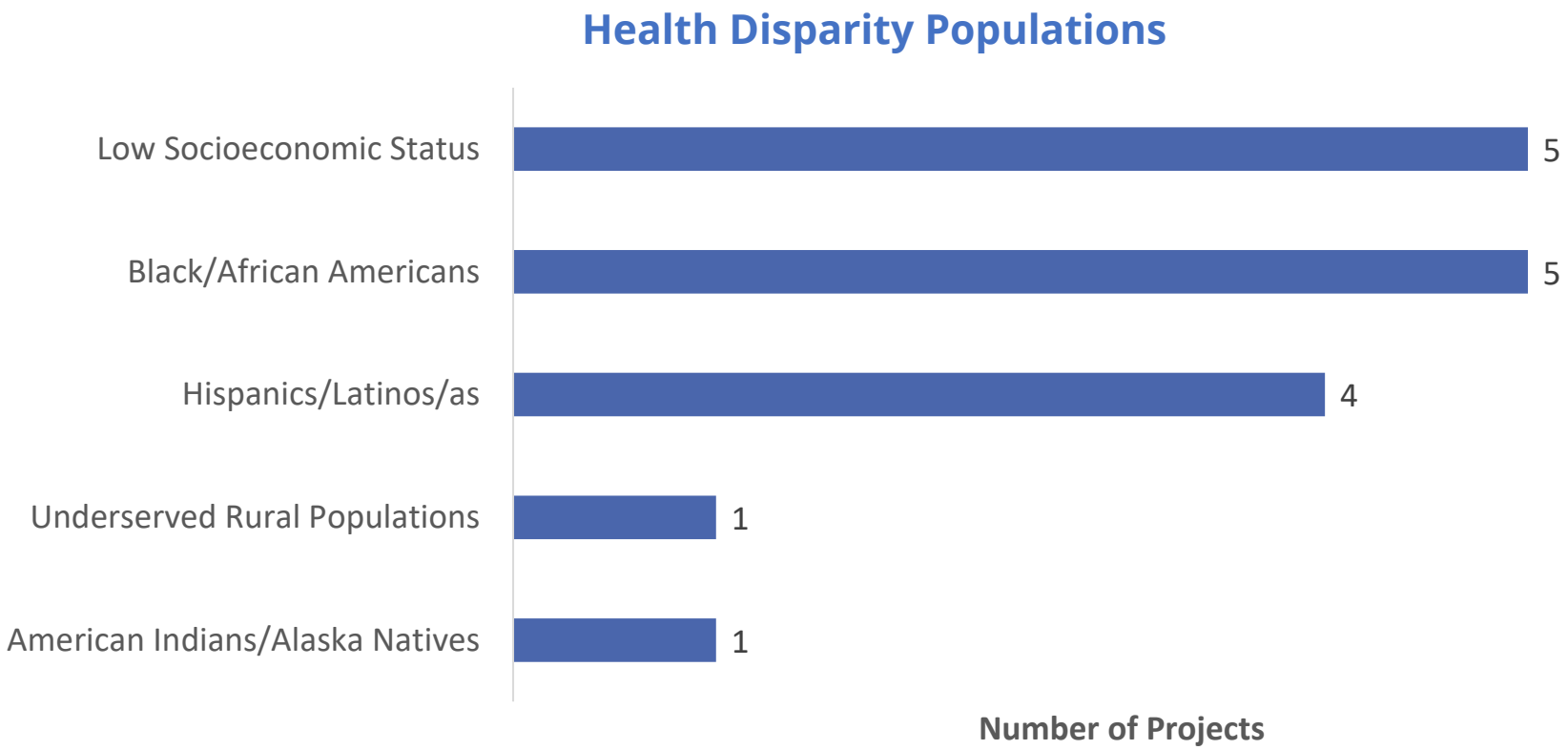
Project Settings – Awarded Projects



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

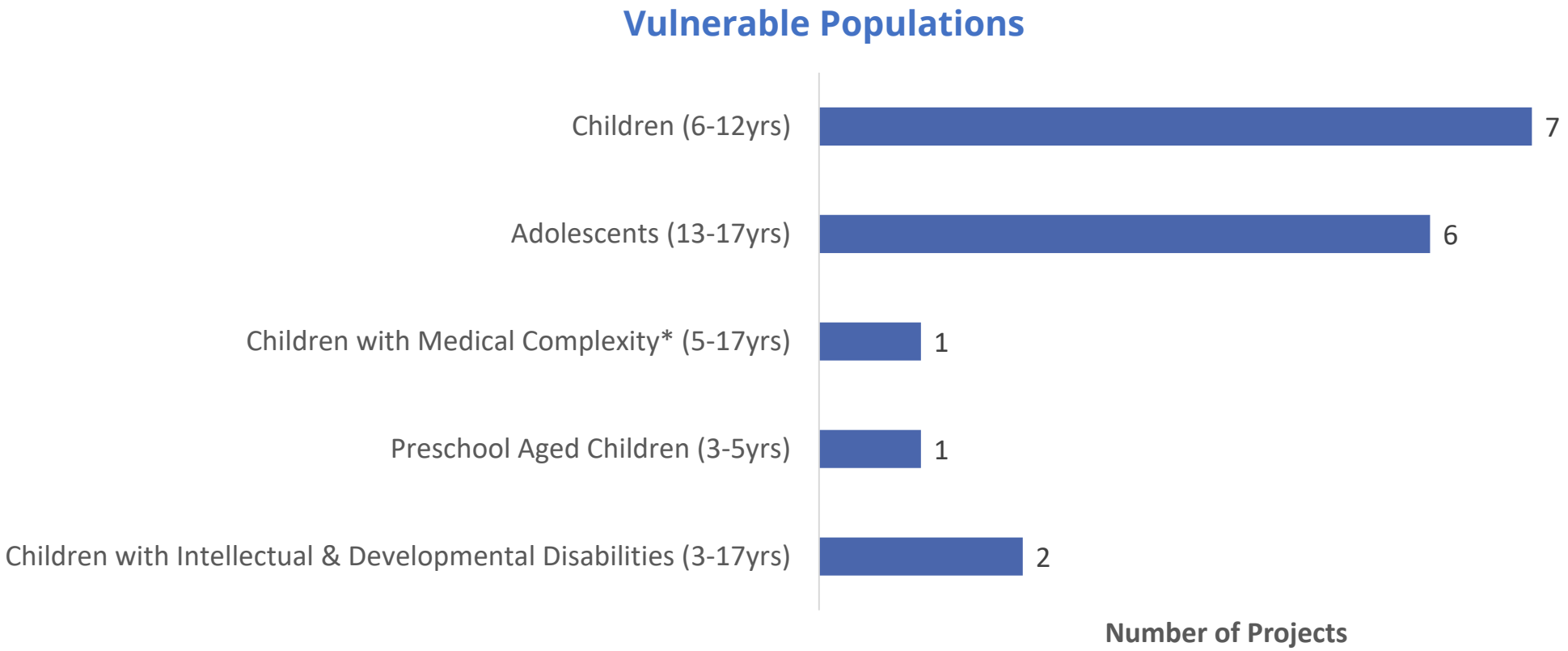
Return to School Phase I

Target Health Disparity Populations



Return to School

Vulnerable Populations



*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

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.

Mary Cariola Center

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 URMC Central Laboratories

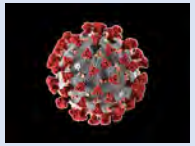
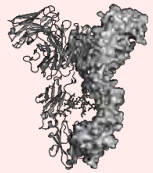


Table 1: URMC COVID-19 Testing Capacity and Modalities		
Platform	Capacity: Tests/Day	Certification
Roche 8800	2000	FDA-EUA
Cepheid	500	FDA-EUA
Hologic	500-1000	FDA-EUA
TF Amplitude	3000-6000	FDA-EUA

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 URMC 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

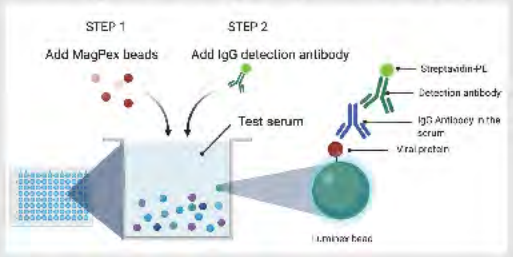
FDA EUA

High throughput (500-800 per day)

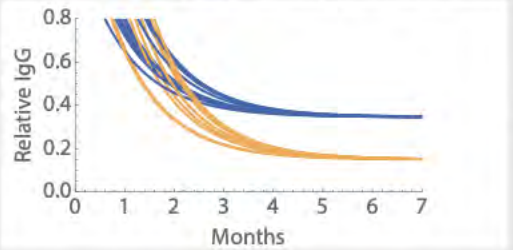
High sensitivity and specificity

Volumetric Micro Sampling

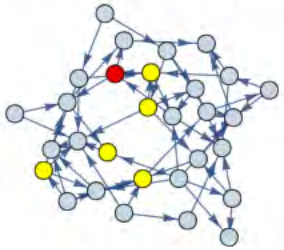
Multiplex Analysis (mPLEX-CoV)

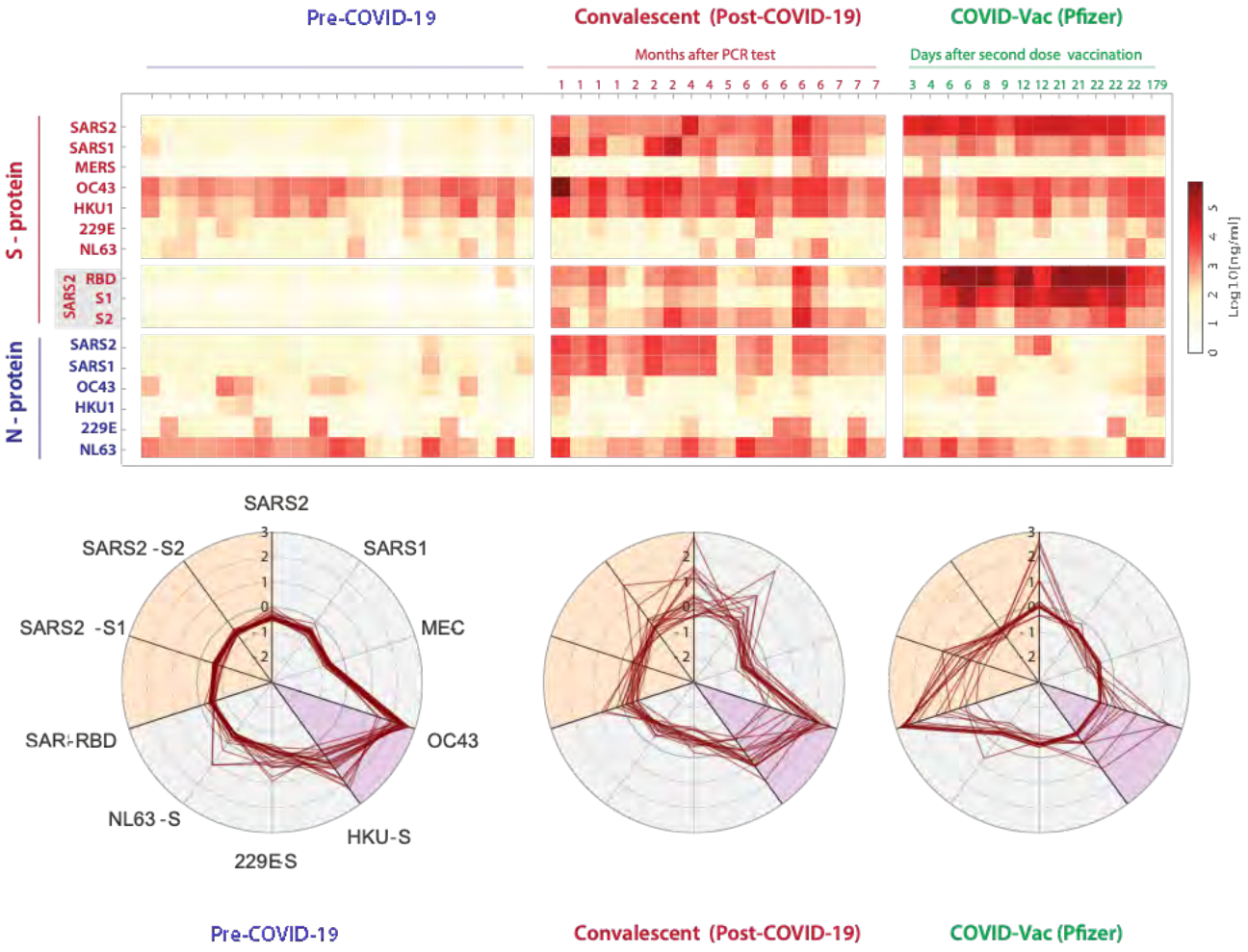


Anti-SARS-CoV-2 RBD Levels



Modeling of immunity levels



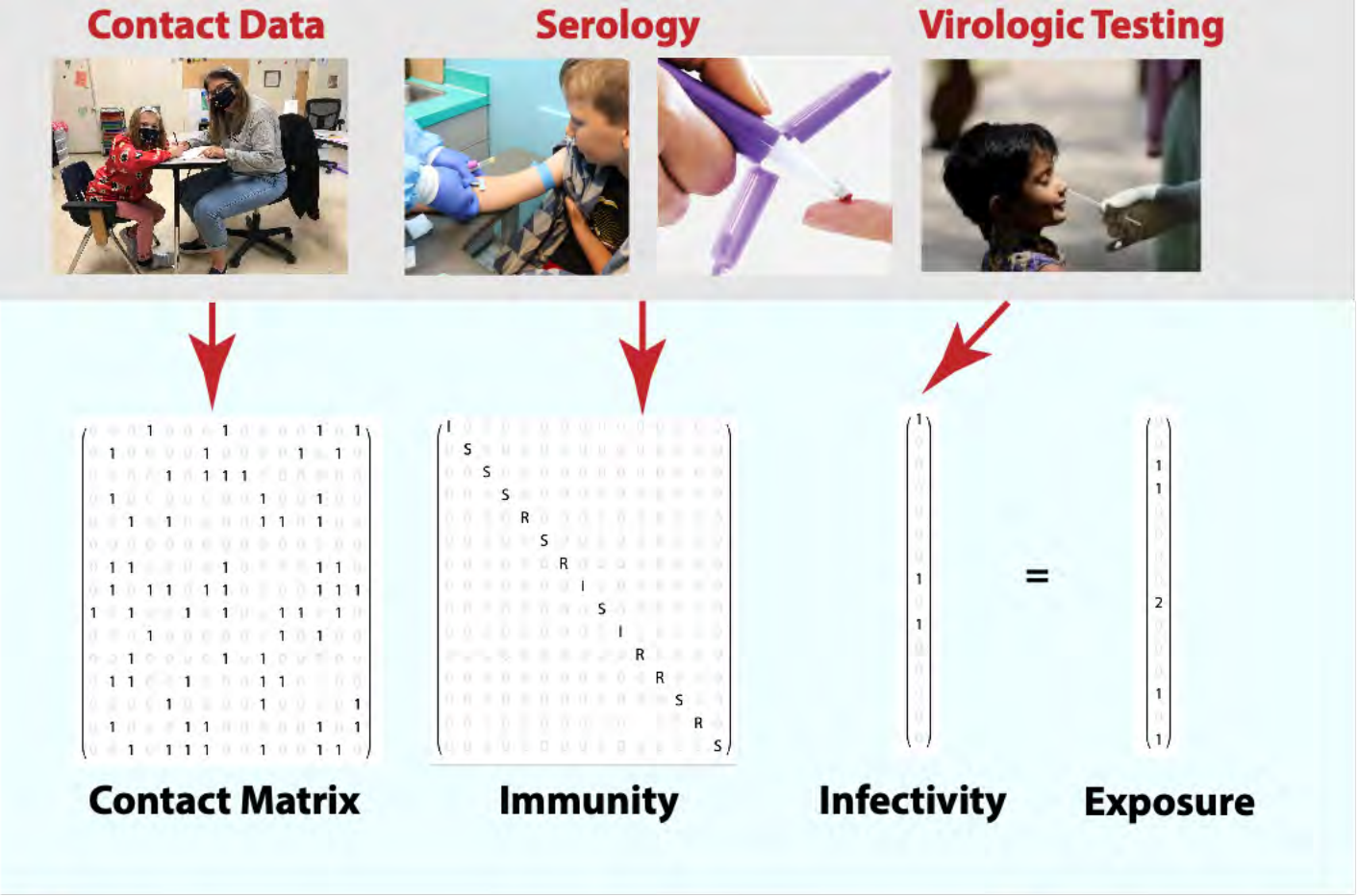


Scientific Questions:

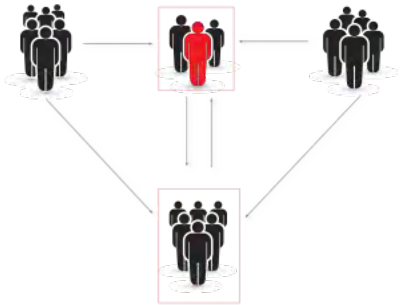
How does IgG antibody reactivity against SARS-CoV-2 change over time in teachers, staff, and IDD students?

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

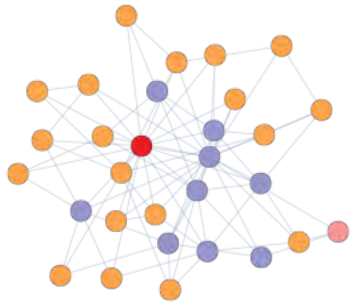
What are the rates of asymptomatic transmission in vaccinated staff and IDD students?



Susceptible
Exposed
Infected
Recovered



Agent Based Models



Stochastic Mobility Models

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 attendence?

- Class size
- Contact patterns
- Community previlence of viral varients

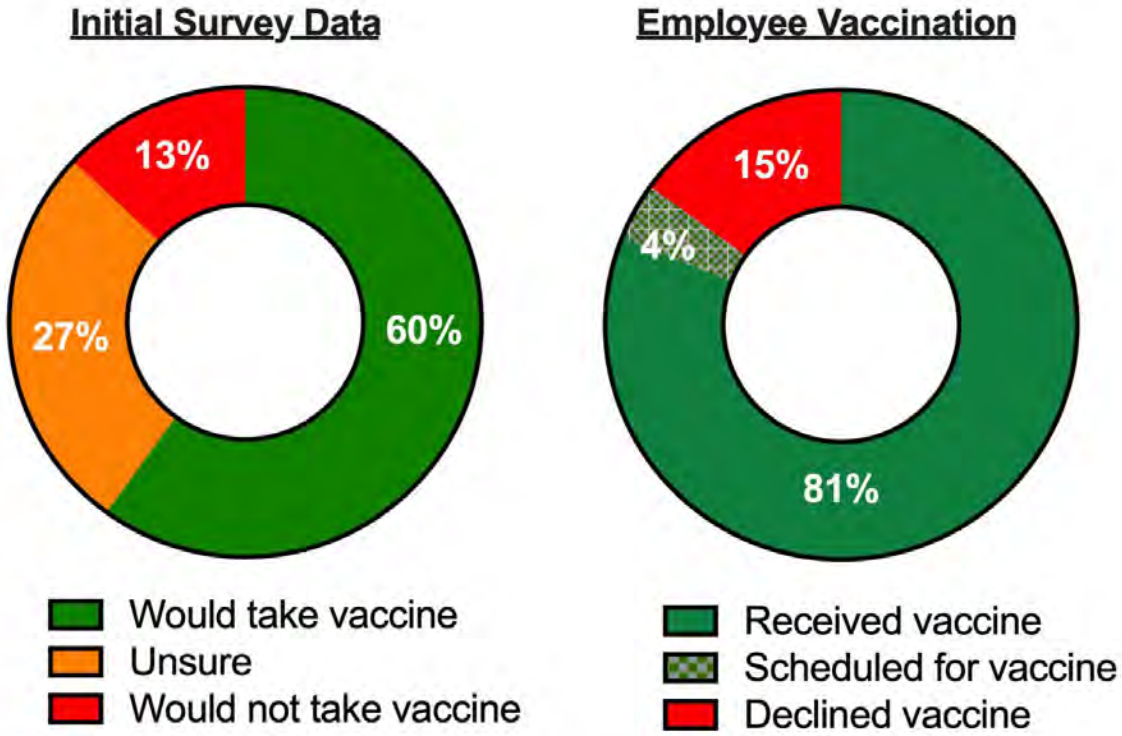
General Deliverables:

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

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



PROMIS: Patient-Reported Outcome Measurement Information System

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

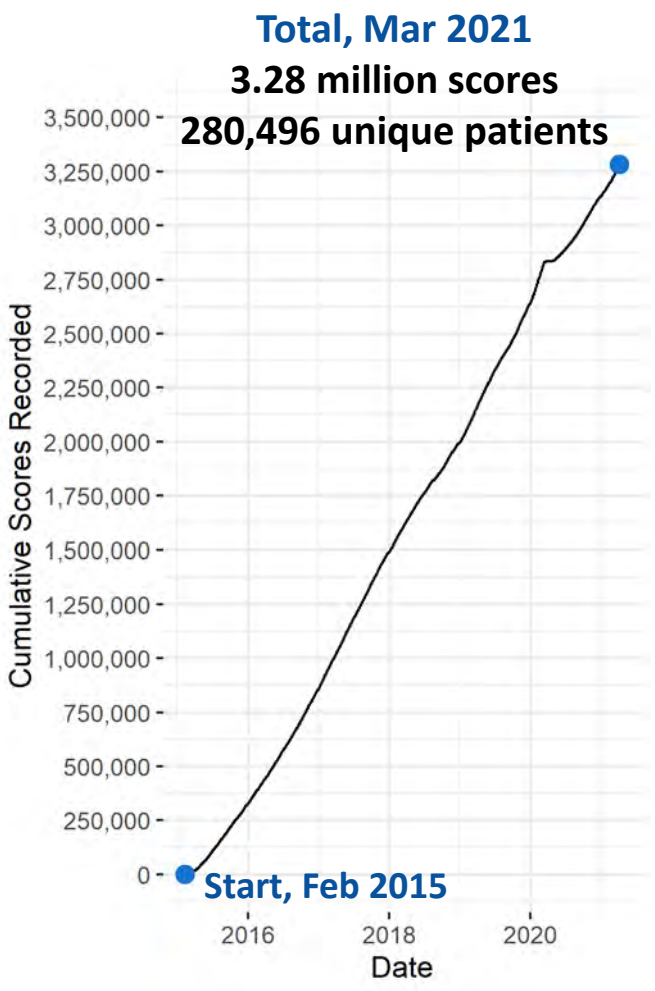
- Efficient, precise, responsive and validated patient-reported outcome measure (PROM)
- Produce comparable *domain*-focused, PROM of health across patient subgroups and therapies
  - 11-year, $100 million effort by NIH
  - Produces validated data quickly
    - Item Response Theory
    - Computer Adaptive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

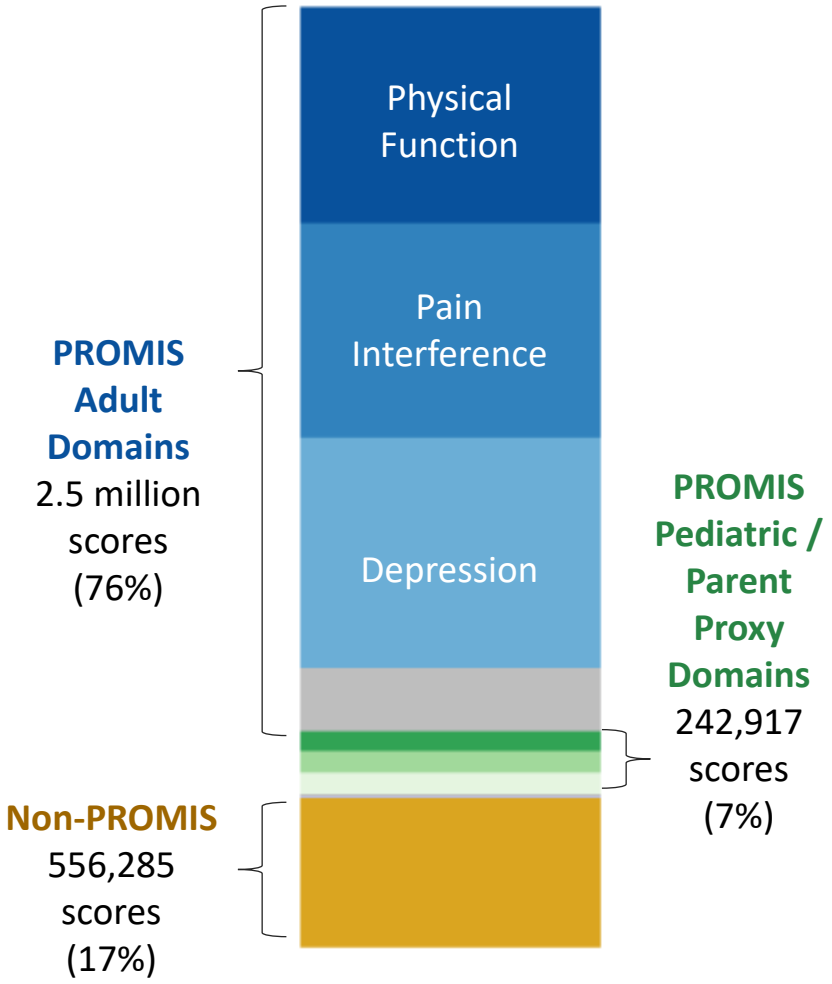
PROMIS

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*

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

THE ABC SCIENCE COLLABORATIVE

Learning | Informed Decision-Making | Research

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

THE ABC SCIENCE COLLABORATIVE

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.

THE ABC SCIENCE COLLABORATIVE

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 ≥30% increase in the proportion of Black and ≥ 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.

THE ABC SCIENCE COLLABORATIVE

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

THE ABC SCIENCE COLLABORATIVE

Learning | Informed Decision-Making | Research

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.

Duke University School of Medicine

UNC HEALTH CARE

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

THE ABC SCIENCE COLLABORATIVE

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

THE ABC SCIENCE COLLABORATIVE

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

THE ABC SCIENCE COLLABORATIVE

Thank you.

THE ABC SCIENCE
COLLABORATIVE

Learning | Informed Decision-Making | Research

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

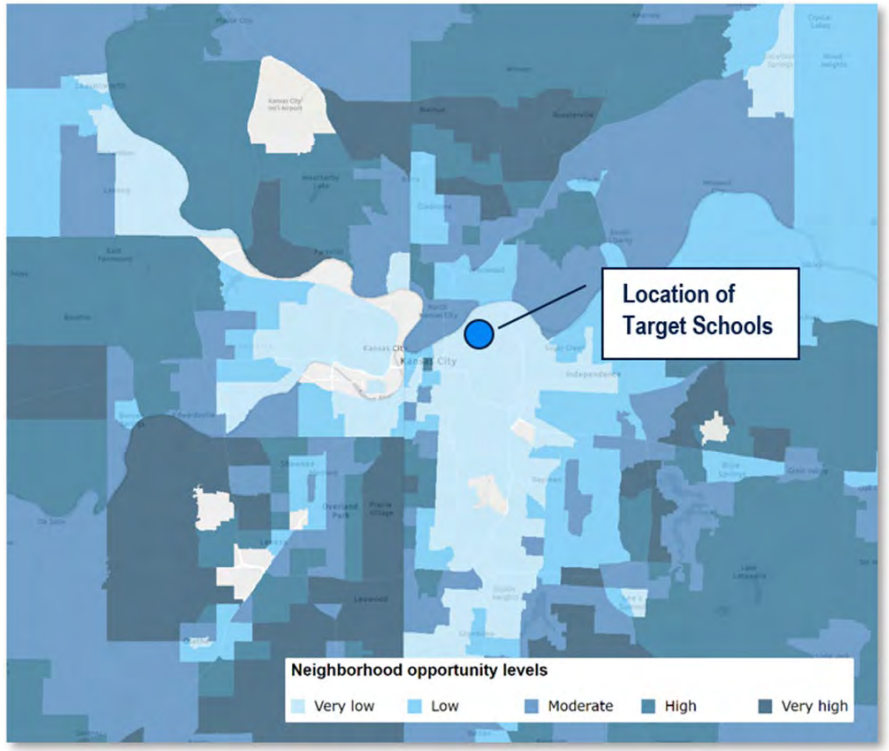
Jennifer Goldman, MD
Children's Mercy Kansas City

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

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



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

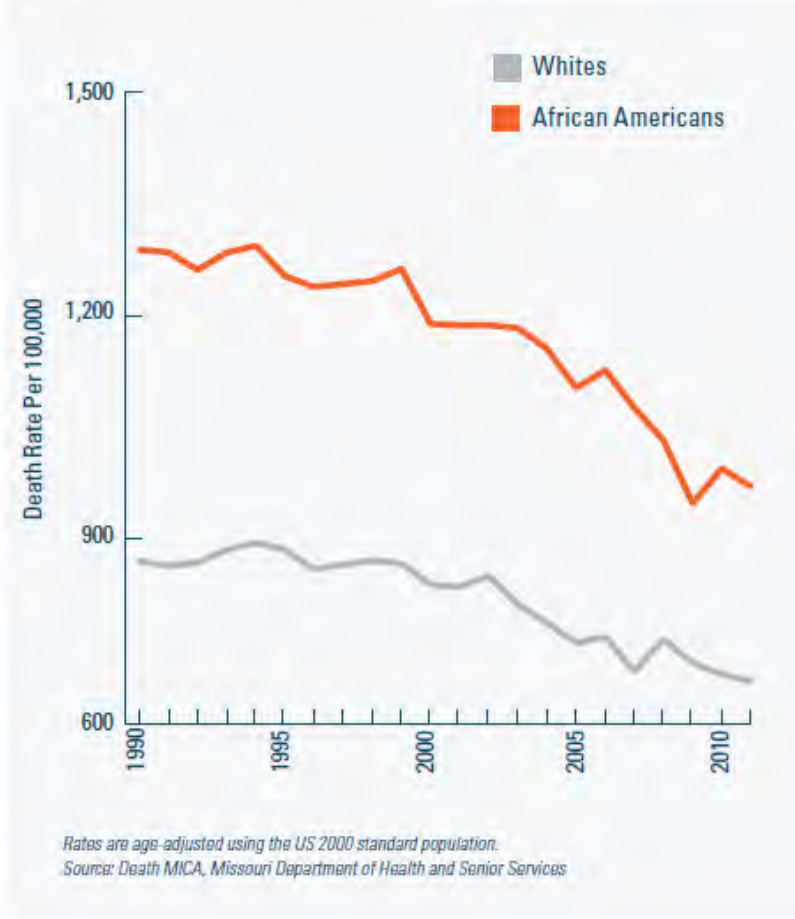
COVID-19

- Most heavily impacted
  - More cases early
  - More deaths

Purnell J. et al “For The Sake of All” 2015

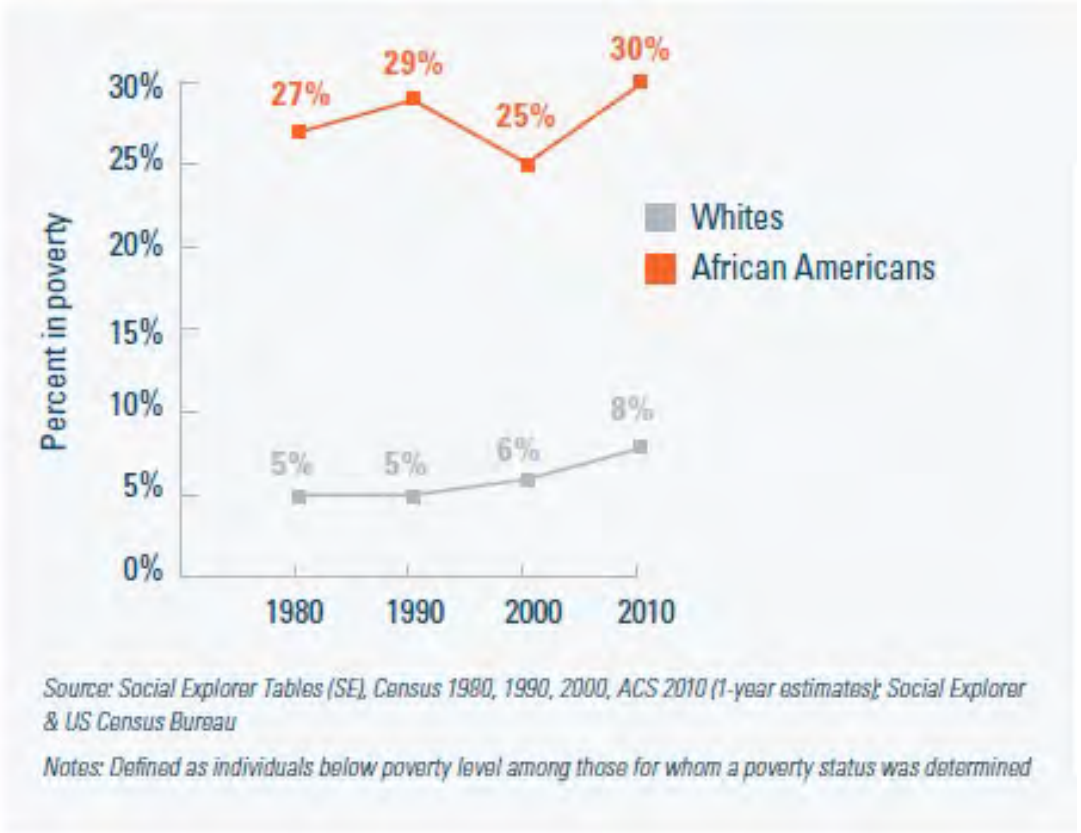
St. Louis- For The Sake of All

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



Rates are age-adjusted using the US 2000 standard population.
Source: Death MICA, Missouri Department of Health and Senior Services

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



Source: Social Explorer Tables (SE), Census 1980, 1990, 2000, ACS 2010 (1-year estimates); Social Explorer & US Census Bureau

Notes: Defined as individuals below poverty level among those for whom a poverty status was determined

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

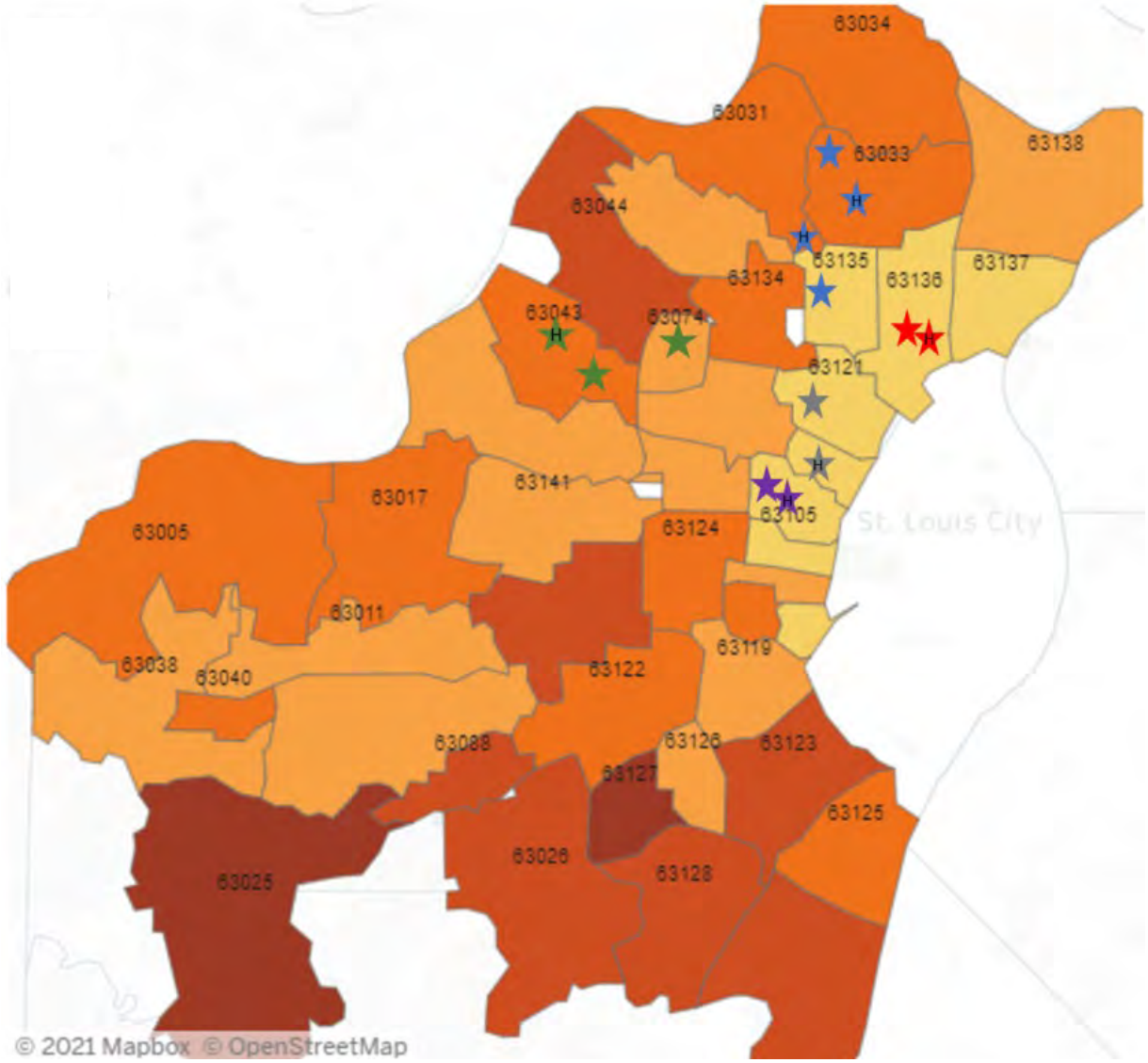

Home of
the Warriors
J
JENNINGS
SCHOOL DISTRICT


FERGUSON-FLORISSANT SCHOOL DISTRICT


NORMANDY SCHOOLS
COLLABORATIVE


THE SCHOOL DISTRICT OF
UNIVERSITY CITY
Transform the Life of Every Student Every Day!


PATTONVILLE
SCHOOL DISTRICT



North County Schools

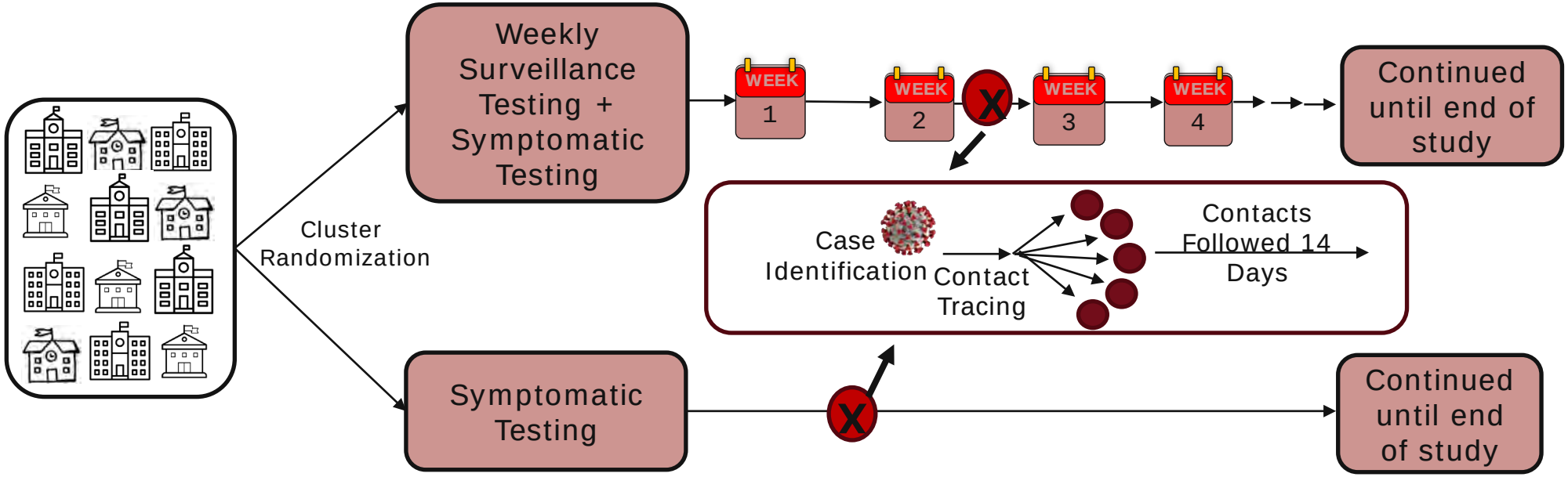
- Predominantly African-American
- All receive Title 1 funding
- 100% free or reduced lunch
- In-person attendance 30-40%

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

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

School of Medicine and Public Health
UNIVERSITY OF WISCONSIN–MADISON

College of Engineering
UNIVERSITY OF WISCONSIN–MADISON

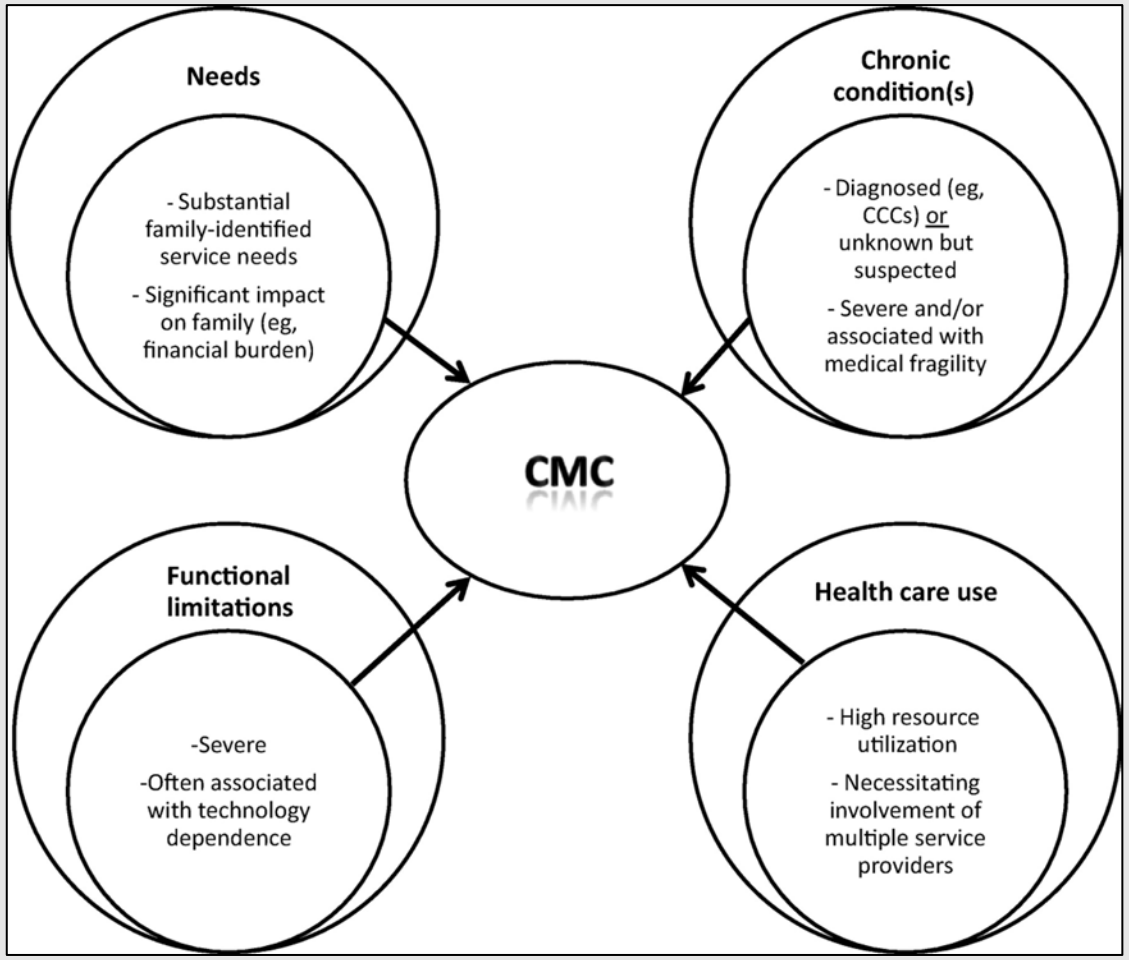
UWSC
UNIVERSITY of WISCONSIN
SURVEY CENTER

Healthy Kids Collaborative

Family Voices of Wisconsin

Children and Youth with Special Health Care Needs

Medical Complexity and RADx-UP

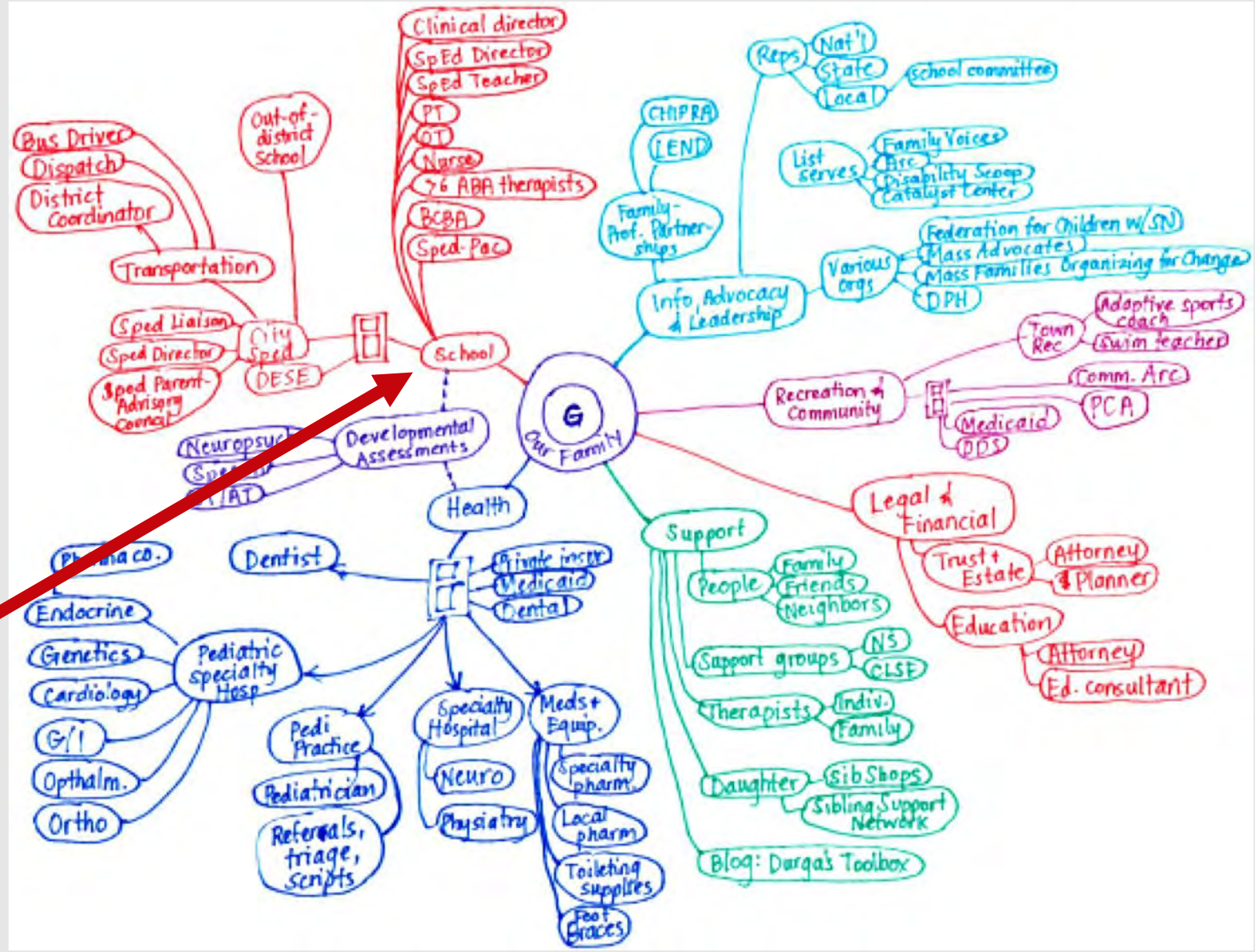


Children with Medical Complexity = CMC

- ***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

Cohen E et al. Pediatrics. 2011
Berry et al. JAMA Pediatr. 2020
Coller et al. Health Serv Res. 2016
Romley et al. Pediatrics. 2017

Medical Complexity and School



Kuo DZ et al. Pediatrics. 2016

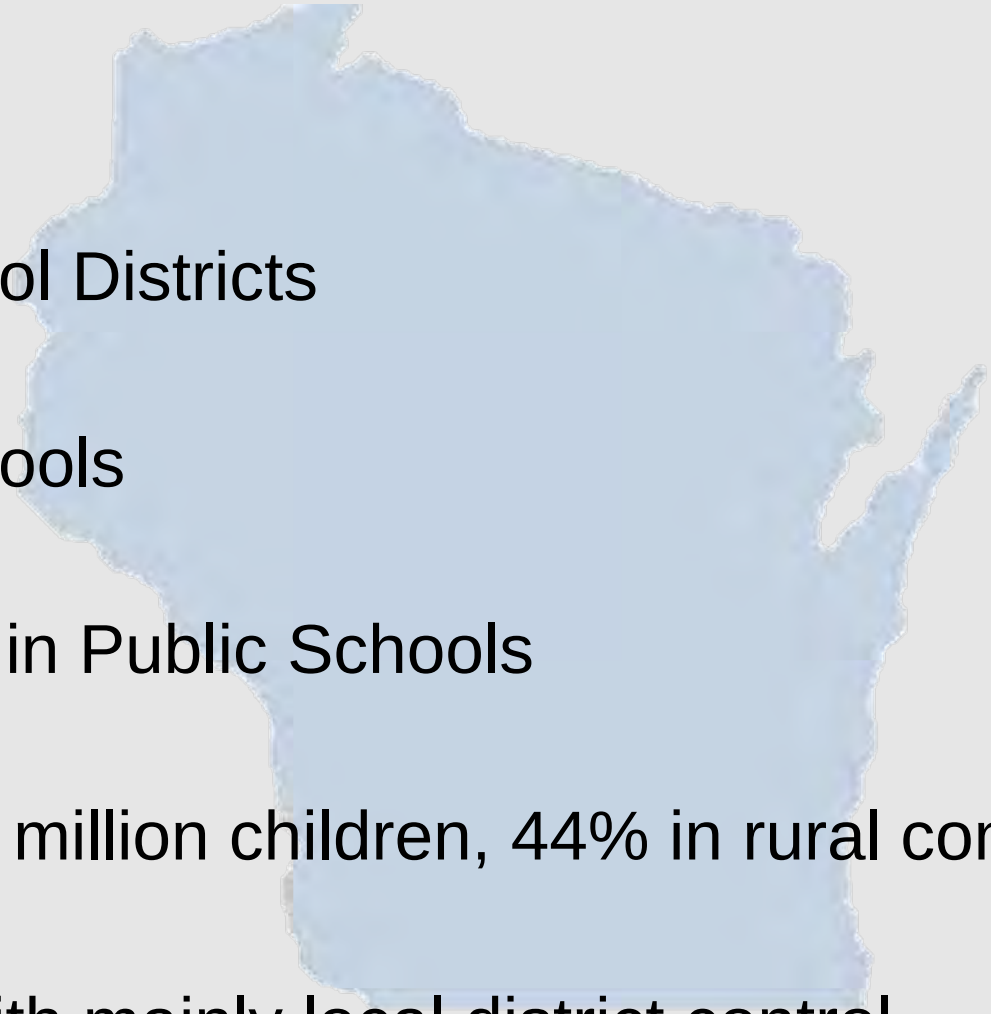
Unique School Challenges

- 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**

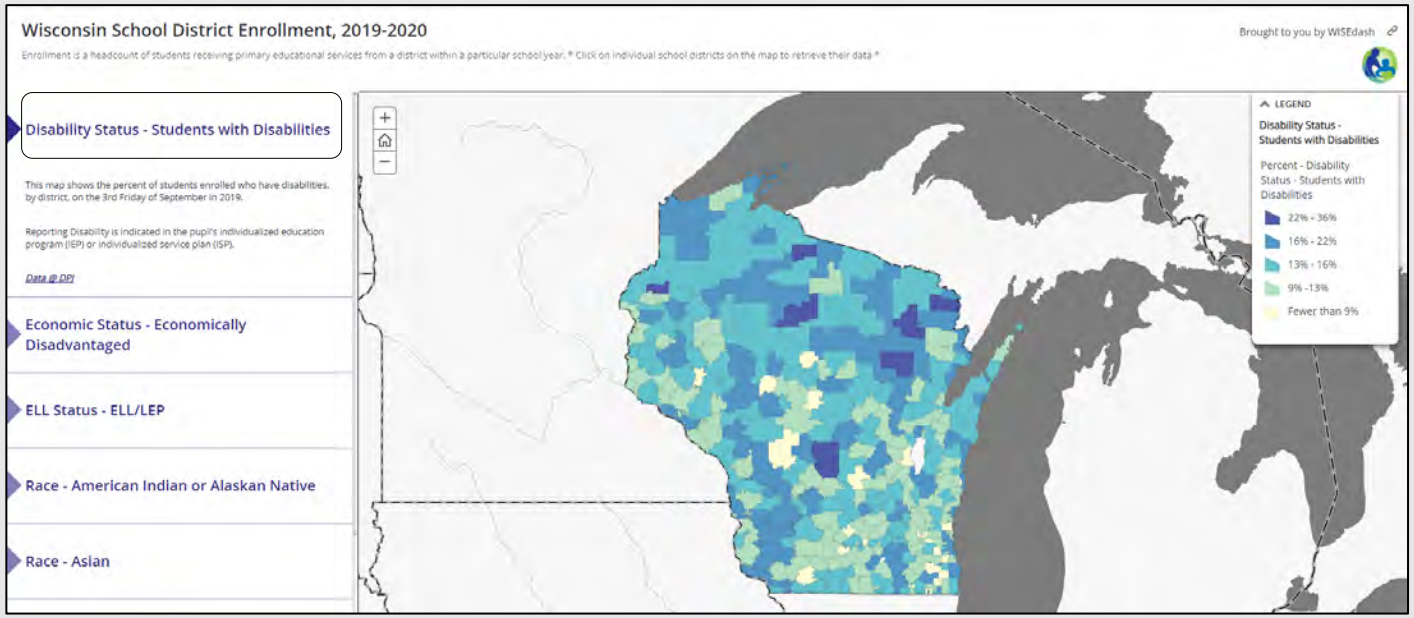
Wisconsin School System



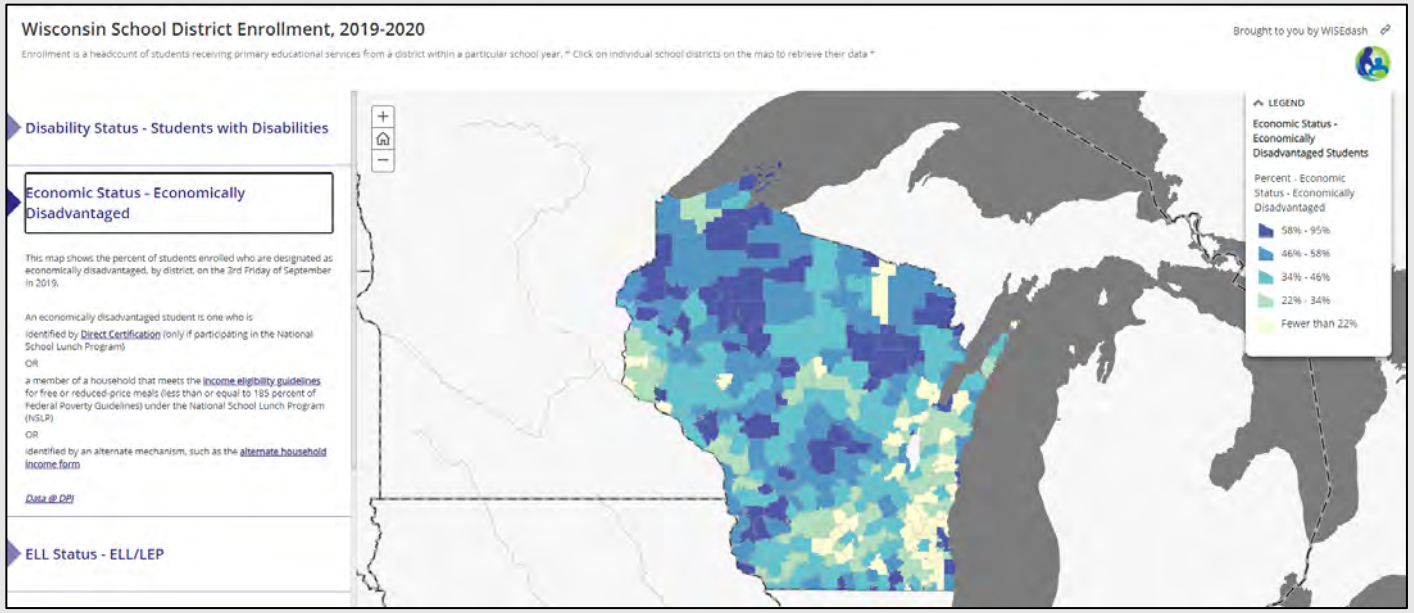
- 72 Counties
- 421 Public School Districts
- 2190 Public Schools
- 86% Enrollment in Public Schools
- Approximately 1 million children, 44% in rural communities
- Decentralized with mainly local district control

Variation across WI Districts

Disability Status

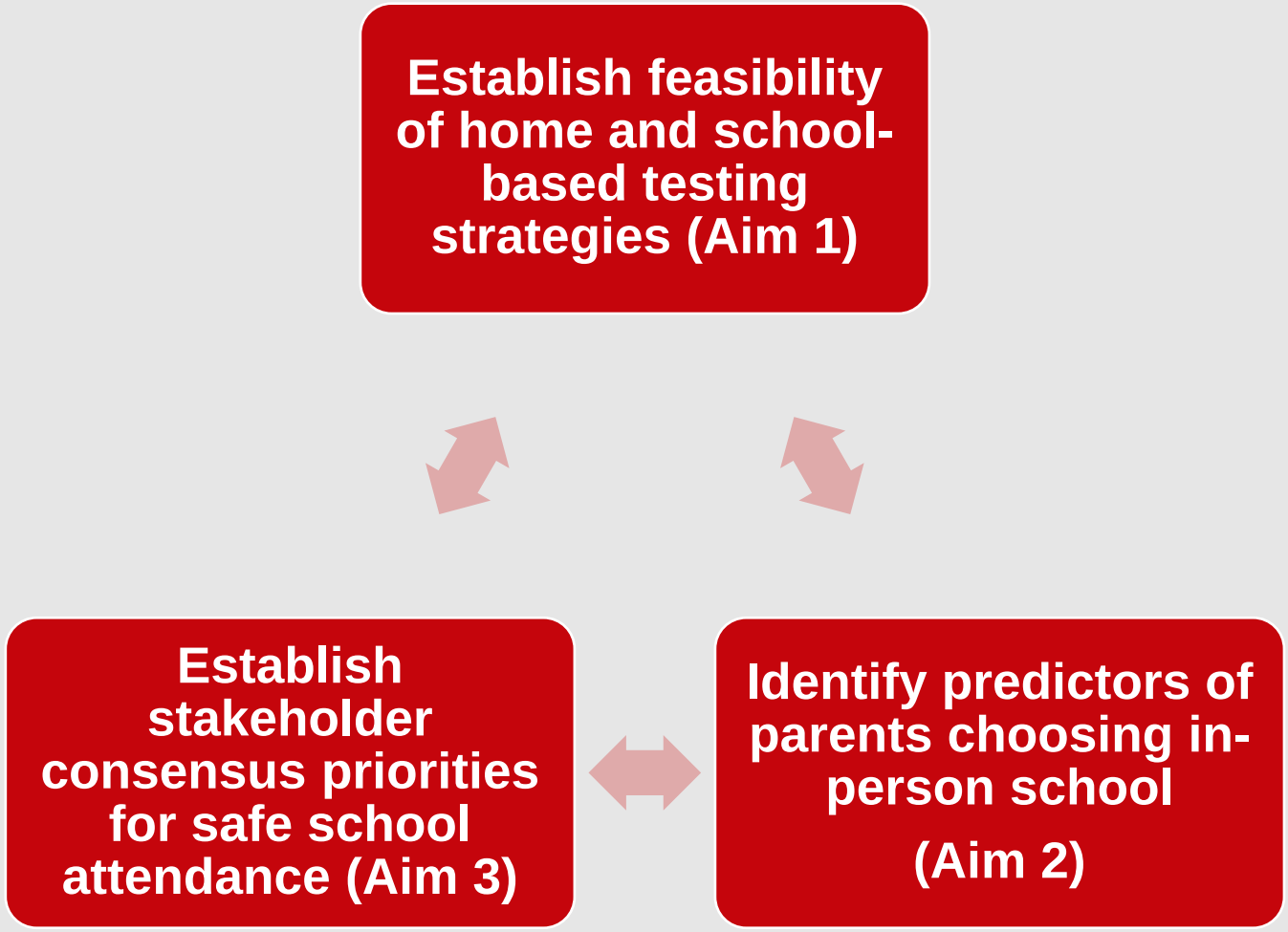


Economic Disadvantage

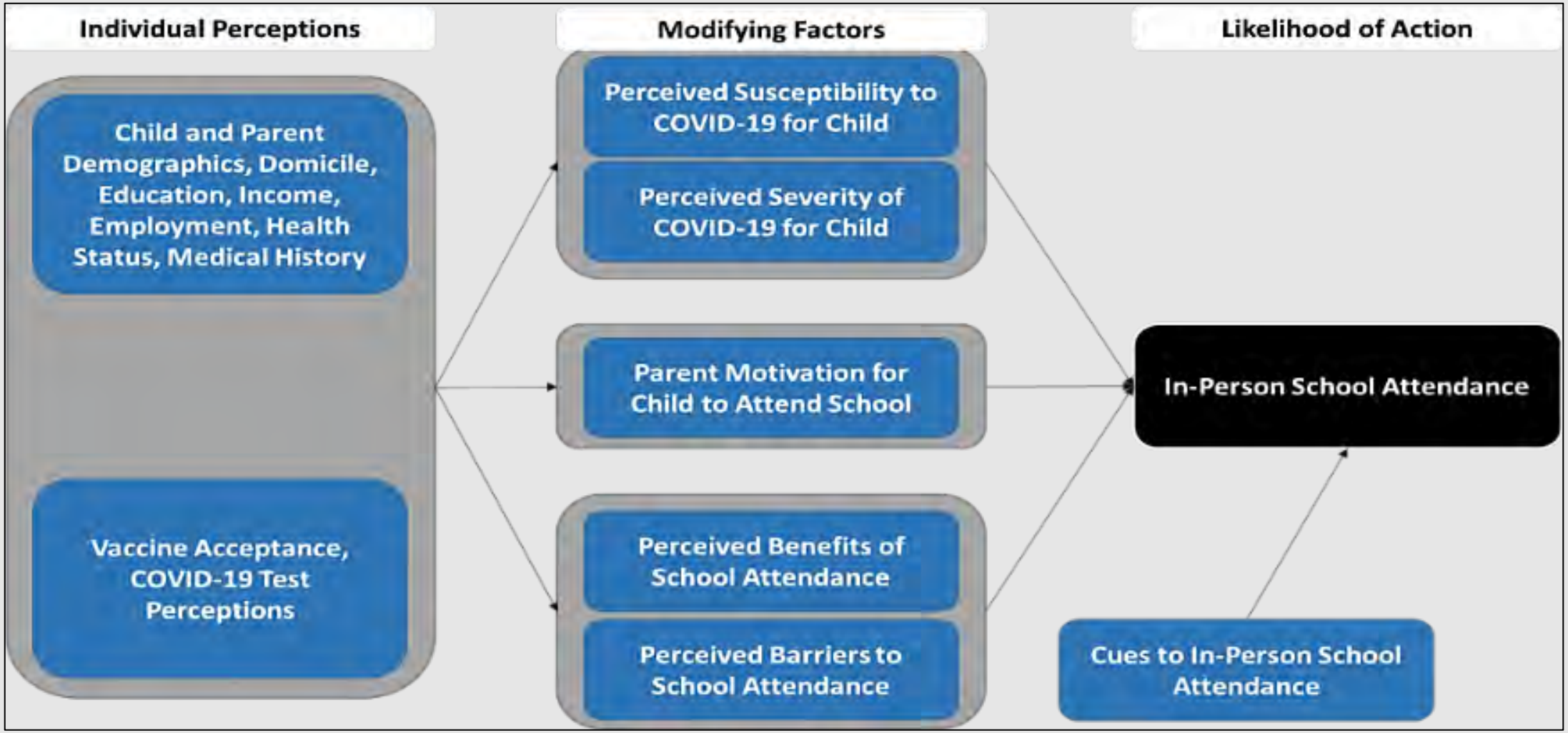


Research Objective

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



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.

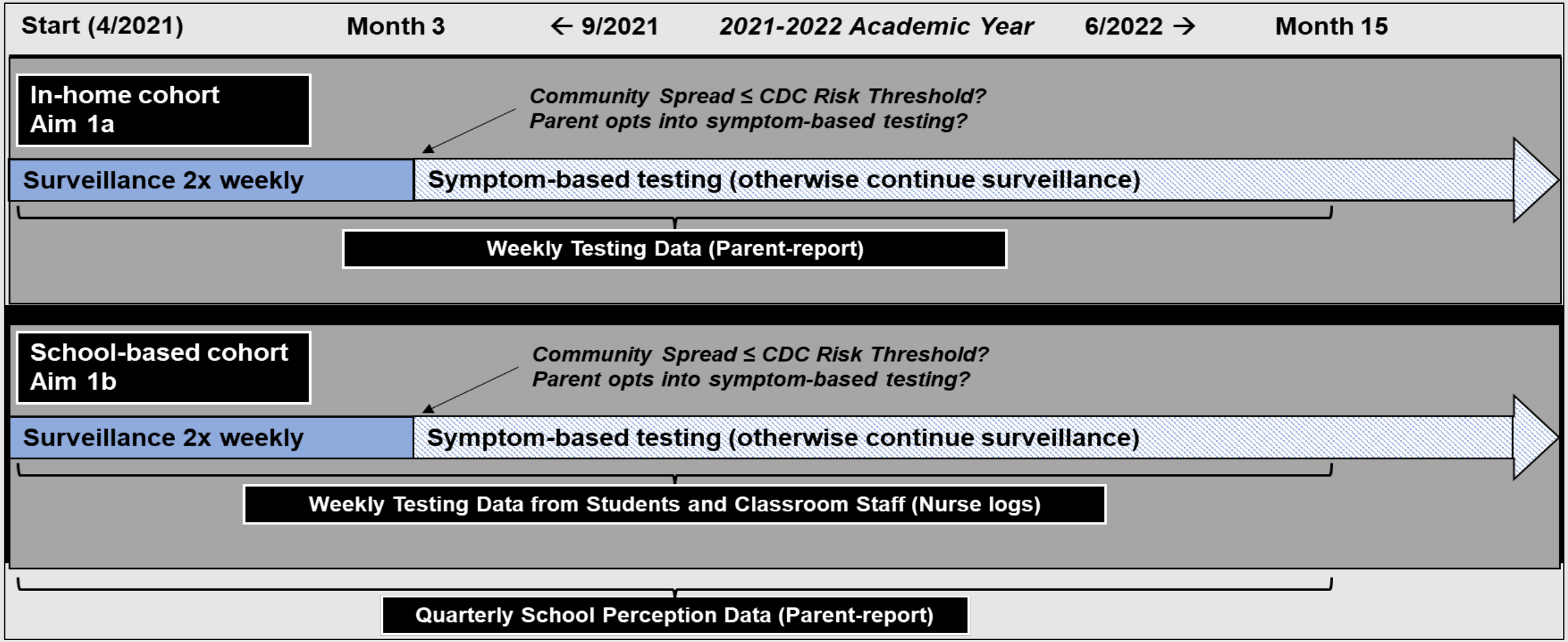
In-Home Cohort

- Recruited from UW Pediatric Complex Care Program

School Cohort

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

Aim 1 – Adaptive Design

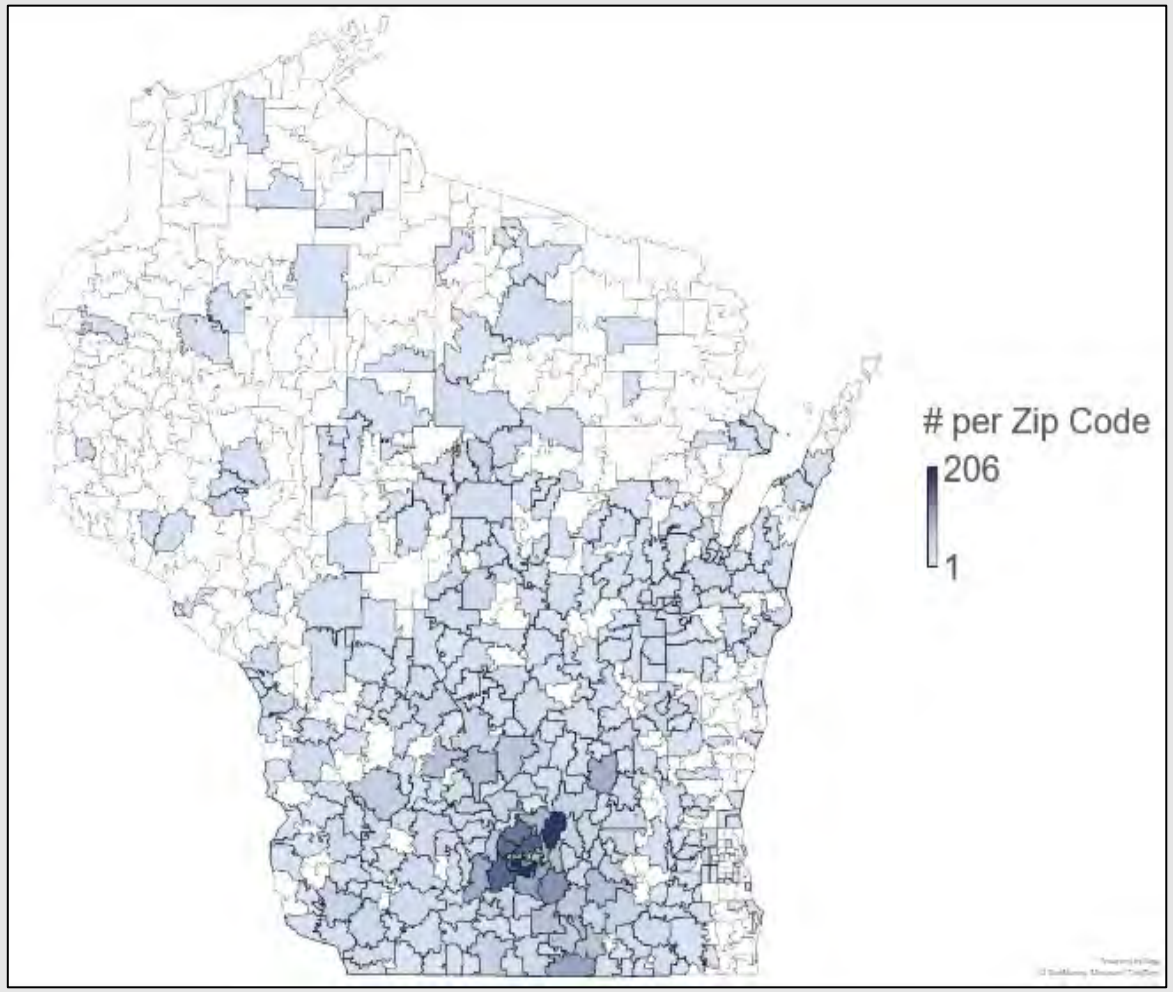


Aim 1 – Analysis Goals

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

Aim 2 – Return to School Decisions

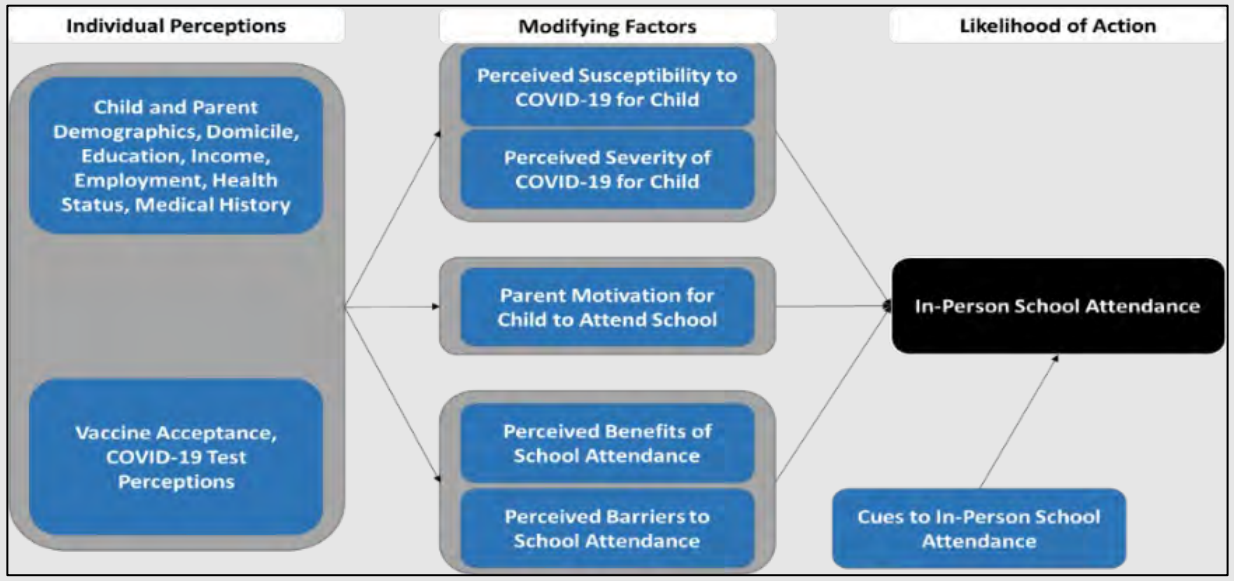
Identify parent perceptions predicting school attendance for WI CMC in 2021 and 2022



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

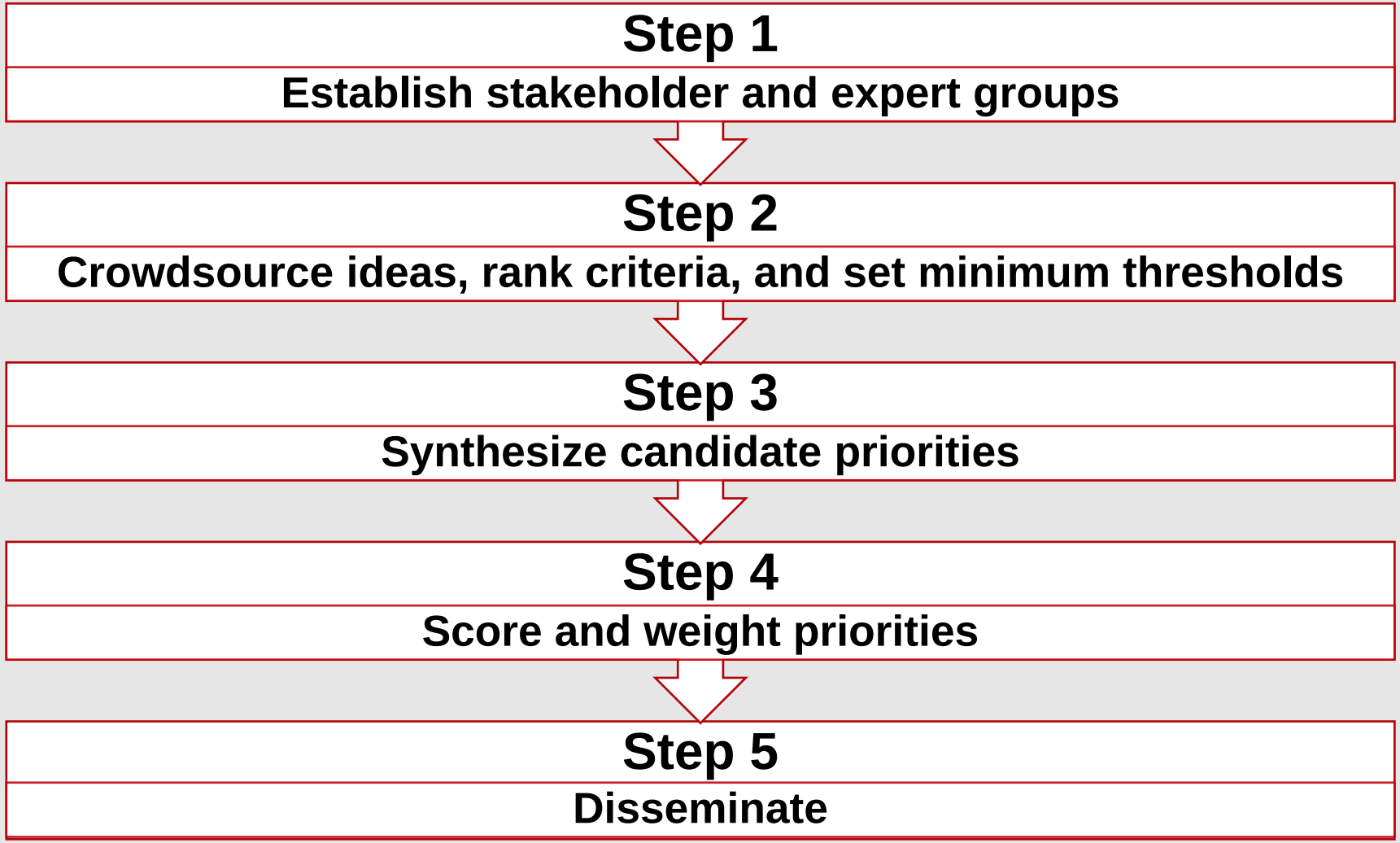


Analysis Goals

- 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)
Greg DeMuri (demuri@pediatrics.wisc.edu)
Gemma Warner (gwaner@pediatrics.wisc.edu)

Investigator

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

NICHD, Washington University; Kennedy Krieger Institute

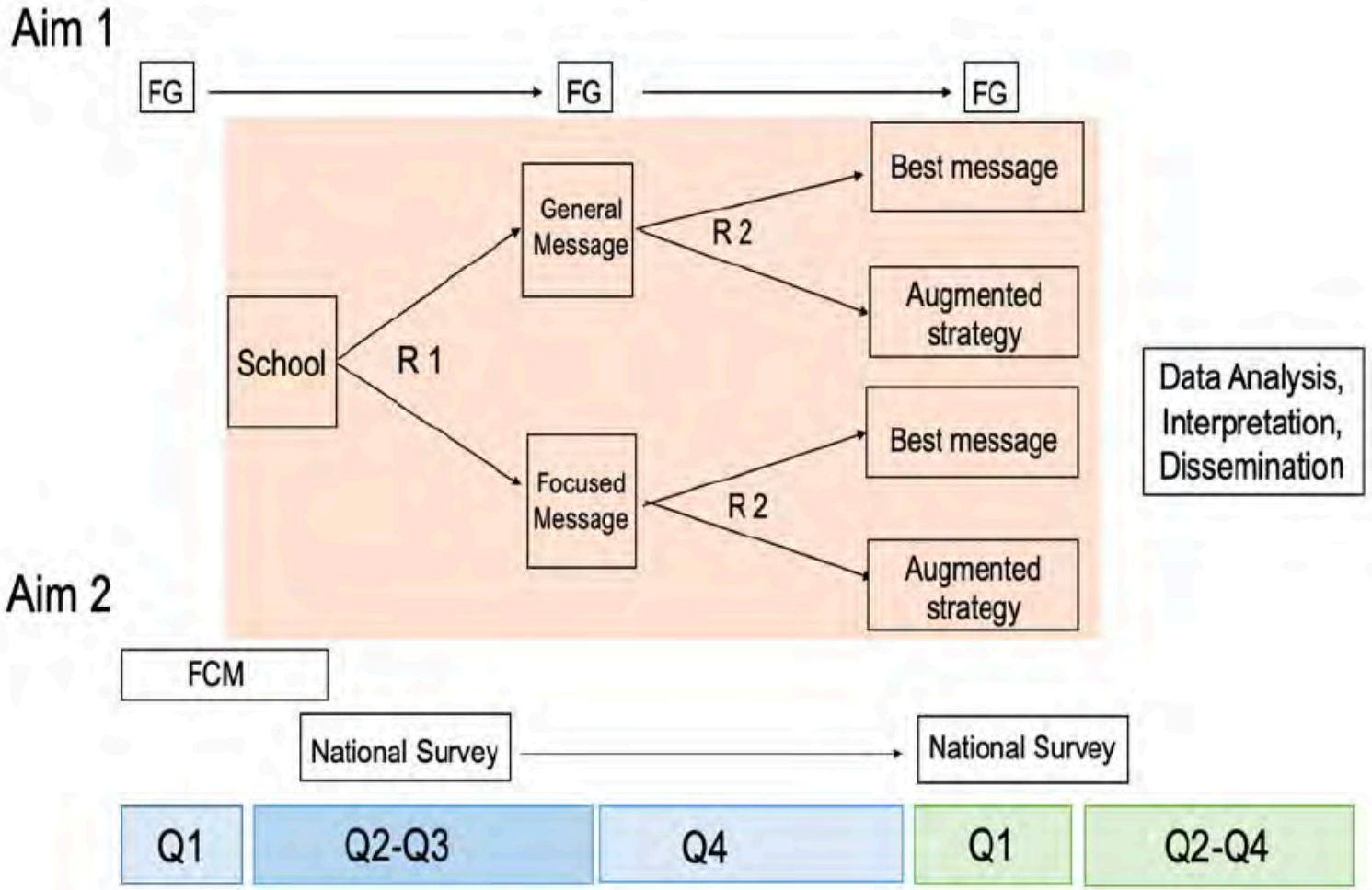
Washington University Intellectual and Developmental Disabilities Research Center and Kennedy Krieger Institute Safe Return to School (1OT2HD107556-01)

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 **M**essaging for S**P**eci**A**l **S**chool Di**S**trict **T**esting



Special School District of St Louis County

COMPASS-T

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

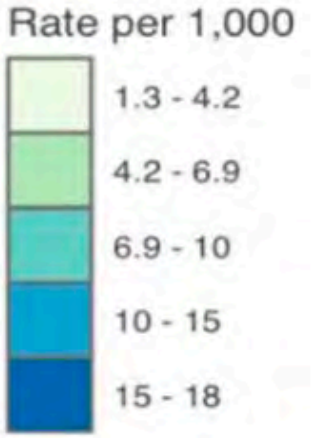
RADx-UP P50HD103525-01S1

IDDRC Washington University in St. Louis — Intellectual and Developmental Disabilities Research Center

COVID-19 **M**essaging for S**P**eci**A**l **S**chool Di**S**trict **T**esting

partners for student success

SSD



COMPASS-T

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%)
Total	909

RADx-UP P50HD103525-01S1

SARS-CoV-2 diagnostic test developed at Washington University

BSL2 Environment

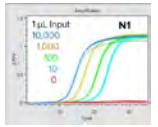
Rack tubes for de-capping and re-capping

Collection into 2D barcoded tube

Robotic transfer of plate 1 to plate 2 for STA (Pre-amplification Step)

tubes to plates
tivation

Remainder of Fluidigm workflow is unchanged

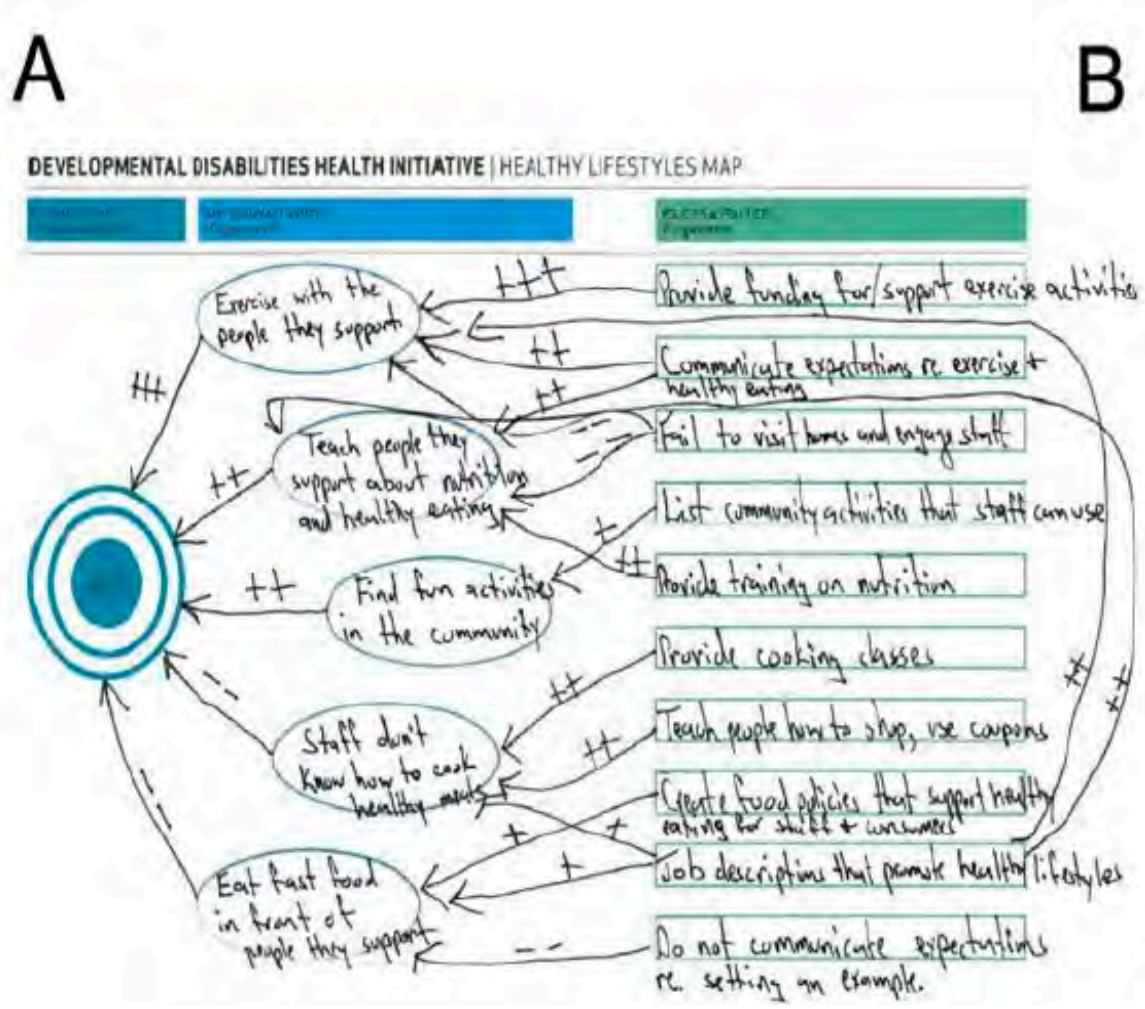


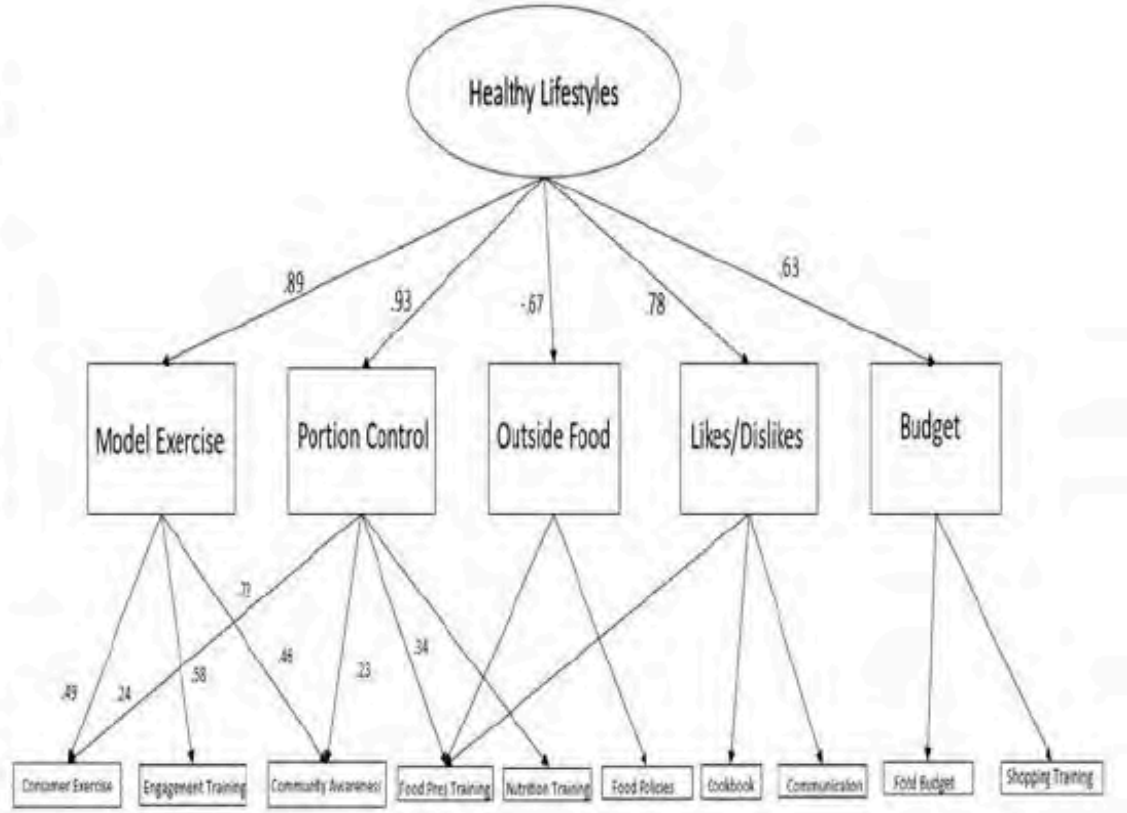
Sample Name	IFC Inlet Location	N1	N2	RNase P	Interpretation
G023	S001	+	+	+	Positive
G032	S002	+	+	+	Positive
G042	S003	+	+	+	Positive
G070	S006	-	-	+	Negative
G058	S005	-	-	+	Negative
G050	S004	-	-	+	Negative
G079	S013	+	+	+	Positive
G095	S014	-	-	+	Negative

- 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

Genome Technology Access Center
@ MCDONNELL GENOME INSTITUTE

Fuzzy cognitive mapping of COVID-19 decision-making





National Survey to Assess COVID-19 Impact and Mitigation Strategies

Table 3: Community Partners Who Will Distribute IDD Focused COVID-19 Survey	
Stakeholder	**Description**
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 childre n 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 Commun ity 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 Adm inistration 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

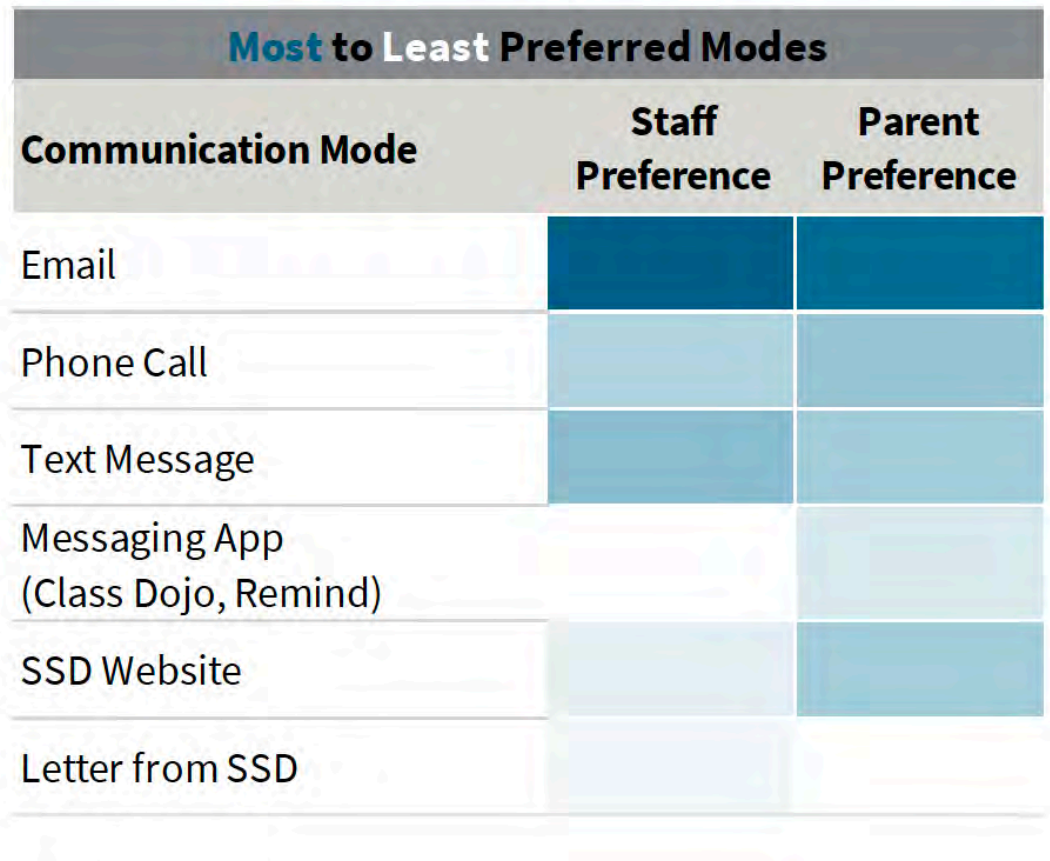
1. Challenges implementing social hygiene or prevention strategies
2. Challenges implementing quarantining and/or isolation practices
3. At higher risk of having severe complications

Who are trusted sources of information?

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

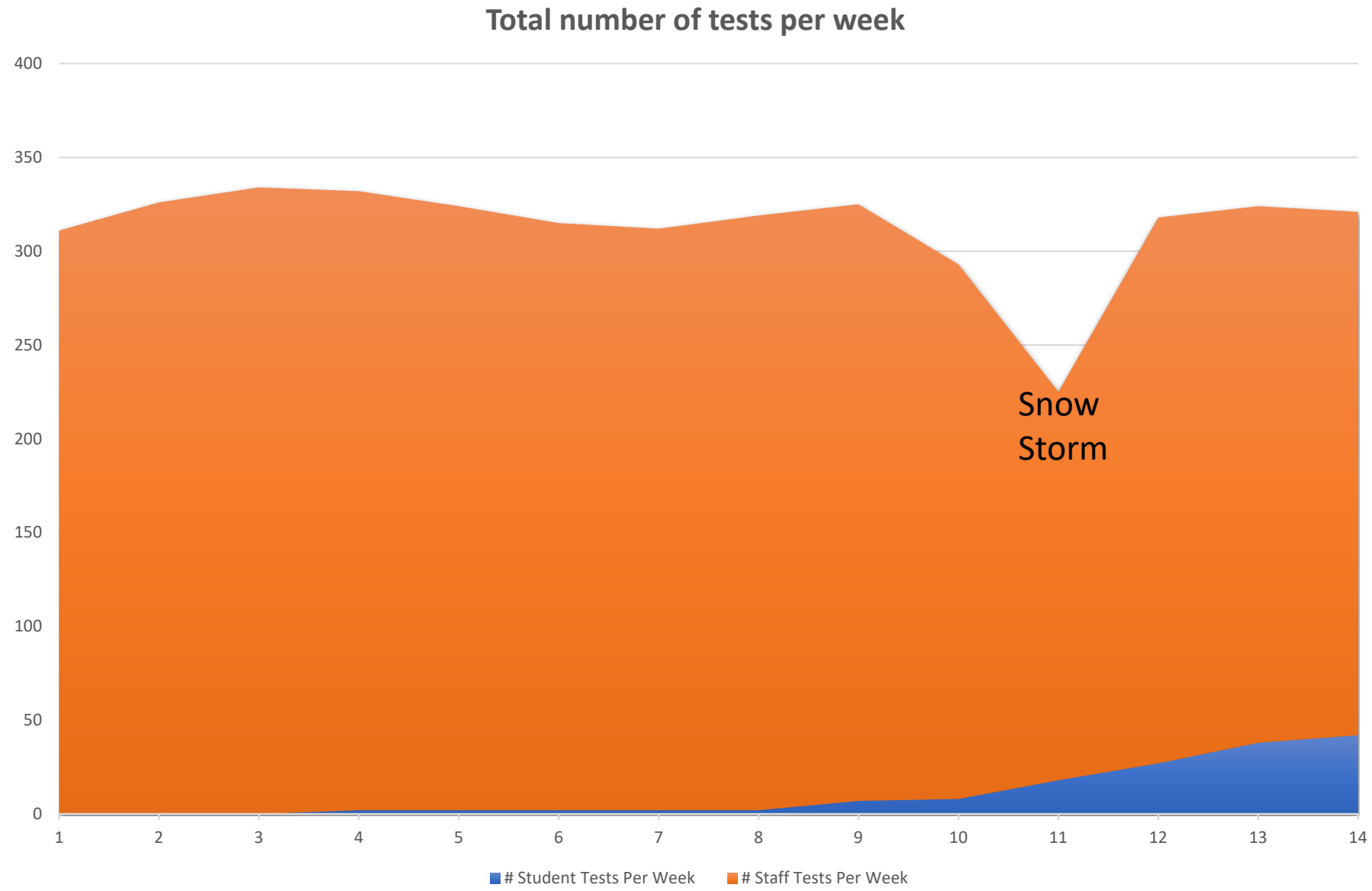
General COVID info: CDC, primary care physicians, and health professionals

COVID test results: Washington University research team

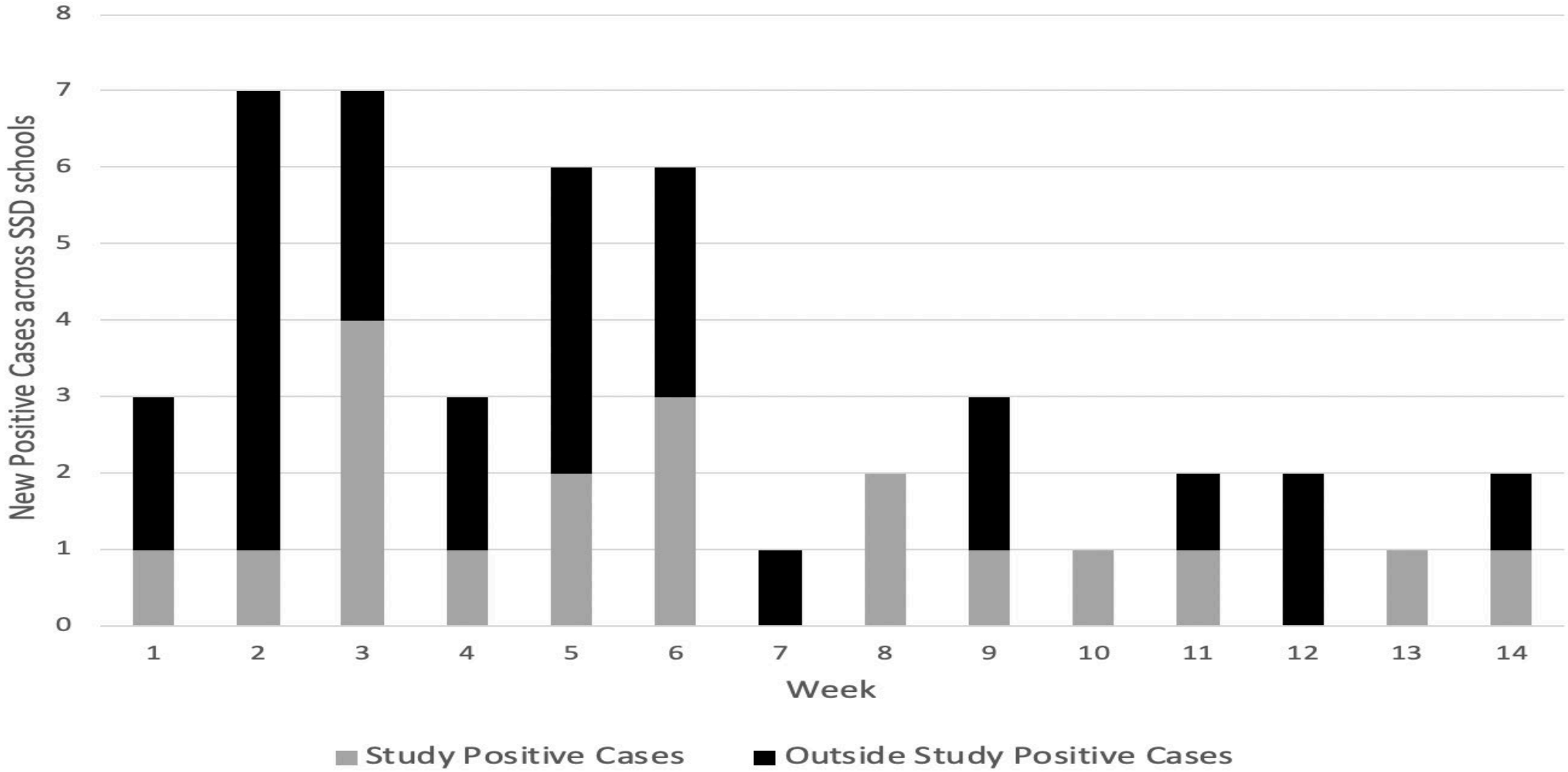


Staff and student SARS-CoV-2 surveillance testing volume

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



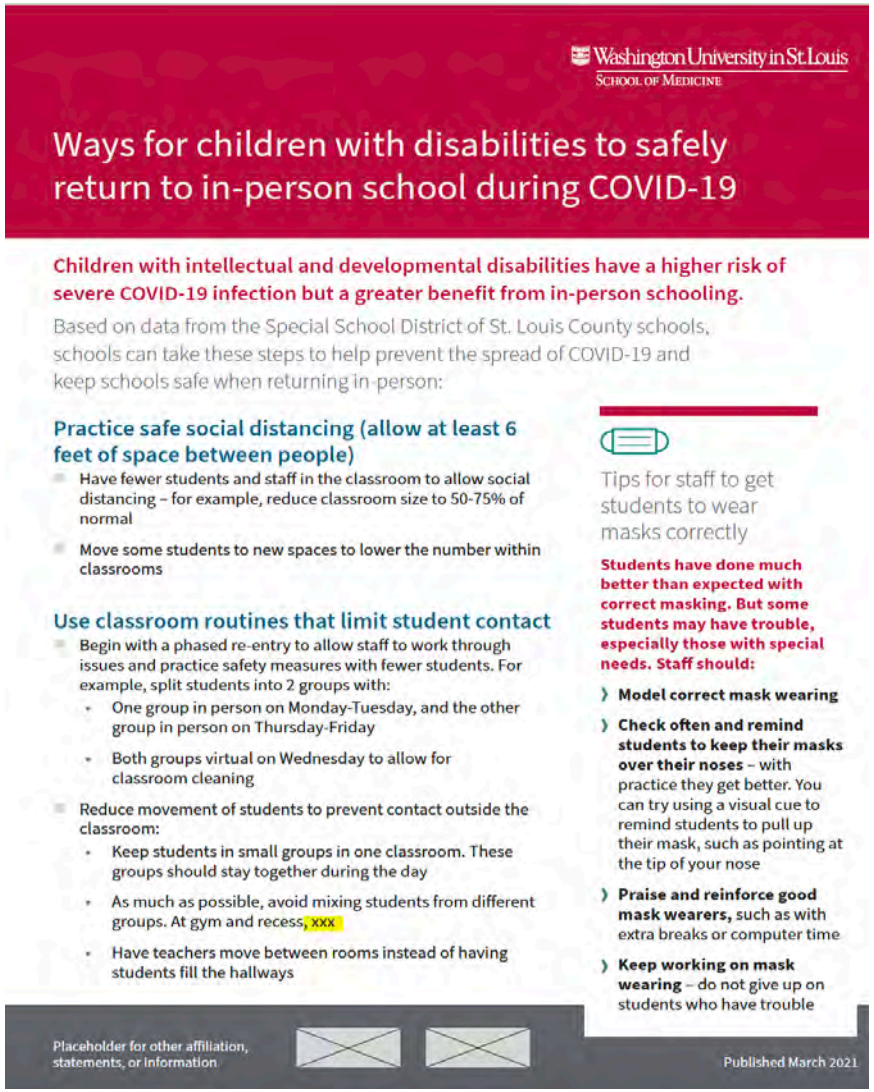
SARS-CoV-2 test positivity among school staff participants



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



Washington University in St. Louis
School of Medicine

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

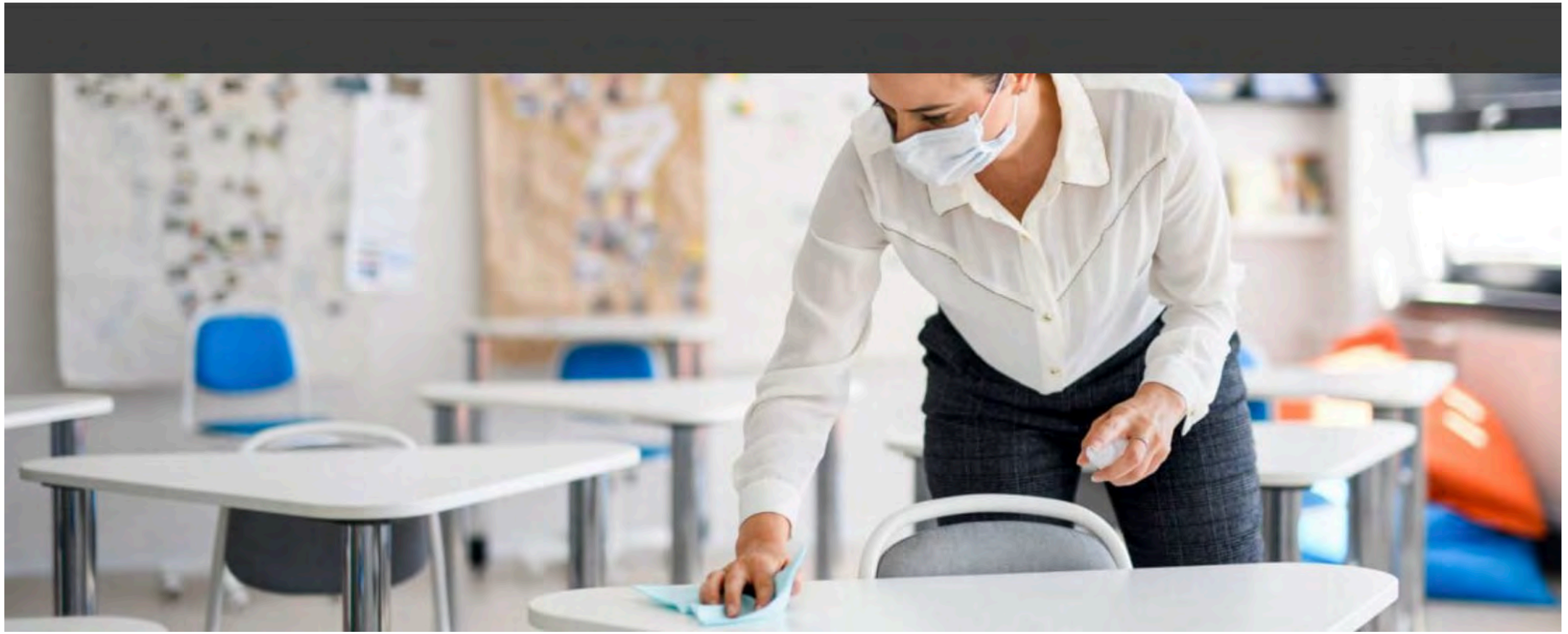
Placeholder for other affiliation, statements, or information

Published March 2021

https://sites.wustl.edu/safereturn/

Washington University School of Medicine in St. Louis

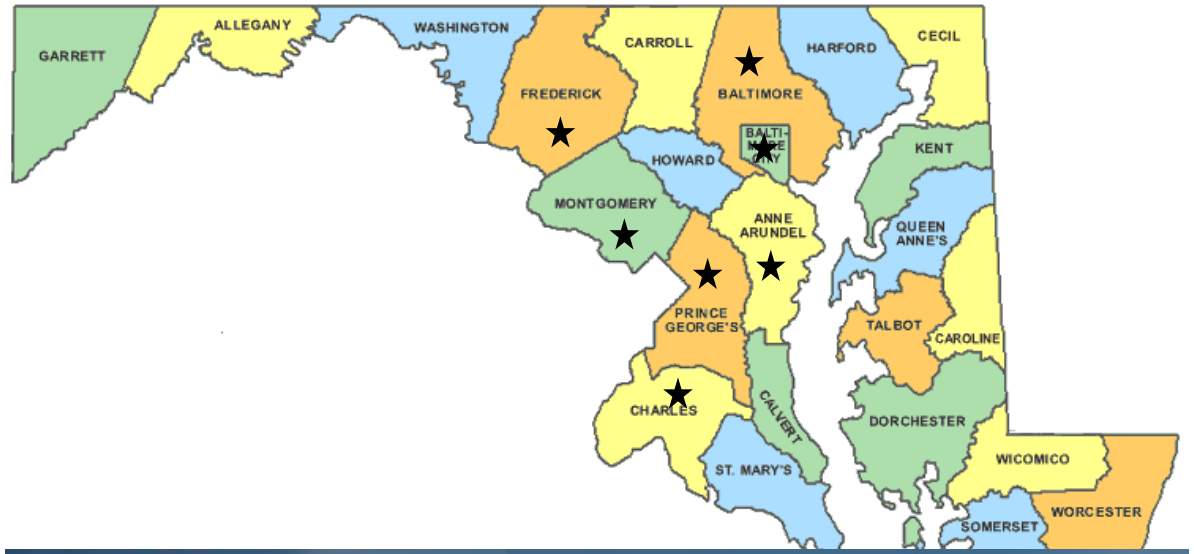
Safe return to school for all



https://sites.wustl.edu/safereturn/

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:

Luther G. Kalb, PhD, Kennedy Krieger Institute, Baltimore, MD
Linda S. Myers, EdD, Kennedy Krieger Institute, Baltimore, MD
Aaron Milstone, MD Johns Hopkins University, Baltimore MD
Anna Sick-Samuels, MD, Johns Hopkins University, Baltimore, MD
Bradley L. Schlaggar, MD, PhD, Kennedy Krieger Institute, Baltimore, MD

John N. Constantino, MD, Washington University School of Medicine, St. Louis, MO
Victor B. Brodskey, MD, Washington University School of Medicine, St. Louis, MO
Julie A. Neidich, MD, Washington University School of Medicine, St. Louis, MO
Albert M. Lai, PhD, Institute for Informatics, Washington University School of Medicine, St. Louis, MO
Brett B. Maricque, PhD, McDonnell Genome Institute, Washington University School of Medicine, St. Louis, MO
Stephanie A. Fritz, MD, MSCI, Washington University School of Medicine, St. Louis, MO
Esther Lu, PhD, Washington University School of Medicine, St. Louis, MO
Virginia R. McKay, PhD, Brown School of Social Work, Washington University in St. Louis, St. Louis, MO
Stephanie M. Morris, MD, Washington University School of Medicine, St. Louis, MO
Byron J. Powell, PhD, Brown School of Social Work, Washington University in St. Louis, St. Louis, MO
Nancy B. Mueller, MPH, Brown School Evaluation Center, Washington University in St. Louis, St. Louis, MO
James M. Dubois, PhD, Institute for Public Health, Brown School of Social Work, Washington University in St. Louis, St. Louis, MO
Joyce E. Balls-Berry, PhD, Institute of Clinical and Translational Sciences, Washington University School of Medicine, St. Louis, MO
Charlene A. Caburnay, PhD, MPH, Health Communication Research Laboratory, Brown School of Social Work, Washington University in St. Louis, St. Louis, MO

George S. Gotto IV, PhD, University of Missouri-Kansas City

Melissa Parisi, NICHD

Investigator

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

Safe Schools Project

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

JOHNS HOPKINS
CENTER FOR AMERICAN
INDIAN HEALTH

RADx-UP

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.

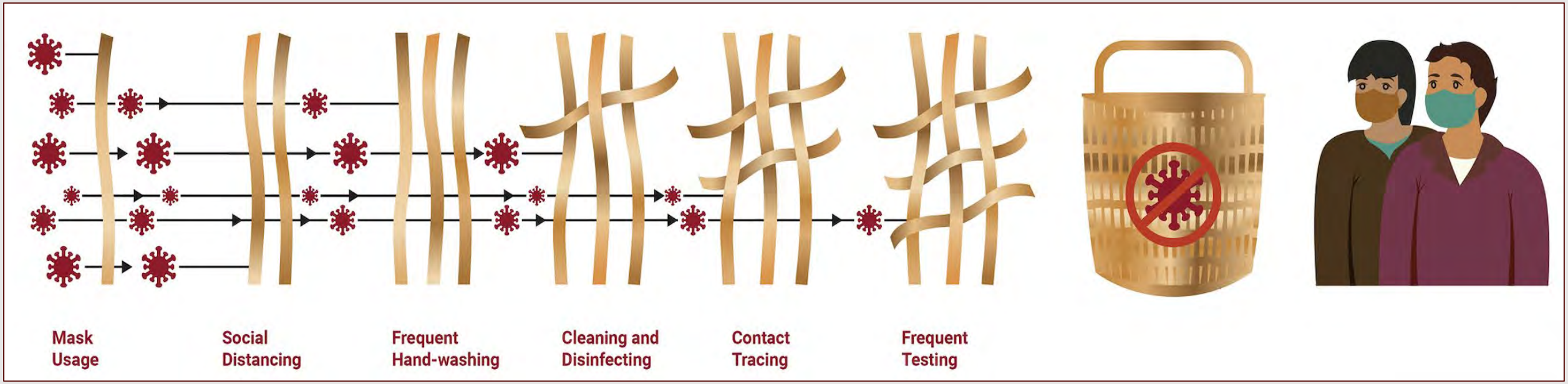
Significance

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



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?

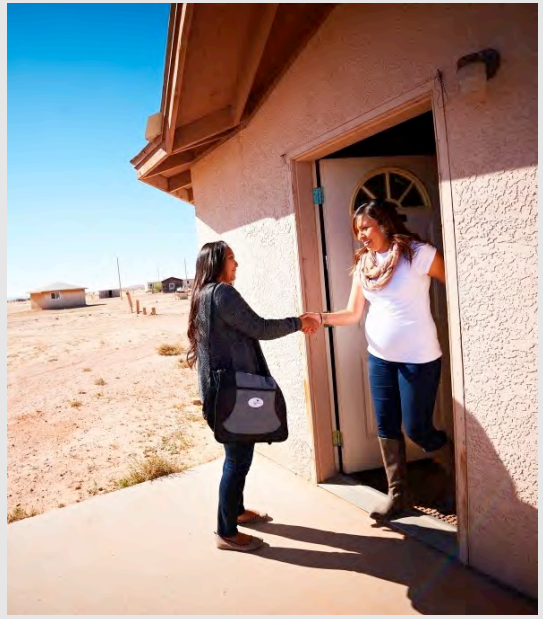
3. What are the educational, social, emotional, physical and mental health impacts of returning to in-person learning for Native American youth ages 3-16 years?

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



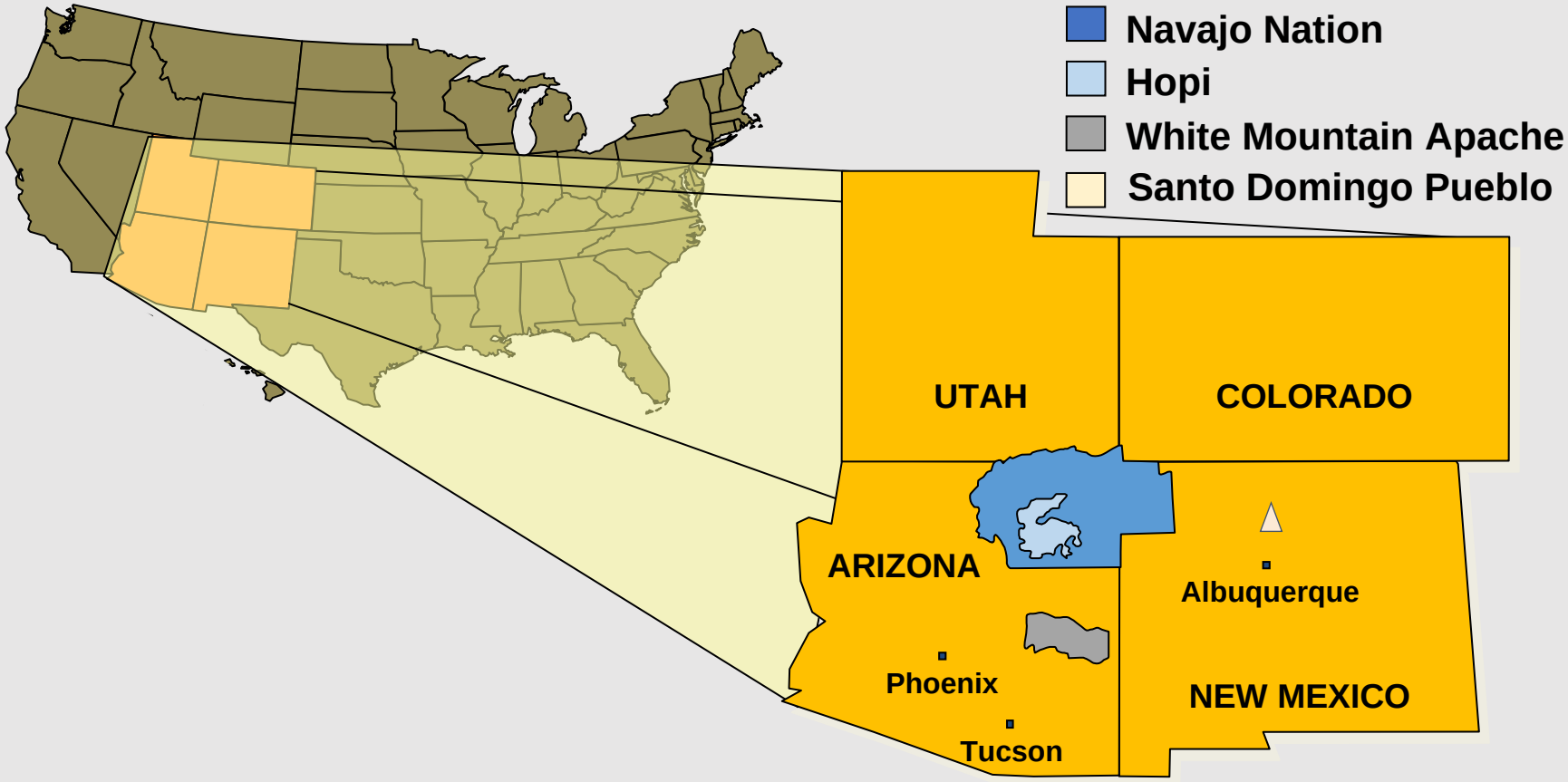
JHCAIH Offices Serving Reservation Communities

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

UNIVERSITY of WASHINGTON

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

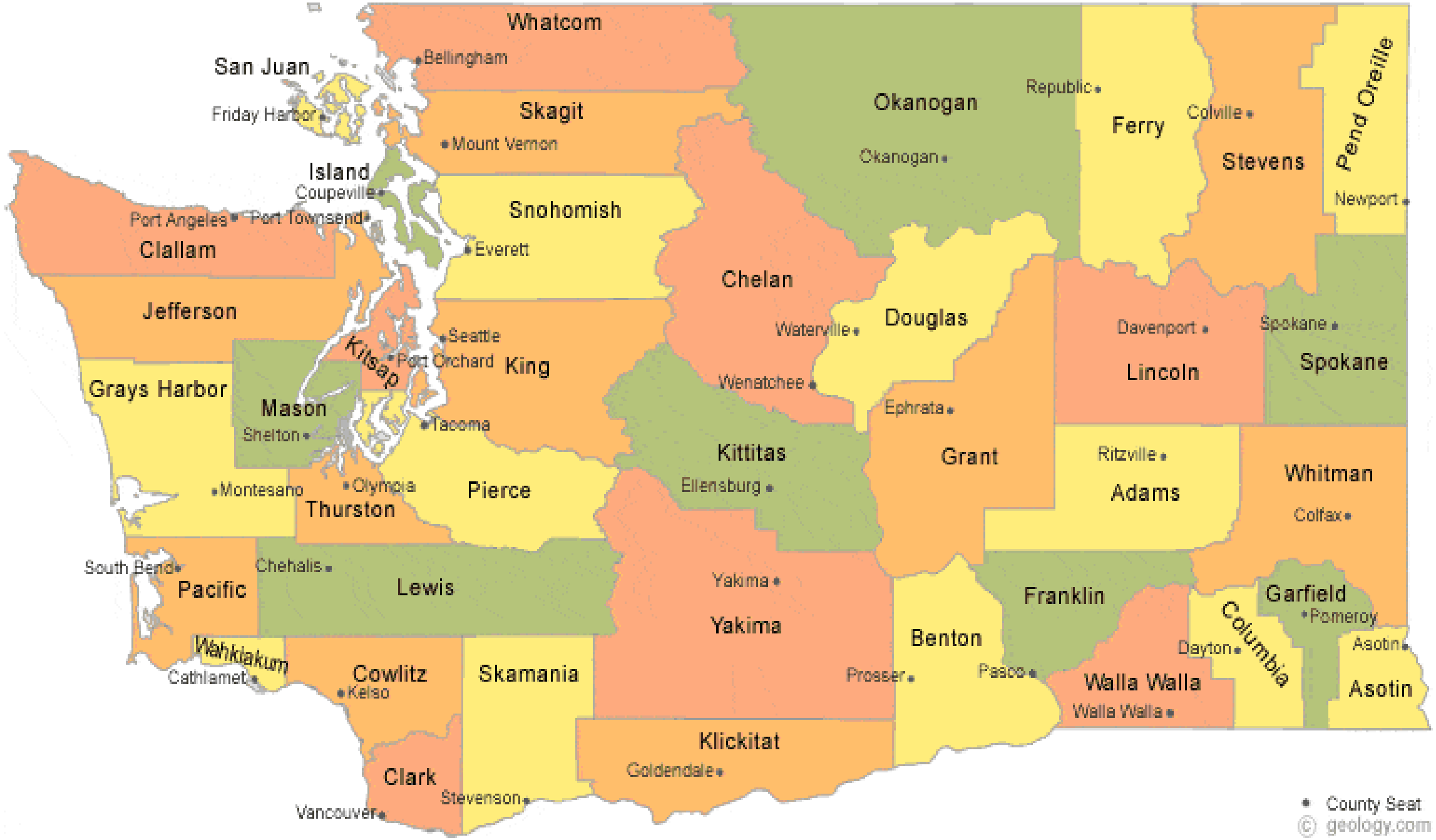
1. increase access to SARS-CoV-2 testing to Latino students in rural agricultural communities
2. develop a manual on social, ethical and behavioral concerns and mitigation strategies for students safe return to school, COVID-19 testing hesitancy, and vaccination
3. produce a safety-focused and community-driven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


Whatcom
Bellingham
San Juan
Friday Harbor
Skagit
Mount Vernon
Island
Coupeville
Snohomish
Everett
Port Angeles
Port Townsend
Clallam
Jefferson
Seattle
Kitsap
Port Orchard
King
Grays Harbor
Mason
Shelton
Tacoma
Montesano
Olympia
Thurston
Pierce
South Bend
Chehalis
Pacific
Lewis
Wahkiakum
Cathlamet
Cowlitz
Kelso
Skamania
Clark
Vancouver
Stevenson
Okanogan
Okanogan
Republic
Ferry
Colville
Stevens
Pend Oreille
Newport
Chelan
Waterville
Douglas
Wenatchee
Ephrata
Grant
Davenport
Lincoln
Spokane
Spokane
Kittitas
Ellensburg
Ritzville
Adams
Whitman
Colfax
Yakima
Yakima
Franklin
Garfield
Pomeroy
Benton
Prosser
Pasco
Dayton
Columbia
Asotin
Asotin
Walla Walla
Walla Walla
Klickitat
Goldendale
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

CDCC Overview

Beda Jean-Francois, Ph.D.

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

Michael Cohen-Wolkowiez, M.D., Ph.D.

CDCC, Duke University

RADx-UP Coordination and Data Collection Center (CDCC)

April 2021

Duke Clinical Research Institute

UNC SCHOOL OF MEDICINE Center for Health Equity Research

RADXUP

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

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

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

BUDGET
$500 Million

RADx Radical (RADx-rad)

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

BUDGET
$200 Million

This is us

RADXUP

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-Wolkowiez, MD, PhD
Duke Clinical Research Institute (DCRI)

Giselle Corbie-Smith, 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

Renee Leverty, 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

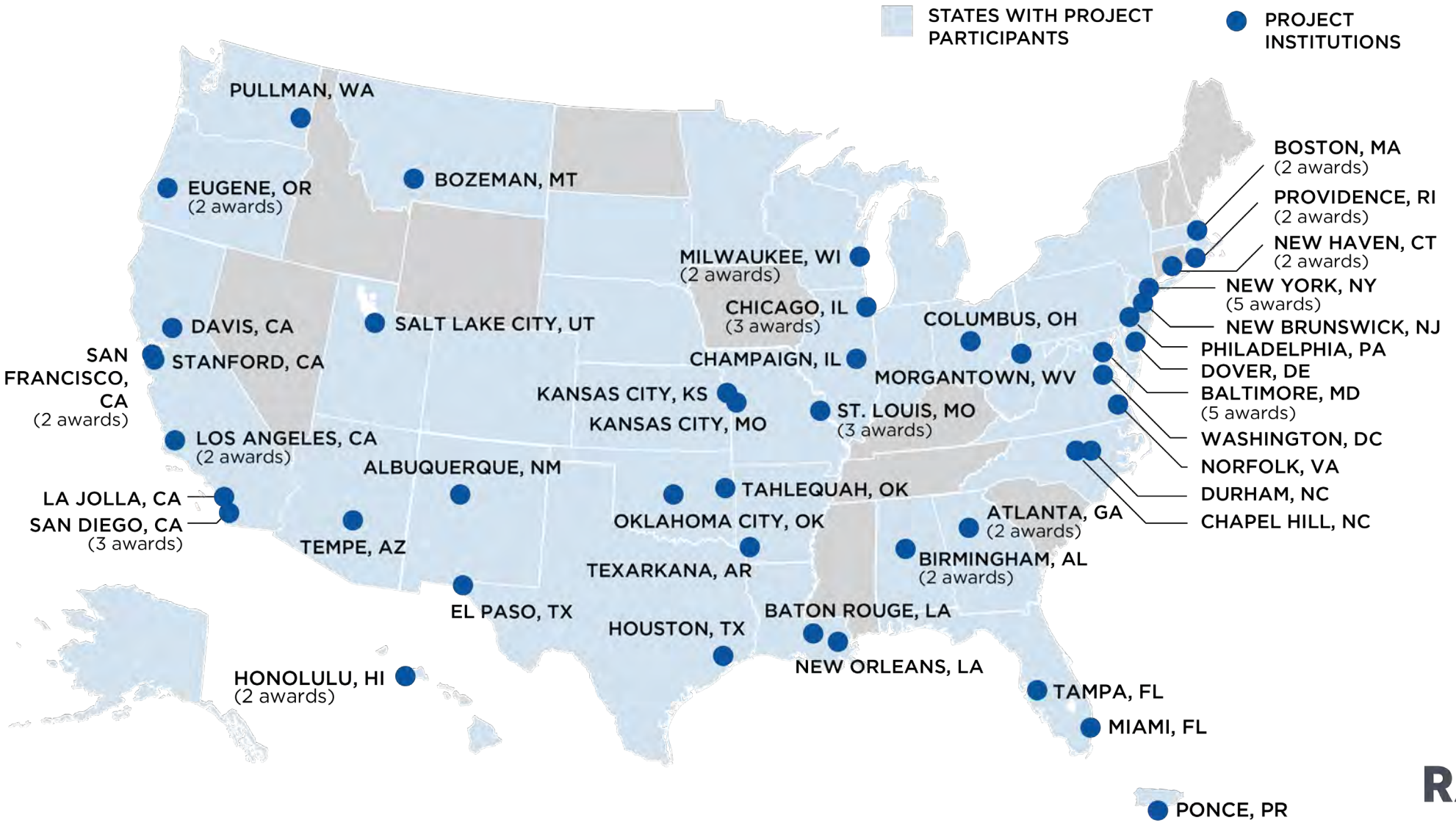
Erich Huang, MD, PhD
Duke University

Duke Clinical Research Institute

UNC SCHOOL OF MEDICINE
Center for Health Equity Research

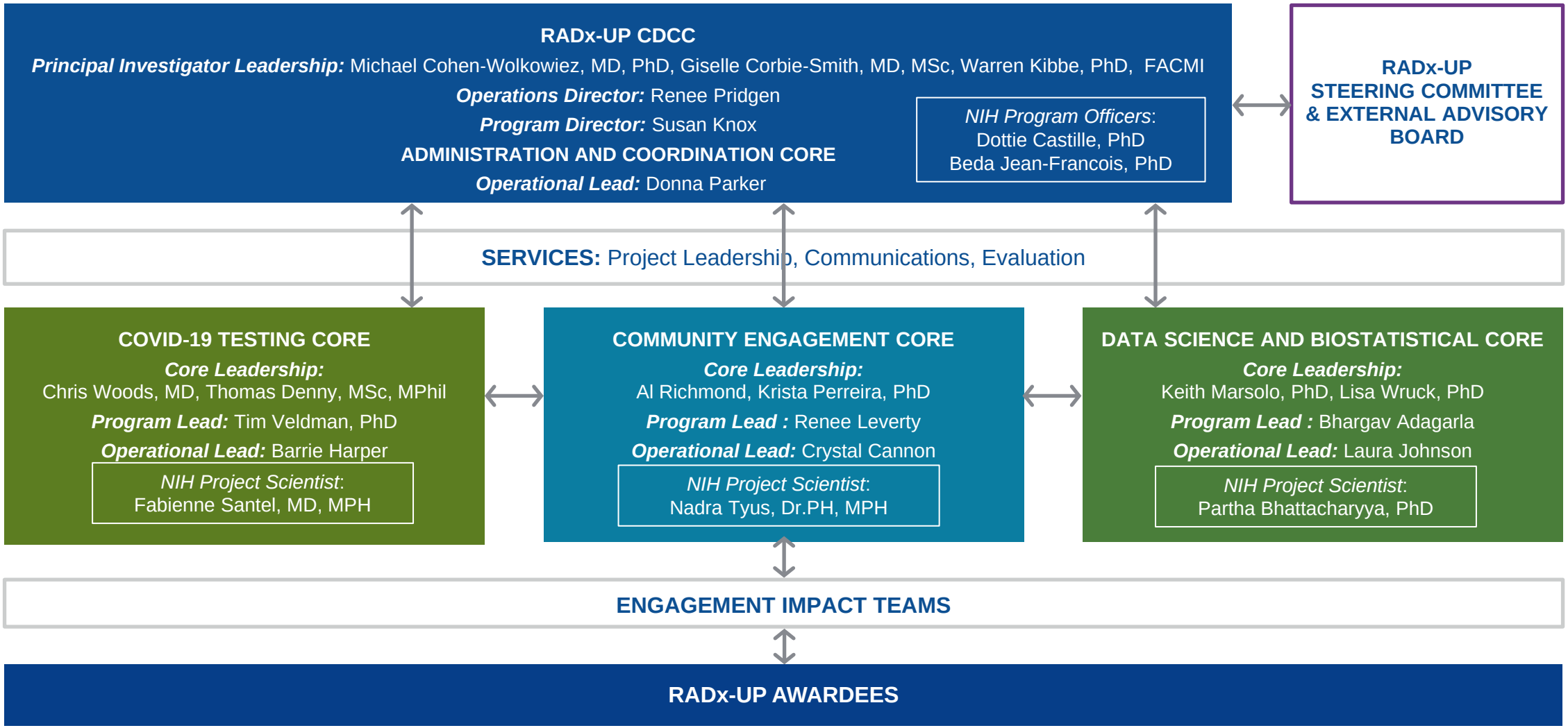
RADXUP

Organizations Participating in RADx-UP



RADXUP

NIH


RADx-UP CDCC
Principal Investigator Leadership: Michael Cohen-Wolkowiez, MD, PhD, Giselle Corbie-Smith, MD, MSc, Warren Kibbe, PhD, FACMI
Operations Director: Renee Pridgen
Program Director: Susan Knox
ADMINISTRATION AND COORDINATION CORE
Operational Lead: Donna Parker
NIH Program Officers:
Dottie Castille, PhD
Beda Jean-Francois, PhD
RADx-UP STEERING COMMITTEE & EXTERNAL ADVISORY BOARD
SERVICES: Project Leadership, Communications, Evaluation
COVID-19 TESTING CORE
Core Leadership:
Chris Woods, MD, Thomas Denny, MSc, MPhil
Program Lead: Tim Veldman, PhD
Operational Lead: Barrie Harper
NIH Project Scientist:
Fabienne Santel, MD, MPH
COMMUNITY ENGAGEMENT CORE
Core Leadership:
Al Richmond, Krista Perreira, PhD
Program Lead : Renee Leverty
Operational Lead: Crystal Cannon
NIH Project Scientist:
Nadra Tyus, Dr.PH, MPH
DATA SCIENCE AND BIOSTATISTICAL CORE
Core Leadership:
Keith Marsolo, PhD, Lisa Wruck, PhD
Program Lead : Bhargav Adagarla
Operational Lead: Laura Johnson
NIH Project Scientist:
Partha Bhattacharyya, PhD
ENGAGEMENT IMPACT TEAMS
RADx-UP AWARDEES

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**

RADXUP

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

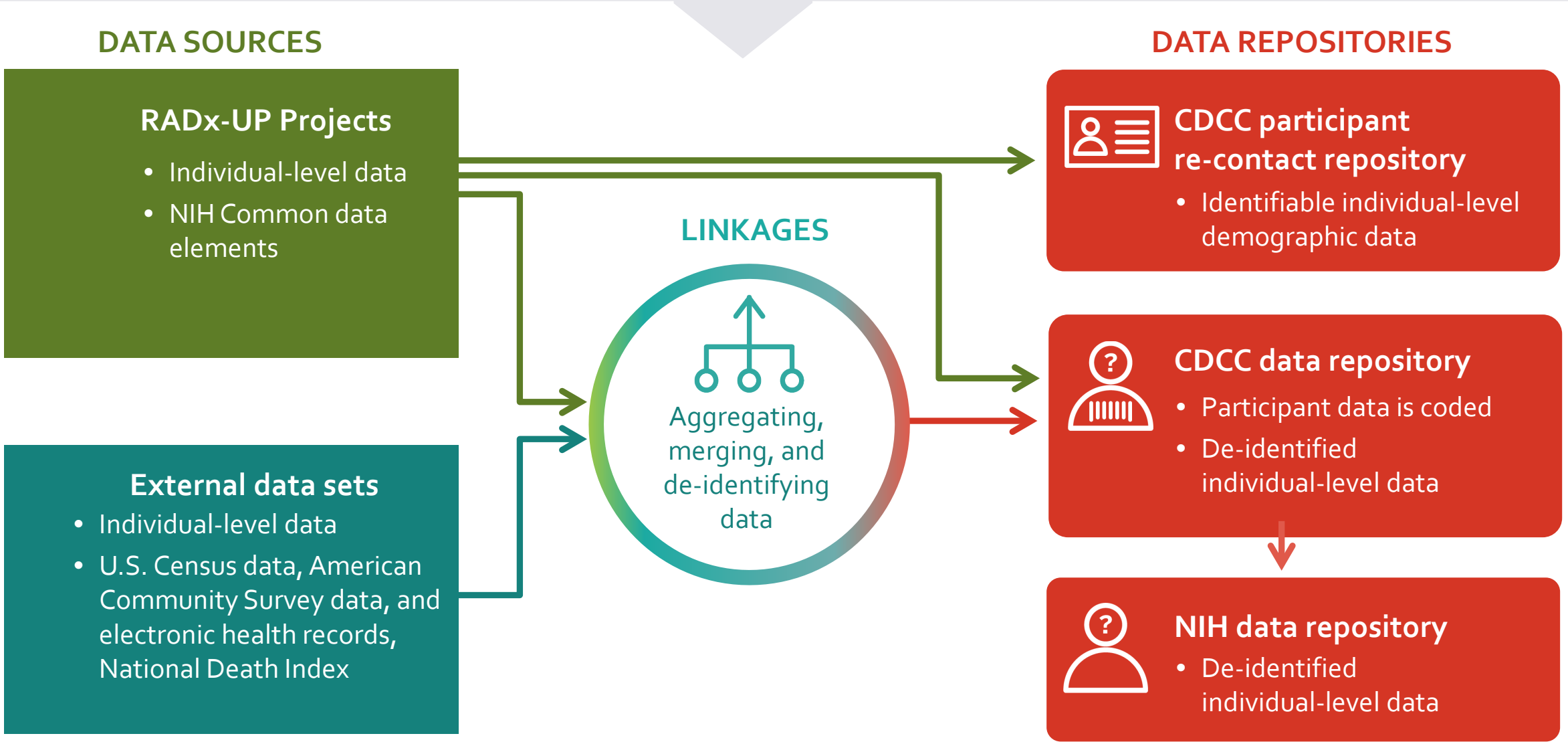
- Best practices
- Engagement Resource Library
- Equity Evidence Academy
- Community of Practice
- Community Collaboration Grants
- Working groups

DATA SCIENCE & BIOSTATISTICS

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

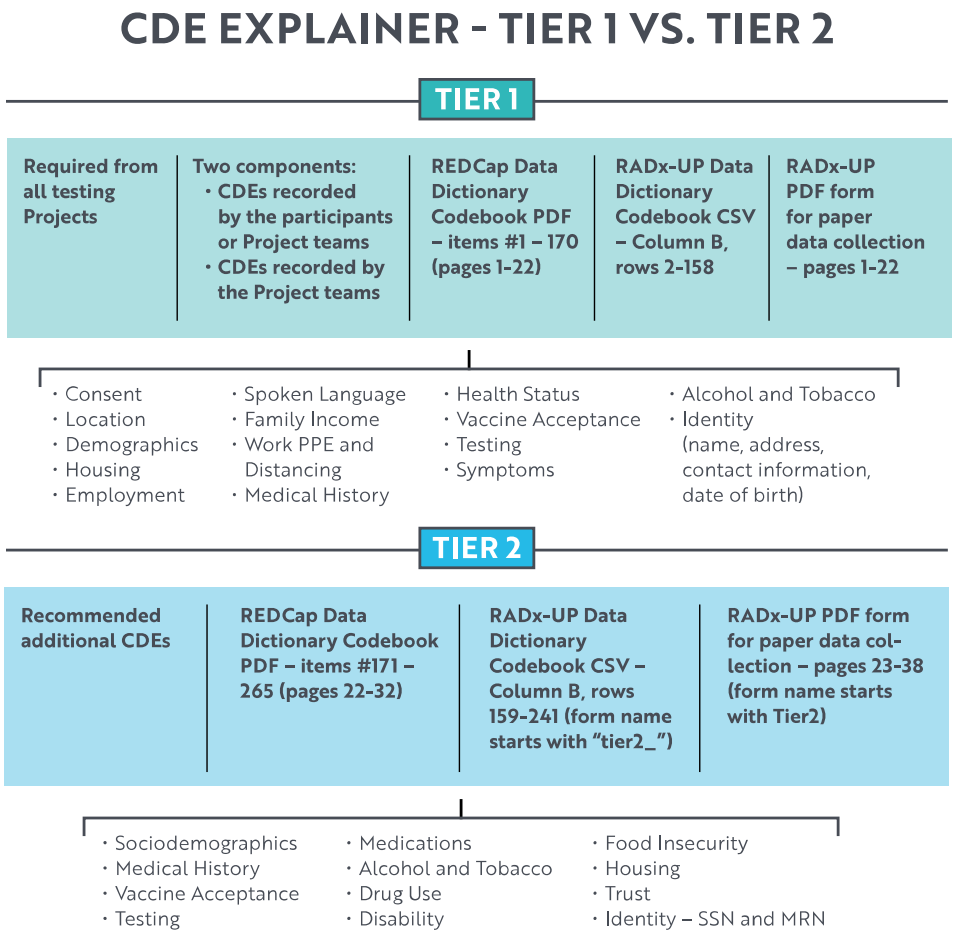
RADXUP

Data Flow

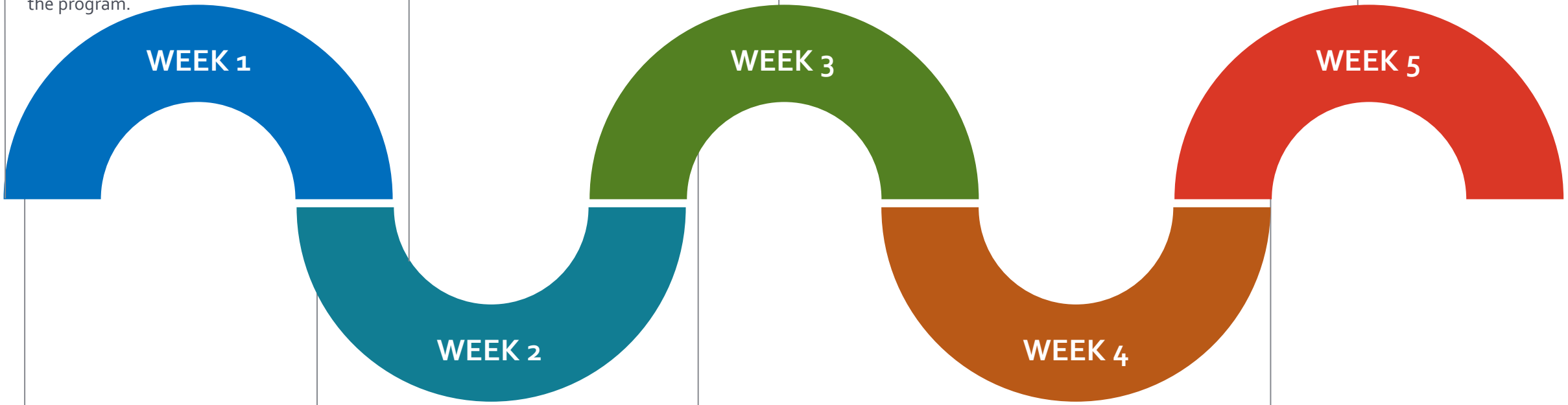

DATA SOURCES
RADx-UP Projects
• Individual-level data
• NIH Common data elements
External data sets
• Individual-level data
• U.S. Census data, American Community Survey data, and electronic health records, National Death Index
LINKAGES
Aggregating, merging, and de-identifying data
DATA REPOSITORIES
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



Typical RADx-UP Onboarding Timeline



Day 1
- Email from RADx-UP Coordination and Data Collection Center (CDCC) leadership welcoming you to the program.

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.

Day 8
- An invitation to complete the CDCC Intake Survey will be sent out through REDCap

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*

Day 15
- CDCC Intake Surveys are due.

Week 5
- EITs will begin holding initial meetings with new projects.

RADXUP

Thank you.

Please contact us with your questions and ideas:

RADx-UP-CDCC@duke.edu

RADXUP

radx-up.org

QUESTIONS & ANSWERS

Q&A / Discussion

Sonia Lee Ph.D.

Eunice Kennedy Shriver **National Institute of Child Health and Human Development (NICHD)**

THANK YOU!