

# RADx Underserved Populations (RADx-UP) Return to School August Workshop

August 9, 2021



# Agenda

| Topic  | Speaker   | Time                       |
|--|---|----------------------------|
| Welcome & Introductions                                | Dr. Alison Cernich  | 1:30pm                     |
| Overview of RADx-UP Initiative                         | Dr. Eliseo J. Pérez-Stable  | 1:35 pm                    |
| Overview of the Return to School Initiative            | Dr. Alison Cernich  | 1:40 pm                    |
| Phase II Overview of Projects                          | Dr. Sonia Lee   | 1:45 pm                    |
| COVID-19 and Children                                  | Dr. Shamez Ladhani  | 1:50 pm                    |
| HHS Partner Programs                                   | Angelica O'Conner (CDC)<br>Dr. Matthew Humbard (HHS)<br>Dr. Joseph Miller (HHS) | 2:15 pm                    |
| RADx-UP Coordination and Data Collection Center (CDCC) | Dr. Michael Cohen-Wolkowicz   | 2:45                       |
| Break  | All   | 3:00                       |
| Team Presentations                                     | Dr. Chris Lindsey   | 3:15 (15 minutes per team) |
| Closing Remarks  | Dr. Alison Cernich  | 5:15                       |

# RADx-UP Program



**Eliseo J. Pérez-Stable, M.D.**

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

# Rapid Acceleration of Diagnostics (RADx) Initiative

## **RADx Tech – \$908M\***

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

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

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

## **RADx Radical (RADx-rad) – \$187M**

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

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

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

## **Data Management Support – \$70M**

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

## **At-Home Diagnostic Testing– \$20M**

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

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

# RADx-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-UP Strategies

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- **Expand capacity to test broadly** for SARS-CoV-2 in highly affected populations, including asymptomatic persons only with tests with FDA Emergency Use Authorization. These may include self-test and saliva-based methods.
- **Deploy surveys with Common data Elements** that will be applied across all RADx projects plus additional survey items that are defined for RADx-UP consortium.
- **Inform implementation of mitigation strategies** based on isolation, testing and contact tracing to complement mask wearing and physical distancing to limit community transmission and maximize implementation of vaccines.
- **Understand factors** that contribute to COVID-19 disparities and **implement interventions** to reduce these disparities.
- **Establish research and data infrastructure** that could facilitate data sharing and current and future research questions

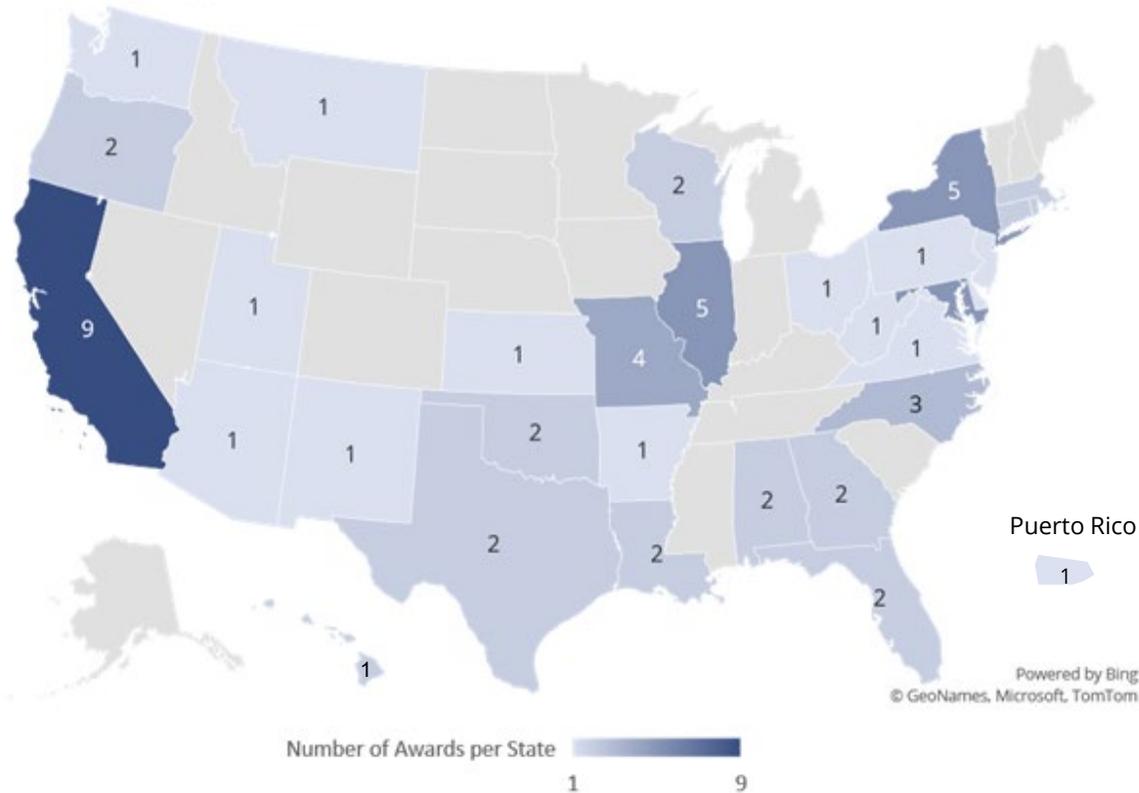
# RADx-UP Phase I Snapshot: 69 Funded Research Projects and Coordination and Data Collection Center

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

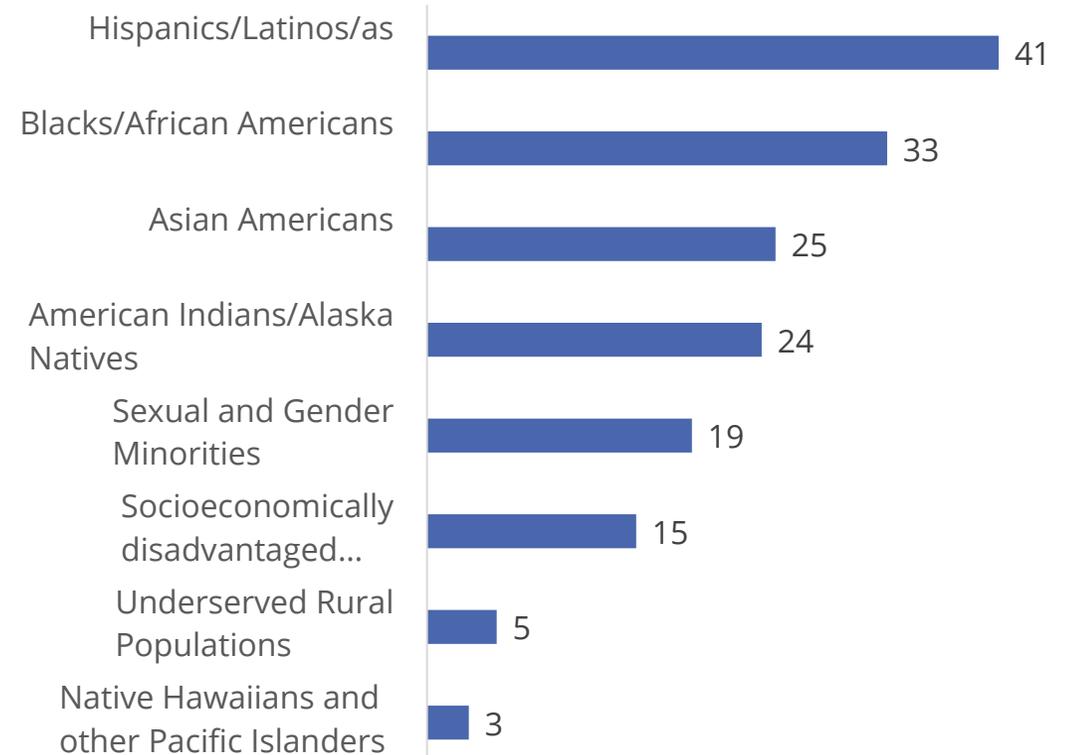
Funded sites and research projects span a total of **31 states** in addition to DC and Puerto Rico and include **55 institutions**.

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

**Geographic Distribution of Award Institutions**



**Populations with Health Disparities**



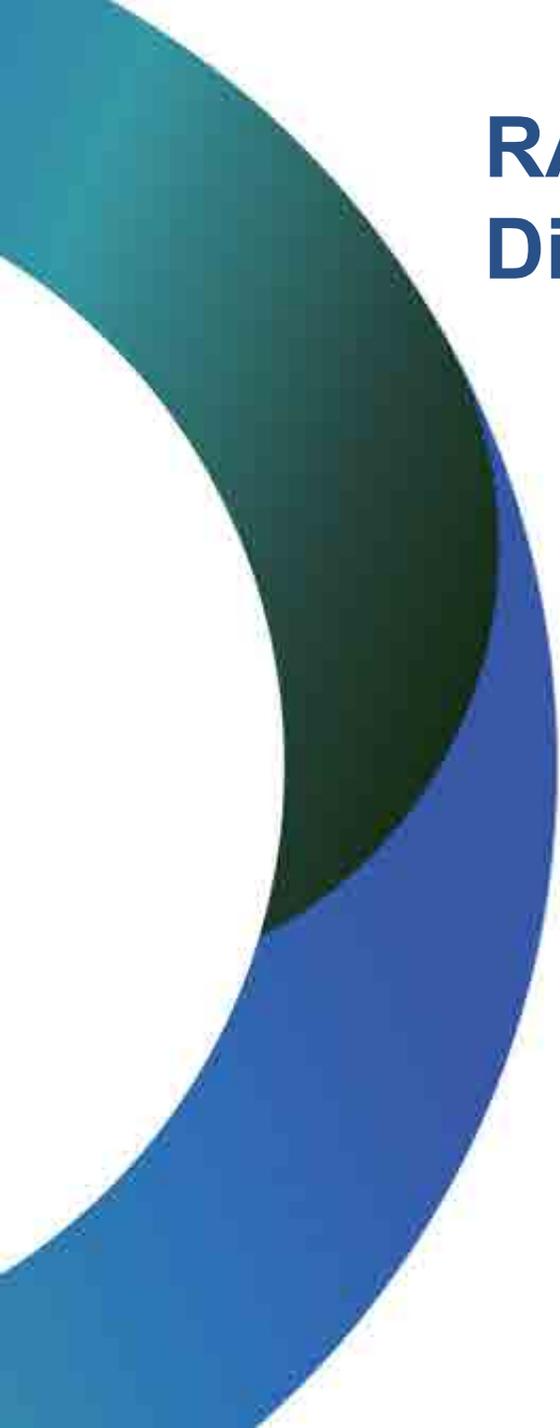
# RADx-UP Return to School Diagnostic Testing Initiative



**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

## 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

## Approach

- Focus on children and adolescents below the age eligible for vaccination via Emergency Use Authorization (age 12+) and all school personnel
- Advance methods to integrate testing in return to or maintenance of in-person instruction
- Identify effective, scalable, and sustainable testing implementation strategies

## Budget

\$50 million commitment from the OD congressional appropriation

# Return to School Phase I

OTA-21-004

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

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

## Overview

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



# Return to School Phase II

OTA-21-007

**Program Information: ~\$23M awarded in Phase II; 8 sites**

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

## Overview

- **Awarded 8 projects** in June and July 2021
- **Strategies for school-based settings** to combine frequent testing with proven safety measures to reduce the spread of COVID-19



# Overview of Phase II Projects



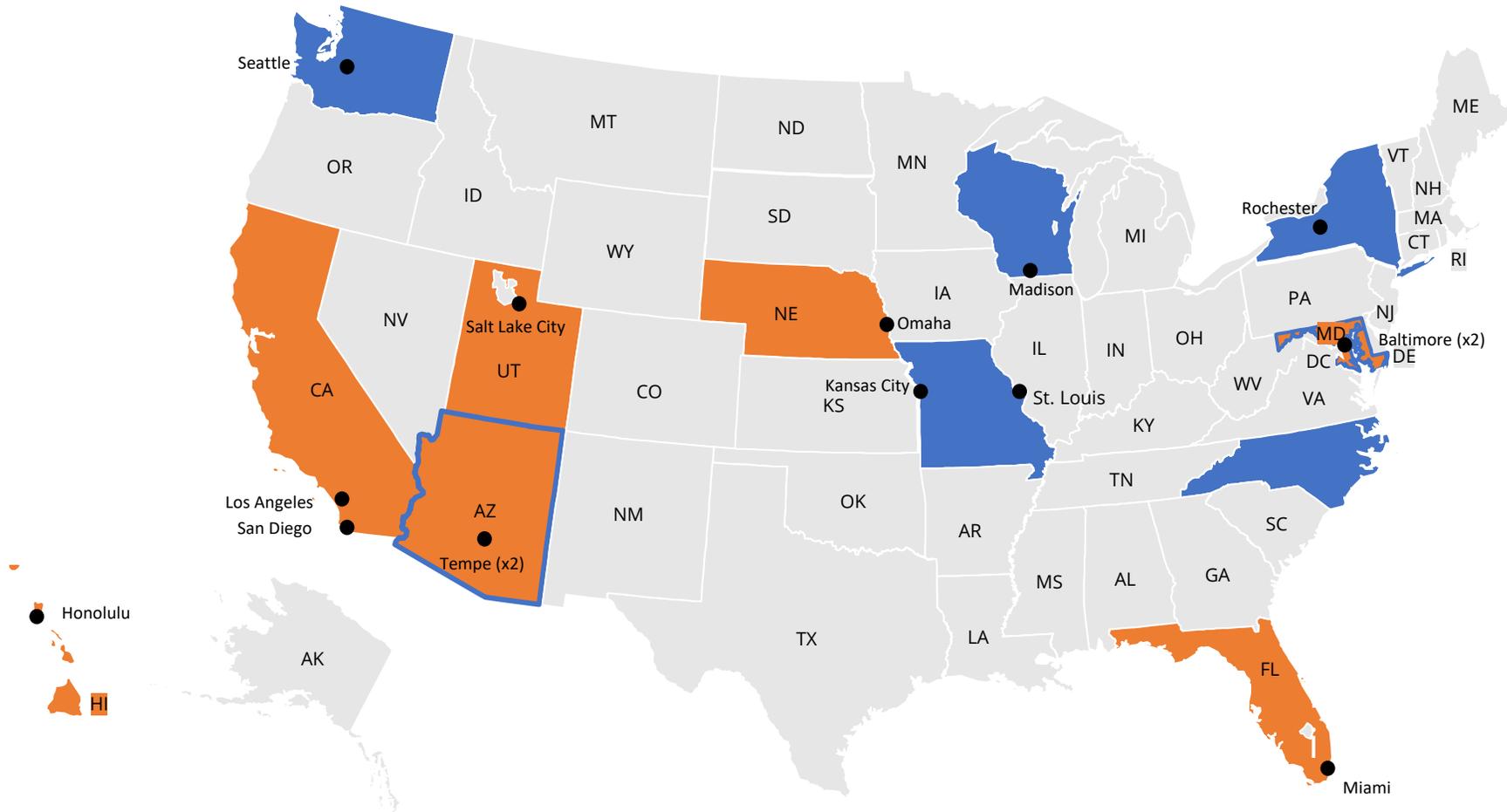
**Sonia Lee Ph.D.**

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

# Applications Awarded during Phase II

| PI              | INSTITUTION   | Project Title   | GEOGRAPHIC LOCATION                        |
|-----------------|---|---|--|
| <b>Inkelas</b>  | University of California, Los Angeles                                     | Impact of COVID-19 testing and mitigation on equitable return-to-school in the second largest US school district  | Los Angeles, California                    |
| <b>Lee</b>      | Arizona State University-Tempe Campus                                     | Back to ECE Safely with SAGE: Reducing COVID-19 Transmission in Hispanic and Low-income Preschoolers  | Phoenix, Arizona                           |
| <b>Okihiro</b>  | University of Hawaii at Manoa   | Empowering schools as community assets to mitigate the adverse impacts of COVID-19  | Hawaiian Islands                           |
| <b>Gwynn</b>    | University of Miami School of Medicine                                    | Maximizing Child Health and Learning Potential: How to Promote A School Culture of Safety in the era of COVID-19  | Miami, Florida                             |
| <b>McCulloh</b> | University of Nebraska Medical Center                                     | Mobile Health-Targeted SARS-CoV-2 Testing and Community Interventions to Maximize Migrant Children's School Attendance During the COVID-19 Pandemic         | Buffalo, Hall and Adams Counties, Nebraska |
| <b>Kiene</b>    | San Diego State University  | Communities Fighting COVID!: Returning Our Kids Back to School Safely   | South San Diego County, California         |
| <b>Wu</b>       | University of Utah  | SCALE-UP Counts: A health information technology approach to increasing COVID-19 testing in elementary and middle schools serving disadvantaged communities | Granite School District, Utah              |
| <b>Johnson</b>  | Johns Hopkins University, University of Maryland, Morgan State University | Social, ethical, and behavioral factors in the return to school among underserved communities in Maryland   | Baltimore, Maryland                        |

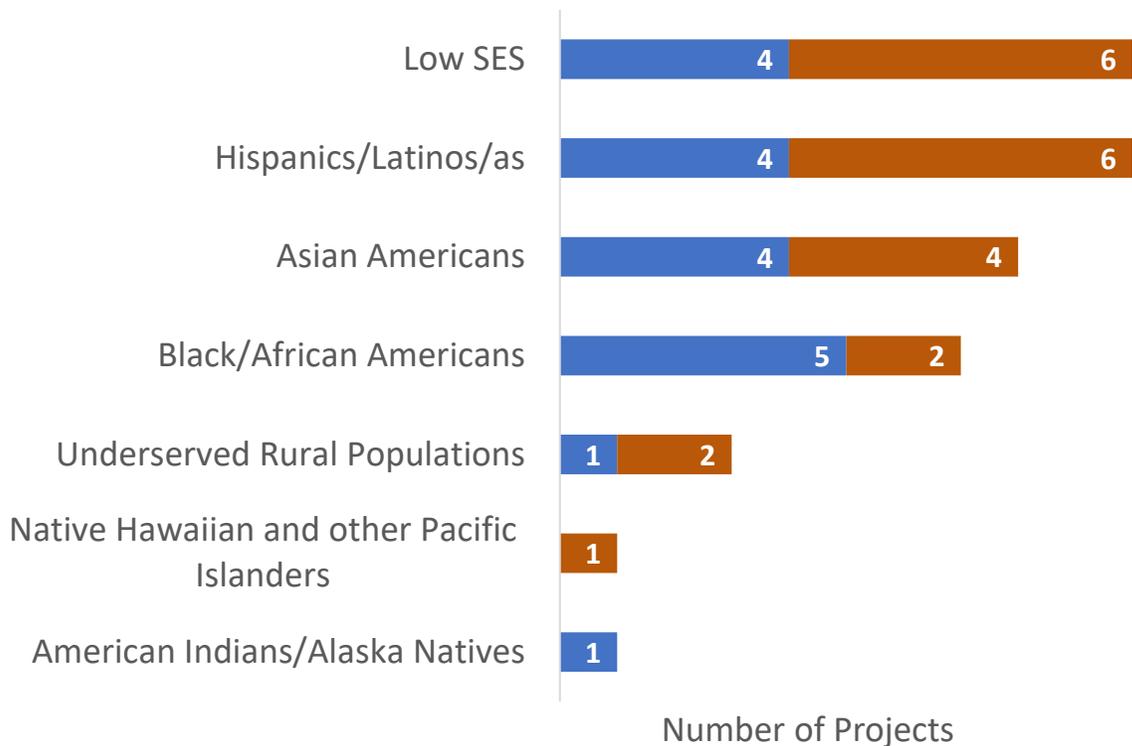
# Geographic Distribution of Awarded Projects



# Health Disparity and Vulnerable Populations

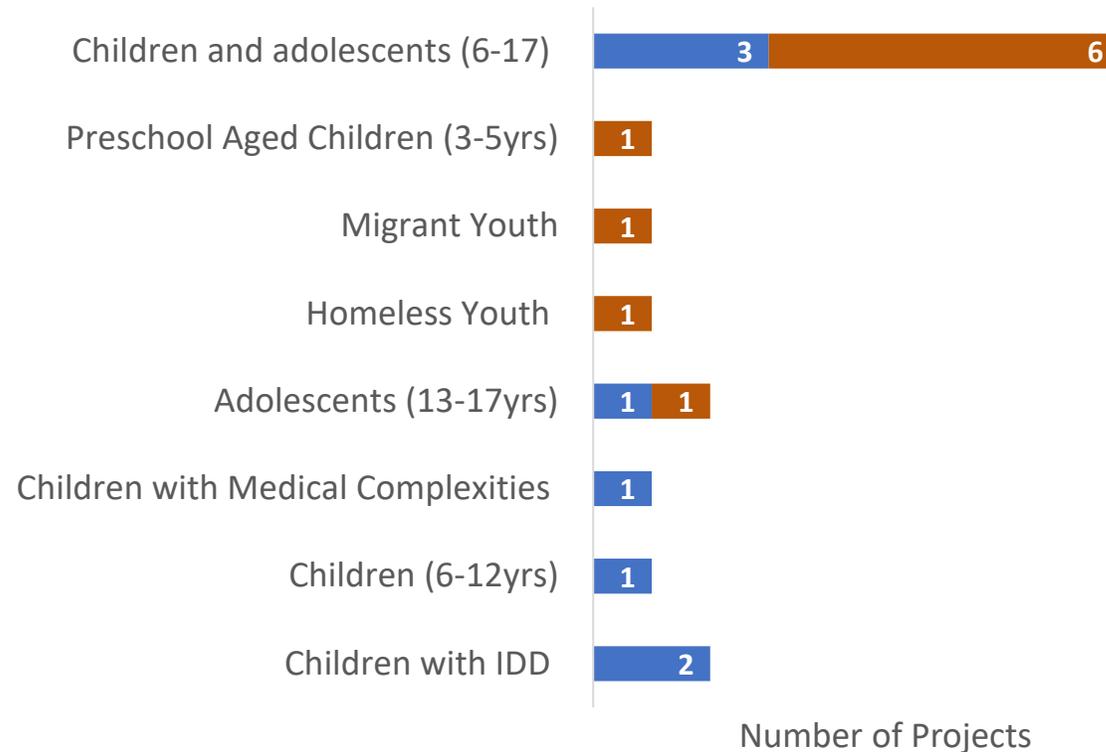
## Populations with Health Disparities

■ Phase I Awards ■ Phase II Awards



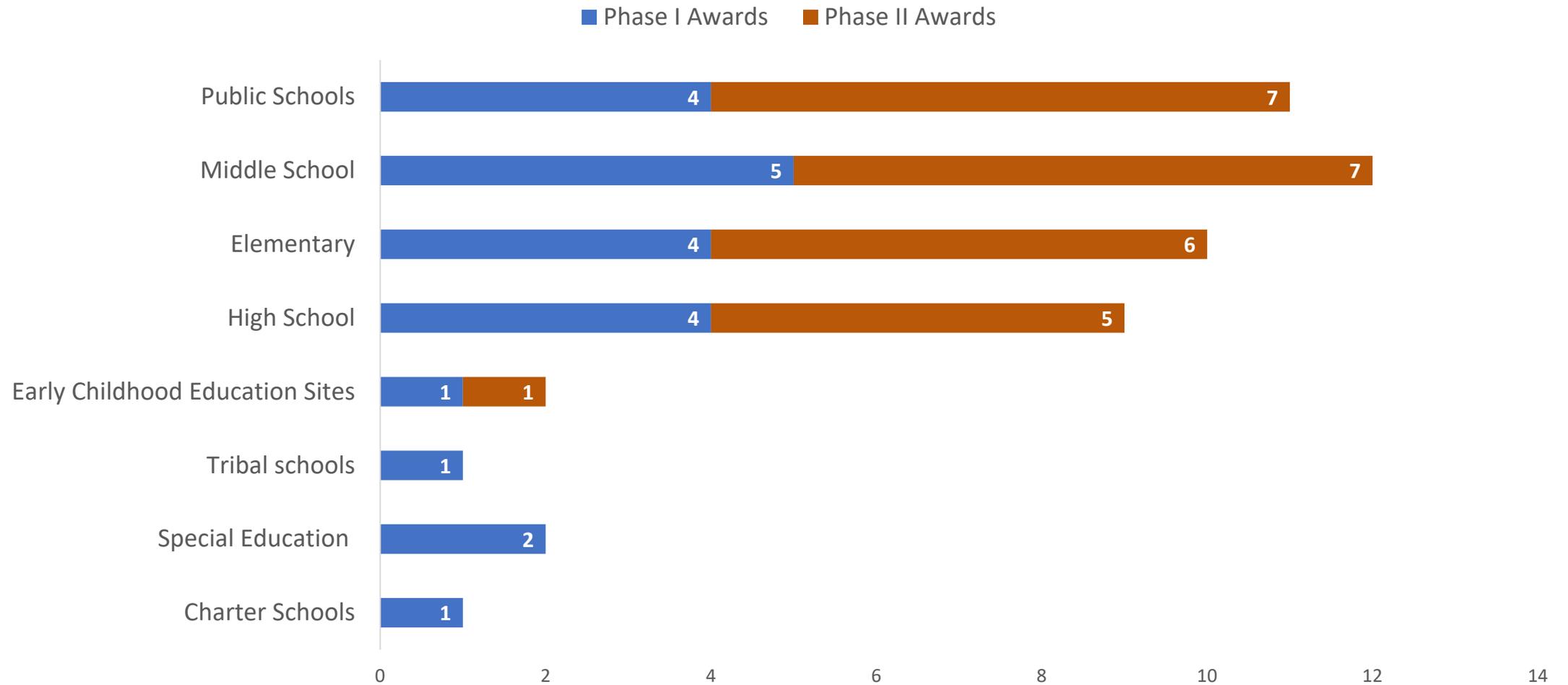
## Vulnerable Populations

■ Phase I Awards ■ Phase II Awards



**Note:** There are projects working with multiple populations; the number of projects is not additive

# Educational Settings



**Note:** There are projects working with multiple populations; the number of projects is not additive



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# COVID-19 & Children

*What have we learnt so far?*

**Dr Shamez Ladhani**

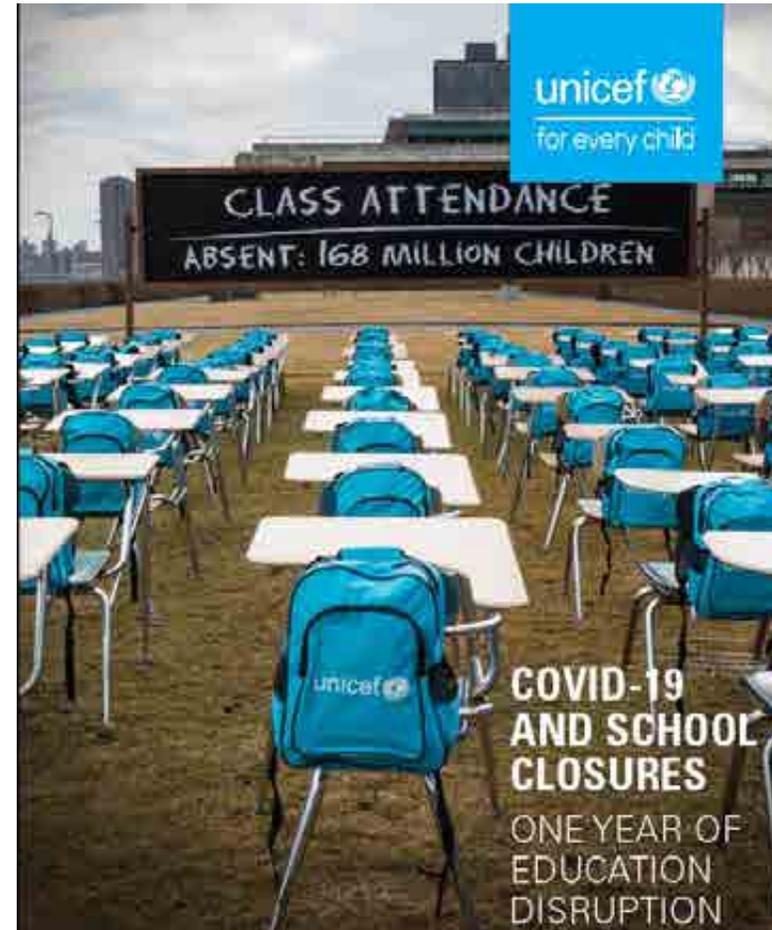
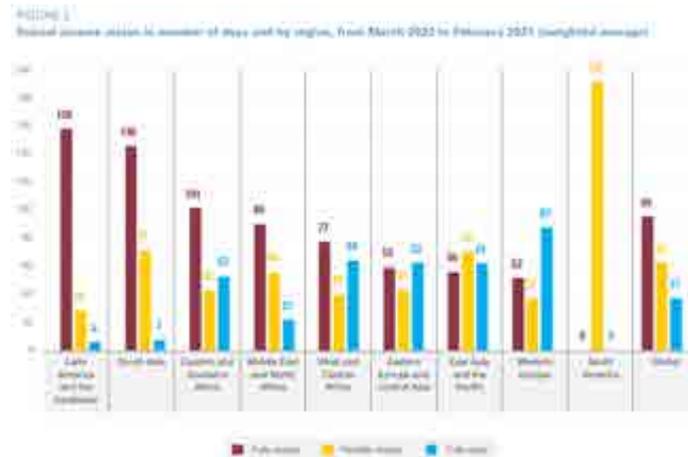
**Paediatric Infectious Diseases Consultant**

**Email: [shamez.Ladhani@phe.gov.uk](mailto:shamez.Ladhani@phe.gov.uk)**

**Twitter: [@shamezladhani](https://twitter.com/shamezladhani)**

# Impact of School Closures on children

- Educational development
- Emotional development
- Social development
- Physical activity
- School meals
- Child protection & social services
- School vaccinations





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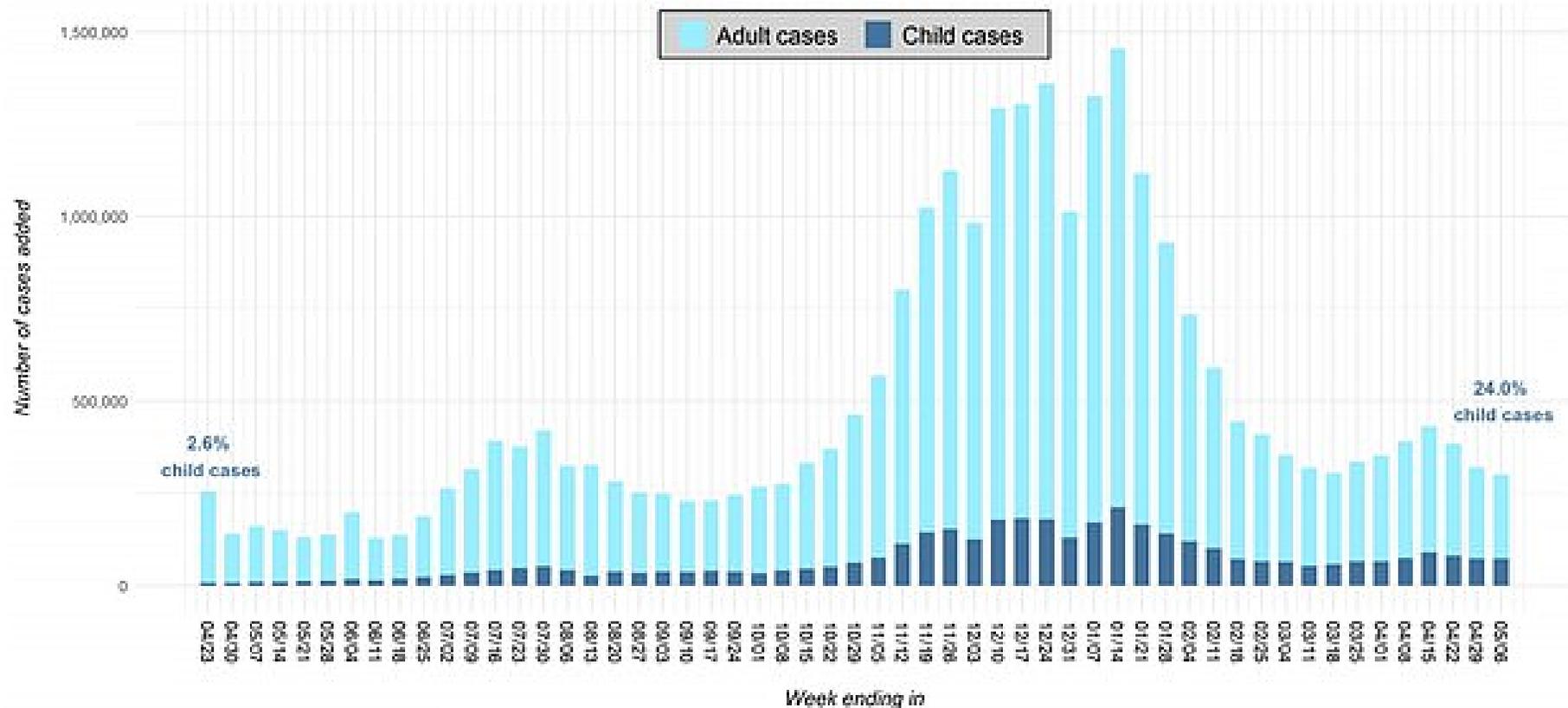
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# Risk of SARS-CoV-2 Infection

## Children vs Adults

# Children as likely to be infected as adults

Fig 7. United States: Number of COVID-19 Cases Added in Past Week for Children and Adults\*



\* Note: 4 states changed their definition of child cases: AL as of 8/13/20, HI as of 8/27/20, RI as of 9/10/20, MD as of 10/1/20; TX reported age for only a small proportion of total cases each week (eg, 3-20%). See detail in Appendix. Data from 49 states, NYC, DC, PR and GU.

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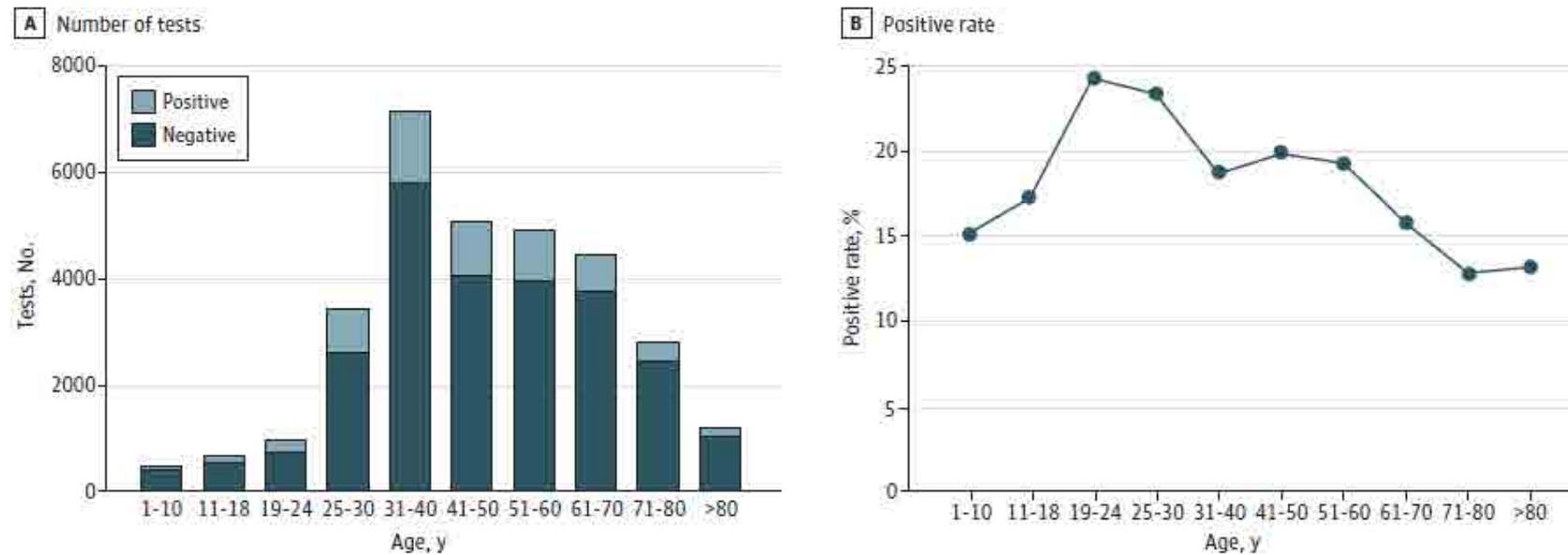


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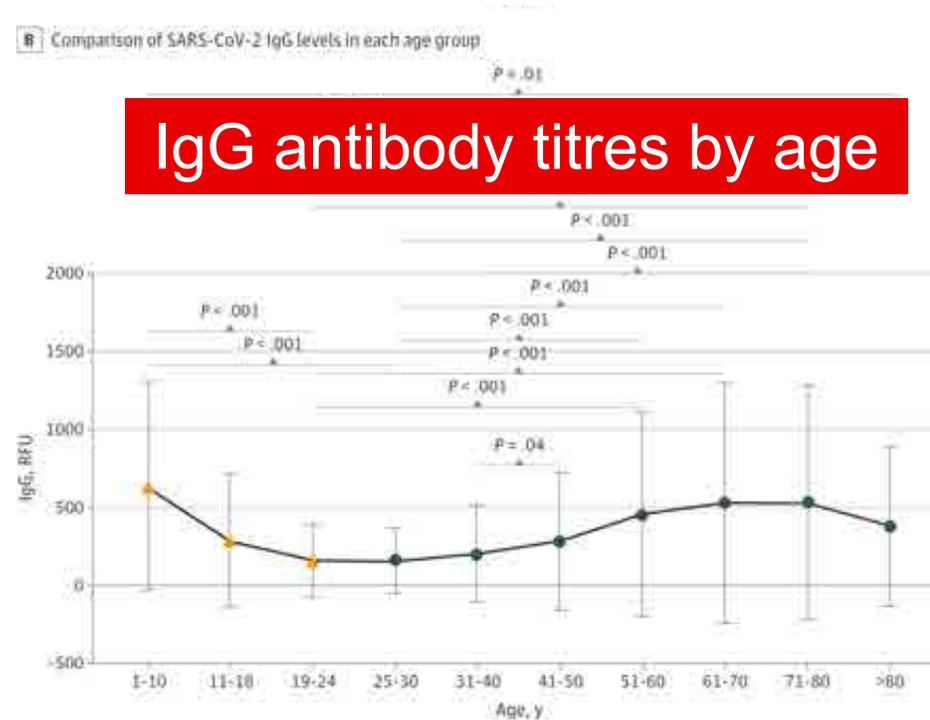
# Antibody Seroprevalence in a New York City Hospital

Figure 1. Severe Acute Respiratory Syndrome Coronavirus 2 Antibody Test Frequencies and Positivity Rates from April 9 to August 31, 2020

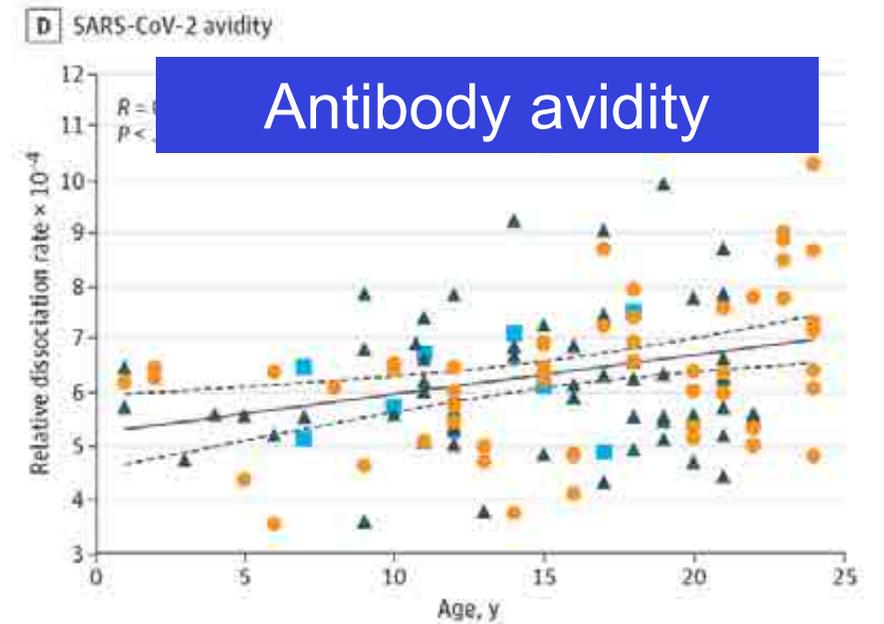
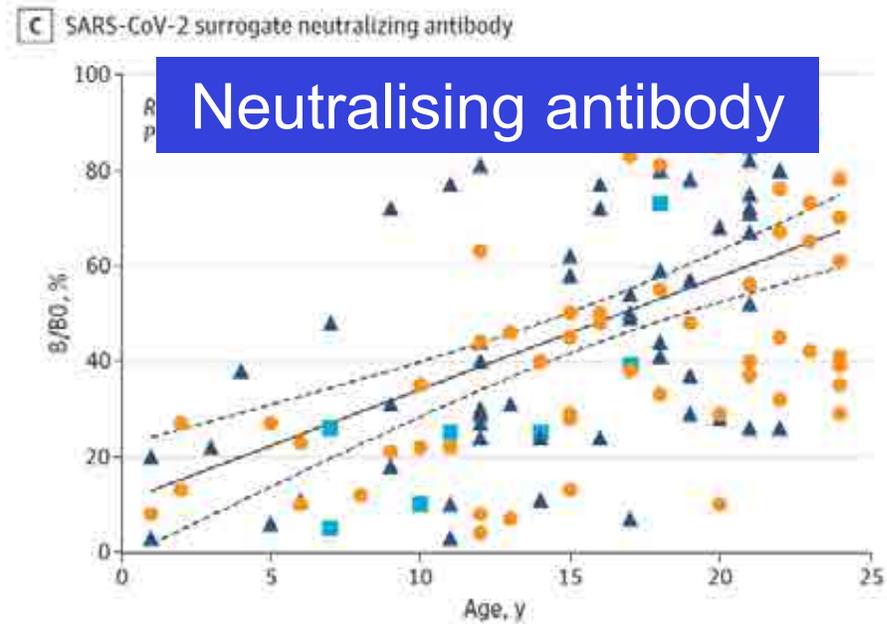
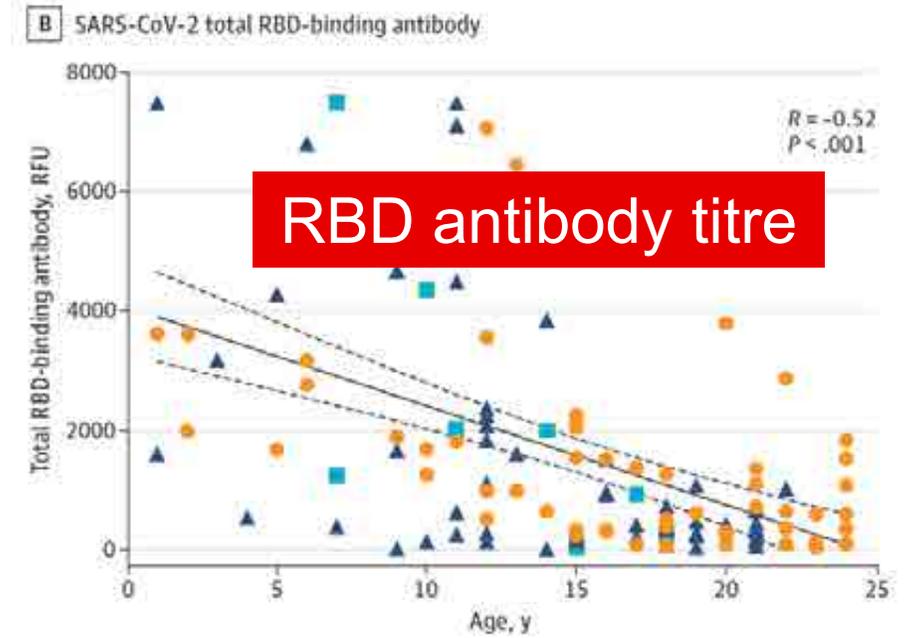
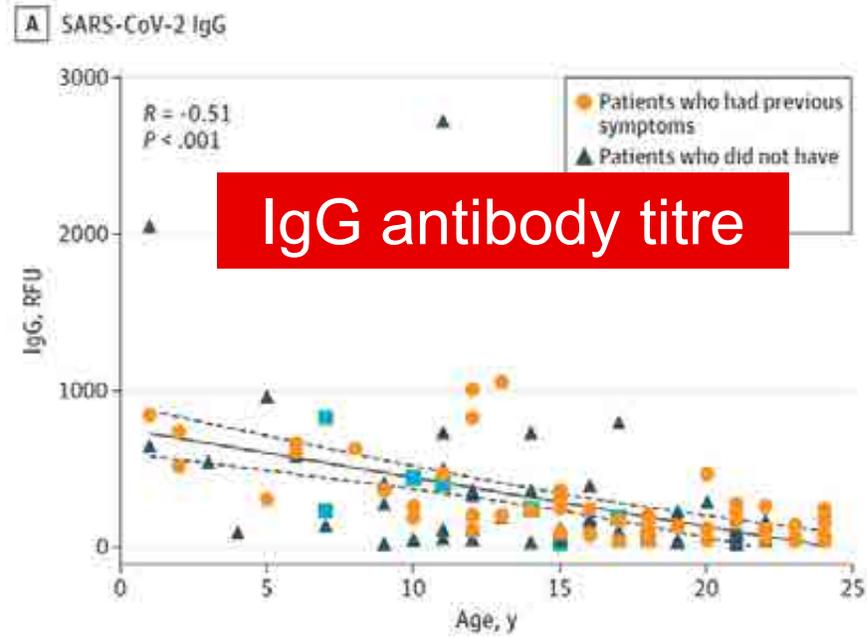


# Antibody Seroprevalence in a New York City Hospital

- Antibody levels in children decline with age and then increase in adults



# Antibody Rates



# sKIDs

## COVID-19 Surveillance in School Kids

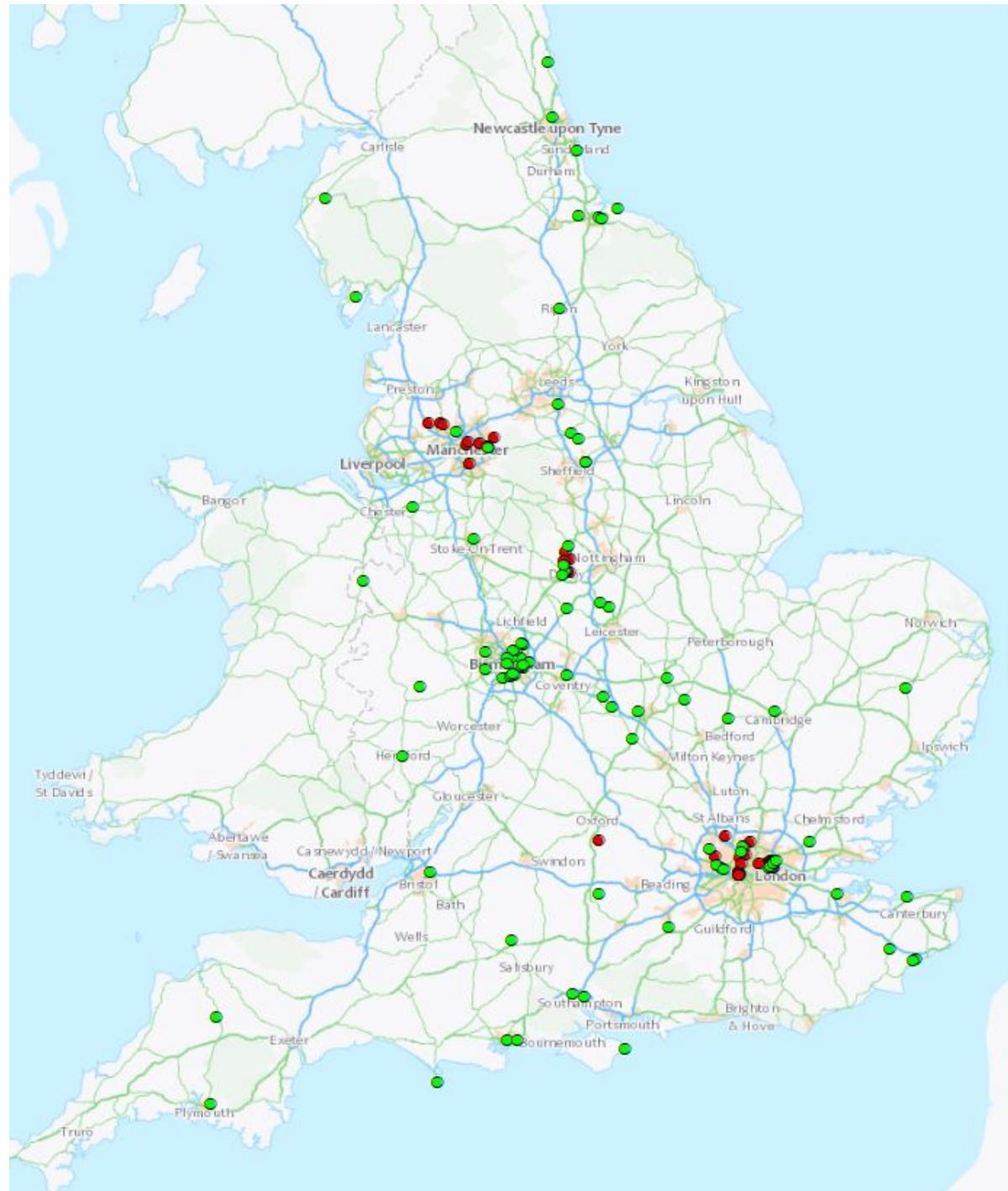
192 Primary Schools Contacted

138 Primary Schools recruited

- Weekly Swabs: 89
- Bloods & Swabs: 49

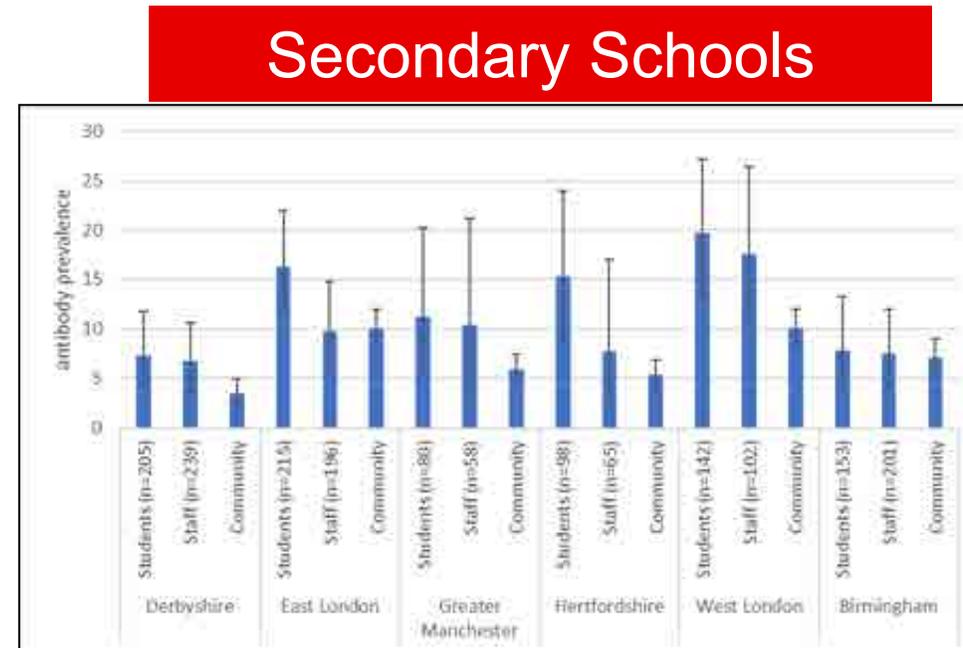
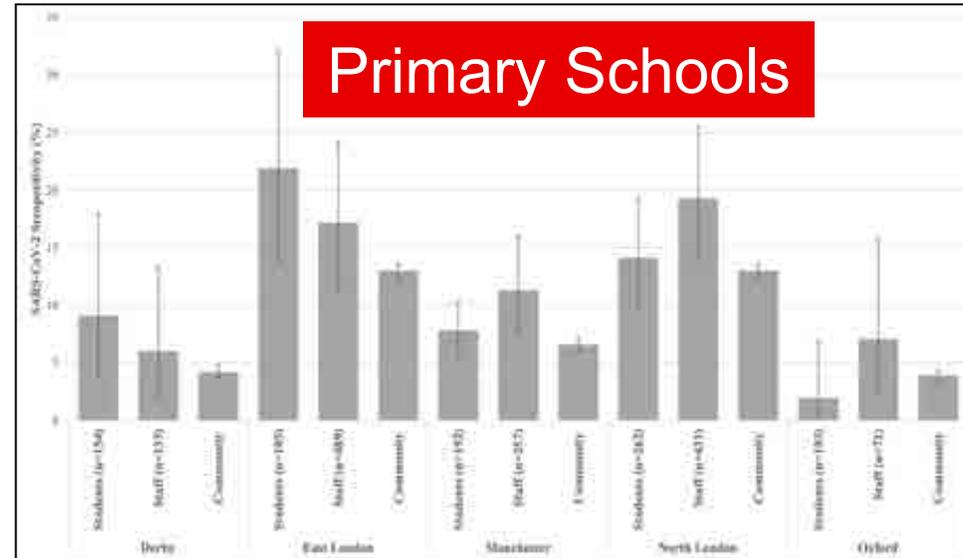
Participants recruited:

>12,000 staff & students



# Infection rates in primary and secondary schools

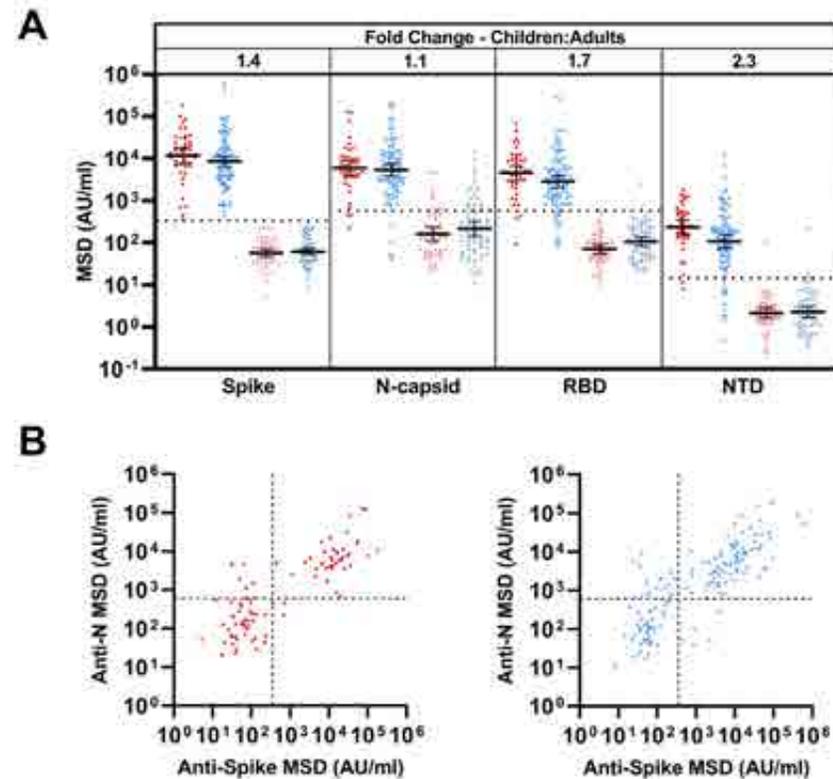
- Early studies showed lower infection rates in children vs adults:
  - Children less likely to be exposed than adults
  - Symptoms-based testing
  - PCR-testing
- More recent antibody studies show similar seropositivity in adults and children



# Higher Antibody titres in Children than Adults

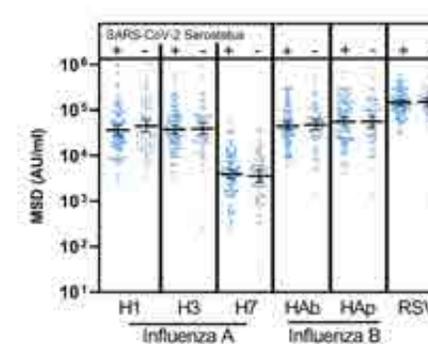
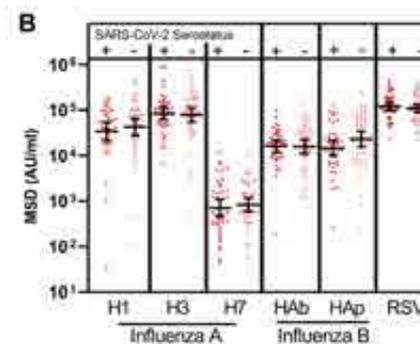
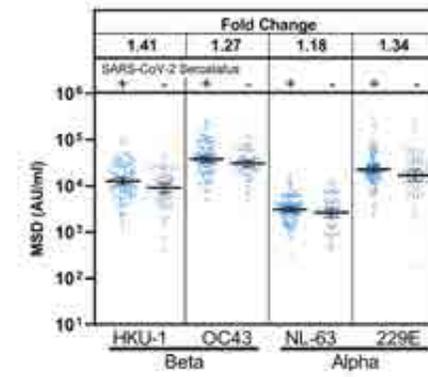
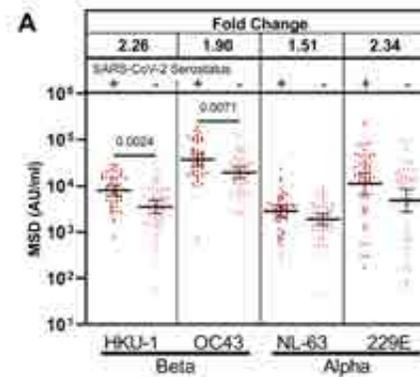
Children retain higher antibodies than adults >6 months after SARS-CoV2 infection:

- Spike
- Nucleocapsid
- RBD
- N-terminal domain



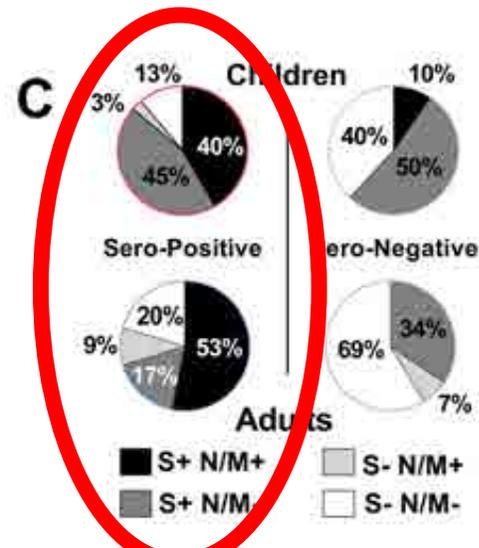
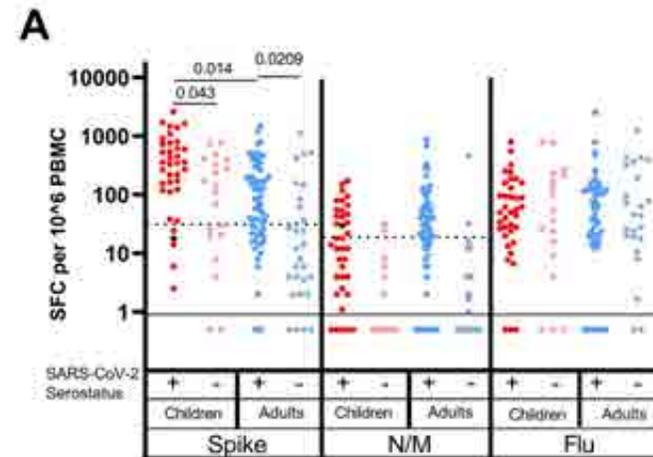
# Antibodies against other coronaviruses

- Antibody positive children develop strong immune responses against beta-coronaviruses than adults
- *No such effect seen with influenza virus controls*



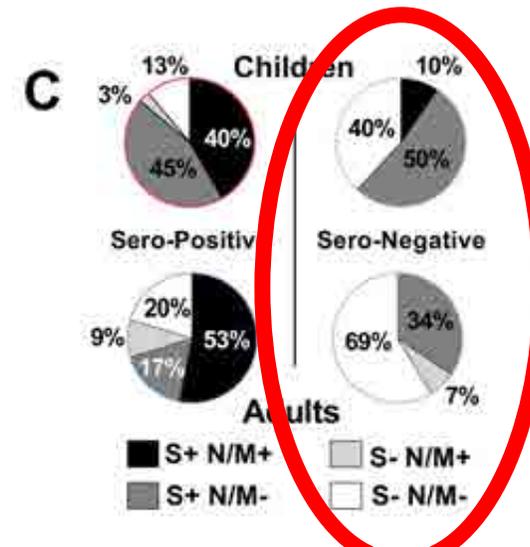
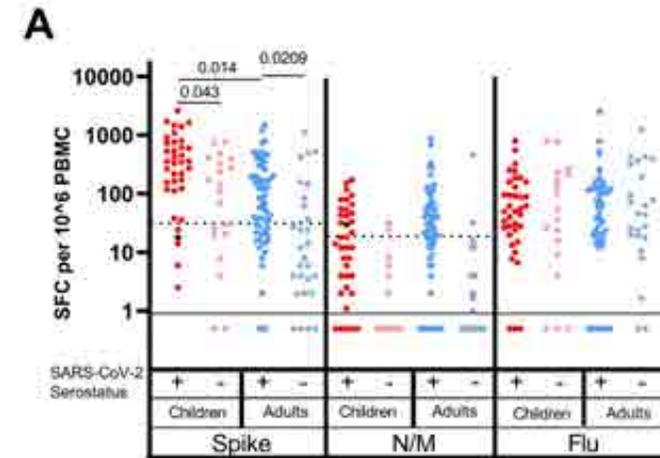
# Cellular responses in seropositive children

- Elispot responses to Spike were 86% (32/37) of seropositive children vs 69% (45/64) of seropositive adults
- Magnitude of cellular response against spike was 2.1-fold higher in children ( $p=0.0003$ )



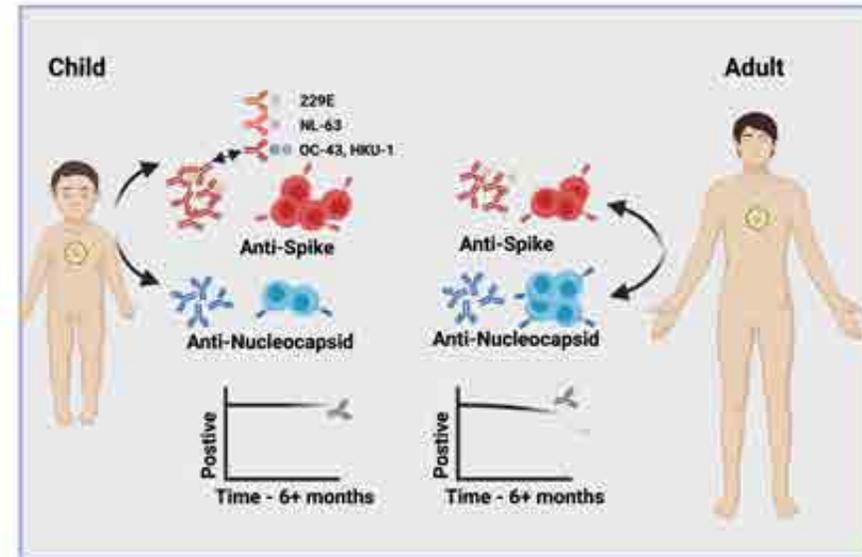
# Cellular Responses in Seronegative Kids

- Robust cellular responses in 60% (12/20) seronegative children (3 different assays)
- Cellular responses variable but lower magnitude in 34% (10/29) of sero-negative adults
- Cellular responses in seronegative donors markedly spike-specific: ? pre-existing cross-reactive immunity
- 7/12 seronegative children & 6/10 seronegative adults with positive ELISpot also had increased HCoV antibodies: ? recent HCoV infection
- Alternatively, responses might represent cellular sensitisation without sero-conversion



# Antibody persistence in Seropositive Kids

- After 6 months, children have better antibody persistence than adults, possibly because they start with higher antibodies



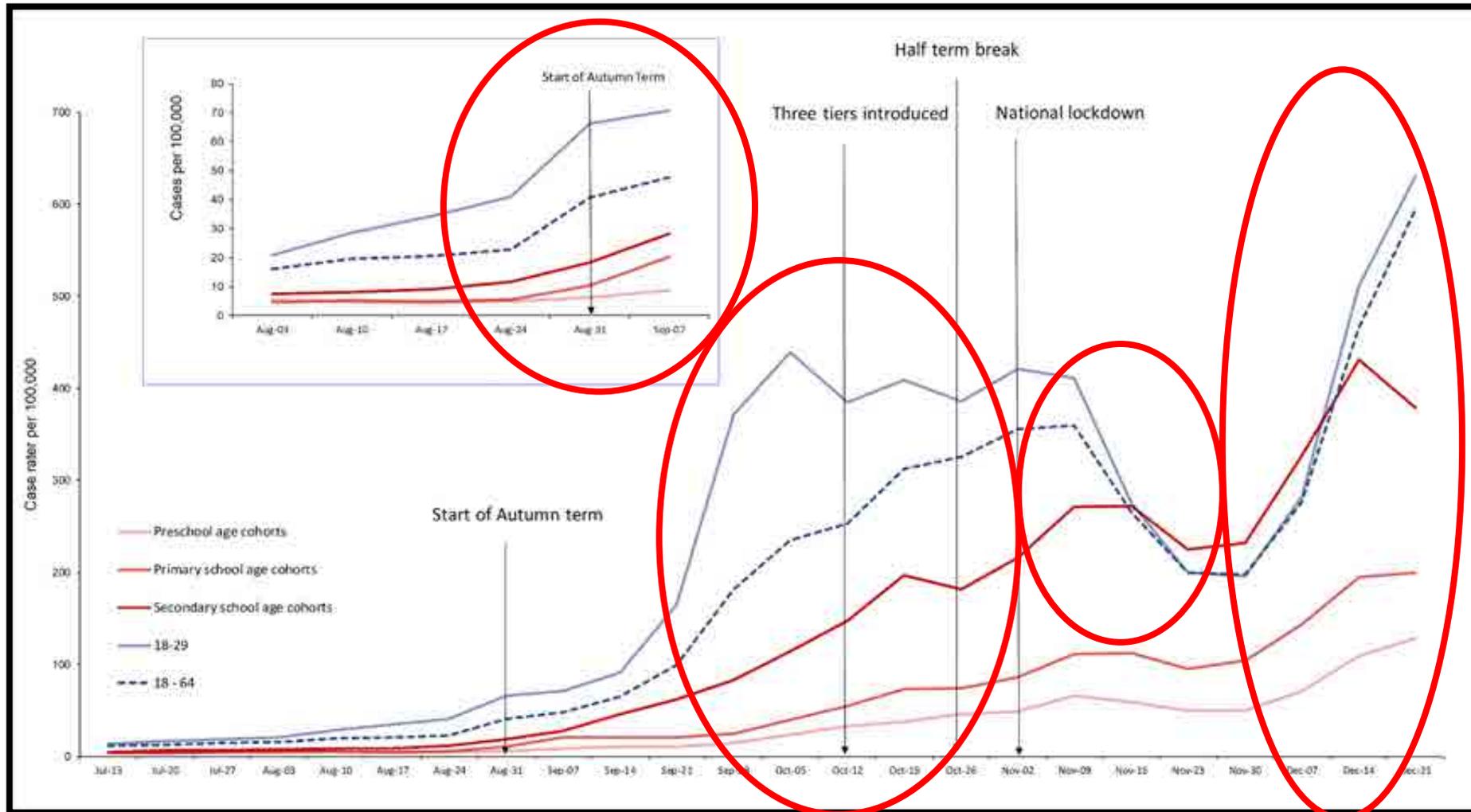


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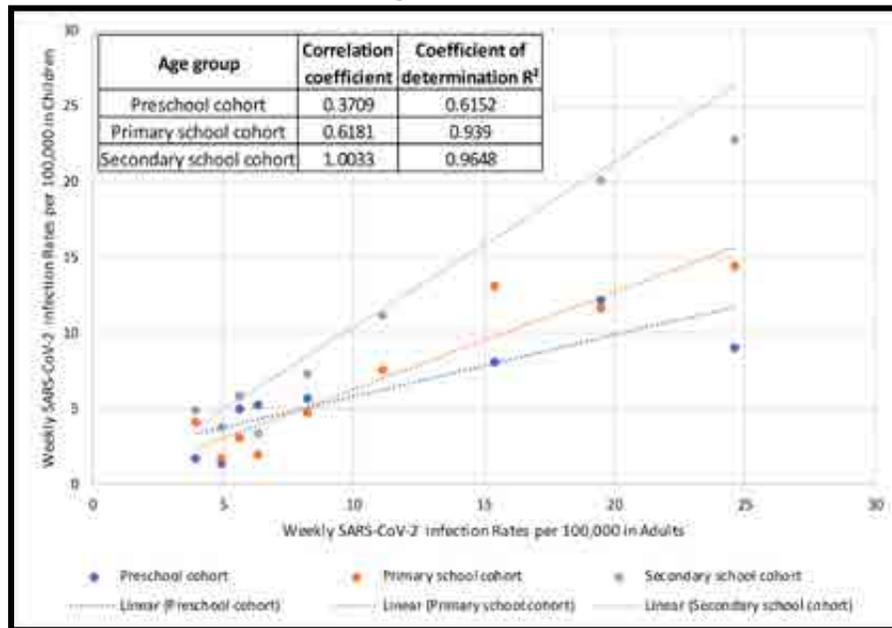
# Infection Trends in School-aged Children

# Trends in school-aged children

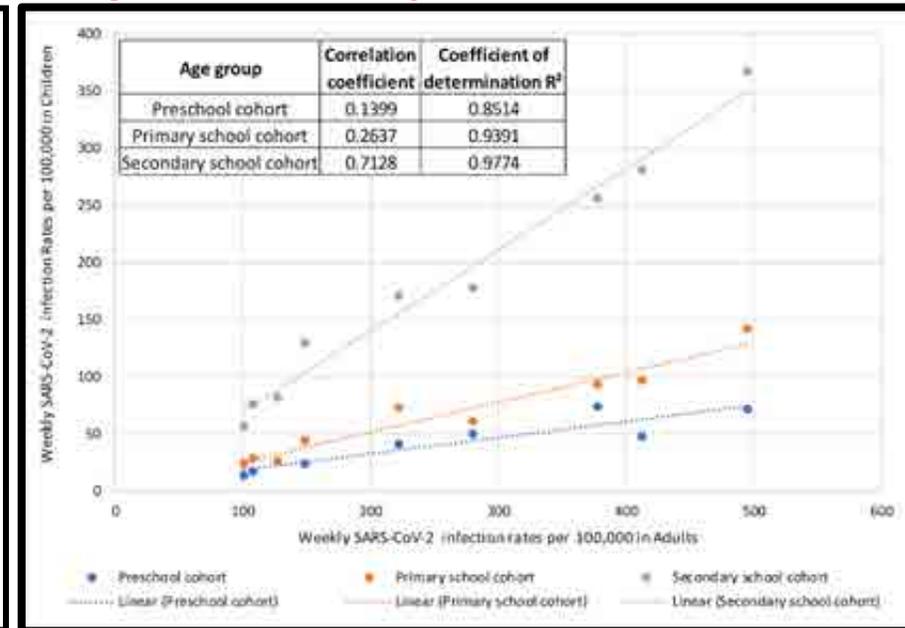


# Weekly SARS-CoV-2 infection rates in children: Correlation with Community Rates (England)

Low Community Transmission Week



High Community Transmission Week





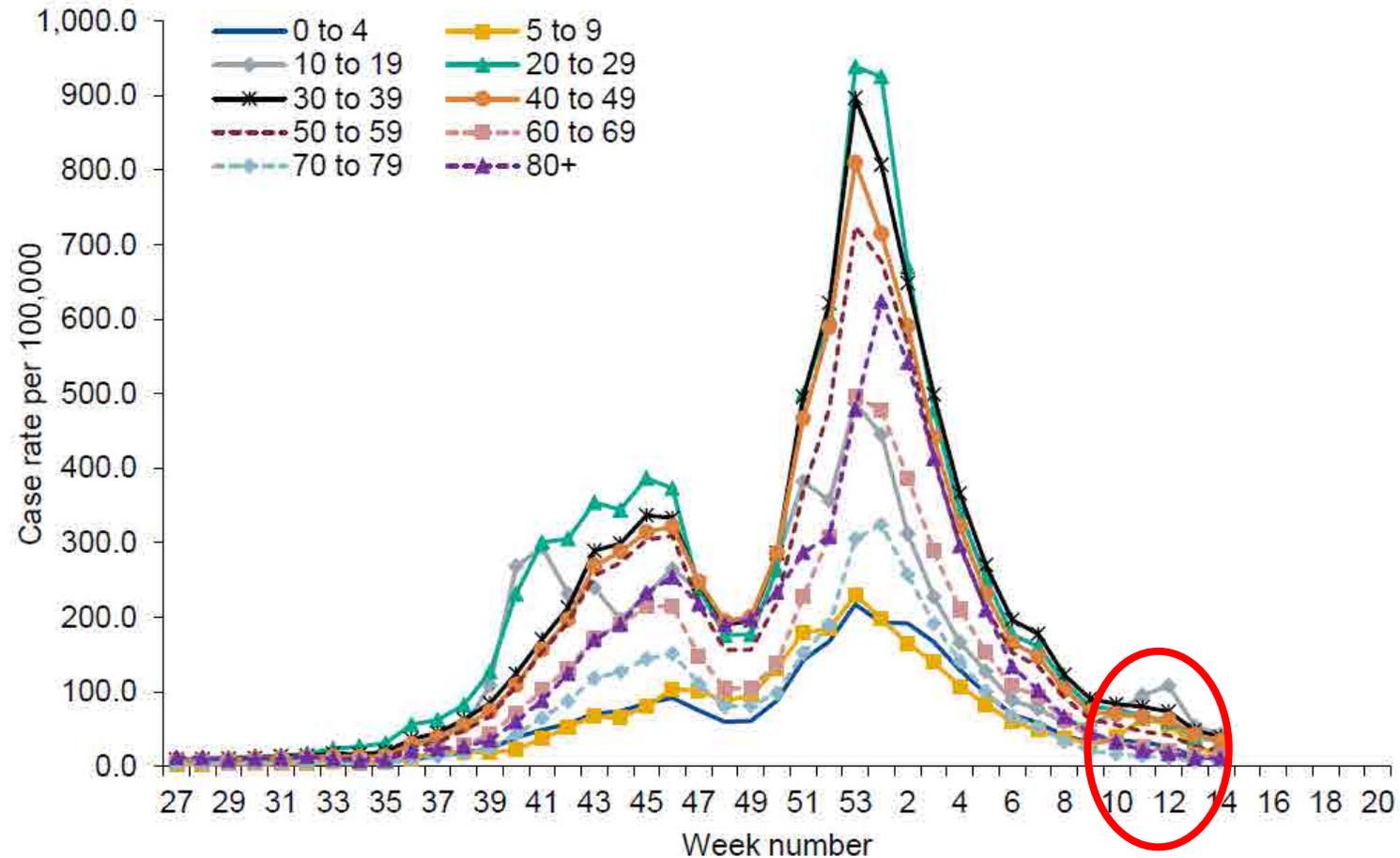
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# **Schools Reopening during national lockdown (March 2021)**

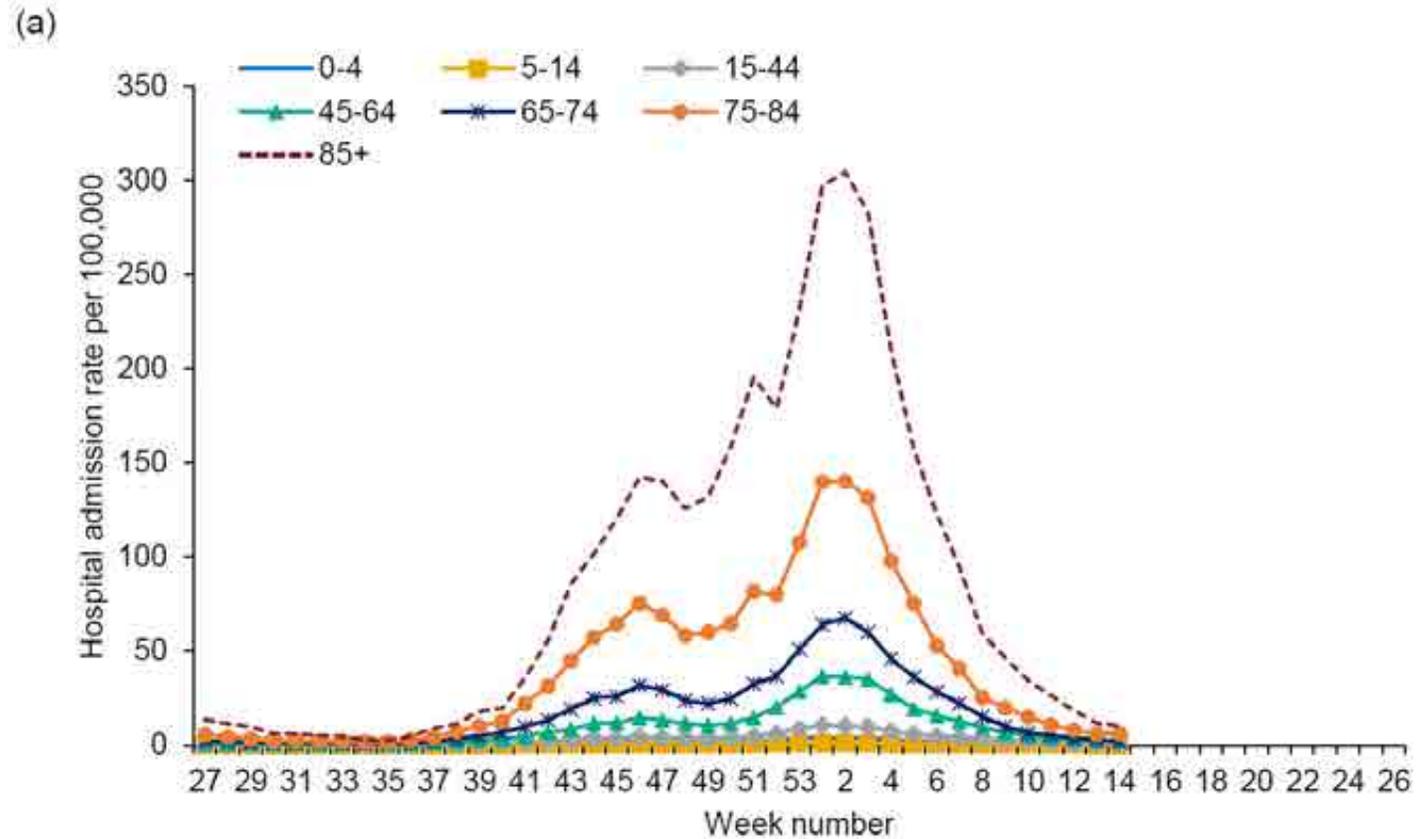
# Schools Reopening (March 08-31, 2021)

Figure 5: Weekly confirmed COVID-19 case rates per 100,000, tested under Pillar 1 and Pillar 2, by age group



# Schools Reopening: Hospitalisations by age

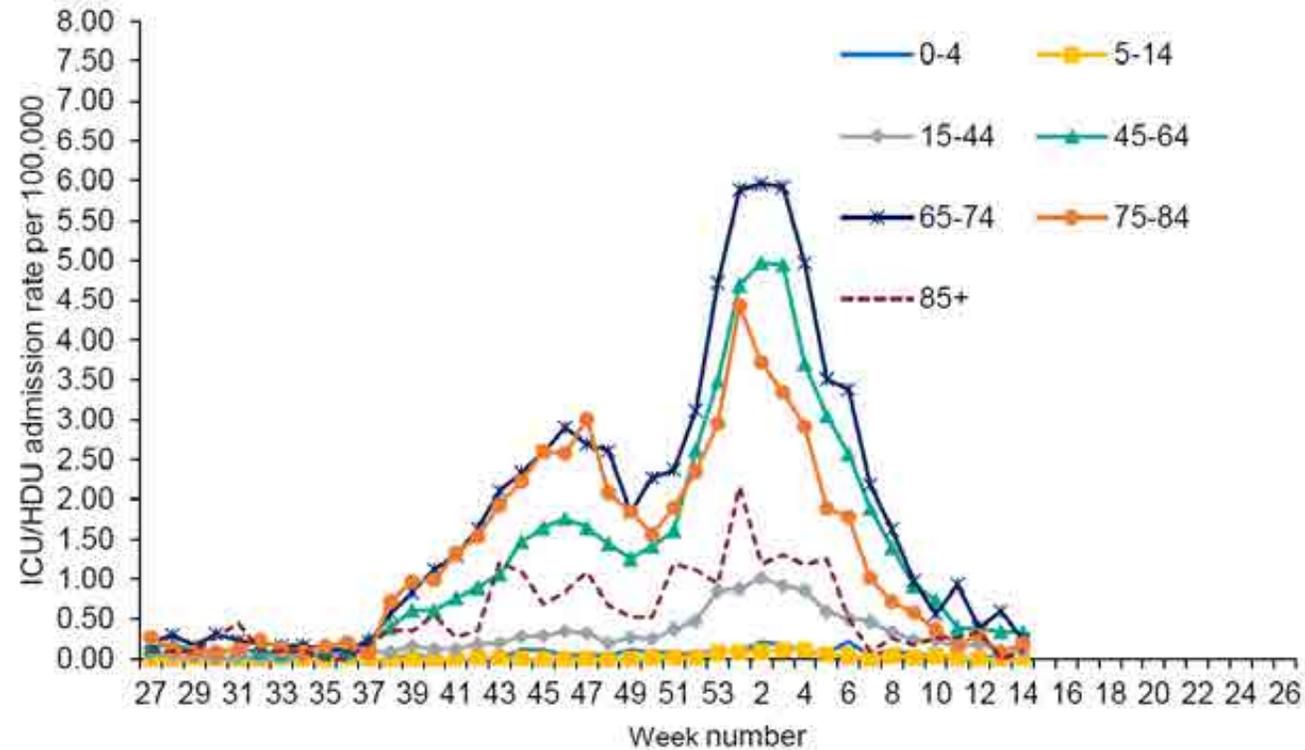
Figure 39: Weekly hospital admission rate by age group for new (a) COVID-19 positive cases and (b) influenza reported through SARI Watch



# Schools Reopening: ICU admissions by age

Figure 44: Weekly ICU/HDU admission rate by age group for new (a) COVID-19 positive cases and (b) influenza reported through SARI Watch

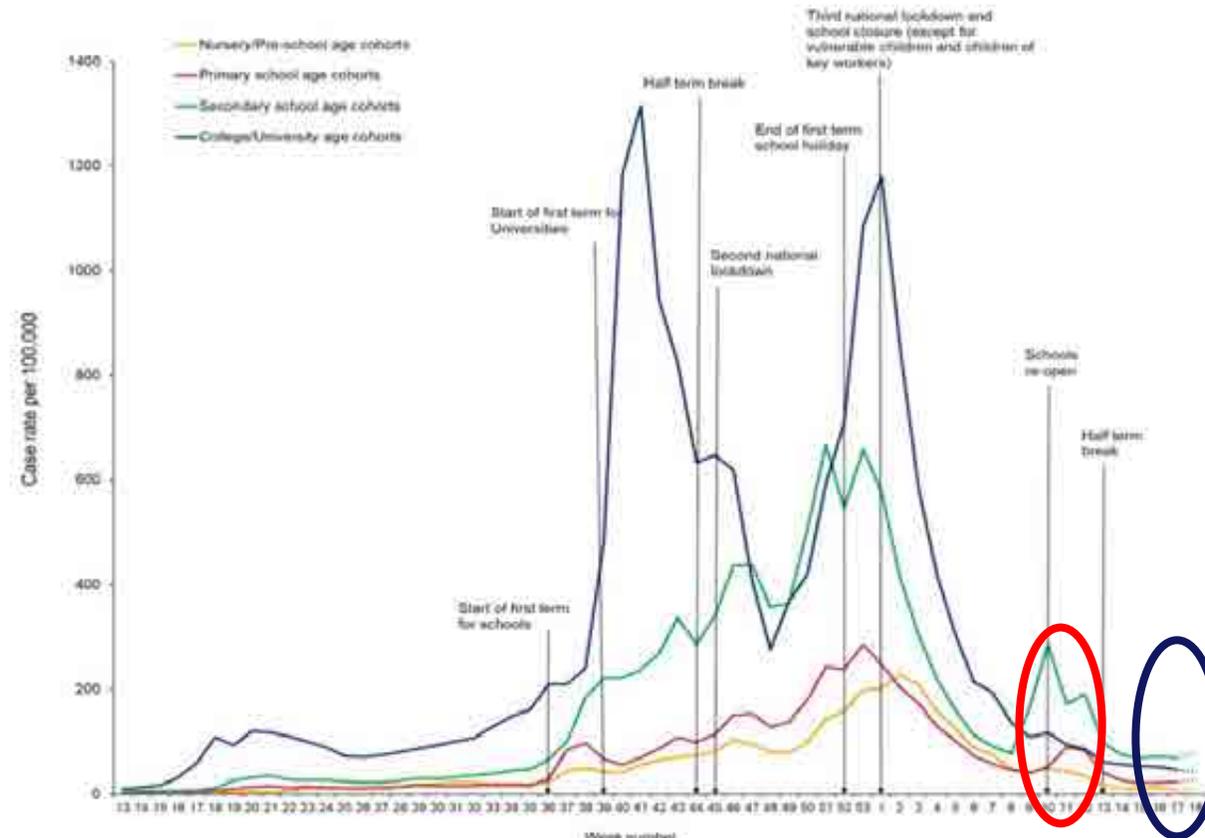
(a)



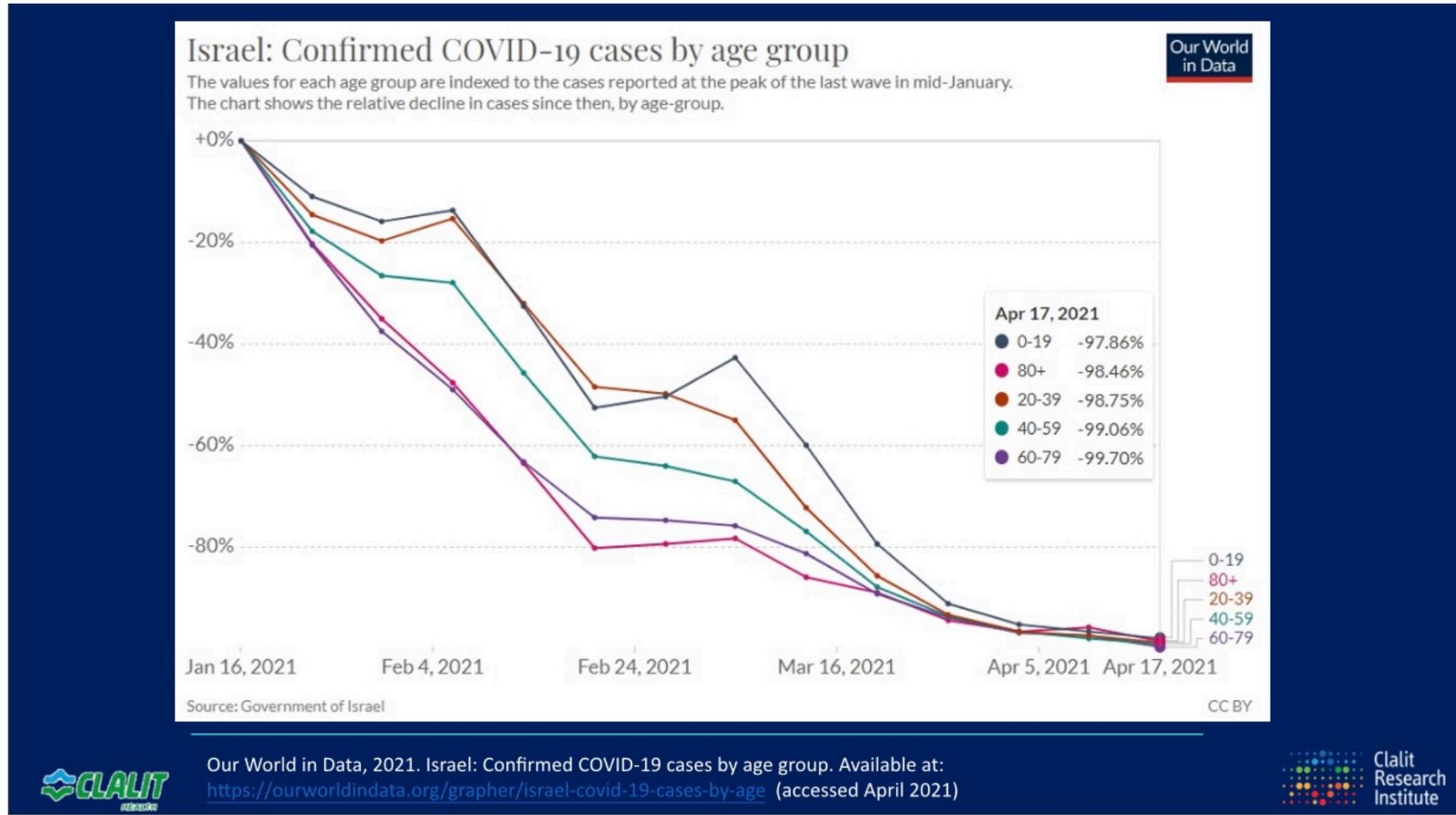
# Schools Reopening 2: 19 April 19 – 08 May, 2021



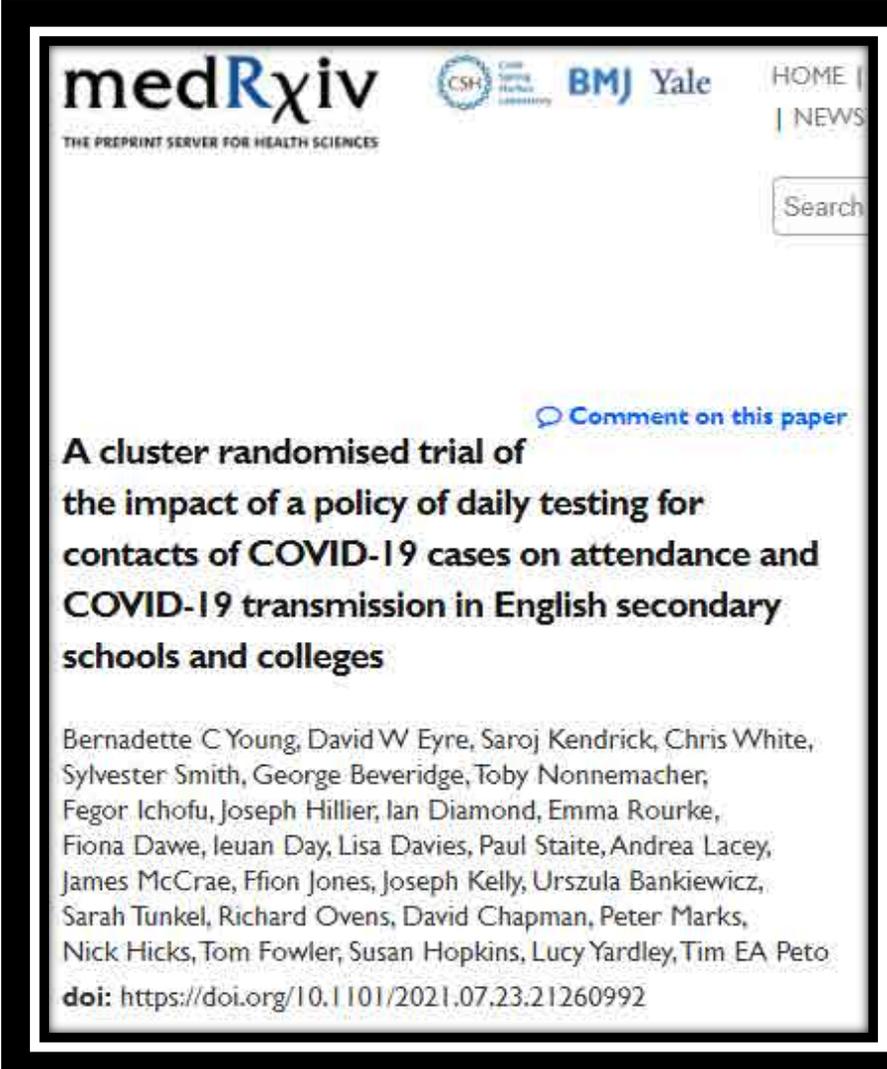
Weekly incidence of laboratory confirmed COVID-19 cases per 100,000 population in nursery/preschool, primary school, secondary school and college/university age cohorts



# Vaccinating adults protects children, Israeli study



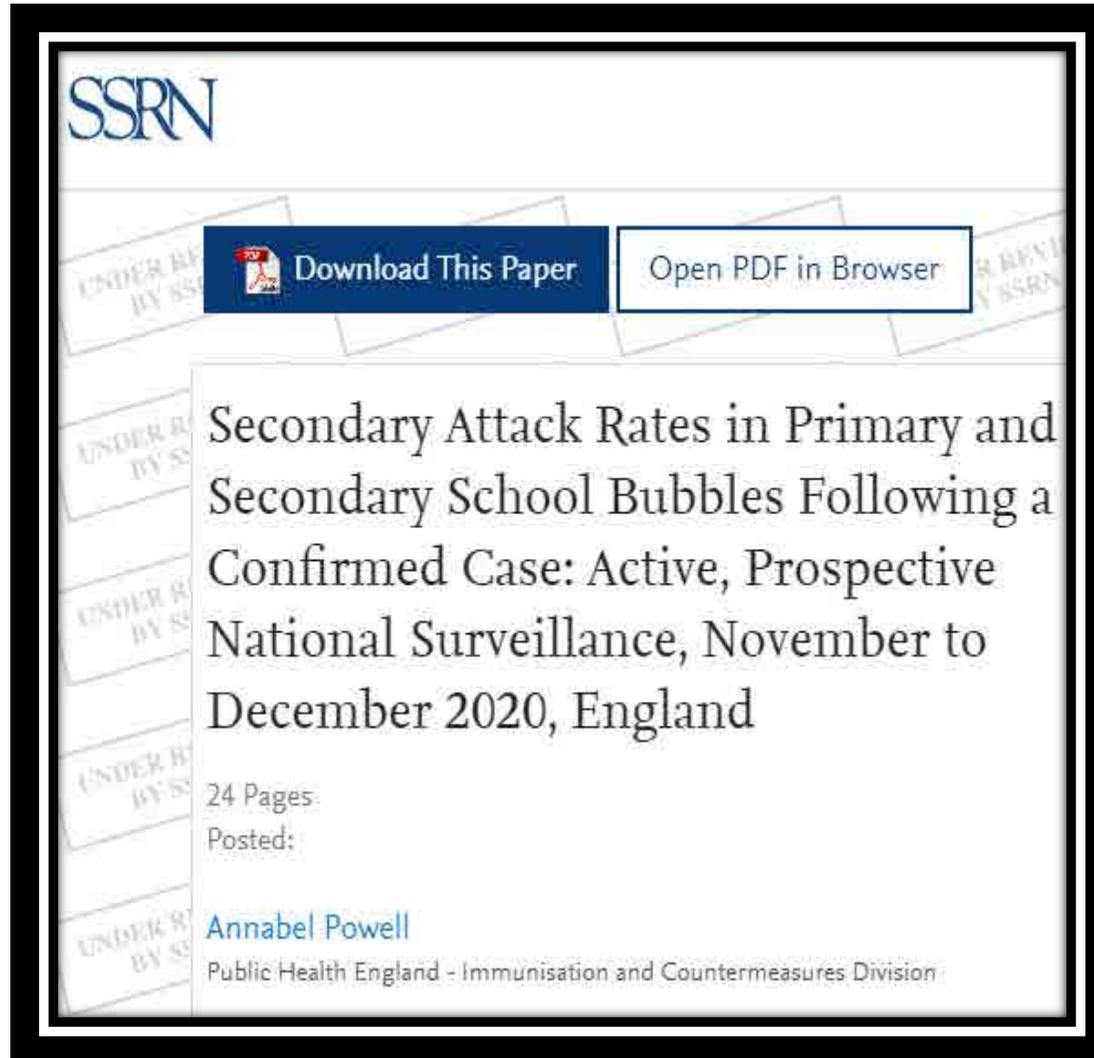
# Infection rates in children who continued to attend school with daily LFD testing were similar compared to those who were sent home to self-isolate



The screenshot shows the medRxiv preprint server interface. At the top, there are logos for medRxiv, CSH (Center for Systems Health), BMJ, and Yale. Navigation links for HOME and NEWS are visible, along with a search bar. The main content area features a blue link to 'Comment on this paper' and the title of the preprint: 'A cluster randomised trial of the impact of a policy of daily testing for contacts of COVID-19 cases on attendance and COVID-19 transmission in English secondary schools and colleges'. Below the title, the authors' names are listed: Bernadette C Young, David W Eyre, Saroj Kendrick, Chris White, Sylvester Smith, George Beveridge, Toby Nonnemacher, Fegor Ichofu, Joseph Hillier, Ian Diamond, Emma Rourke, Fiona Dawe, Ieuan Day, Lisa Davies, Paul Staite, Andrea Lacey, James McCrae, Ffion Jones, Joseph Kelly, Urszula Bankiewicz, Sarah Tunkel, Richard Ovens, David Chapman, Peter Marks, Nick Hicks, Tom Fowler, Susan Hopkins, Lucy Yardley, and Tim EA Peto. At the bottom, the DOI is provided: <https://doi.org/10.1101/2021.07.23.21260992>.

- Infection rates in children who continued to attend school with daily LFD testing were similar compared to those who were sent home to self-isolate (<2%)
- Not powered to detect improvement in school attendance rates → but logical?

# Secondary attack rates in primary and secondary school bubbles



Secondary attack rate in students:

- \* 10.0% (6/60) primary
- \* 3.9% (4/102) secondary

Secondary attack rate in staff:

- \* 6.3% (1/16) primary
- \* 0% (0/1) secondary

Household contacts of students:

- \* 6.6% (12/183) primary
- \* 3.5% (11/317) secondary

Household contacts of staff:

- \* 3.7% (1/27) primary
- \* 0% (0/1) secondary

# Conclusions

- School closures have a wider impact on children than loss of education
- Children as likely as adults to be infected with SARS-CoV-2
- Children develop robust and persistent immunity against the virus
- Risk of infection in school is low for staff and students, and no higher than risk in the local community
- Risk of infection and outbreaks in schools correlates strongly with local community infection rates
- Active case finding: very low rates of in-school transmission in staff or students
- Vaccinating teachers and adults family member will allow children to safely attend school safely, without
- Early evidence from Israel: vaccinating adults protects children
- *? Is there a need to vaccinate children against SARS-CoV-2*

# Acknowledgements

**SKIDs Investigators:** Frances Baawuah, Joanne Beckmann, Ifeanichukwu Okike, Shazaad Ahmad, Joanna Garstang, Andrew J Brent, Bernadette Brent

**sKIDs Team:** Felicity Aiano, Zahin Amin-Chowdhury, Louise Letley, Oliver Martin, Jessica Flood, Emily-Jane Picton, Samuel Jones, Anna Mensah, Paul Charter, Corinne Whillock, Deborah Cohen, Kim Taylor, Johanna Bosowski, Yves-Pearl Hurley, Cherstyn Hurley, Francine Stalham, Hiran Hirani, Alpa Shah

**PHE Statisticians:** Jemma Walker, Nick Andrews

**PHE Immunisation and Countermeasures Division:** Vanessa Saliba, Gayatri Amirthalingam, Jamie Lopez Bernal, Michael Lattimore, Kevin Brown, Mary Ramsay

**PHE Virus Reference Department:** Maria Zambon, John Poh, Shabnam Jamarani, Andrew Mumford, Neil Woodford, Steve Harbour

**PHE Manchester:** Ray Borrow, Ezra Linley

**Birmingham:** Paul Moss, Alexander Dowell

# Girl with COVID-19 warrior sign





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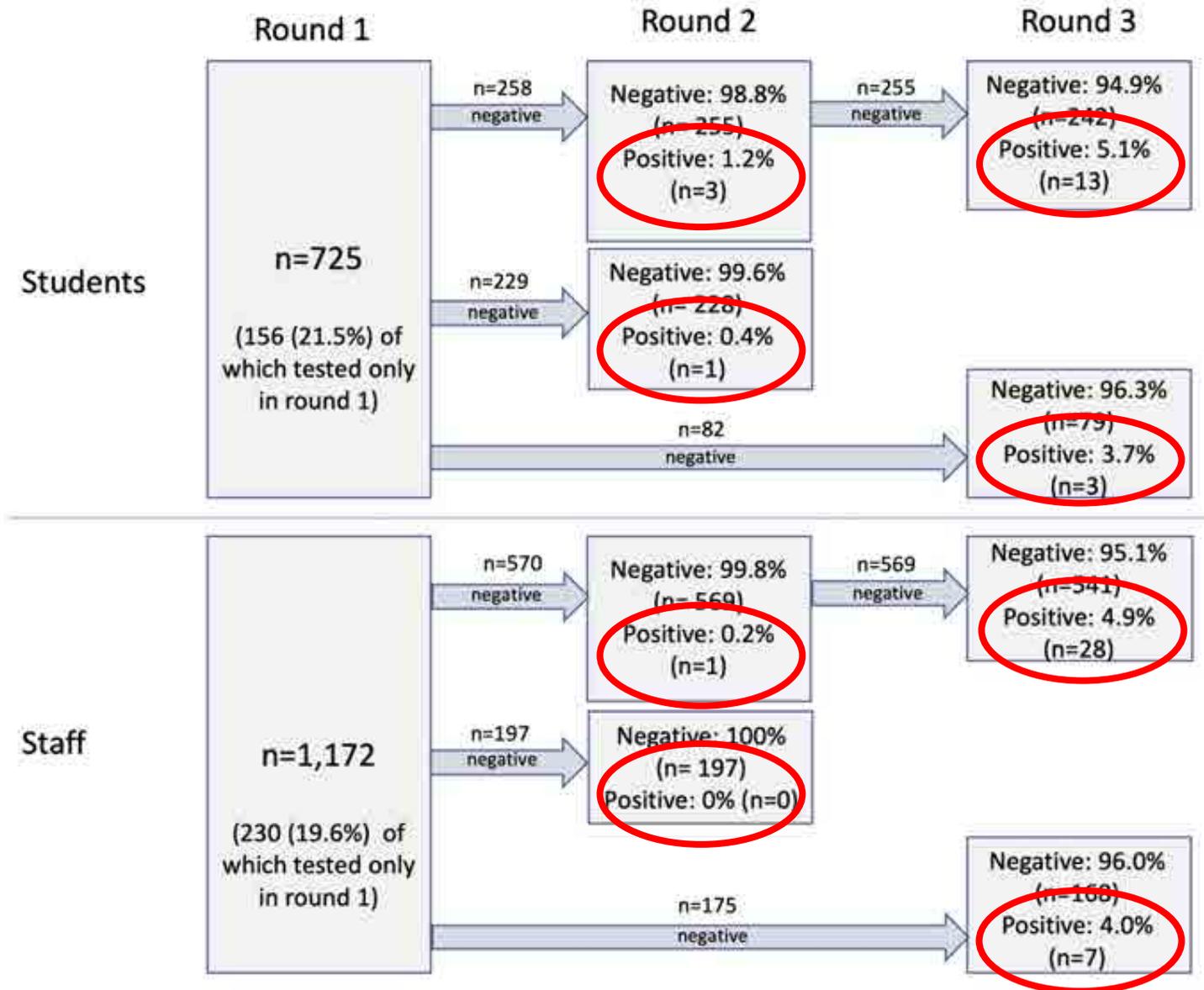
# skids

COVID-19 Surveillance  
in  
Primary School Kids

# Girl getting a COVID serology test



## Seroconversion in primary school staff and students





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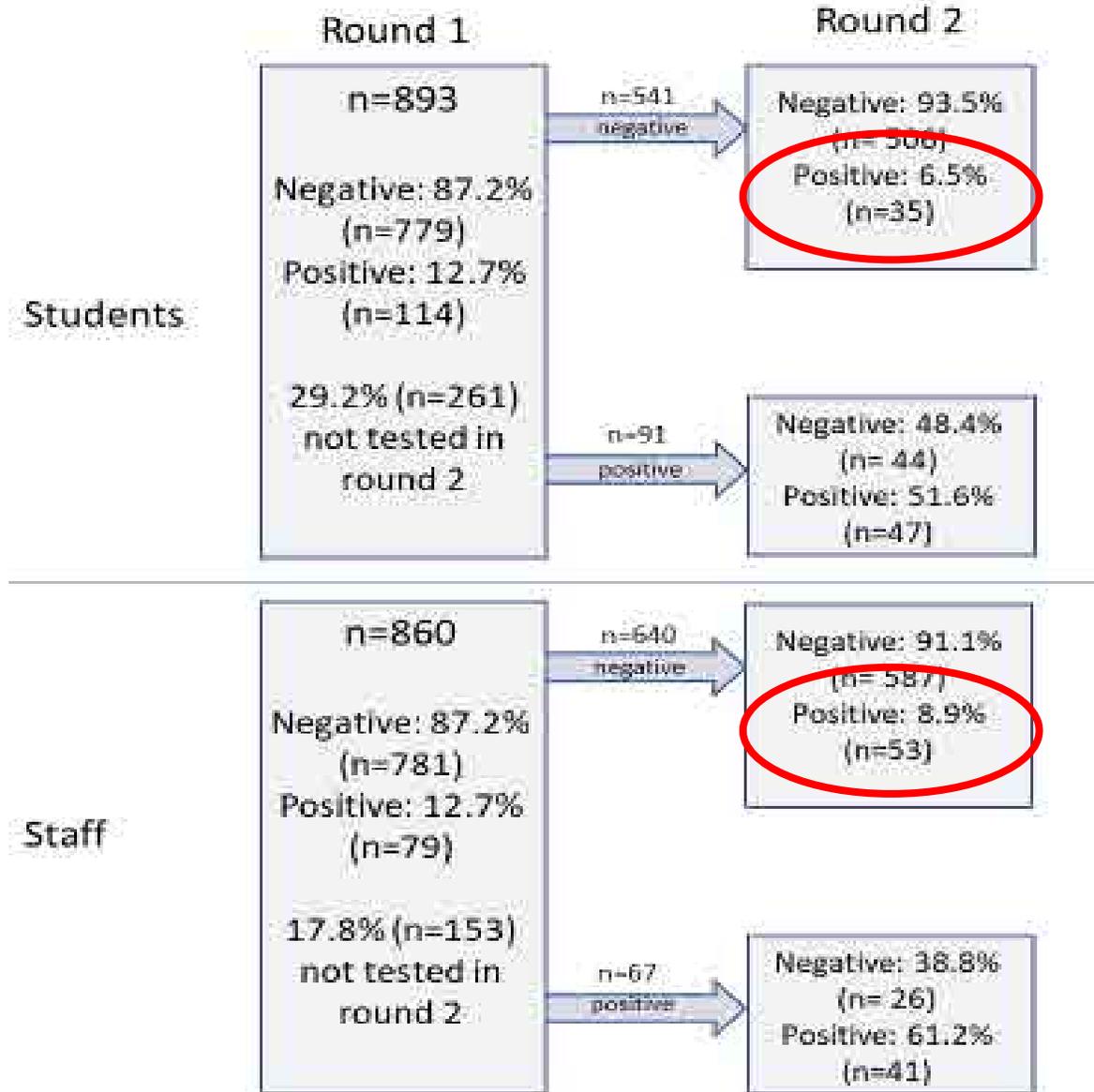
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COVID-19 Surveillance  
in  
Secondary School Students

# sKIDsPLUS:

## COVID-19 surveillance in Secondary Schools

### Seroconversion rates in staff and students





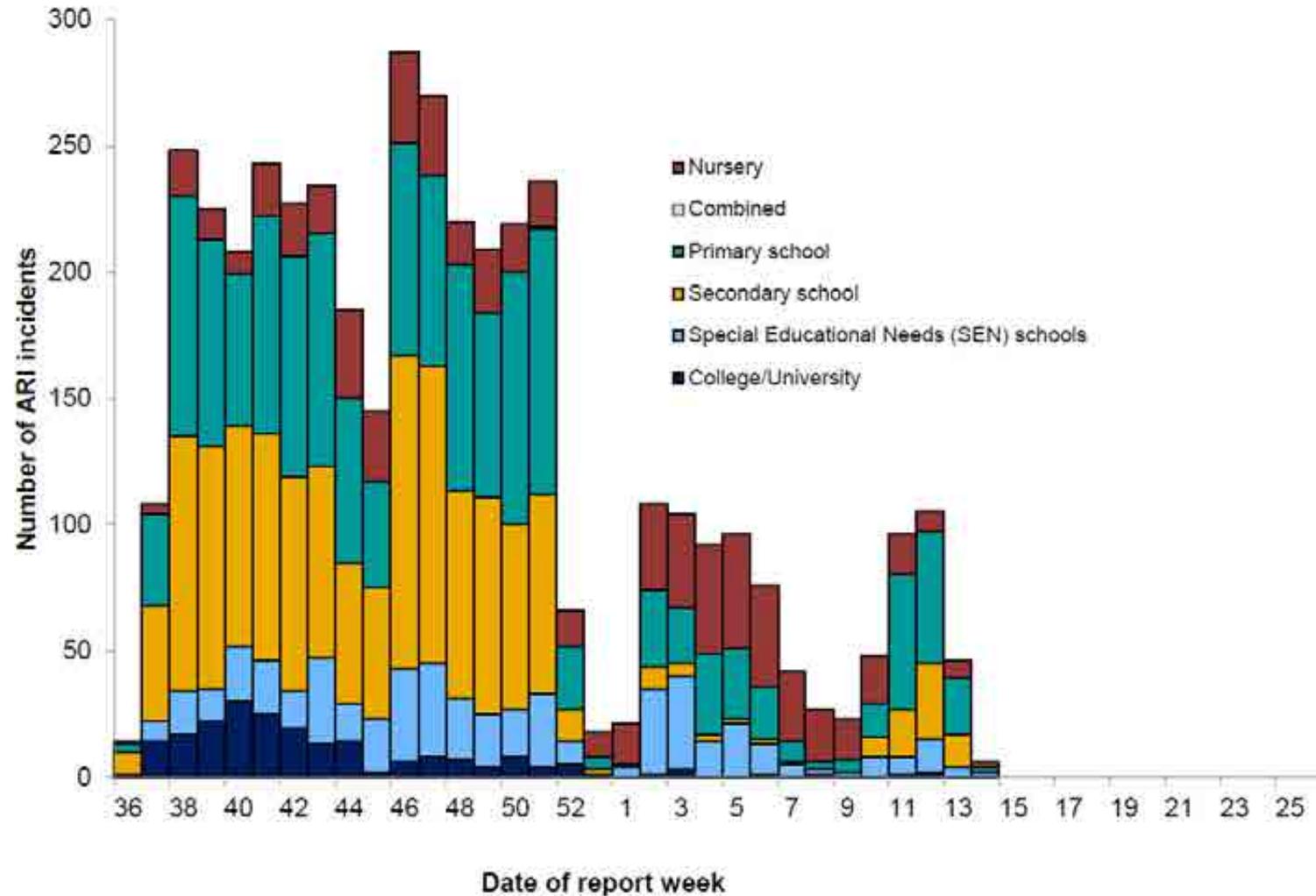
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# **COVID-19 outbreaks in Educational Settings after full reopening of schools**

(September – October 2020)

# Outbreaks in Educational Settings



# Outbreaks in Educational Settings

- Full reopening of all preschool, primary school and secondary school years in September 2020
- Outbreak investigation during first half-term (31 August - 18 October 2020)
- 969 primary (n=450) & secondary school outbreaks (n=519) reported to PHE → 3% of primary schools and 15% of secondary schools in England.
- 369 schools contacted in November 2020 → 190 geographically-representative schools completed questionnaire; 2,425 cases reported.

# Size of outbreaks

|                      | School Type                                 |   |  | All settings<br>n (%) |
|----------------------|---|---|--|-----------------------|
|                      | Primary<br>n (% of cases in<br>the setting) | Secondary<br>n (% of cases in<br>the setting) | Combined (% of<br>cases in the<br>setting) |                       |
| Student cases        | 328 (41%)                                   | 1105 (73%)                                    | 66 (59%)                                   | 1499 (62%)            |
| Staff cases          | 471 (59%)                                   | 410 (27%)                                     | 45 (41%)                                   | 926 (38%)             |
| Total cases          | 799 (33%)                                   | 1515 (62%)                                    | 111 (5%)                                   | 2425 (100%)           |
| Number of outbreaks  | 100   | 79  | 11   | 190                   |
| Median, days (IQR)   | 6 (4-10)                                    | 15 (8.5-27)                                   | 6 (4.5-15.5)                               | 9 (5-16)              |
| Interquartile range  | 6   | 18.5  | 11   | 11                    |
| Mode number of cases | 3   | 6   | 5  | 6                     |
| Range per outbreak   | 2-35  | 2-100   | 2-26                                       | 2-100                 |

# Attack Rates in Students and staff

|  | School Type              |                           |                          |                              |
|--|--------------------------|---------------------------|--------------------------|------------------------------|
|  | Primary<br>(100 schools) | Secondary<br>(79 schools) | Combined<br>(11 schools) | All schools<br>(190 schools) |
| Total student cases                    | 328                      | 1105                      | 66                       | 1499                         |
| Total students                         | 39,027                   | 91,919                    | 8,551                    | 139,497                      |
| Student attack rate, % (95% CI)        | 0.84%<br>(0.75-0.94%)    | 1.20<br>(1.13-1.28%)      | 0.77%<br>(0.60-0.99%)    | 1.08%<br>(1.02-1.13%)        |
| Total staff cases                      | 471                      | 410                       | 45                       | 926                          |
| Total staff                            | 5852                     | 11510                     | 1721                     | 19083                        |
| Staff attack rate, % (95% CI)          | 8.05%<br>(7.37-8.78%)    | 3.56%<br>(3.24-3.92%)     | 2.62%<br>(1.94-3.51%)    | 4.85%<br>(4.55-5.17%)        |
| Teaching staff cases                   | 378                      | 284                       | 31                       | 637                          |
| Total teaching staff                   | 3852                     | 7146                      | 1039                     | 12,037                       |
| Teaching staff attack rate, % (95% CI) | 9.81%<br>(8.90-10.82%)   | 3.97%<br>(3.54-4.46%)     | 2.98%<br>(2.07-4.26%)    | 5.76%<br>(5.35-6.19%)        |
| Non-teaching staff cases               | 93                       | 126                       | 14                       | 233                          |
| Total non-teaching staff, % (95% CI)   | 2000                     | 4364                      | 682                      | 7,046                        |
| Staff attack rate                      | 4.65%<br>(3.79-5.69%)    | 2.89%<br>(2.42-3.44%)     | 2.05%<br>(1.17-3.51%)    | 3.31%<br>(2.91-3.76%)        |
| Total cases                            | 799                      | 1515                      | 111                      | 2425                         |
| Total population (staff & students)    | 44879                    | 103429                    | 10272                    | 158580                       |
| Attack rate, % (95% CI)                | 1.78%<br>(1.66-1.91%)    | 1.47%<br>(1.39-15.4%)     | 1.08%<br>(0.89-1.31%)    | 1.53%<br>(1.47-1.59%)        |

# Index Case in Outbreaks

|  | School type |           |           |            |
|--|-------------|-----------|-----------|------------|
|  | Primary     | Secondary | Combined  | Total      |
| <b>Index case in the outbreak</b>      | n (%)       | n (%)     | n (%)     | %          |
| Teaching staff                         | 48 (48%)    | 25 (32%)  | 4 (36%)   | 77 (40.5%) |
| Student                                | 35 (35%)    | 47 (59%)  | 5 (45%)   | 87 (45.8%) |
| Non-teaching staff                     | 9 (9%)      | 6 (8%)    | 1 (9%)    | 16 (8%)    |
| Another source                         | 1 (1%)      | 0 (0%)    | 0 (0%)    | 1 (1%)     |
| Not reported                           | 7 (7%)      | 1 (1%)    | 1 (9%)    | 9 (5%)     |
|  |             |           |           |            |
| <b>Groups affected by the outbreak</b> | n (%)       | n (%)     | n (%)     | %          |
| Staff only                             | 6 (6%)      | 1 (1%)    | 1 (9%)    | 8 (4%)     |
| 1 year group only                      | 39 (39%)    | 5 (6%)    | 2 (18%)   | 46 (24%)   |
| More than 1 year group                 | 55 (55%)    | 73 (92%)  | 8 (73%)   | 136 (72%)  |
| More than 3 year groups                | 13 (13%)    | 54 (68%)  | 5 (45%)   | 72 (38%)   |
| <b>Total</b>                           | <b>100</b>  | <b>79</b> | <b>11</b> | <b>190</b> |

# Staff / Students affected

|                    |                | School type |              |            |             |
|--------------------|----------------|-------------|--------------|------------|-------------|
| Index Case         | Group affected | Primary     | Secondary    | Combined   | All         |
| Teaching staff     | Staff only     | 4/48 (08%)  | 0/25 (-)     | 1/4 (25%)  | 5/77 (06%)  |
|                    | Student only   | 0/48 (-%)   | 0/25 (-)     | 0/4 (-)    | 0/77 (-)    |
|                    | Both           | 44/48 (92%) | 25/25 (100%) | 3/4 (75%)  | 72/77 (94%) |
| Student            | Staff only     | 0/35 (-)    | 1/47 (2%)    | 0/5 (-)    | 1/87 (1%)   |
|                    | Student only   | 10/35 (29%) | 6/47 (13%)   | 0/5 (-)    | 28/87 (32%) |
|                    | Both           | 25/35 (71%) | 40/47 (85%)  | 5/5 (100%) | 48/87 (55%) |
| Non-teaching staff | Staff only     | 2/9 (22%)   | 0/6 (-)      | 0/1 (-)    | 2/16 (13%)  |
|                    | Student only   | 0/9 (-)     | 0/6 (-)      | 0/1 (-)    | 0/16 (-%)   |
|                    | Both           | 7/9 (78%)   | 6/6 (100%)   | 1/1 (100%) | 14/16 (88%) |

# Serological studies in Educational Settings

| Lachassinne,<br>France (Jun-Jul 2020)<br>22 daycare centres | <ul style="list-style-type: none"> <li>• 327 children, 197 staff, 164 controls</li> <li>• 3.7% (1.3–6.8), children, 6.8% (3.2-11.5) staff, 5.0% adult controls – children most likely exposed to household adult with COVID-19 (43% vs 19; RR 7.1 [2.2-22.4).</li> <li>• ol adults</li> </ul>             |
|---|---|
| Ladhani<br>England (Jun-Dec 2020)<br>45 primary schools     | <ul style="list-style-type: none"> <li>• 5.6% (19/340; 3.4-8.6) children vs. 4.8% (36/745; 3.4–6.6) staff seroconverted</li> <li>• Seropositivity not associated with school attendance during lockdown or staff contact with students in school</li> </ul>   |
| Ladhani<br>England (Sep-Dec 2020)<br>18 secondary schools   | <ul style="list-style-type: none"> <li>• 2,209 participants: 1,189 (53.8%) students &amp; 1,020 (46.2%) staff</li> <li>• SARS-CoV-2 infection rates similar in staff &amp; students, and national prevalence</li> <li>• 8.3% (53/641) staff vs. 6.5% (35/542) students seroconverted (p=0.24).</li> </ul> |
|   |   |

# SARS-CoV-2 Transmission in Schools

|                                |  |
|--------------------------------|--|
| Buonsenso, Italy               | 1,350 (1,059 students, 145 teachers, 146 others) had COVID-19<br>1,212/65,104 (1.8%) schools affected<br>>90% had only 1 case in school, only 1 high school had >10 cases<br>192 (15.8%) schools closed entirely, esp nursery/kindergartens                              |
| Larosa, Italy                  | SARS-CoV-2 transmission in 41 classes of 36 schools<br>Secondary attack rate was 3.2%, reaching 6.6% in middle/high schools.<br>More timely isolation and testing of classmates reduce transmission  |
| Zimmerman, North Carolina, USA | 11 school districts, >90,000 students and staff attending school in-person for 9 weeks<br>773 community-acquired SARS-CoV-2 infections<br>Only 32 additional infections identified through contact tracing that were acquired in school                                  |
| Falk Wisconsin USA             | 17 rural Wisconsin schools, 4,876 students & 654 staff (August 31–November 29, 2020)<br>Incidence (3,453/100,000) lower than in the county overall (5,466 per 100,000).<br>Of 191 cases in students/staff, only 7 (3.7%), all among students, linked to in-school spread |
| Varma, New York USA            | COVID-19 prevalence in public schools similar or less than community rates (Oct-Dec 2020)<br>Of 36,423 school-based close contacts, only 191 (0.5%) subsequently tested positive<br>Likely index case was an adult for 78.0% of secondary cases.                         |
| RIVM, Netherlands              | Just over half the cases in secondary school clusters were acquired outside school,<br>Mainly during intensive contact with friends or classmates in their free time<br>Most infections restricted to small groups of students without affecting teachers                |



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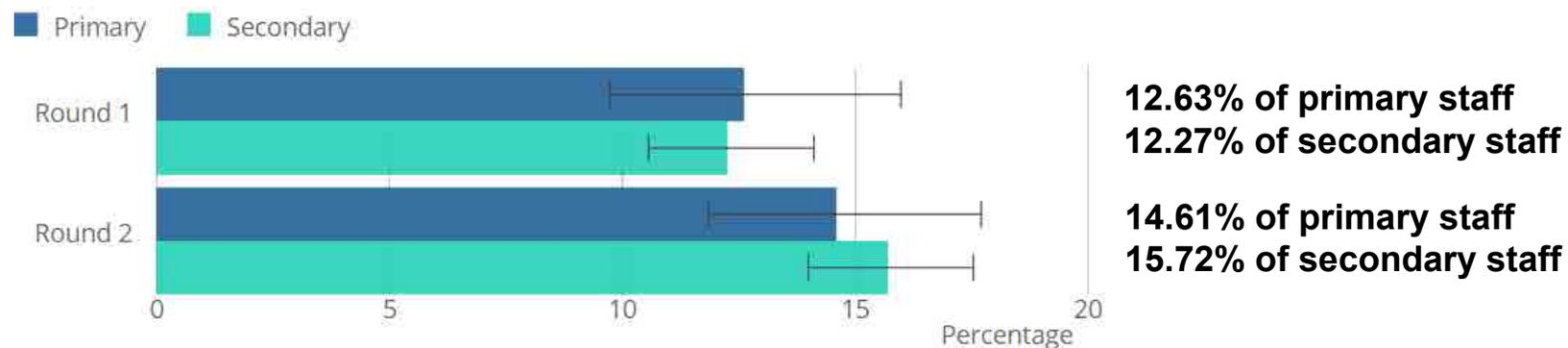
# SIS

## School Infection Survey

(PHE, ONS, LSHTM)

- 12,204 participants (5,114 staff; 7,089 pupils)
- 121 Primary (41) & Secondary (42) Schools
- 7,751 both rounds (3,322 staff; 4,429 pupils)

# SARS-CoV-2 antibodies in School Staff



Source: Office for National Statistics: COVID-19 Schools Infection Survey

## Covid-19 Infection Survey, working age population same local authorities

- 12.51% (November)
- 18.22% (December)



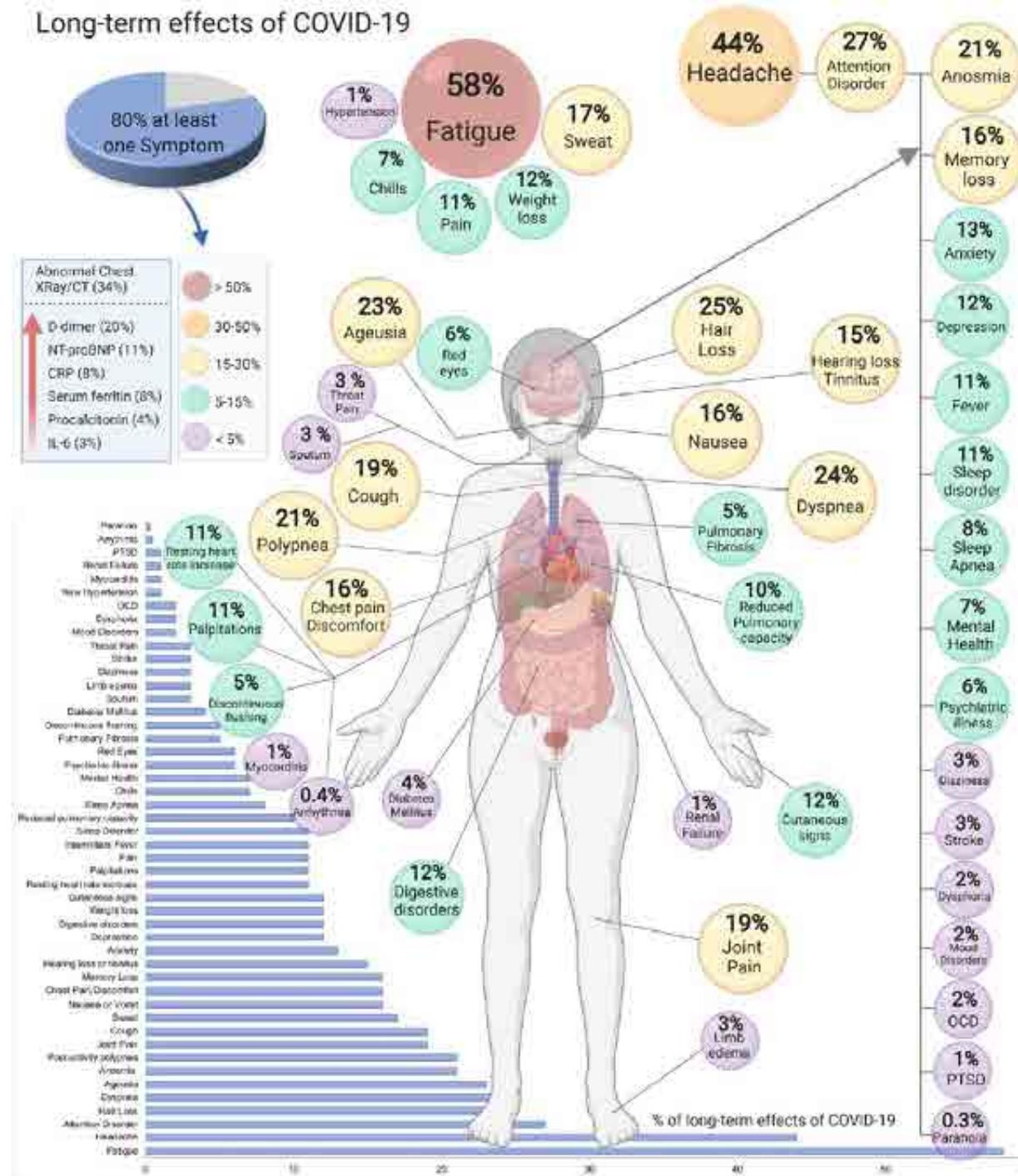
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# Long COVID in Children

# COVID effect on the body

Long-term effects of COVID-19



- After symptomatic or **asymptomatic** infections

- After confirmed or **suspected** COVID-19

- *Persistent*
- *Intermittent*
- *Relapsing*
- *New onset*

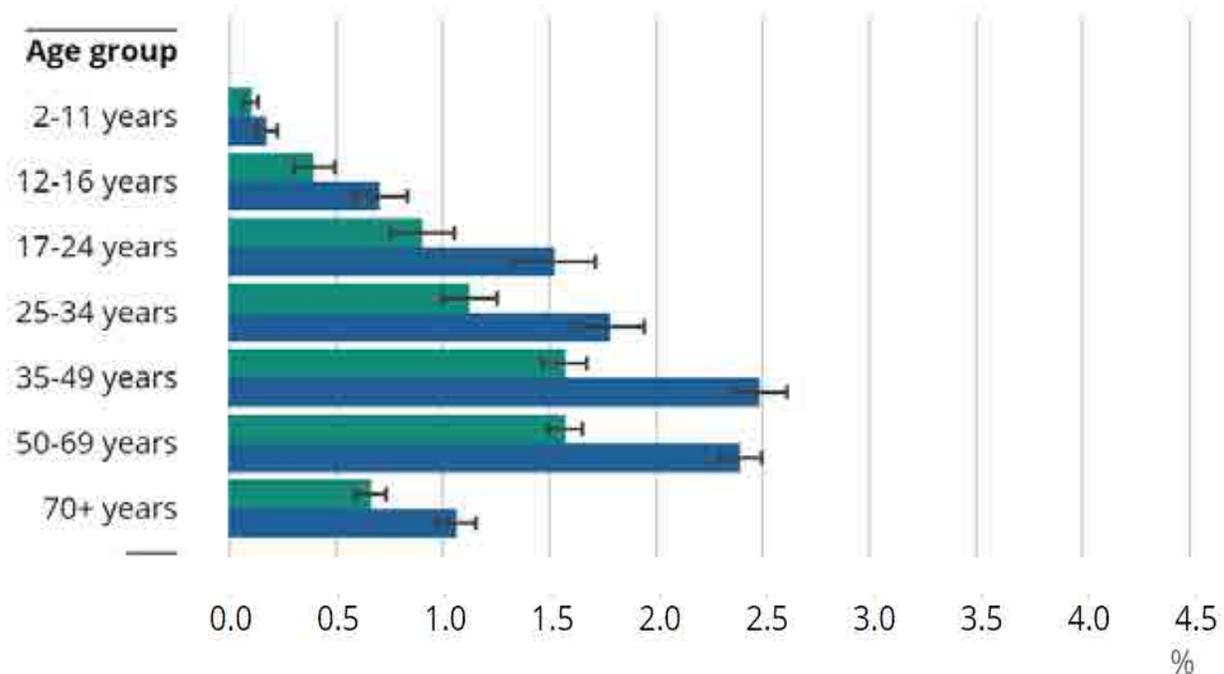
Lopez-Leon et al. MedRxiv  
20 January 2021: doi:  
<https://doi.org/10.1101/2021.01.27.21250617>

# Office for National Statistics, UK (March 2021)

Over the four-week period ending 6 March 2021, an estimated 1.1 million people in private households in the UK were experiencing self reported long COVID.

Any duration      Duration 12+ weeks

*“Would you describe yourself as having ‘long COVID’, that is, you are still experiencing symptoms more than 4 weeks after you first had COVID-19, that are not explained by something else?”*



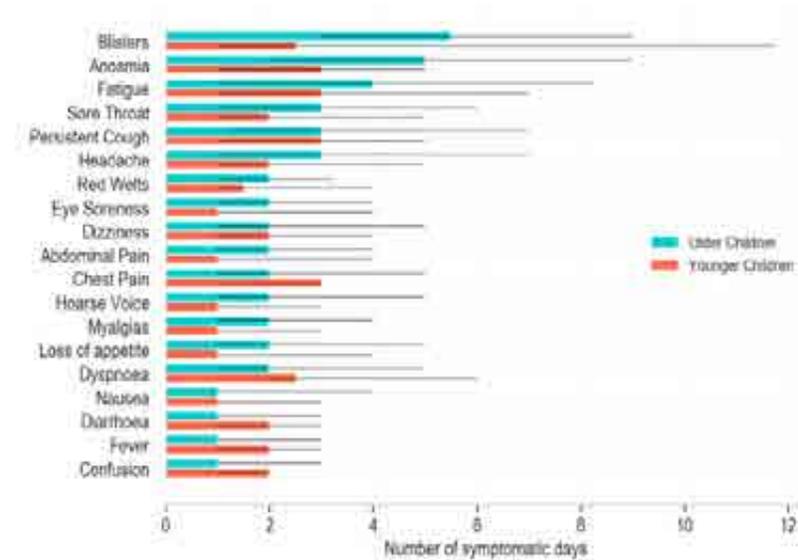
# Illness duration and symptom profiles

## Illness duration and symptom profile in a large cohort of symptomatic UK school-aged children tested for SARS-CoV-2

Erika Molteni PhD<sup>1\*</sup>, Carole H. Sudre PhD<sup>1,2,3\*</sup>, Liane S. Canas PhD<sup>1</sup>, Sunil S. Bhopal PhD<sup>4</sup>, Robert C. Hughes MPH MB ChB<sup>5</sup>, Michela Antonelli PhD<sup>1</sup>, Benjamin Murray MSc<sup>1</sup>, Kerstin Kläser MSc<sup>1</sup>, Eric Kerfoot PhD<sup>1</sup>, Liyuan Chen MSc<sup>1</sup>, Jie Deng PhD<sup>1</sup>, Christina Hu BA<sup>6</sup>, Somesh Selvachandran MEng<sup>6</sup>, Kenneth Read BSc<sup>6</sup>, Joan Capdevila Pujol PhD<sup>6</sup>, Alexander Hammers PhD<sup>1,7</sup>, Tim D. Spector PhD<sup>8</sup>, Sebastien Ourselin PhD<sup>1</sup>, Claire J. Steves PhD<sup>9</sup>, Marc Modat PhD<sup>1</sup>, Michael Absoud PhD<sup>6,10</sup>, Emma L. Duncan PhD<sup>6,10</sup>.

- 1,734 children with confirmed COVID-19
- Median illness duration: 6 days (vs. 3 days in test-negative children)
- Positive association between illness duration and increasing age ( $p < 0.0001$ )
- 77 (4.4%) had illness  $\geq 28$  days (older > younger children; 5.1% vs. 3.1%;  $p = 0.046$ )
- Commonest symptoms: fatigue (84%), headache (80%) & anosmia (80%);
- At 56 days, 1.8% had persistent symptoms vs. 0.9% of controls

Figure 3. Median duration of each symptom [IQR] in younger (5-11 years) and older (12-17 years) children.



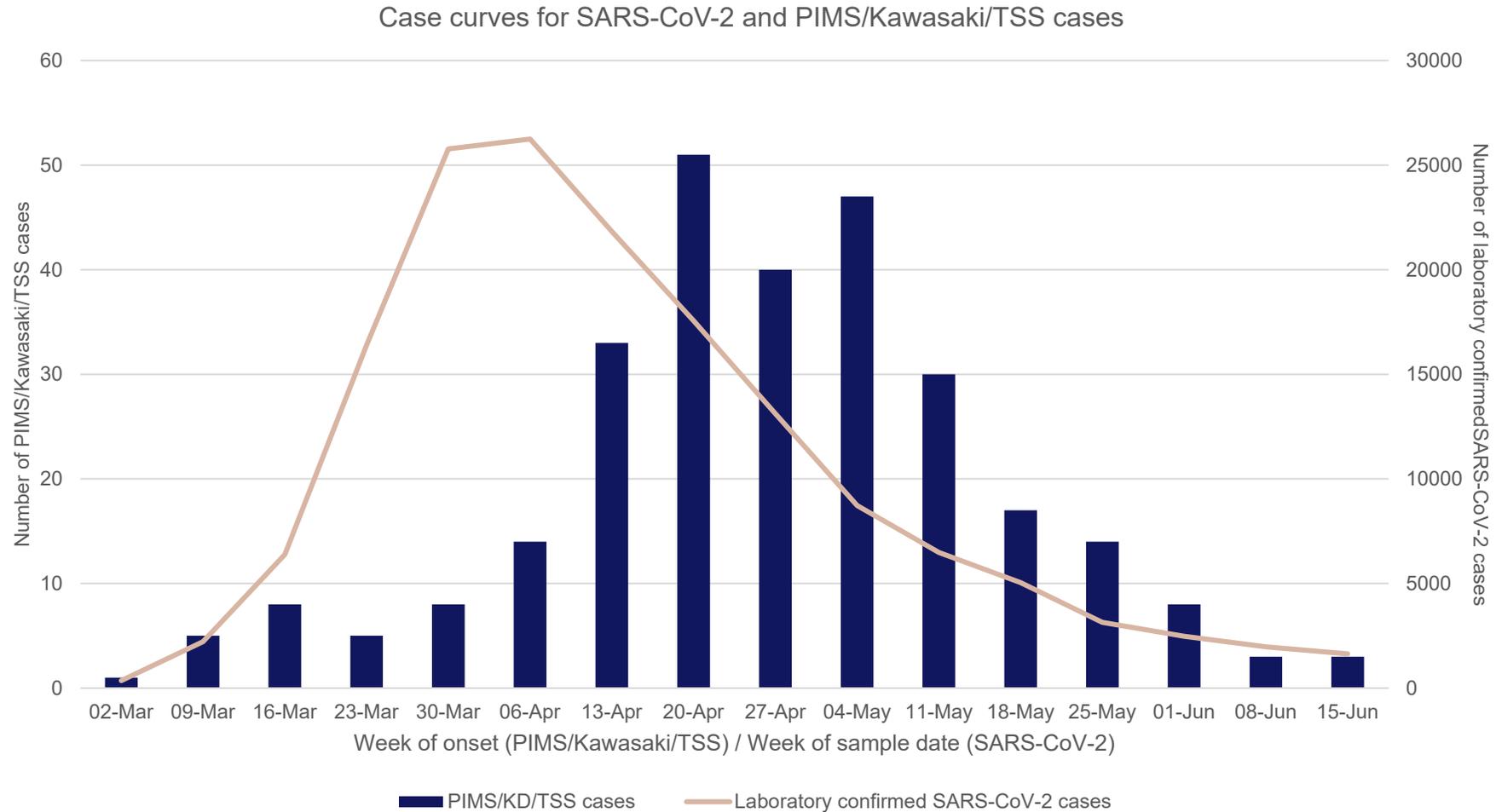


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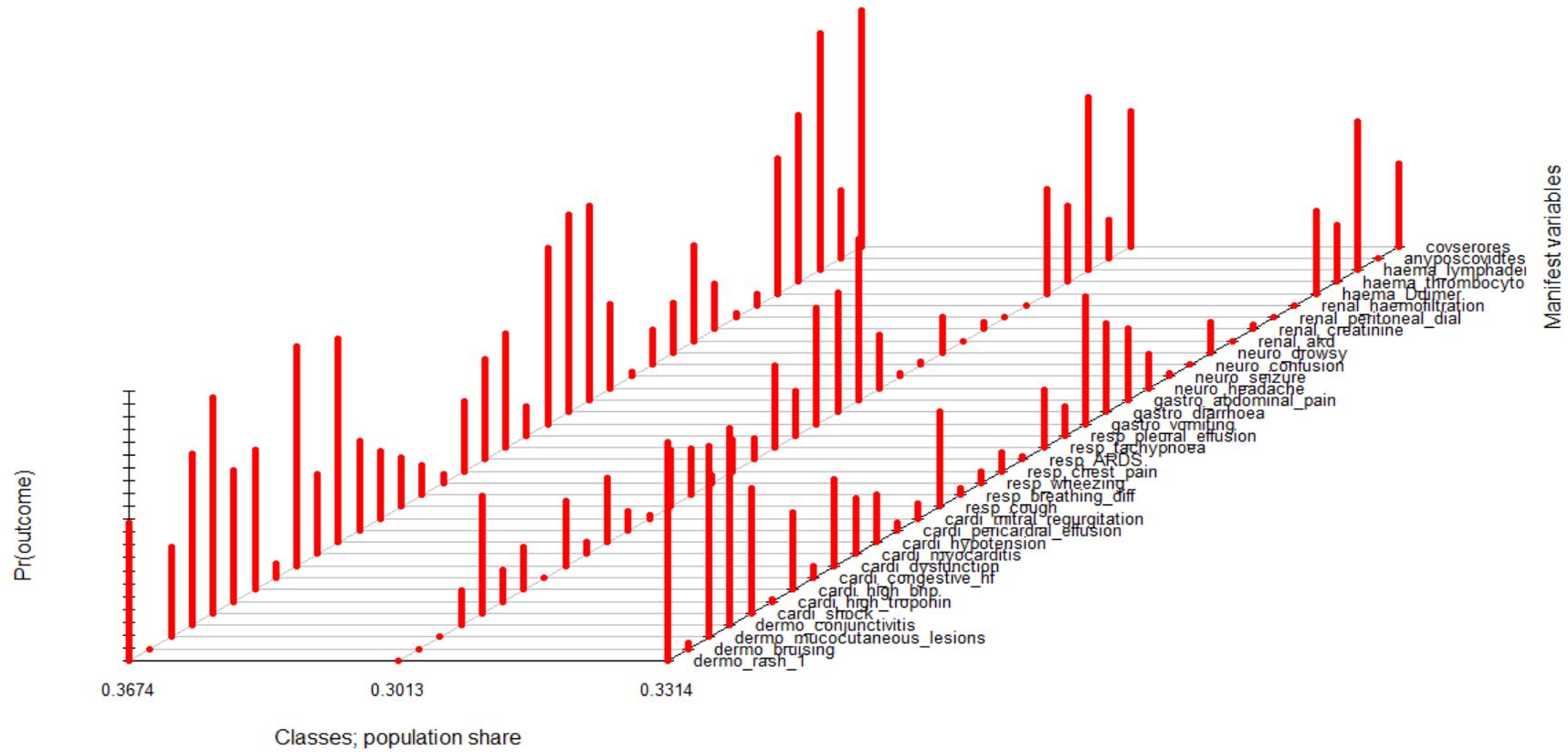
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# PIMS-TS / MIS-C in Children

# Hyperinflammatory syndrome, UK



# Latent Class analysis, PIMS cases



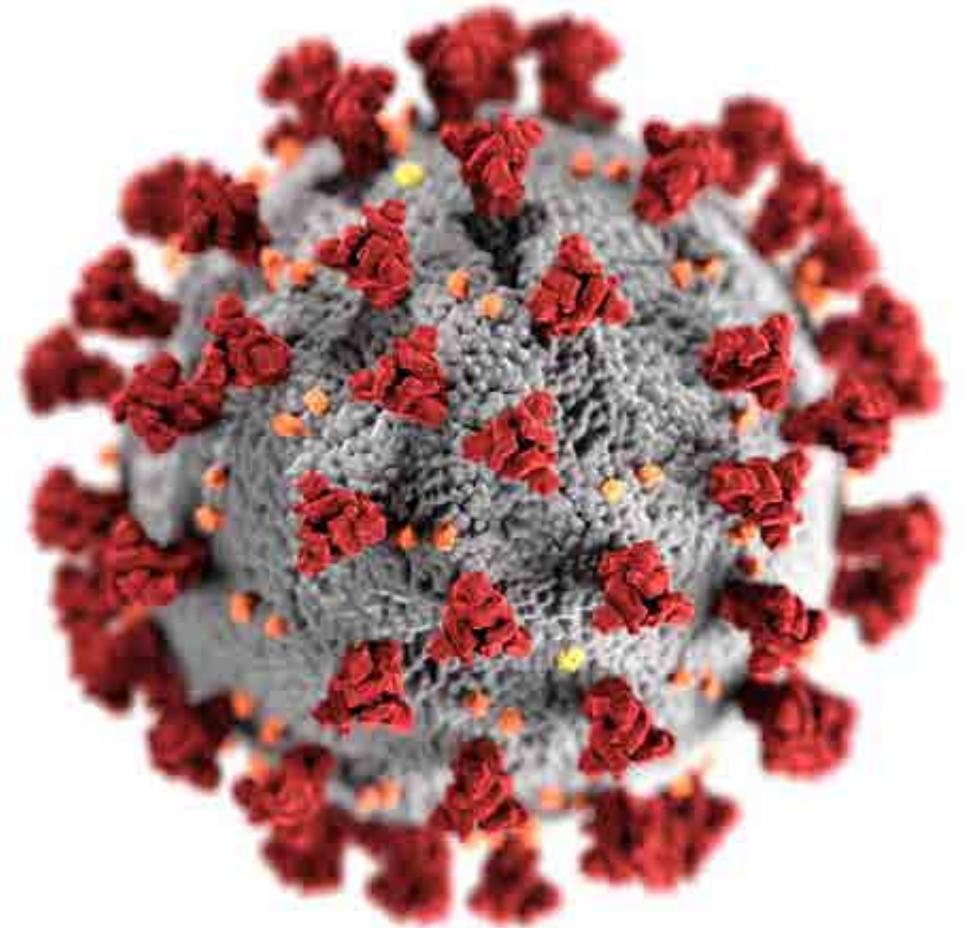
# Supporting implementation of screening testing in K-12 schools

**Angelica O'Connor, MPH**

**ELC Program Coordinator**

**Division of Preparedness and Emerging Infections**

**National Center for Emerging and Zoonotic Infectious Diseases**



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

# National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

## Division of Preparedness and Emerging Infections

Director: Henry Walke, MD, MPH

Deputy Director: Satish Pillai, MD, MPH (CAPT, USPHS)

Deputy Director for Management & Operations: Zach Braden, MBA

### Associate Director for Science

Scott Santibañez, MD, MPHTM (CAPT, USPHS)

### Associate Director for Laboratory Science

Todd Parker, PhD

### Communication Lead

Elizabeth Allen, MSPH

### Program Management Official

Traci Simpson

### Senior Scientific Advisor to the Director

Margaret (Peggy) Honein, PhD, MPH

### Policy Lead

Amanda Raziano, MPH

### Senior Advisor for Strategy & Partnerships

Kay Hogue, MBA

### Arctic Investigations Program

Michael Bruce, MD, MPH (CAPT, USPHS)  
Director

### Emergency Preparedness and Response Branch

Dale Rose, PhD, MSc,  
Branch Chief

### Laboratory Preparedness and Response Branch

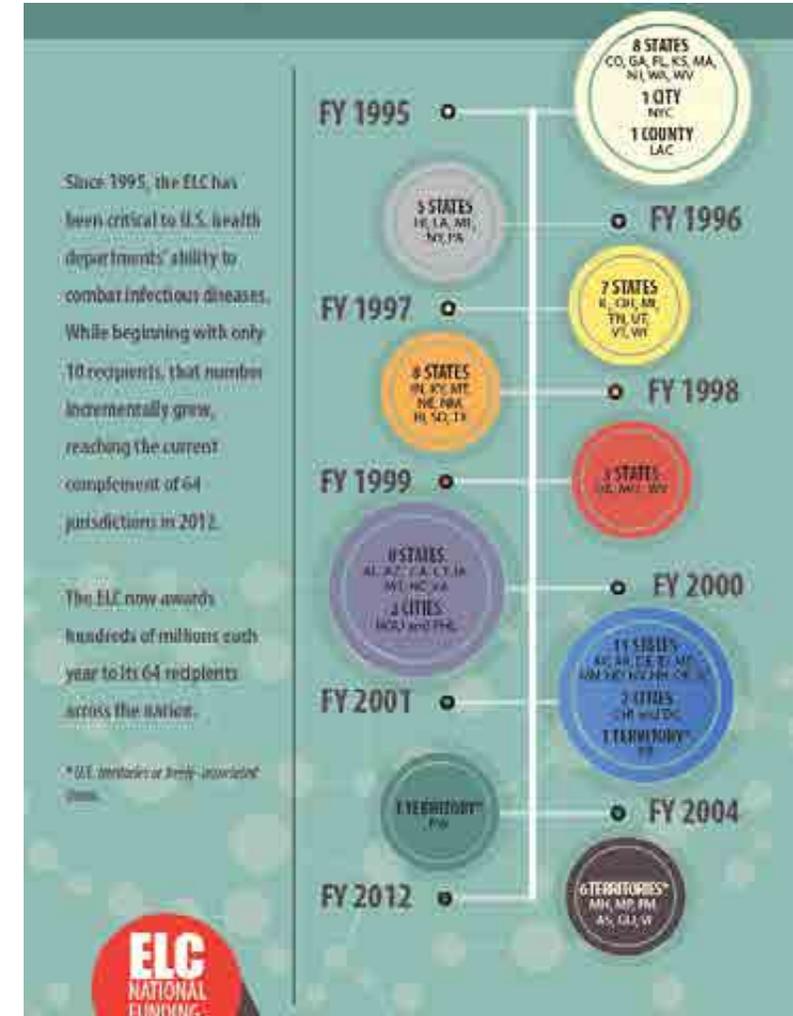
Julie Villanueva, PhD,  
Branch Chief

### Scientific Programs and Development Branch

Alvin Shultz, MSPH,  
Branch Chief

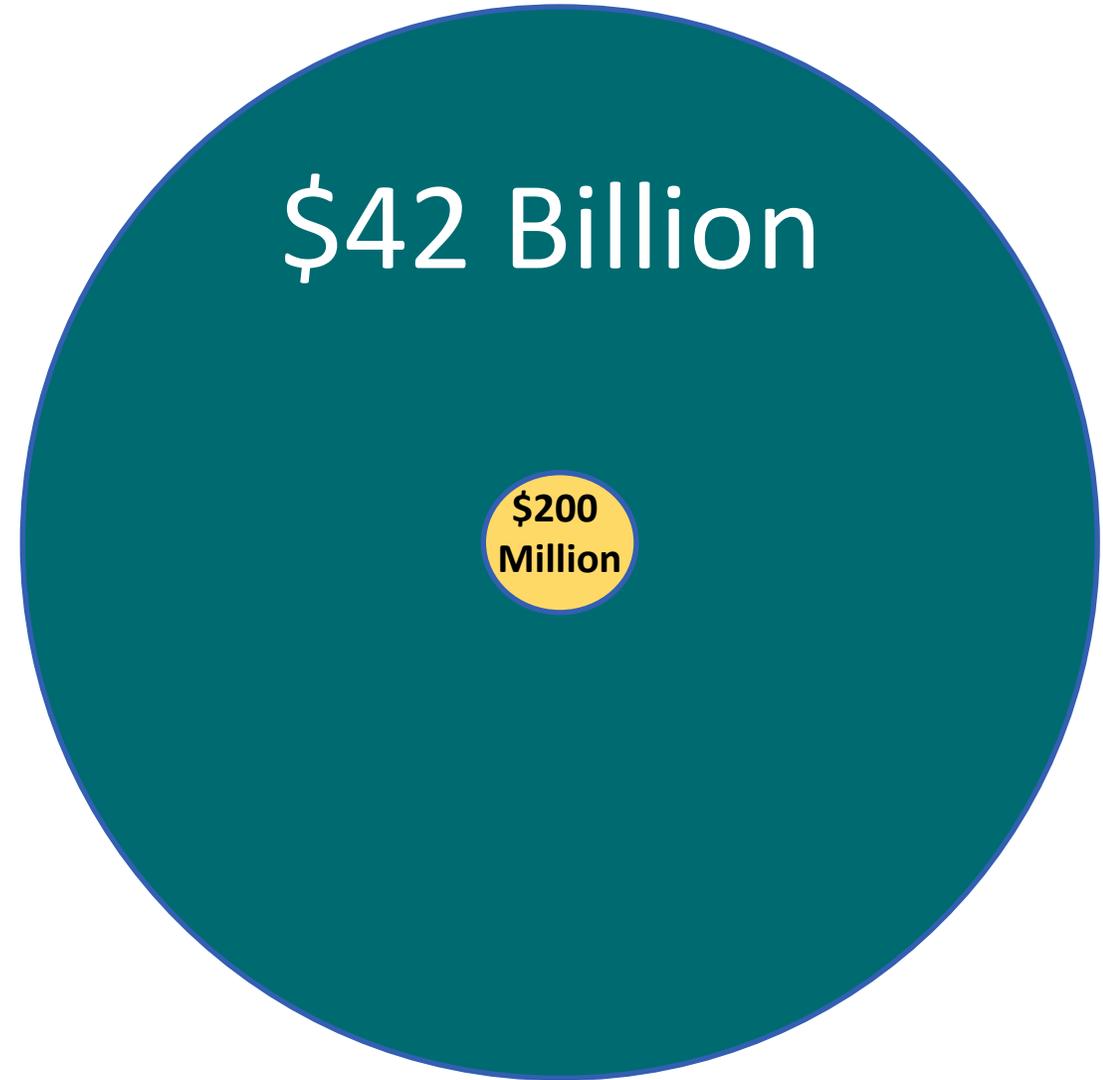
# National Capacity Building Cooperative Agreement

- **Mission:** To build the governmental public health system capacity for emerging infectious disease prevention, detection, response, and control.
- **ELC supports the nation**
  - State Health Departments = 50
  - Largest Local Health Departments = 6
  - Territories and affiliates = 8
- **Customer-service focus**



# Federal COVID funding and impact on ELC budget

- Coronavirus Aid Relief and Economic Security Act (CARES Act)
- Paycheck Protection Program and Health Care Enhancement Act
- Coronavirus Preparedness and Response Supplemental Appropriations Act
- Coronavirus Response and Relief Supplemental Appropriations Act
- **American Rescue Plan Act**



# ELC Reopening Schools award

- \$10 billion to 64 ELC recipients from American Rescue Act Plan of 2021
- Comprehensive screening testing for K-12 schools (public, charter, and private)
  - 2020-2021 School year
    - Spring: immediate implementation of pilot school screening testing where possible
    - Summer: summer school, camps and planning for Fall
  - 2021-2022 School year:
    - Fall: Widespread screening testing implemented in schools
    - Summer: Funding period ends 7/31/22



# Technical Assistance: School Support Section and ELC

- One-on-one calls with jurisdictions
- Rockefeller STAT K-12 Calls
- Bi-weekly Community of Practice Calls
- Targeted regional and topical calls
- Communication toolkit in development

To get kids back in-person safely, schools should monitor



Community Transmission    Vaccination Coverage    Testing    Outbreaks

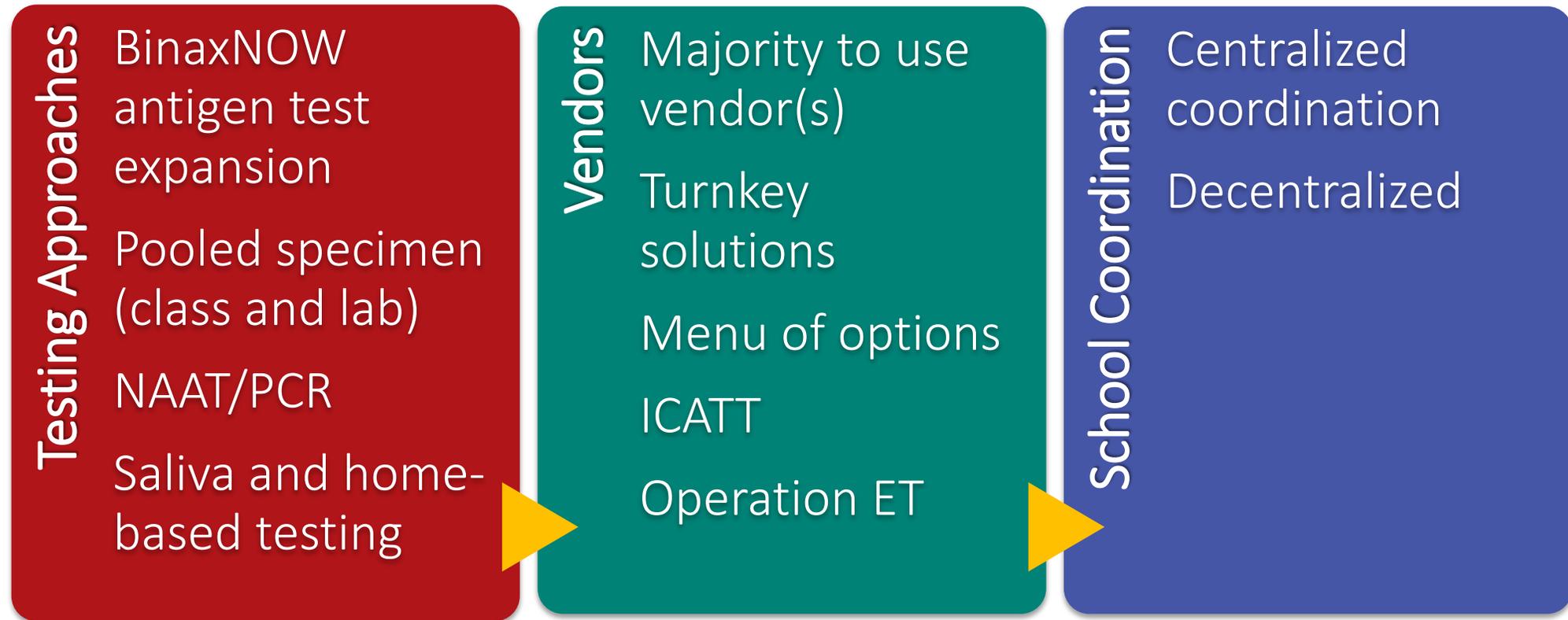
to help prevent the spread of COVID-19



[cdc.gov/coronavirus](https://www.cdc.gov/coronavirus)

(CDC/ASPP/2020)

# Initial K-12 Plans for screening testing



# Challenges

## School Participation

- Schools overwhelmed by numerous priorities
- For schools that stayed open, uncertainty of the need for screening testing
- Lack of support from parents, community members, state/local government
- Continued concern about testing being painful for students

## Trade offs

- Example: Dropping distancing requirements and the need for close contacts to quarantine if schools achieve a certain percentage of participation in screening testing program

# Feedback from recipients

## Alternatives to full screening testing implementation

- Only providing screening testing at high-risk sports or events
- Testing for surveillance purposes
- Limiting screening testing to a particular subset of students (e.g., those living and going to school in a confinement setting for youths)

## Common feedback and requests

- Diagnostic testing
- Ventilation upgrades
- Vaccination promotion

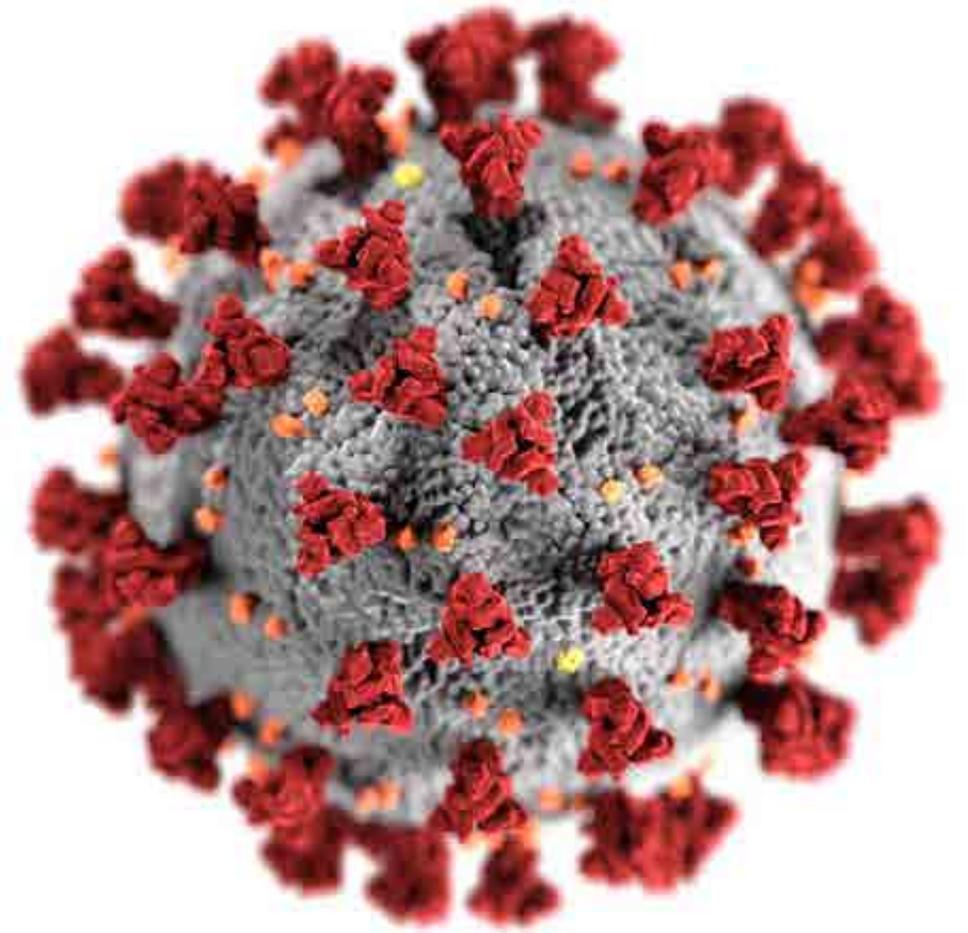
# Integrating feedback: Updated *ELC Reopening Schools*

- Focus remains on screening testing as a critical layer of protection against the spread of COVID-19 in K-12 setting
- Scope broadened and/or explicitly allows for:
  - Diagnostic testing
  - Testing events at school that may include family and/or community members (e.g., athletic events)
  - PPE
  - Portable HEPA filtration units or fans
- Description of current plan for the Fall and how districts may scale based on community transmission levels

<https://www.cdc.gov/ncezid/dpei/pdf/guidance-elc-reopening-schools-508.pdf>

# Next steps





For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

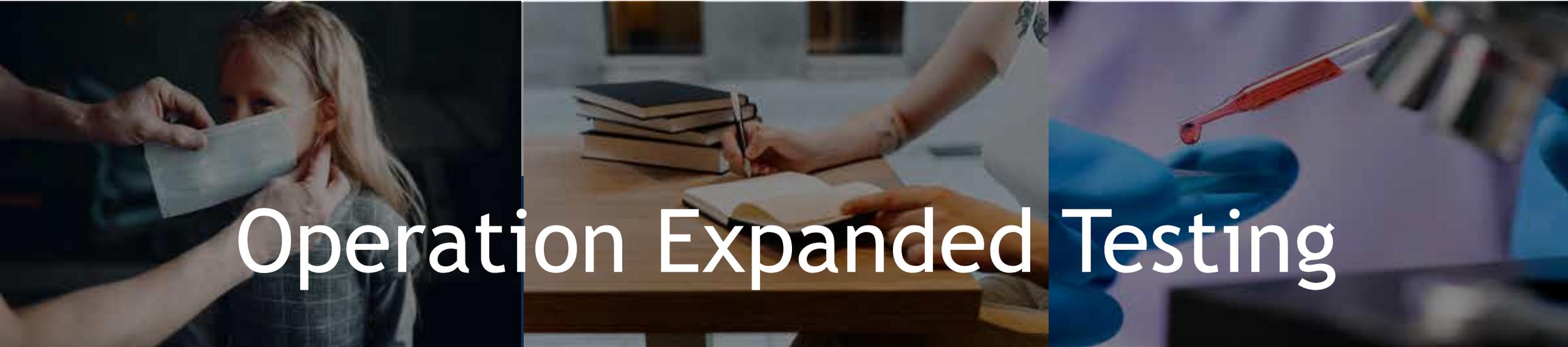
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



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# Operation Expanded Testing

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HHS Testing and Diagnostics Work Group

Dr. Matthew Humbard | Operation E.T. Program Lead

AUGUST 2021

# Testing and Diagnostics Working Group (TDWG) administers 2 testing programs focused on support of vulnerable and underserved groups

Focus for today

## 1 Testing Programs

### Operation Expanded Testing (Op ET):

- Provides no-cost testing to K-8 schools and underserved congregate settings
- Manages testing through regional "coordination hubs"

### Increasing Community Access to Testing (ICATT):

- Provides no-cost testing to underserved populations
- Operates in pharmacies, schools, surge & pop-up sites, hot spots, and priority surveillance locations

## 2 Procurement & Distribution

### Direct Procurement:

- Purchases constrained (Binax) or novel (Ellume) supplies and distributes to target groups

### Federal Supply Schedule (FSS):

- Supports the addition of tests to the FSS

### Supply Exchange:

- Offers a forum for orgs. to ask for or offer up testing supplies

### Strategic National Stockpile (SNS):

- Builds and stores the national testing supply stockpile

## 3 Information Exchange

### Industry Engagement:

- Engages with MFRs and labs to assess testing landscape and monitor supply trajectory

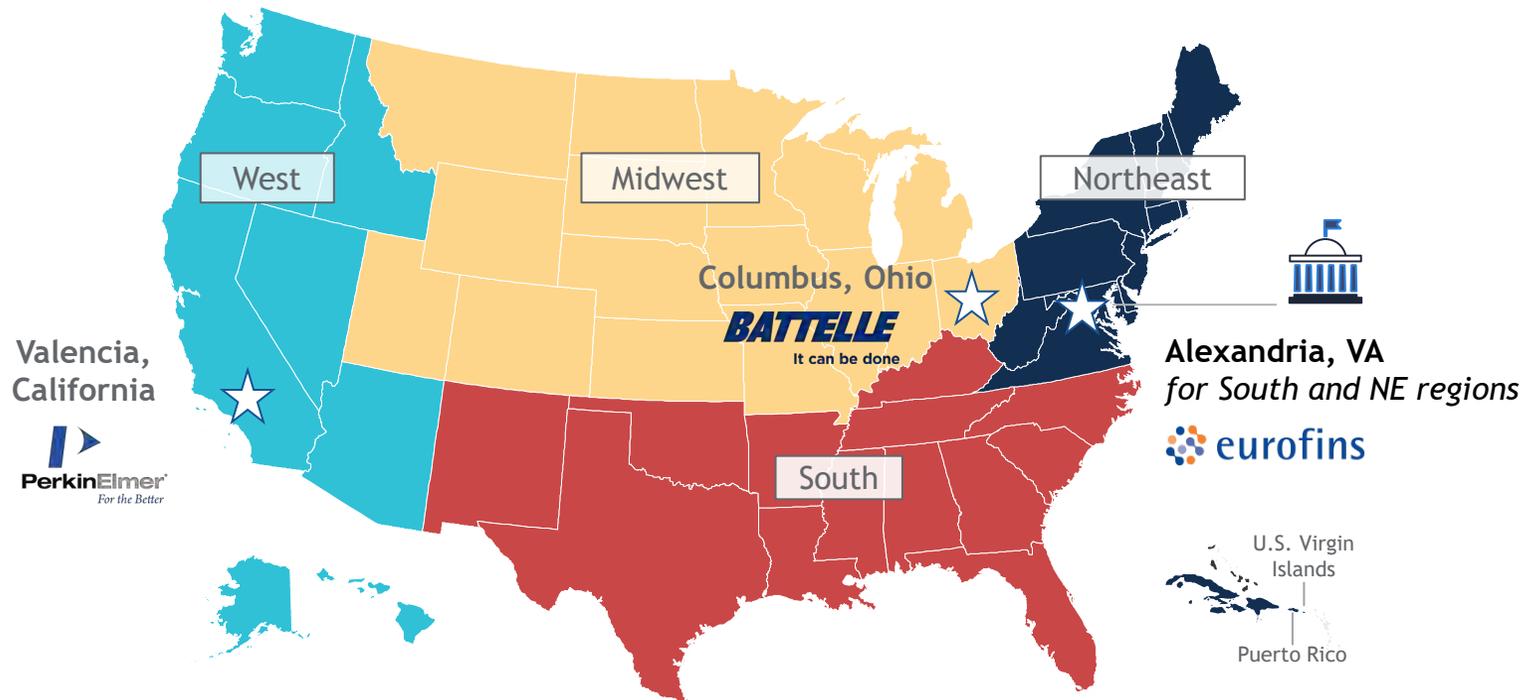
### State Engagement:

- Enable visibility across TDWG of state specific testing issues
- Assists with SW border migration testing needs

### Data Analytics & Informatics:

- Creates automated diagnostic test reporting systems
- Synthesizes federal and state data into cohesive analysis

# OpET objective to expand COVID testing for schools, underserved populations and congregate settings via coordination hubs

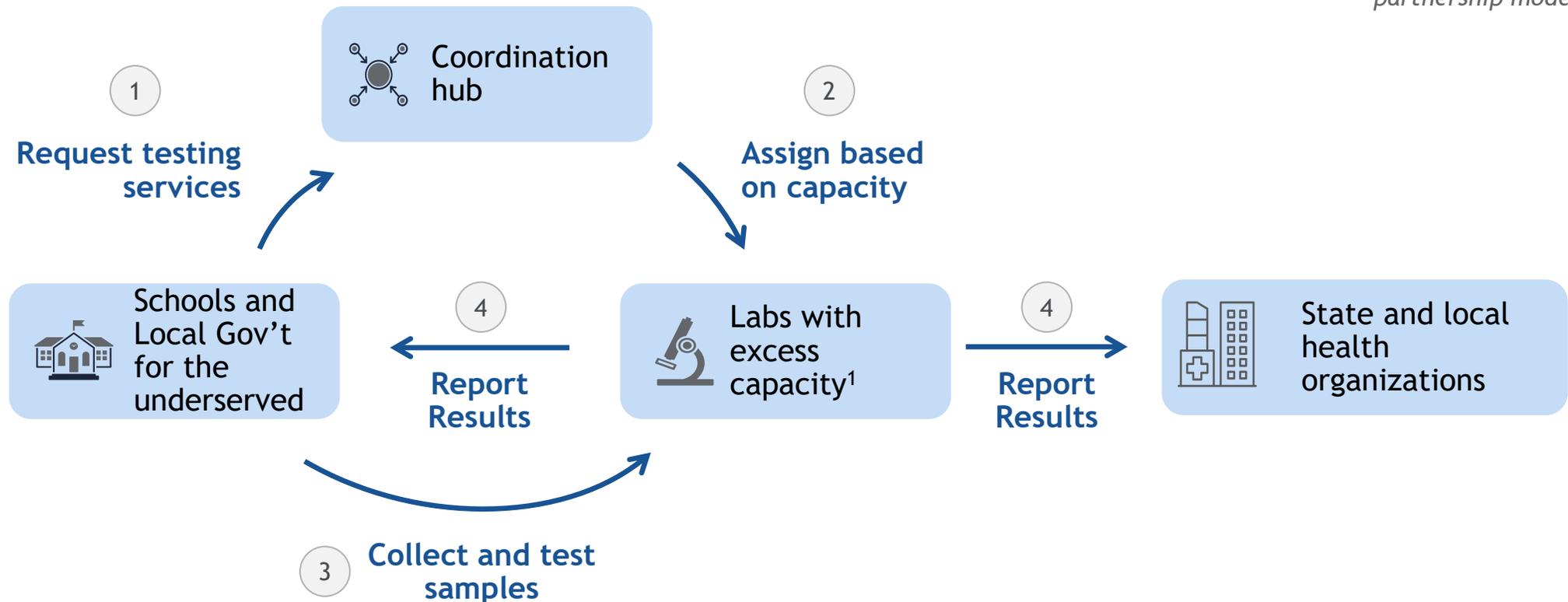


## Program highlights

- Operation E.T. is divided into **4 regions served by 3 coordination hubs**, with USG oversight across the entire program
  - West - Perkin Elmer
  - Midwest - Battelle
  - Northeast - Eurofins
  - South - Eurofins
- **Screening services provided at no-cost** to schools and other qualifying sites (e.g., homeless shelters, women's shelters, prisons, HBCUs, congregate settings with high SVIs etc.)
- Coordination hubs work with enrolled sites to create **tailored testing plan**

# Coordination hubs connect testing laboratories with qualifying sites to rapidly establish COVID-19 screening services

*Illustrative view of partnership model*



1. Patient specific results from non-CLIA certified laboratory cannot be reported to individuals or health care providers, but population-level aggregate results may be reported to public health agencies

# Hub testing approaches vary by hub, but all will leverage PCR testing with <72h turnaround

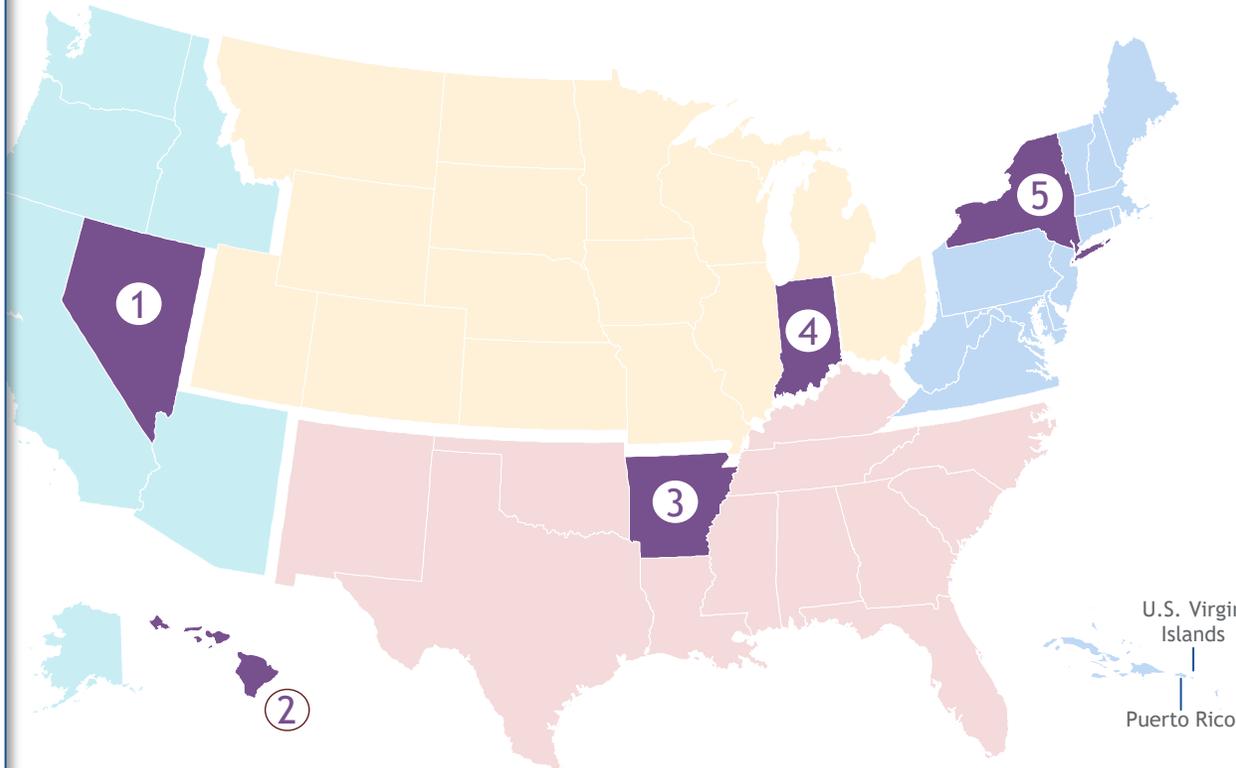


|   | West                               | Midwest   | Northeast/South   |
|---|------------------------------------|---|---|
|  <b>Test type</b>                  | PCR, Antigen <sup>1</sup><br>Nasal | PCR, Antigen <sup>1</sup><br>Nasal, Saliva TBD              | PCR, Antigen <sup>1</sup><br>Nasal                          |
|  <b>Pooling approach</b>          | Not pooled                         | 5-10 samples  | 5-24 samples  |
|  <b>Turn around time targets</b> | <48 hours for tests                | 24 hours (for neg. pools)<br>48 - 72 hours (for pos. pools) | 24 hours (for neg. pools)<br>30 - 48 hours (for pos. pools) |

1. Antigen used for select populations only (e.g., screening of symptomatic participants to minimize positive pools, if common carrier shipments are not possible)

# Examples of enrolled sites from various states

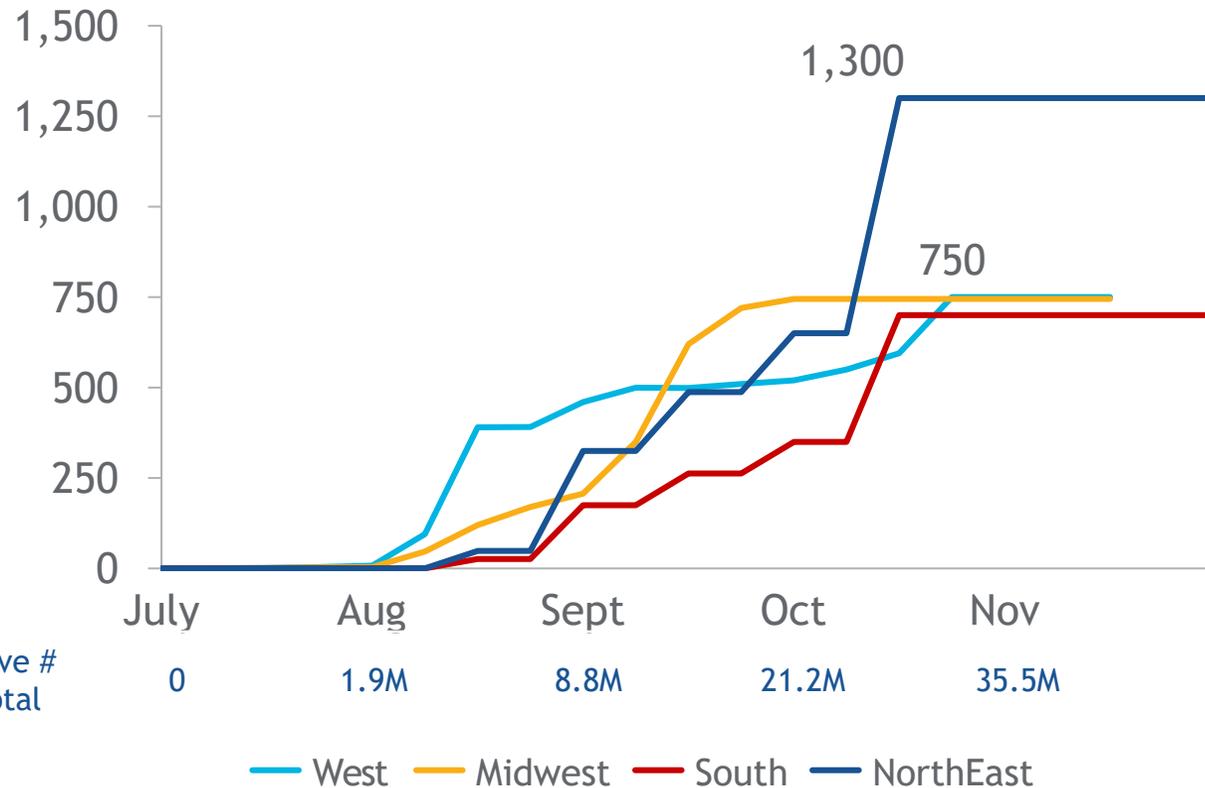
- 1 Nevada**  
Clark County Fire Dept  
Boys and Girls Club  
Nevada YMCA
- 2 Hawaii**  
3 K-12 schools  
Correctional facilities  
Congregate settings
- 3 Arkansas**  
26 prisons via AR Dept  
of Corrections
- 4 Indiana**  
70+ schools  
6 shelters
- 5 New York**  
Buffalo School District



*Anticipate greater number of school enrollments in upcoming weeks as more school decision makers return from summer recess*

# Hubs project testing to increase rapidly once schools begin starting in August

**Projected weekly tests by hub**  
(in thousands)



Cumulative # tests, total

July 0 Aug 1.9M Sept 8.8M Oct 21.2M Nov 35.5M

— West — Midwest — South — NorthEast

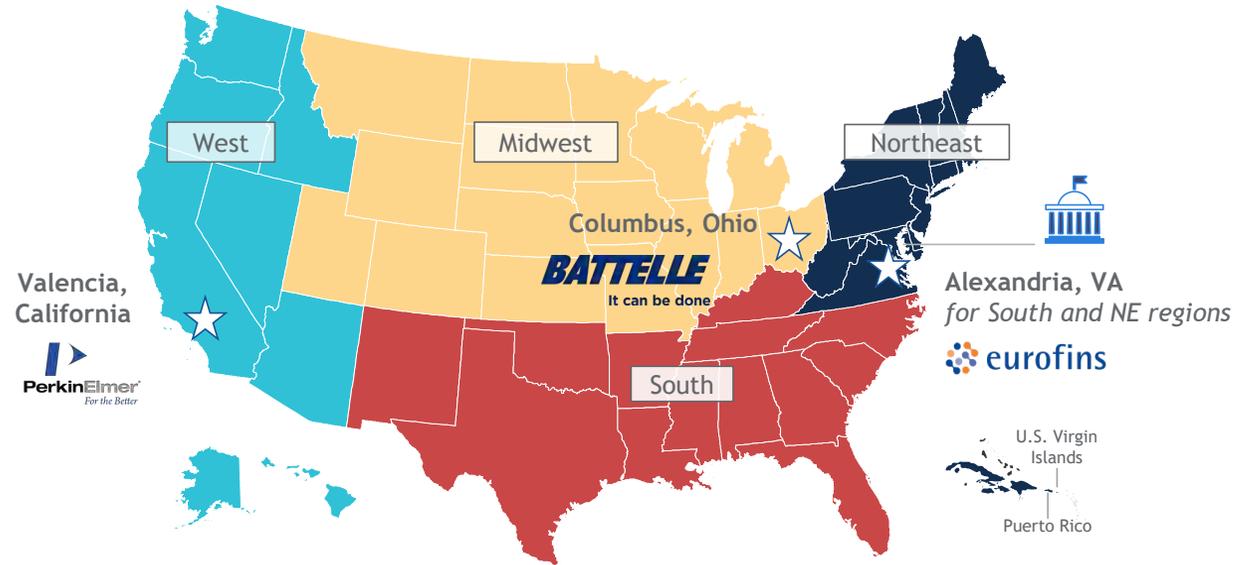
## Enrollment and testing statistics (as of 8/6)

**994**  
Sites enrolled

**4.1k**  
Tests completed



# For more information, please reach out to the appropriate program manager



**MIDWEST**  
Battelle

**Beverly Roberts (Program General Mgr)**  
robertsbd@battelle.org

[Testedandprotected.org](https://Testedandprotected.org)

**SOUTH AND NORTHEAST**  
Eurofins

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Seanplotner@eurofinsUS.com

[www.operationET.com](https://www.operationET.com)

**WEST**  
Perkin Elmer

**John Hicks (Testing Program Leader)**  
John.hicks@perkinelmer.com

<https://perkinelmer-appliedgenomics.com/home/sars-cov-2-testing-solutions/no-cost-covid-19-testing/>

 **OPERATION ET**  
General Program Management

**Matt Humbarð (Program Manager)**  
Matthew.Humbarð@fda.hhs.gov

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# Testing & Diagnostics Working Group: Increasing Community Access to Testing

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NIH RADx Return to School Workshop

AUGUST 9TH 2021

# Agenda

Overview of ICATT

School testing initiatives

School testing feedback and evaluation

Future outlook for school testing

# Agenda

## ➤ Overview of ICATT

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School testing feedback and evaluation

Future outlook for school testing

# Increasing Community Access to Testing (ICATT) has four primary initiatives



## Pharmacy partnerships

~15M tests

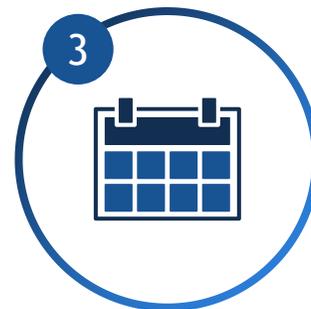
Offer no-cost testing to underserved and vulnerable populations at pharmacies in all 50 states, DC, and PR



## Surge site testing

~1M tests

Rapidly stand-up testing sites in hot spots and priority surveillance locations, in partnership with state and local governments



## Pop-up event testing

~2K tests

Offer no-cost testing for events anticipating high volume of testing

**Today's Focus**



## School screening programs

~5K tests

Provide testing resources to safely reopen K-12 schools, comm. colleges, HBCUs & summer camps in underserved areas

**Transition to Op ET for Fall '21 Testing**

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ICATT program in schools aims to safely re-open schools in underserved school districts by **providing testing resources** and **operational support** to **jumpstart national school testing programs**



## ICATT program in schools has supported the reopening of 150+ schools



Work with existing **ICATT testing contractors** to collect samples, transport and process tests, and provide follow-up testing options



Provide **immediate** school testing support to **underserved school districts**



Help states and school districts **transition to longer-term solutions** or national testing programs that meet school testing needs

# Four criteria guidelines inform ICATT program school district selection



## Criteria

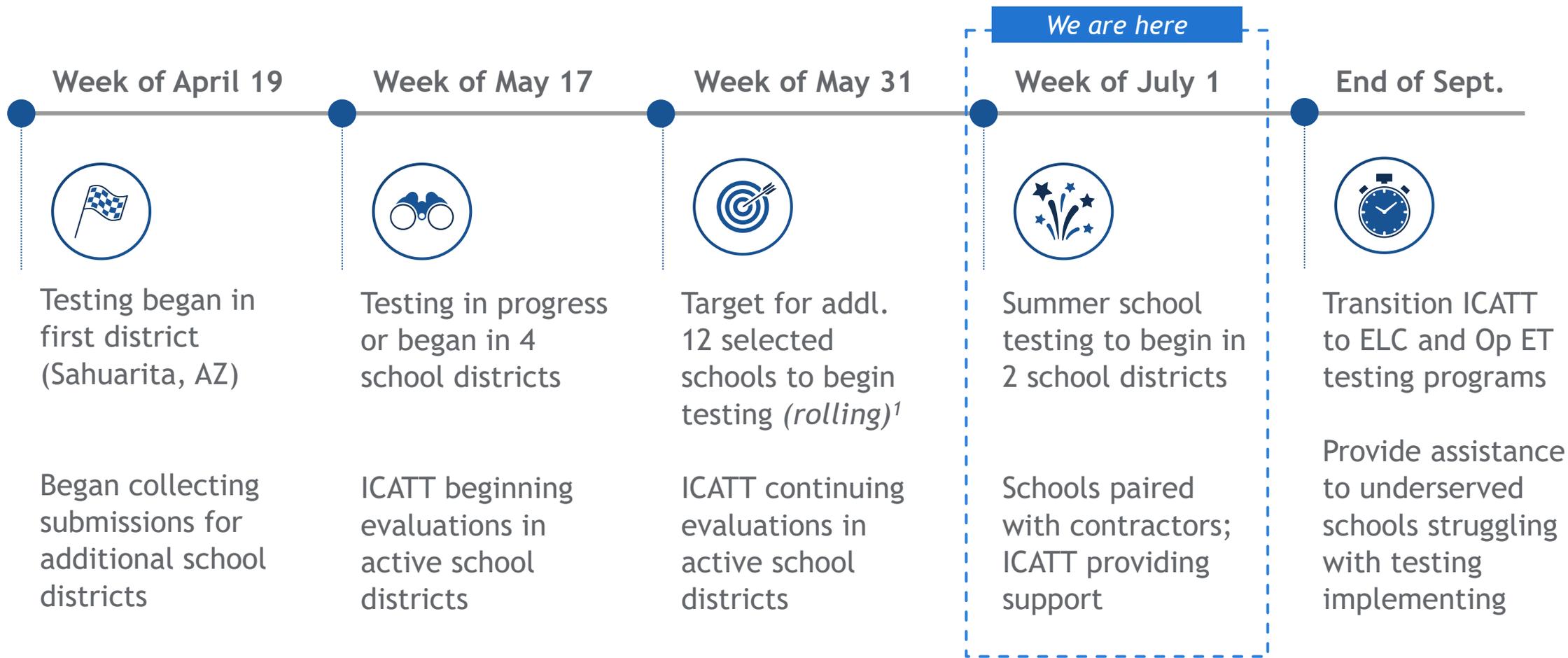


## Requirement

|   |                                    |   |
|---|------------------------------------|---|
| 1 | High Social Vulnerability          | <ul style="list-style-type: none"> <li>Top 40% of the national <b>Social Vulnerability Index (SVI)</b> that identifies communities in need of support during a disaster</li> </ul>                  |
| 2 | High Pandemic Vulnerability        | <ul style="list-style-type: none"> <li>County burden follows a moderate-high <b>Pandemic Vulnerability Index (PVI)</b> with high infection, transmission and testing rates</li> </ul>               |
| 3 | Child Poverty                      | <ul style="list-style-type: none"> <li>Beneficiary of the <b>"Families with Food Stamp/SNAP benefits"</b> provided by the National Center for Education Statistics (NCES)</li> </ul>                |
| 4 | Immediate Need for Testing Support | <ul style="list-style-type: none"> <li>District requires support to <b>open and remain open safely</b></li> <li>District is prepared to implement school testing within <b>2-3 weeks</b></li> </ul> |

# ICATT in Schools began testing in April '21 and will continue through Sep '21

Currently supporting testing in 13 states in districts ranging from 1k-40k students & staff



1. Possible opportunity for ICATT extension to continue testing initiatives

## Detail: ICATT supports 18 school districts with on-site summer school testing through pharmacy partners

|   | Summer schools     |                      |                               |              |
|---|--------------------|----------------------|-------------------------------|--------------|
|   | Assigned districts | Waitlisted districts | # of schools (excl. waitlist) | # of tests   |
|    | 3                  | -                    | 18                            | 740          |
|    | 5                  | 1                    | 54                            | 3,512        |
|    | 6                  | -                    | 78                            | 690          |
|  | 2                  | 1                    | 11                            | 177          |
| <b>Total</b>  | <b>16</b>          | <b>2</b>             | <b>161</b>                    | <b>5,119</b> |

### Status Update

- Districts **continued spring testing** into the summer term
- Testing began 7/28 in **Harford, MD** at a special needs school
- ICATT to understand **fall testing plans** and **transition schools to Op ET**

1. Pending contractor selection or selecting self-administered exams (e.g., Ellume)

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Future outlook for school testing

# ICATT team collected learnings & best practices from school testing programs



Optimize testing process and impact on school openings



Improve expansion of ongoing ICATT school programs



Glean best practices to guide execution of Operation ET

**School survey stakeholder groups include:  
pharmacy partners, district staff, school staff & parents/guardians**

## Recurring themes from Feedback on COVID-19 Testing in Schools validate initial objectives and can inform Operation ET or other future school testing programs



**Schools struggle to generate testing demand and increase consent rates**



**Initial 2+ week time investment in planning is critical to successful school testing program**



**Early and ongoing communication with school staff is important to generate testing program support**



**District and school staff pleasantly surprised by quick results and self-swab testing process**



**Parents & guardians support school testing but are misinformed about program objectives**

Source: Feedback on COVID-19 Testing in Schools (Qualtrics) Note: Survey completion is defined as both indicating background information and answering at least one evaluation content question - ICATT in Schools received 110 total submissions, but 26 did not complete background information and 12 did not complete at least one evaluation content question =  $110 - (26 + 12) = 72$  survey responses

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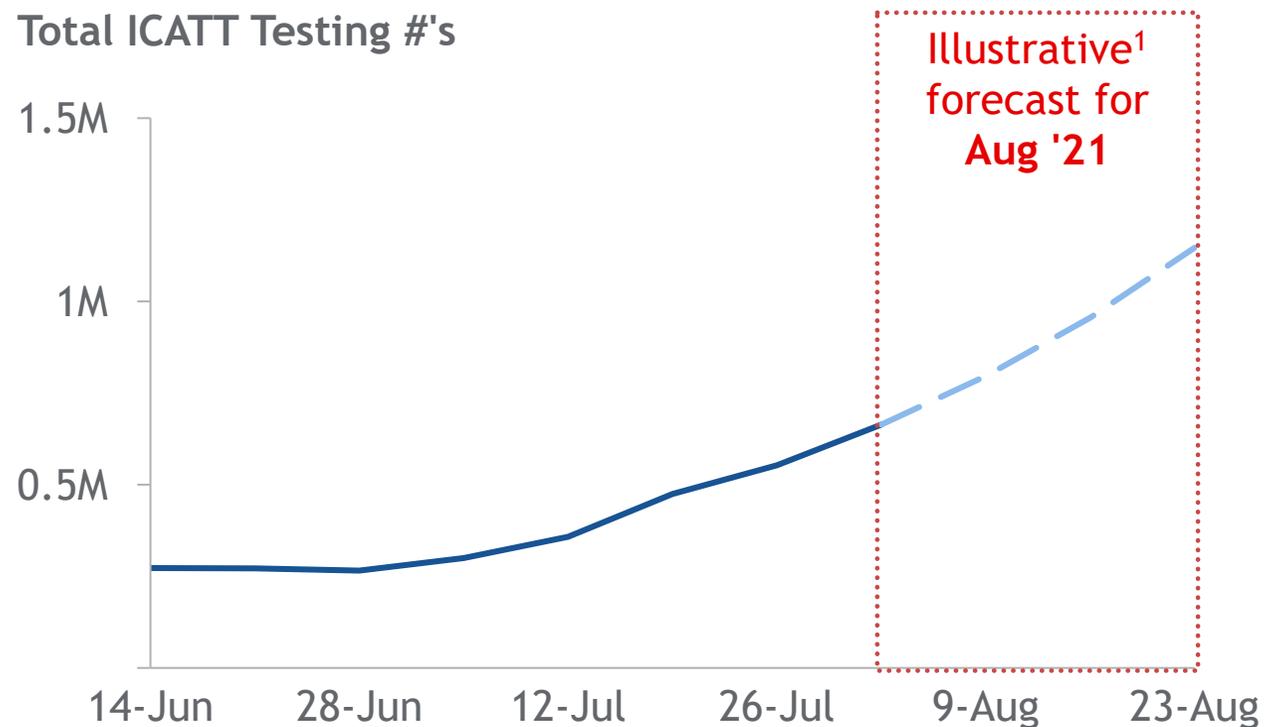
School testing feedback and evaluation

➤ Future outlook for school testing

# Recent uptick in testing demand calls for further school testing support

## Increasing ICATT Testing: June & July '21

Total ICATT Testing #'s



- Increased **school testing projections** for back-to-school in fall '21
  - School districts in AZ, CT, HI, MD, NJ, NY, OH, VA requesting additional ICATT support
- **OTC and POC test sales** rising across ICATT's pharmacy partners
- **HBCU's and state universities** request back-to school support
- Federal and state **testing mandates** require regular testing

Source: Covid Responder 1. Projections based on WOW growth as ICATT testing is increasing significantly and expected to grow in coming weeks



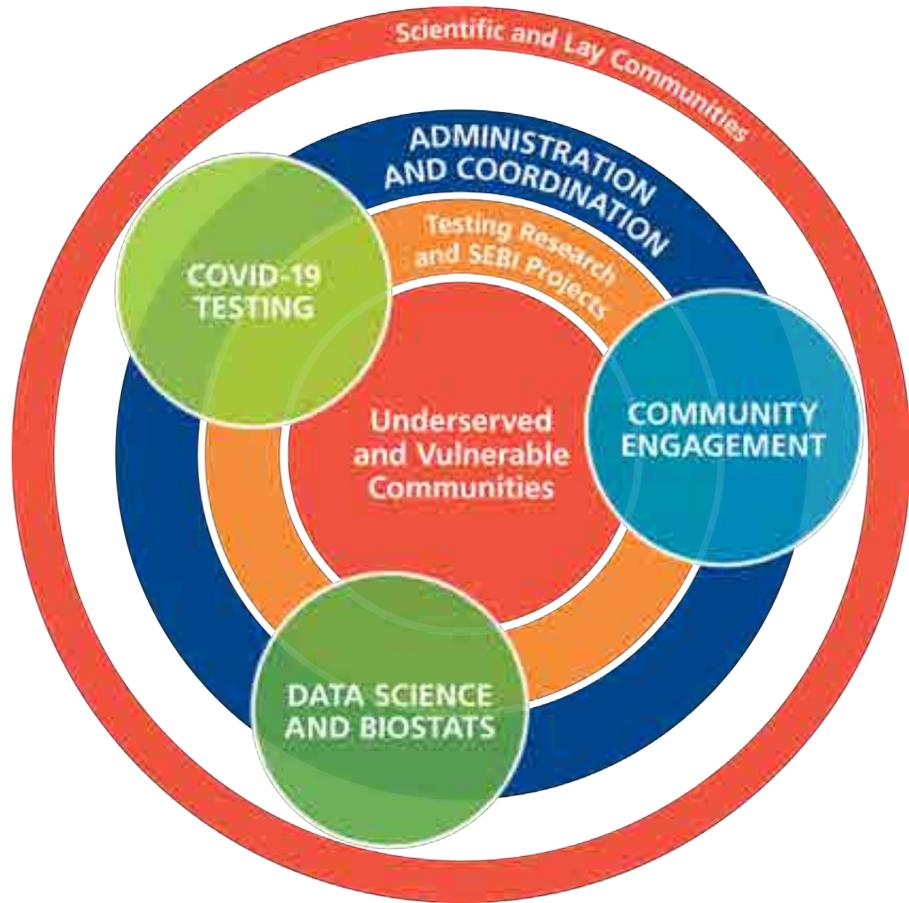
Questions?



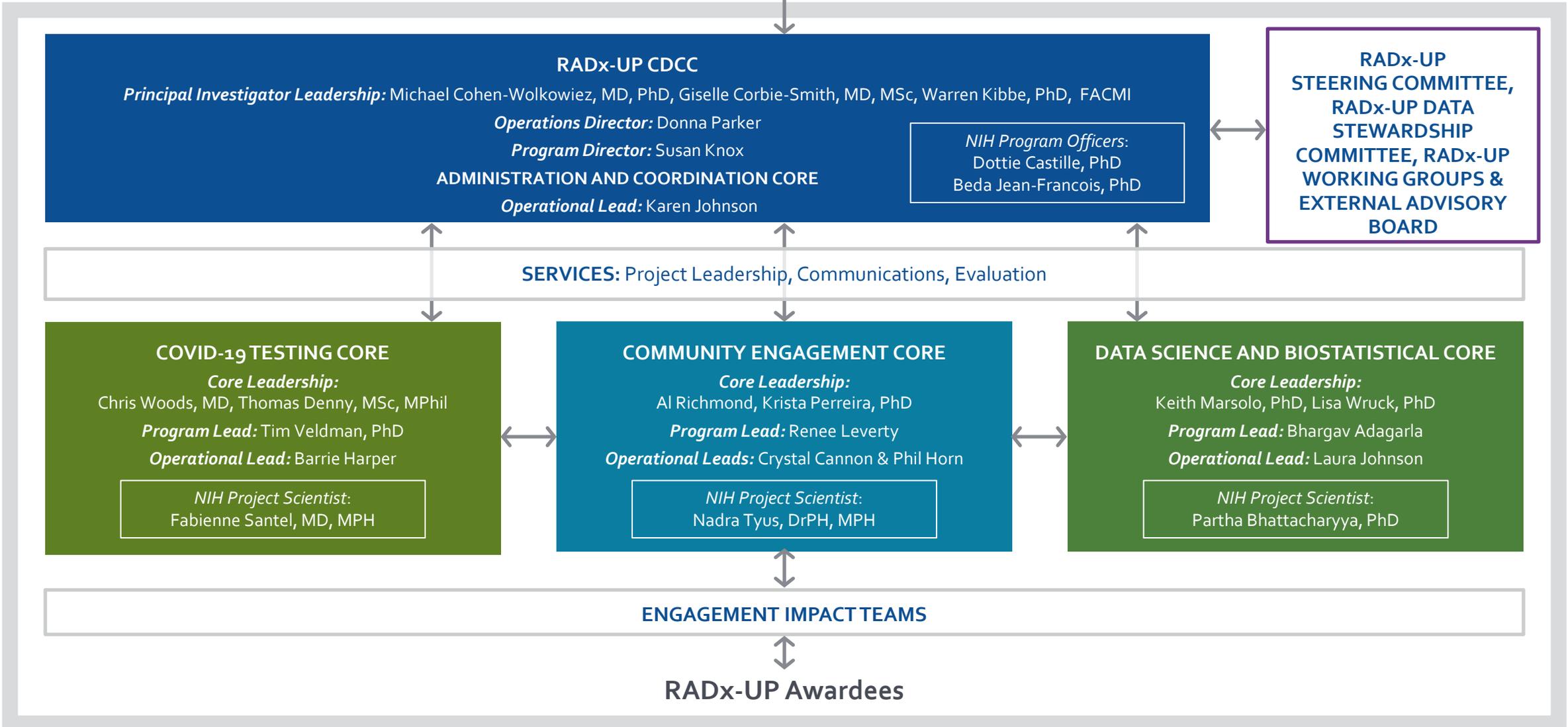
# RADx-UP Coordination and Data Collection Center (CDCC)

August 2021

# RADx-UP CDCC - Guiding Principles



- **Communities** are at the center of our work.
- **Data sovereignty** protections and sharing with communities and participants are essential in building trust and being trustworthy.
- **Intentional support** of study teams is critical to streamline results and troubleshoot.
- **Broad dissemination** of program activities, data, and best practices are key.
- **Strategic partnerships** will augment community benefits from the program.
- **Impact** will be broad and will inform national guidance, strategy, and response to COVID-19.



# CDCC Responsibilities

- Program administration
  - Communications, committees, policies, strategy
- Community engagement
  - Best practices, resources, working groups, community of practice, mini-grants, EITs
- COVID-19 testing technologies
  - Technical support, repository of emerging technologies, pilot grants
- Data and biostatistics
  - Data exchange, harmonization, dissemination, protection, linkages, stats

# More on Community Engagement Support

- Disseminate/support best practices and resources for community engagement in underserved populations
- Translate the utility of new testing technologies to communities
- To date
  - 300+ participants at COVID-19 Equity Evidence Academy
  - 20+ best practices/guidance documents
  - 5 working groups
  - 12+ Community Collaboration Mini-grants (and 5 cycles to come)
  - 4+ channels for Community of Practice : Slack, newsletters, meetings, CCPH consults

## Working Groups

- Child Health
- Engaging Hispanic/Latino/Latinx Populations
- Building Community Capacity and Impact
- Understanding Social Determinants of COVID-19 Testing and Vaccination
- Engaging Black/African Americans

# More on CDCC COVID-19 Testing Support

- Supporting projects with the selection of testing technology
  - Right test is used for the right person, indication, goal, setting
  - FDA EUA
  - To date
    - *75+ testing plans reviewed*
    - *15+ projects switched tests from non-FDA EUA to FDA EUA*
  - 8+ Rapid pilot projects
- Supporting projects with securing testing supplies
  - Connecting projects/negotiating costs directly with partners, vendors, suppliers
    - *>\$850K in cost savings to projects*

# More on CDCC COVID-19 Testing Support

- Testing resources
  - The FDA [lists](#) of authorized assays
  - [Testing Tips](#) webpage for selection and use of FDA EUA assays
  - The May 2021 Project-wide Meeting focused on testing; find materials on [myRADx-UPhome](#).
- Discussions with projects via EITs

# More on CDCC COVID-19 Data and Biostatistics Support

- Supporting projects with project-level data collection questions
- Cross-consortium data collection and harmonization
  - NIH RADx-UP Common data elements (CDEs)
- Collecting different types of data
  - NIH RADx-UP CDEs, electronic health records, qualitative data
- Linkages with external datasets
  - Adds SDOH and increases impact
- Statistical consultations

# Data Flow

## DATA SOURCES



**RADx-UP Projects**

- Individual-level data
- NIH RADx-Up Tier 1 Common Data Elements (CDE)
- Aggregated data



**External data sets**

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

## LINKAGES



## DATA REPOSITORIES



**RADx-UP Participant Re-Contact Registry**

- Identifiable individual-level demographic data



**RADx-UP Data Platform**

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



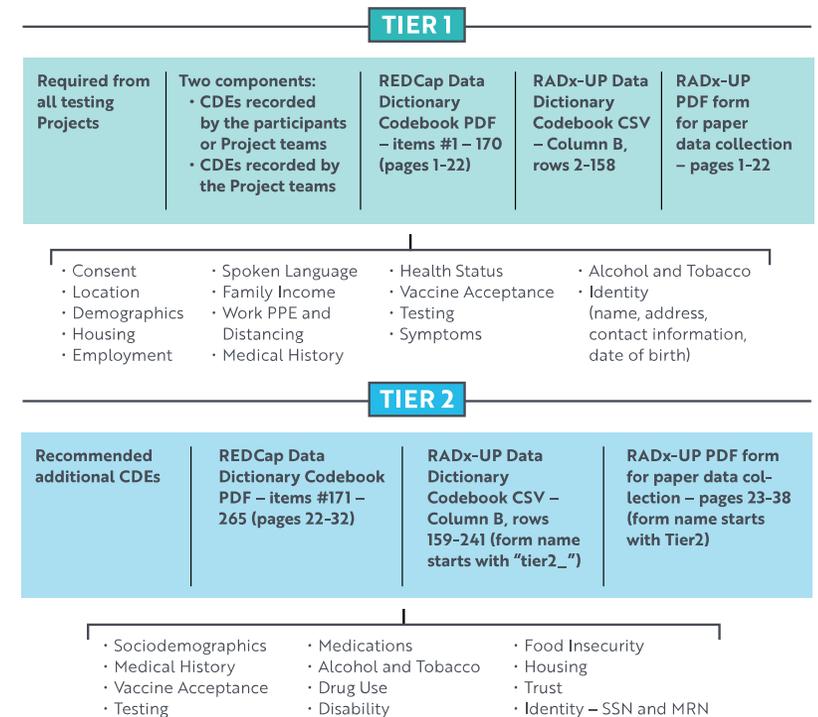
**RADx Data Hub**

- De-identified individual-level CDE data

# What are the NIH RADx-UP Common Data Elements?

- Data items collected in the same format by all projects
- Developed by NIH and catalyzed by the CDCC
- RADx-UP (Phase I) projects contributed
  - Limited, messy, imperfect, and during a pandemic
  - 700+ → 60+
- Tiers
  - Tier 1 = required
  - Tier 2 = recommended
    - New NIH RADx-UP Tier 2 CDEs for pediatrics are in development

## CDE EXPLAINER - TIER 1 VS. TIER 2



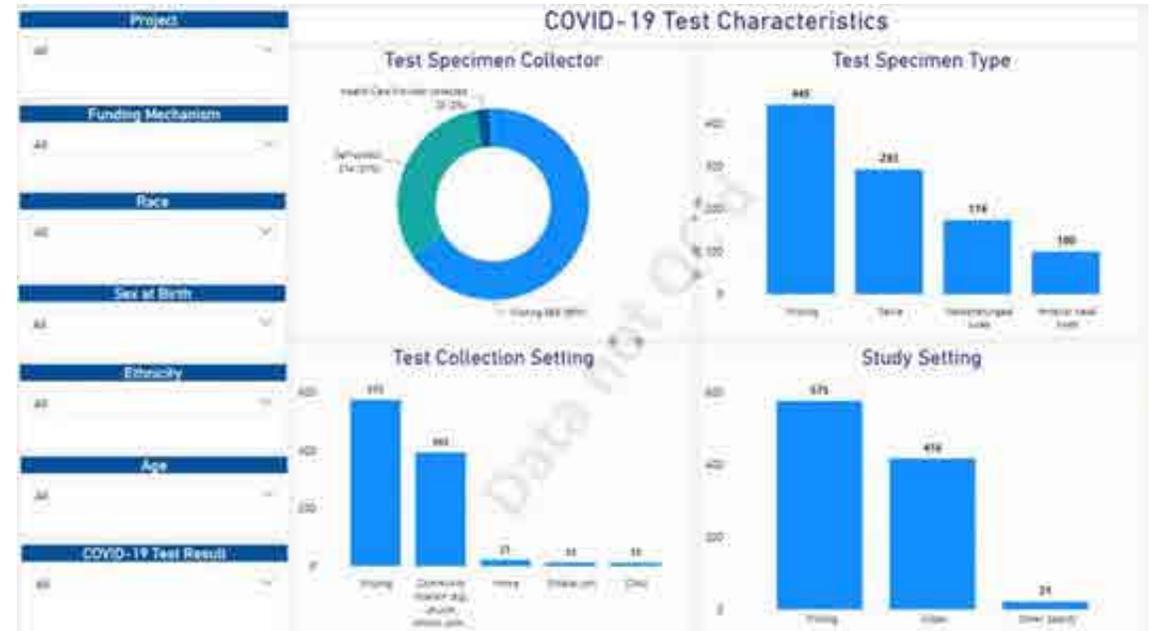
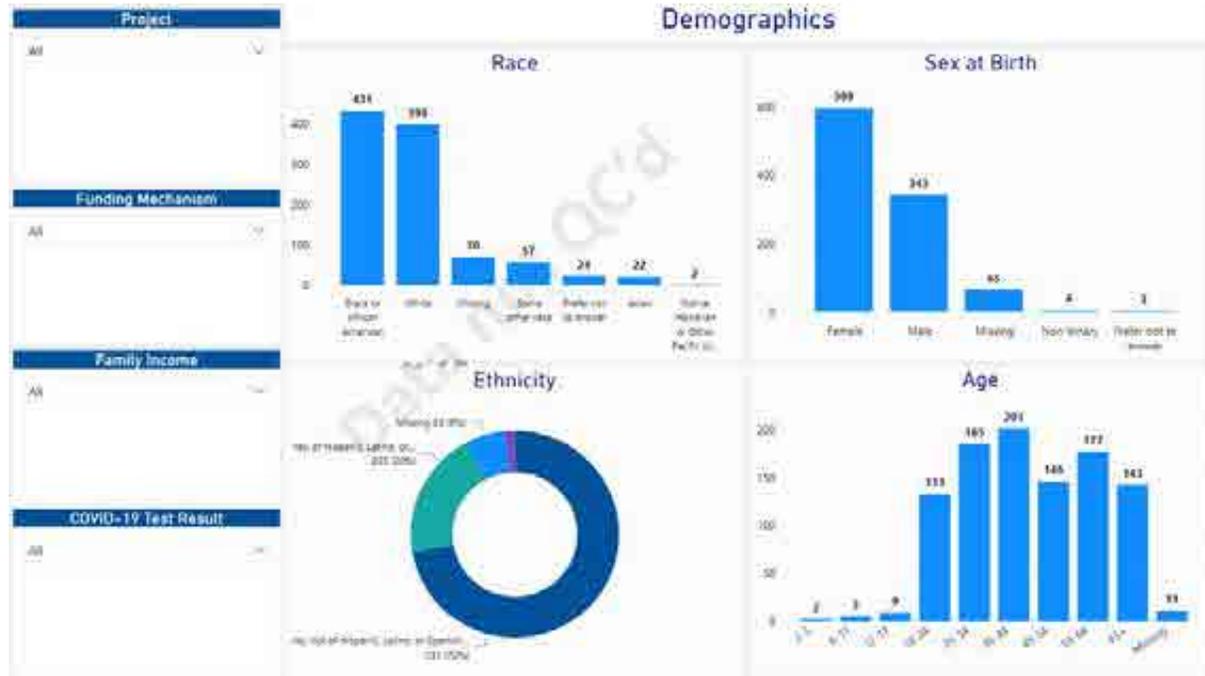
# Why do we need the NIH RADx-UP Common Data Elements?

- Standardized data collection across community engaged projects
- Provides a path to understanding the nuances of health disparities between and within different communities
- Allows data linkages with external datasets (e.g. SDOH) to augment impact
  - Zip code, county
  - Address (census tract or census block)
  - Name and contact information for future re-contact
- Increases the impact of the RADx-UP program

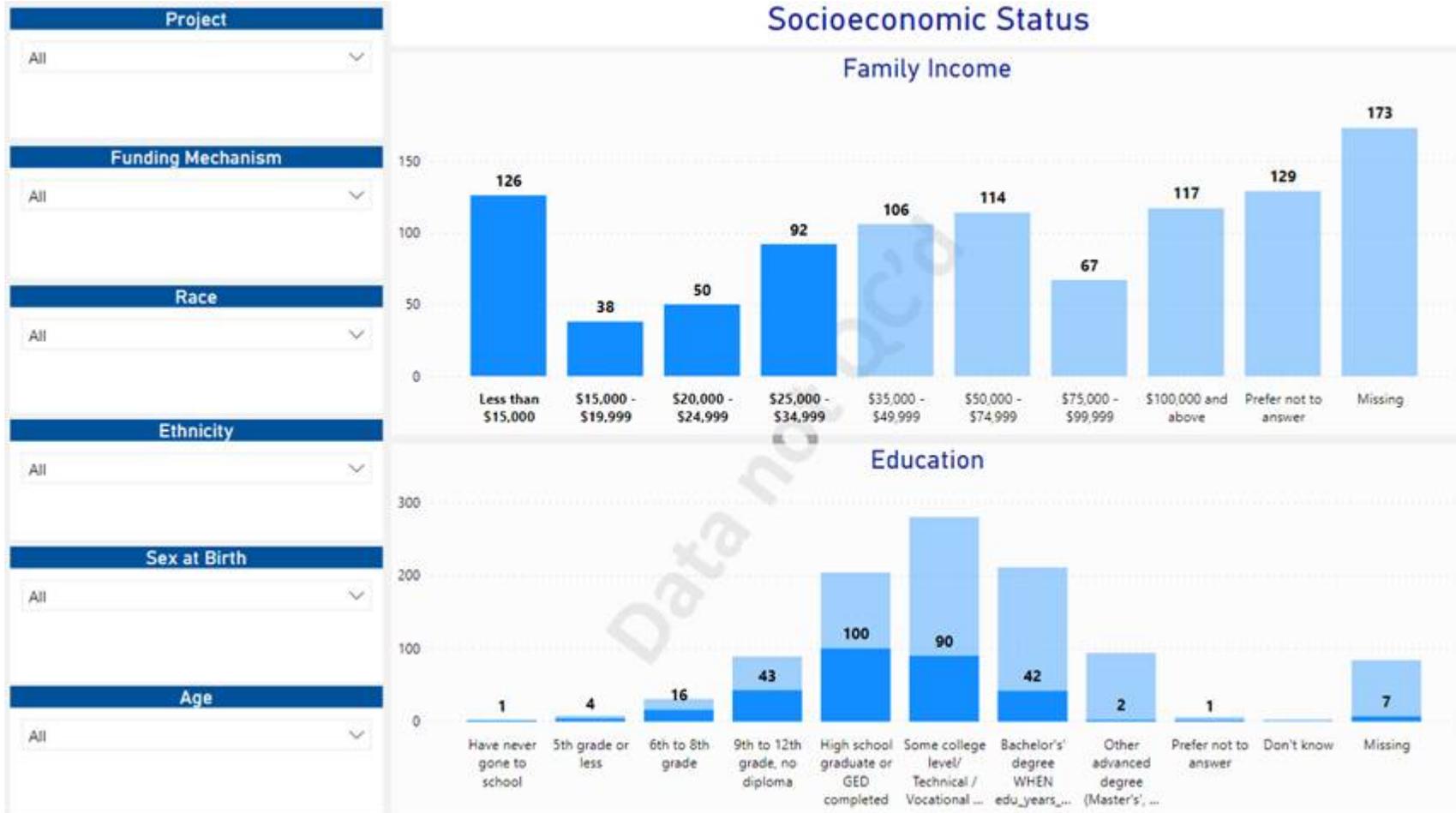
# How does it work?

- CDCC disseminated the NIH RADx-UP CDEs to projects (English and Spanish)
  - Also: data sharing language for the ICF and data use agreements
- CDCC created the codebook for the NIH RADx-UP CDEs (English and Spanish)
  - Ready to upload into databases (e.g., REDCap)
- CDCC provided information and guidance regarding NIH RADx-UP CDEs
  - Written, podcasts, meetings, videos (coming soon)
- Projects are collecting NIH RADx-UP CDEs and uploading data to CDCC
- CDCC will deposit data into the NIH RADx Data Hub

# Examples of NIH RADx-UP Tier 1 CDE data



# Examples of NIH RADx-UP Tier 1 CDE data



# Summary

- The CDCC supports >100 projects in the RADx-UP program
- The CDCC is achieving its goals: CE, testing, and data collection
- The CDCC and projects are changing the paradigm of CE research
- Keeping communities at the center of what we do is key to our success

# 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)

# BREAK



# Team Presentations



**Chris Lindsey Ph.D.**

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



# Project SafeSchools

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

Return to School August Meeting

*Pls: Drs. Allison Barlow, Laura Hammitt, Emily E. Haroz*

*On behalf of our whole JHCAIH team and partners from the White Mountain  
Apache and Navajo Nation*



*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 or April of 2021.
  - Navajo Nation schools were closed to in-person learning for all of 2020-2021 academic year
  - Virtual learning particularly challenging
  - Opting into in-person learning has been variable
  - Most schools are re-opening for in-person learning for the 2021-2022 academic year
3. School attendance and attachment are protective for physical and mental health concerns.

# Research Questions

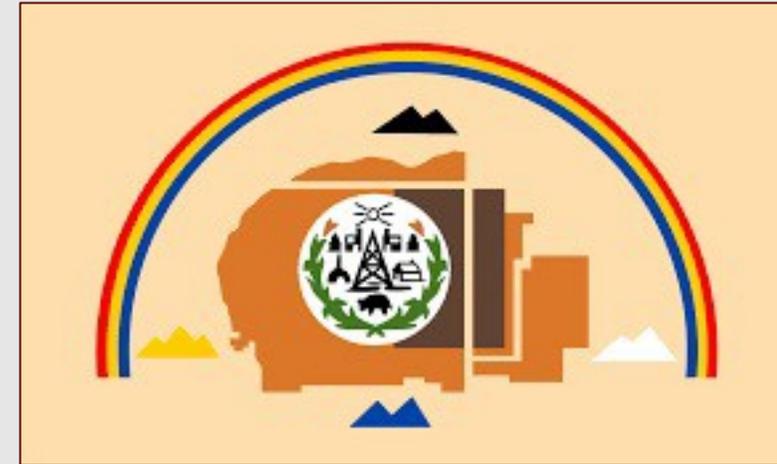
1. What are the barriers and facilitators to school re-openings and COVID-19 testing from the perspective of multiple stakeholders involved in schools that serve Native American youth ages 4-16 years?
2. How acceptable and feasible are various COVID-19 testing strategies for schools? And what is their 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 4-16 years?

# Project Sites



- White Mountain Apache Tribe

- Pilot project activities began in January 2021 with three schools
- Expansion to all other schools



- Navajo Nation

- Shiprock Area Schools
- Tuba City Area Schools

~10,000 students & faculty  
<90% Free or reduced lunch

# Testing approaches

|  | Screening Tests   |   | Surveillance Testing  |
|--|---|---|-----------------------|
|  | Rapid Antigen Tests At Schools                              | Rapid Antigen Tests at Home                                 | Front End PCR Pooling |
| What tests?                            | Abbot Binax Now<br>Ellume Home Test Kits                    | Abbot Binax Now<br>Ellume Home Test Kits                    | Concentric by Gingko  |
| Frequency                              | 2x per week   | 2x per week   | 1-2x per week         |
| Sensitivity/Specificity (asymptomatic) | Binax: 70.2/99.6 <sup>1</sup><br>Ellume: 91/96 <sup>2</sup> | Binax: 70.2/99.6 <sup>1</sup><br>Ellume: 91/96 <sup>2</sup> | 96/100 <sup>3</sup>   |

Teachers  
& Staff

Students

Both

# Design and analytic plan

## **Longitudinal observational cohort**

- Convergent mixed-methods design
  - Qualitative guides informed by Theoretical Domains Framework to understand behavior change and implementation outcomes
- Surveys to understand testing implementation attitudes
- Mental health assessments
- Secondary data analysis of school testing data
- Target sample sizes for primary data collection
  - 500 caregivers
  - 120 youth (11-16)
  - 120 school employees



Results to date



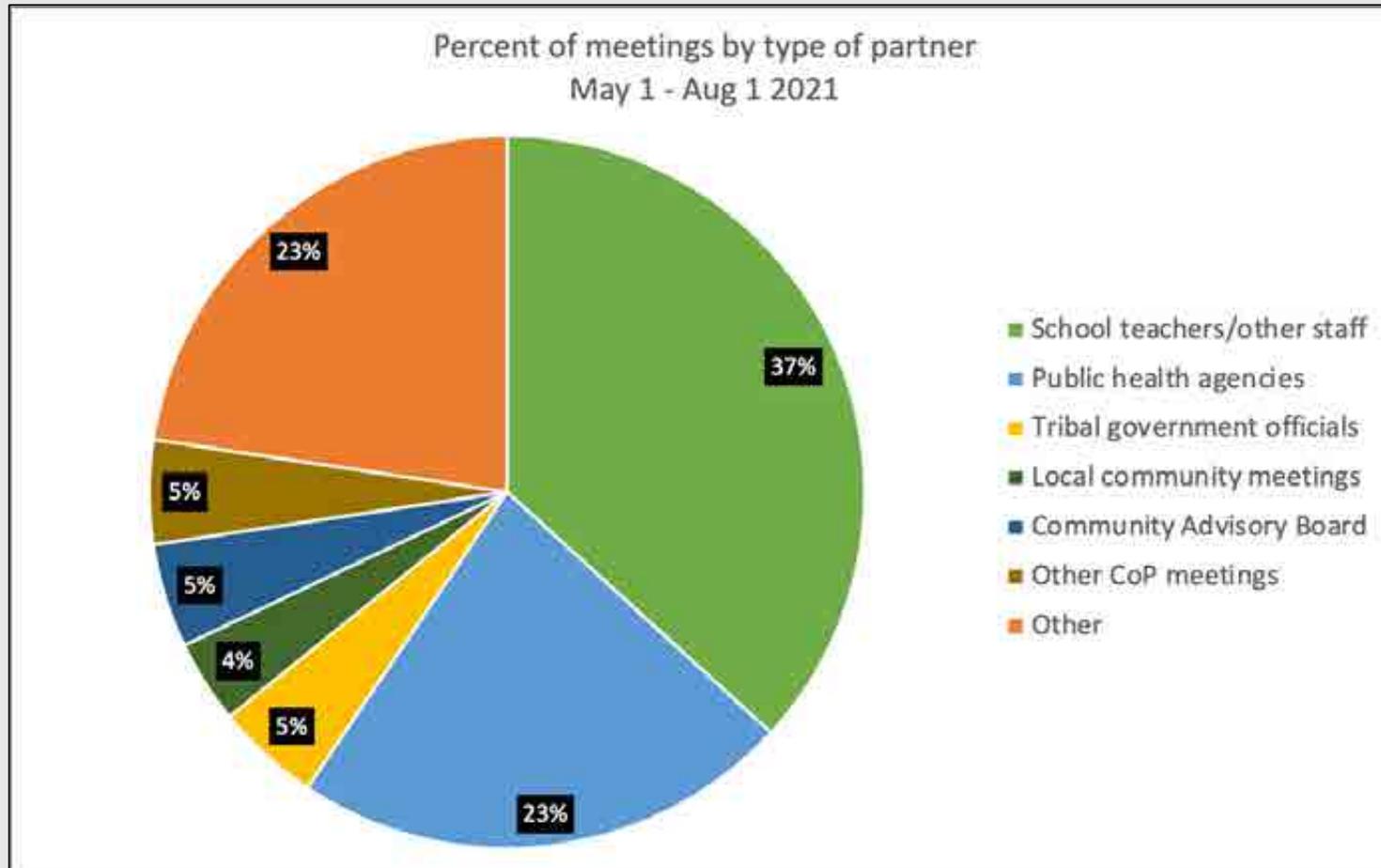
# Community & school engagement activities

- Community Advisory Boards (CABs) in each site
- Community and school engagement activities
- Local approvals
- Three IRBs



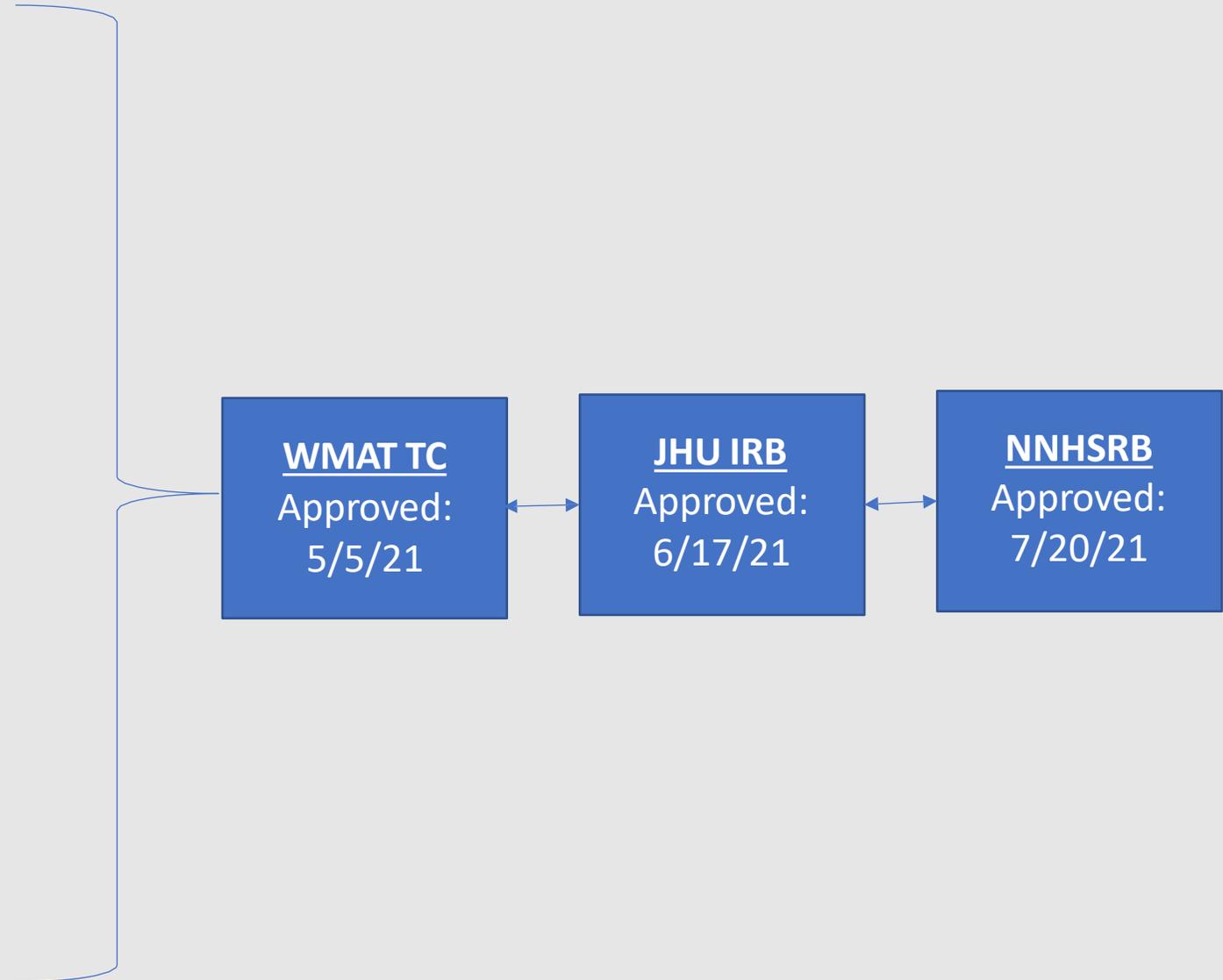
# Community & school engagement activities

- An estimated 140 meetings held with community partners by our team members since May 1<sup>st</sup> 2021.



# Research approval processes

|                               |
|-------------------------------|
| <b>Approvals</b>              |
| WUSD School Board             |
| CBQ School Board              |
| TR School Board               |
| CUSD School Board             |
| PUSD School Board             |
| Navajo Prep School Board      |
| TCUSD School Board            |
| CCSD School Board             |
| NNMC Hospital CEO             |
| CSU CEO                       |
| WR CEO                        |
| Chief of Pediatrics Tuba City |
| Navajo Area Office            |
| WMAT Health Board             |
| WMAT Tribal Council           |
| Shiprock Agency Council       |
| Tuba City Chapter Approval    |
| Western Agency Council        |
| Chinle Chapter Approval       |
| Chinle Agency Council         |



# School testing data

May 1 – July 15

$N = 540$

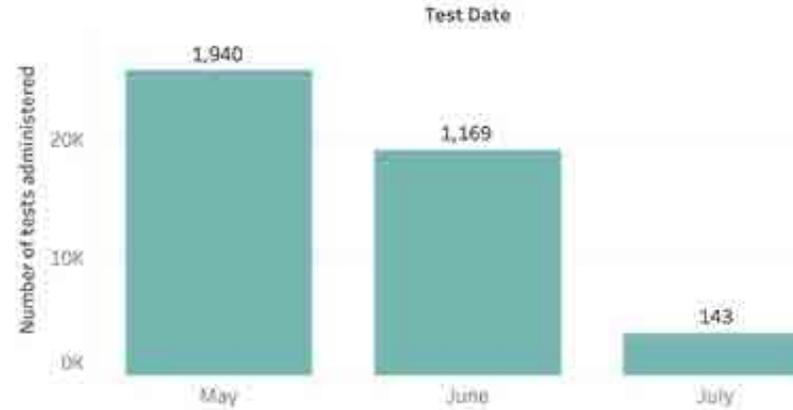
$n = 289$  school personnel

$n = 217$  students

*Over 3000 tests administered*

Figure 1. Testing dashboard for 2x weekly antigen testing approach

SafeSchools Testing Dashboard - WUSD:  
Updated July 11, 2021



Number of tests administered at each school

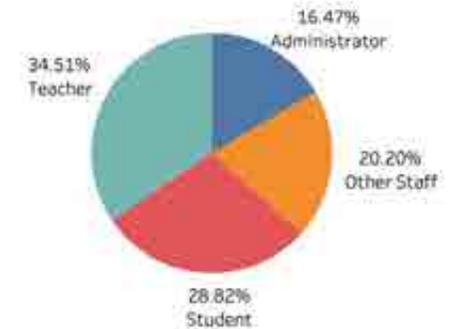


Number of Positive Tests  
*positive tests represent unique cases*



*\* Other cases have been identified in students and staff not participating in this program. These cases are not included in the dashboard.*

Number of tests by role



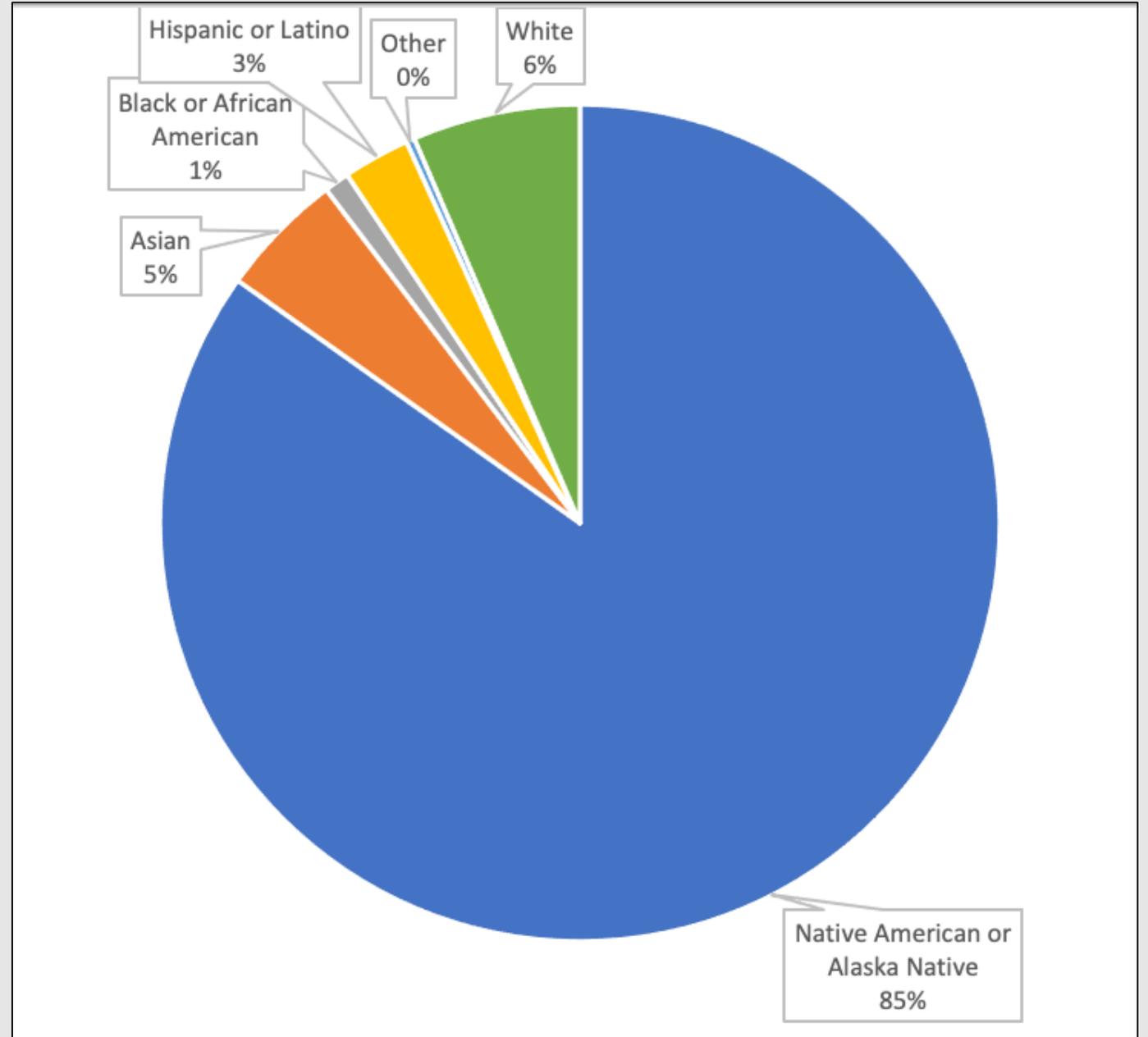
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May 1 – July 15

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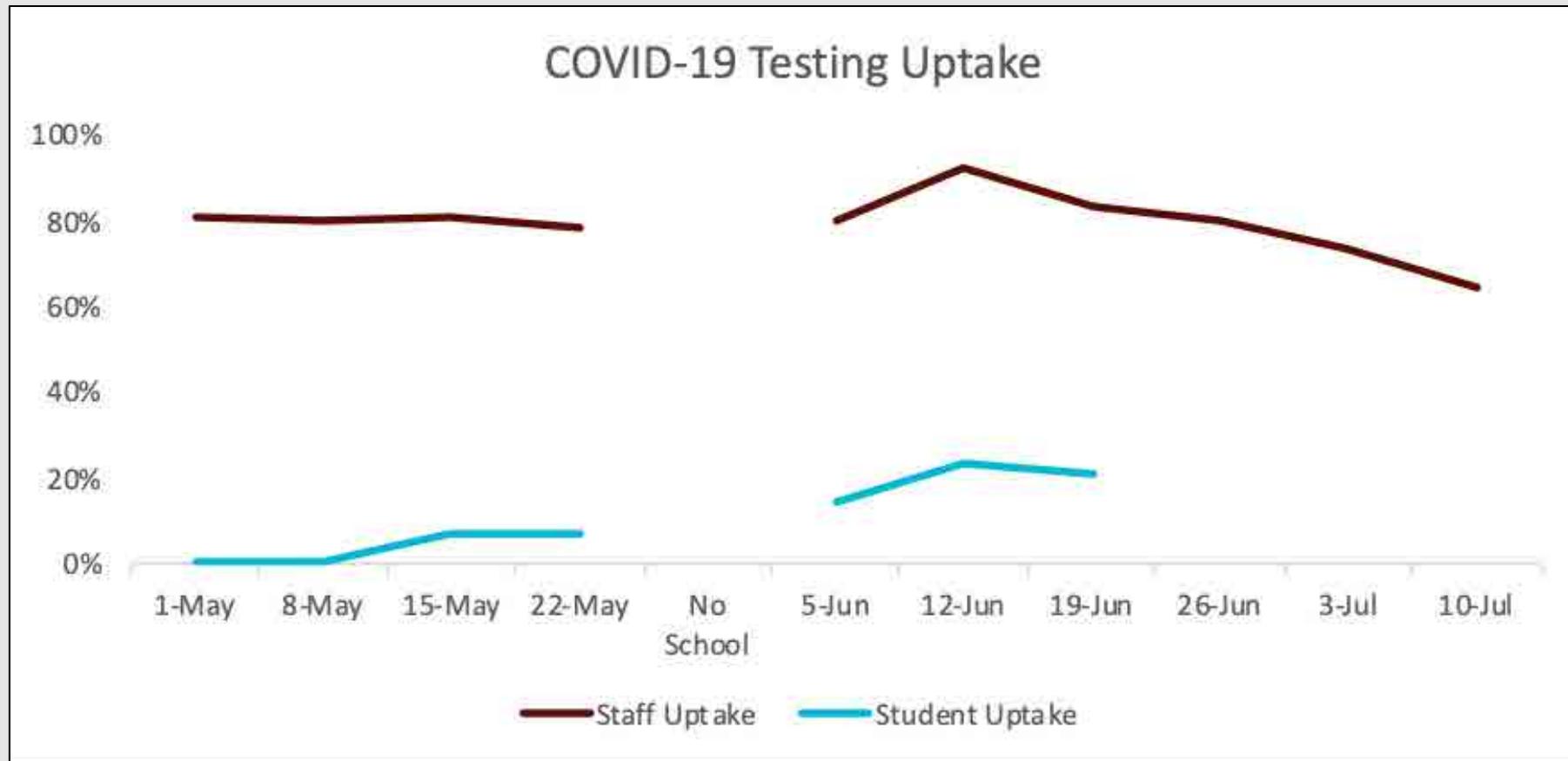
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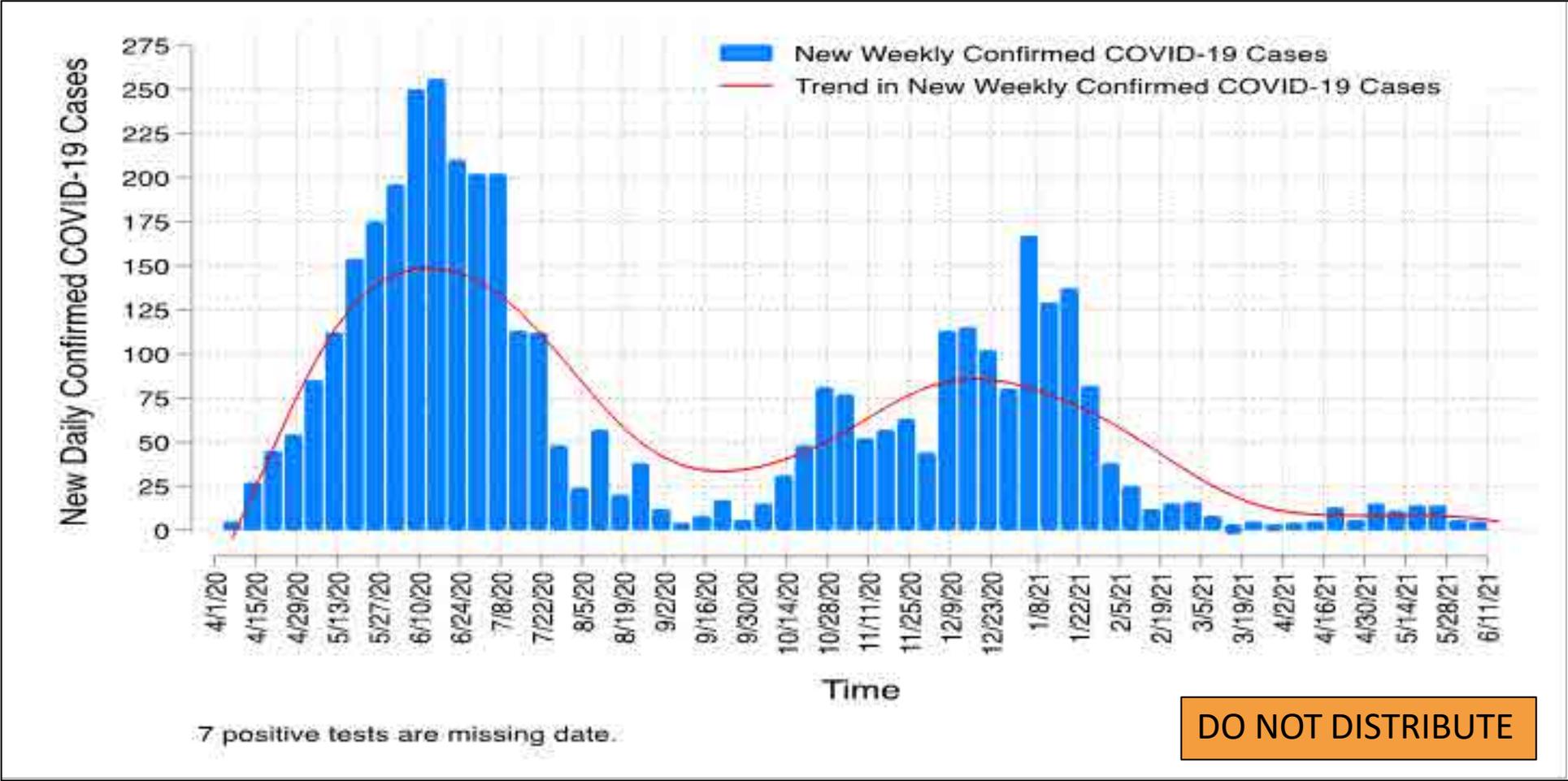


# Testing Uptake

*May 1 – July 15*



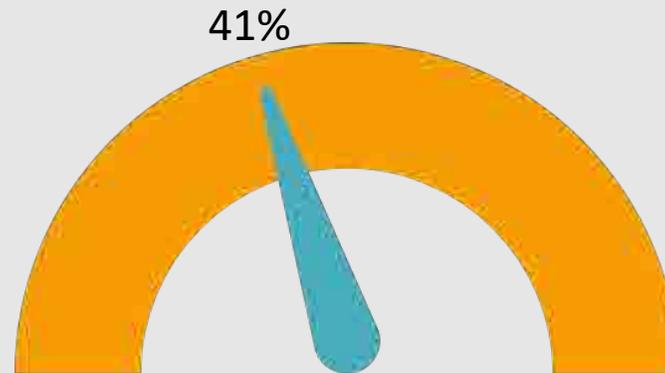
# Zero cases and low community transmission



# Reach of testing overall

*May 1 – August 1*

540 people tested out of our projected 1,300 people in year 1 through our partnerships with schools implementing COVID-19 testing



- Overwhelming demand with schools interested and exceeding our projections for participation
- Exploring leveraging state funding

# Move towards pooled PCR testing



**Total Pools, Swabs, Pool Size, Turnaround Time, and People Tested by Week**

| Week                            | Total Pools | Total Swabs | Average Swabs per Pool | Average Turnaround Time in Hours | Approximate number of people tested |
|---------------------------------|-------------|-------------|------------------------|----------------------------------|-------------------------------------|
| July 26, 2021 - August 01, 2021 | 2           | 31          | 15.5                   | 32                               | 31                                  |
| June 21, 2021 - June 27, 2021   | 1           | 22          | 22                     | 31                               | 22                                  |
| June 14, 2021 - June 20, 2021   | 2           | 30          | 15                     | 29                               | 30                                  |
| June 07, 2021 - June 13, 2021   | 2           | 30          | 15                     | 30                               | 30                                  |

# Research recruitment



# Challenges & lessons learned



Increased funding, but a real need for implementation support



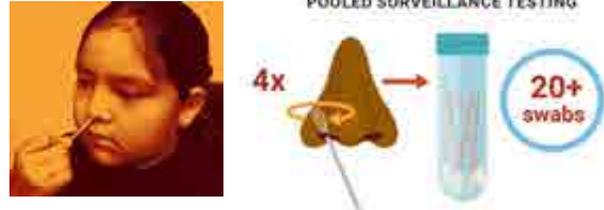
Testing uptake by parents is challenging at the beginning; address myths and beliefs head on and using multiple strategies



Partner research and practice to enhance reach and impact

**No brain ticklers for school testing!**

Schools use swabs like Q-tips that only go in the lower part of the nose. Its easy, fast, and comfortable.



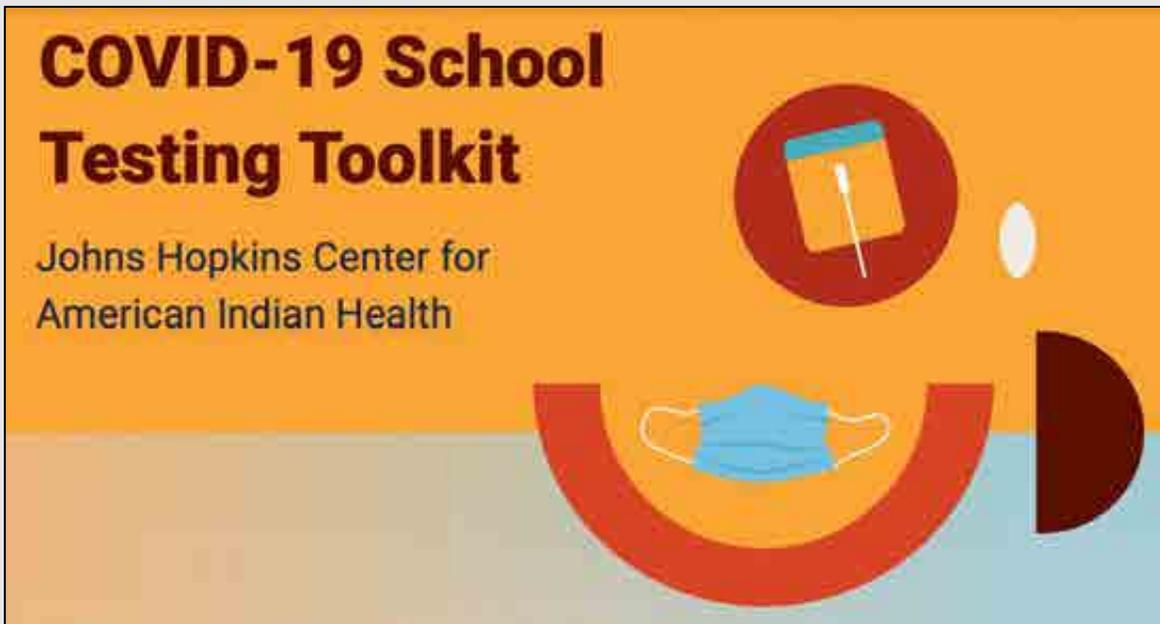
**POOLED SURVEILLANCE TESTING**

4x → 20+ swabs

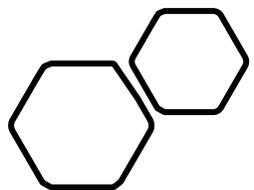


**SAFE SCHOOLS**  
KEEPING SCHOOLS SAFE FROM COVID-19

# Resources for schools serving Native American communities



<https://caih.jhu.edu/schoolresources/>



# Project SafeSchools

Working together to make in-person  
learning safer for ALL.





# Research Objectives



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



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



**Predictors of in-person school (Aim 2)**



**Consensus priorities for safe in-person school (Aim 3)**

# Home and School Testing Feasibility



## *BinaxNOW Rapid Antigen Platform*



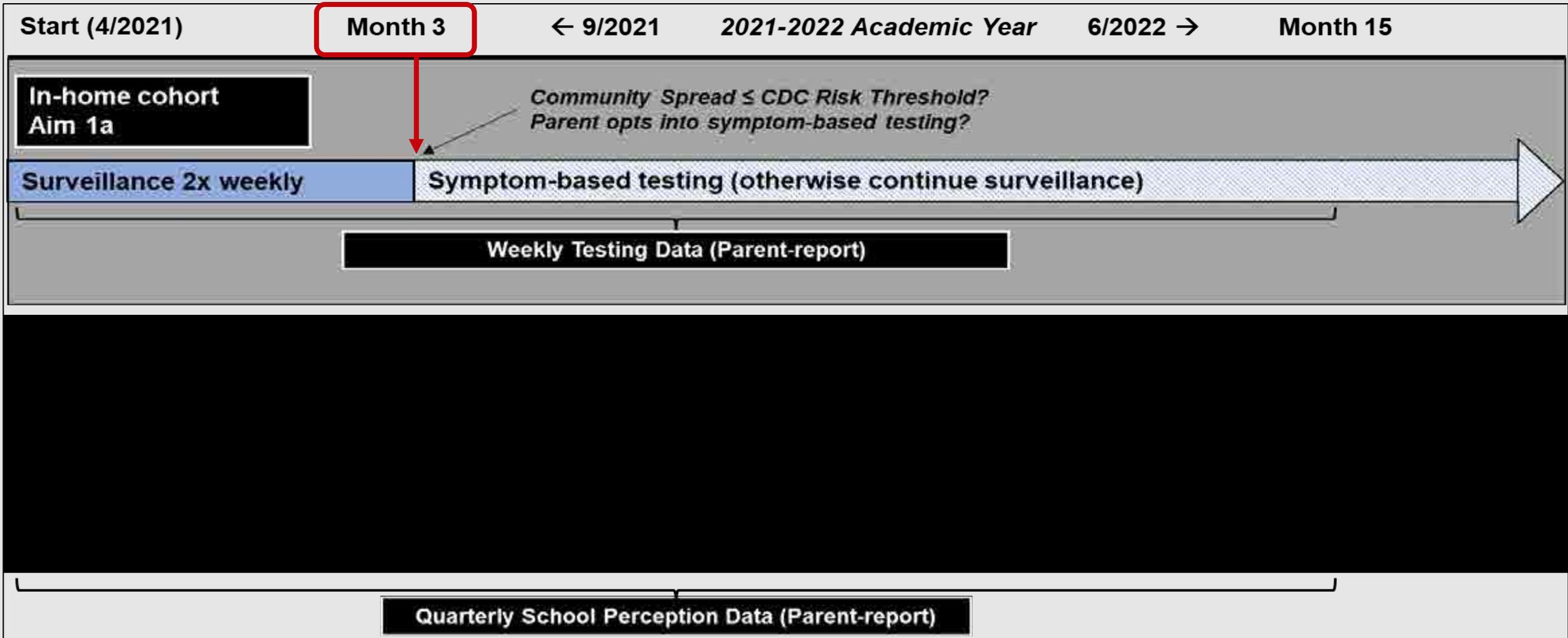
### **In-Home Cohort**

- Recruited from UW Pediatric Complex Care Program
- *Parents test twice-weekly*

### **School Cohort**

- Recruited from Waisman Early Childhood Program
  - 30% have developmental disabilities
- *ReSET staff test twice-weekly*

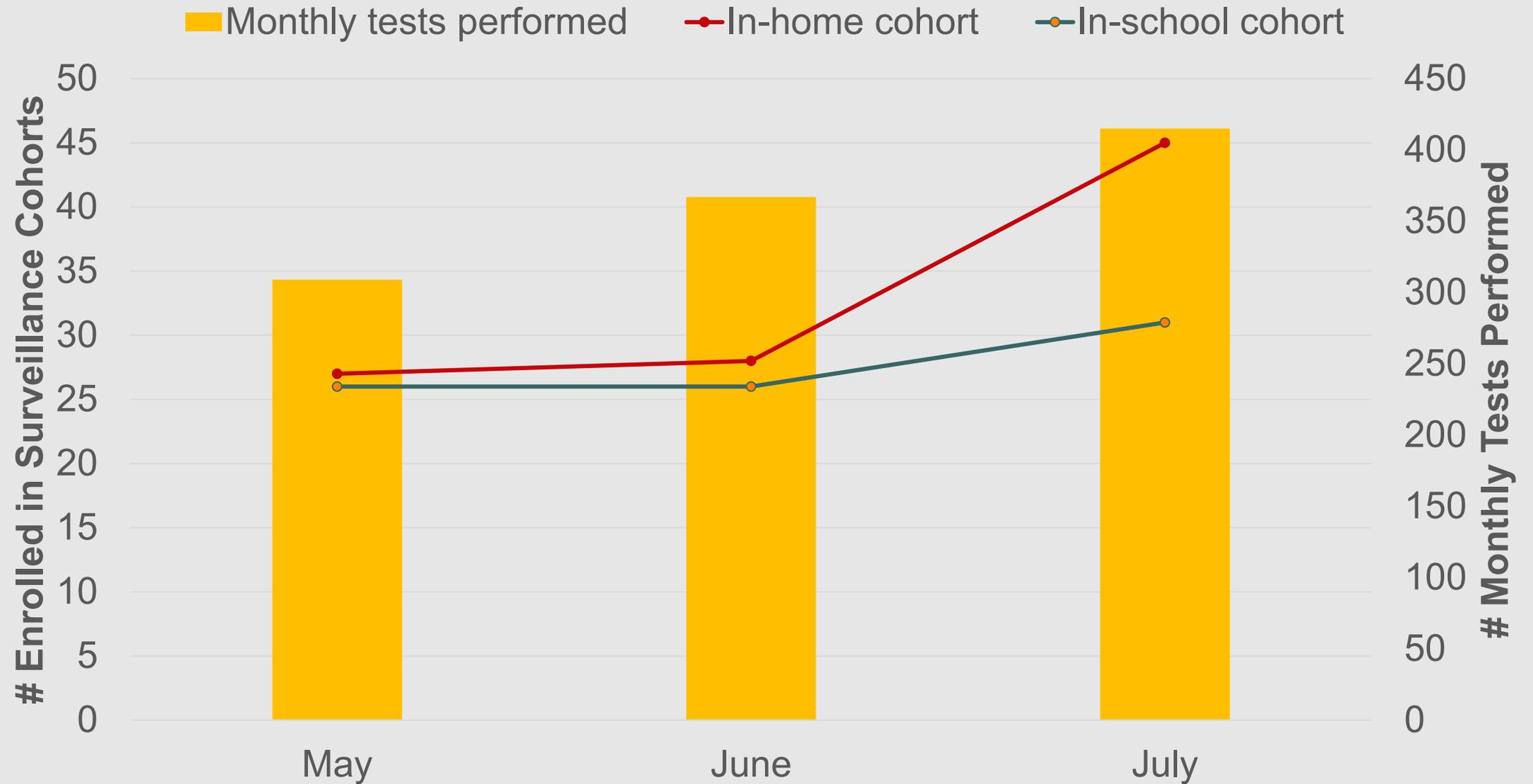
# Aim 1 – Adaptive Design





# Recruitment and Enrollment

# Monthly Enrollment and Surveillance Testing



# Demographics of Study Cohorts



|                            | Testing |                |                 | Non-testing |
|----------------------------|---------|----------------|-----------------|-------------|
|                            | In-Home | In-School Kids | In-School Staff | Survey      |
| <b>Enrolled, n</b>         | 44      | 13 of 57 (23%) | 18 of 23 (78%)  | 1014        |
| <b>Age, years</b>          |         |                |                 |             |
| <b>1-4</b>                 | -       | 8 (62)         | -               | 2 (0.2)     |
| <b>5-10</b>                | 24 (55) | 2 (15)         | -               | 393 (38.9)  |
| <b>11-13</b>               | 10 (23) | -              | -               | 235 (23.3)  |
| <b>14-17</b>               | 4 (8)   | -              | -               | 379 (37.6)  |
| <b>Not yet reported</b>    | 6 (14)  | 3 (23)         | -               | -           |
| <b>Grade</b>               |         |                |                 |             |
| <b>PreK-5</b>              | 25 (57) | 13 (100)       | -               | 453 (44.6)  |
| <b>6-8</b>                 | 11 (25) | -              | -               | 244 (24.1)  |
| <b>9-12</b>                | 1 (2)   | -              | -               | 317 (31.3)  |
| <b>Not yet reported</b>    | 7 (16)  | -              | -               | -           |
| <b>Race/Ethnicity</b>      |         |                |                 |             |
| <b>White, non-Hispanic</b> | 26 (59) | 8 (62)         | 11 (61)         | 776 (76.7)  |
| <b>Black, non-Hispanic</b> | 2 (5)   | 1 (8)          | -               | 30 (3.0)    |
| <b>Hispanic</b>            | 5 (11)  | -              | -               | 86 (8.5)    |
| <b>Multiracial</b>         | 1(3)    | -              | -               | 46 (4.5)    |
| <b>Other</b>               | 5 (11)  | 3 (22)         | 2 (11)          | 55 (5.4)    |
| <b>Not yet reported</b>    | 5 (11)  | 1 (8)          | 5 (28)          | 19 (1.9)    |

# In-Home Testing Cohort



| Clinical Characteristics           | %      |
|------------------------------------|--------|
| Neurologic disease                 | 91     |
| GI disease                         | 78     |
| Genetic / metabolic disease        | 42     |
| Cardiovascular disease             | 40     |
| Subspecialists, mean               | 7.3    |
| Medications, mean                  | 9.0    |
| Children's hospital distance, mean | 64 min |

| Devices       | %  |
|---------------|----|
| Enteral Tube  | 78 |
| Home Oxygen   | 42 |
| BiPAP or CPAP | 20 |
| Tracheostomy  | 13 |



Early data suggest BinaxNOW Ag  
surveillance testing is feasible for CMC



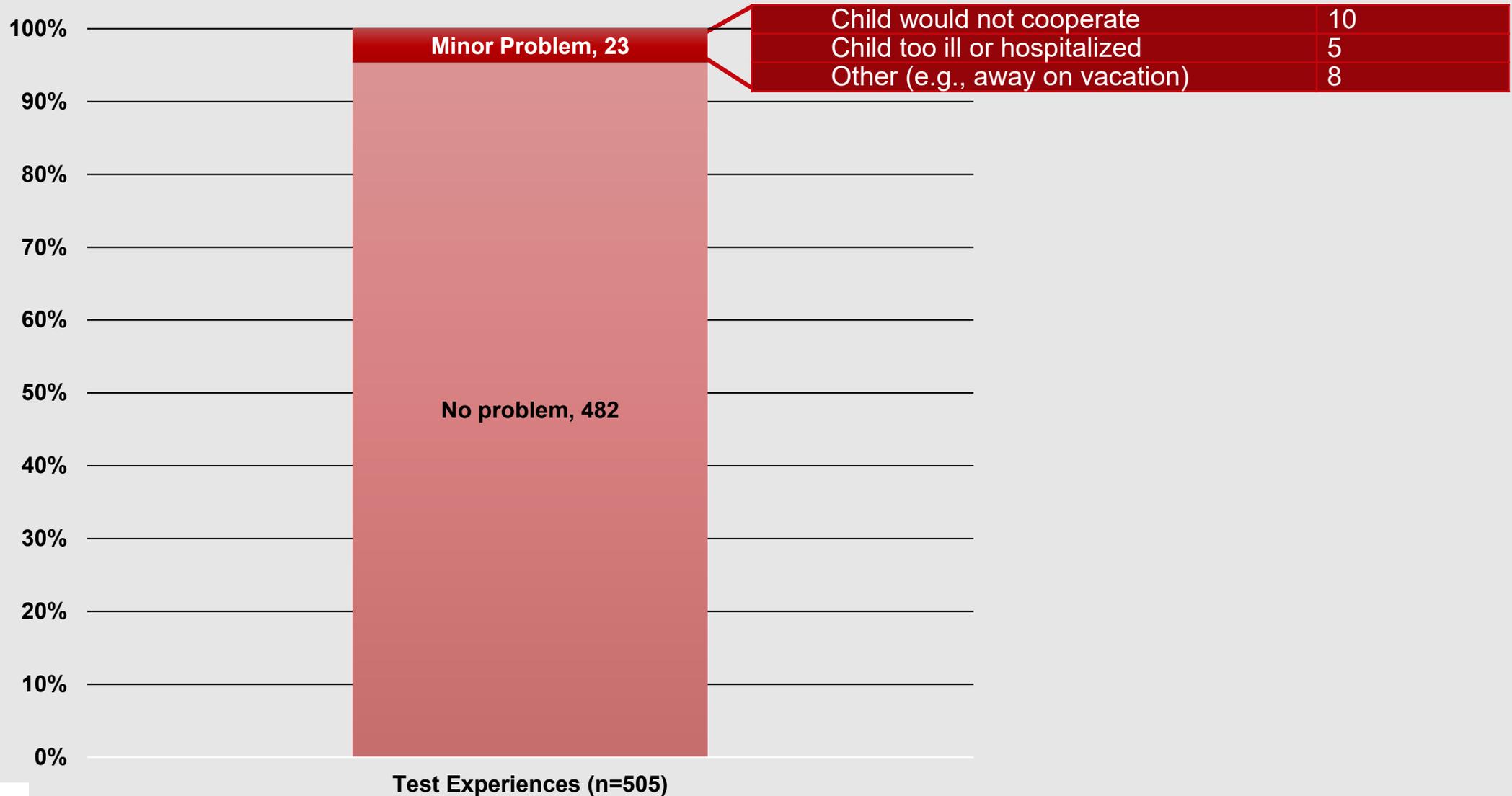
# Test Feasibility

| -                              | In-Home Cohort, n (%) | In-School Cohort, n (%) |
|--------------------------------|-----------------------|-------------------------|
| Total BinaxNOW Tests Conducted | 505                   | 536                     |
| Surveillance (asymptomatic)    | 467 (92.5)            | 518 (96.6)              |
| Symptomatic                    | 38 (7.5)              | 18 (3.4)                |
| Weekly test log response rate  | 252 / 277 (93)        | N/A                     |
| Tests / subject / week, mean   | 1.9                   | 1.6                     |
| Test rate (actual / expected)  | 505 / 554 (91)        | 536 / 615 (87)          |
| Importance to continue testing | 83% very or extremely | N/A                     |

# Test Results

| -                              | In-Home Cohort | In-School Cohort |
|--------------------------------|----------------|------------------|
| Positive BinaxNOW Tests        | 0              | 8                |
| Symptomatic Positive           | -              | 7                |
| Asymptomatic Positive          | -              | 1                |
| Overall BinaxNOW positive rate | NA             | 1.5%             |
| # PCR confirmed                | -              | 0                |
| # PCR negative                 | -              | 8                |
| False-positive rate            | NA             | 1.5%             |

# In-Home Testing Challenges are Rare



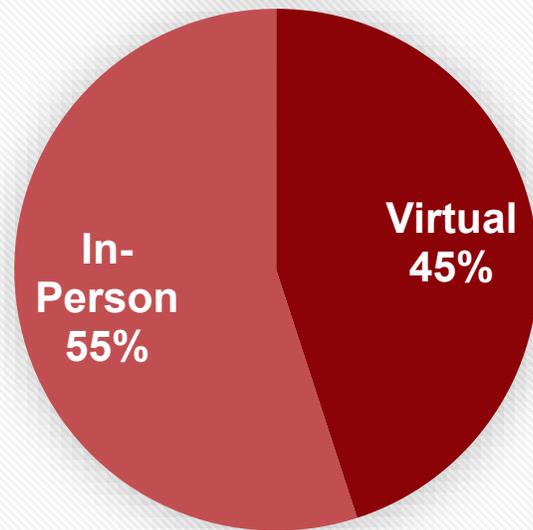


Many CMC were not at school at the end of last academic year

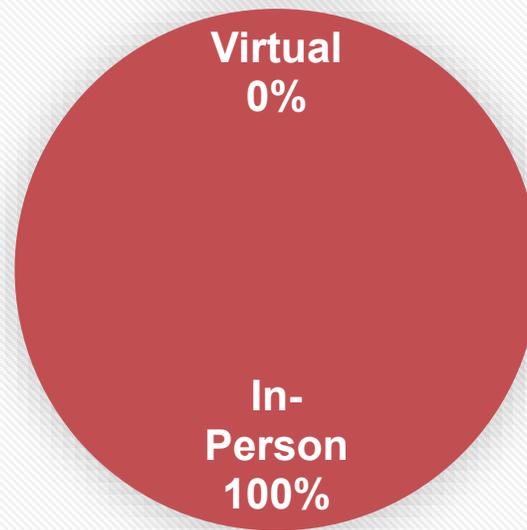
# School Attendance for CMC at end of 2021



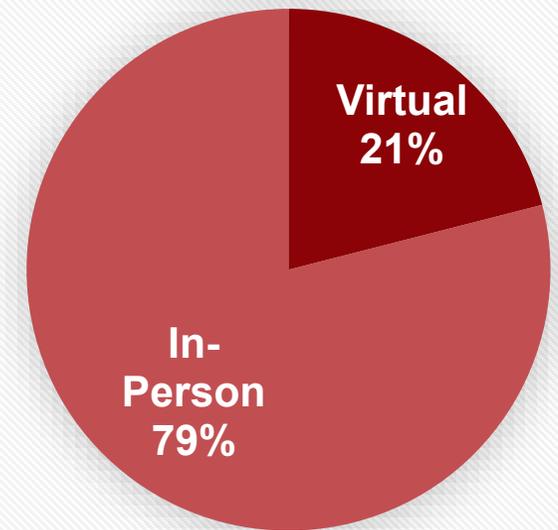
## In-Home Testing Cohort



## In-School Testing Cohort



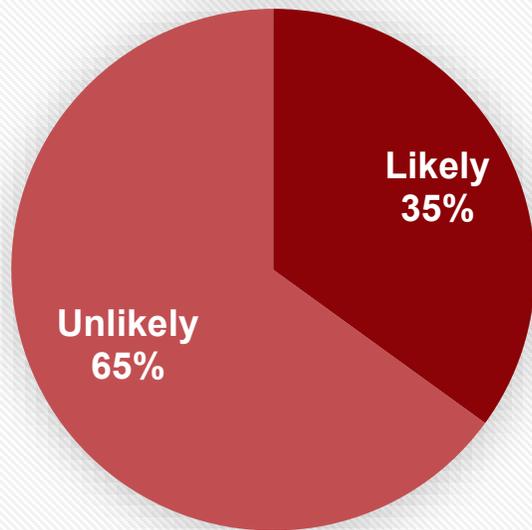
## Non-testing (Survey) Cohort



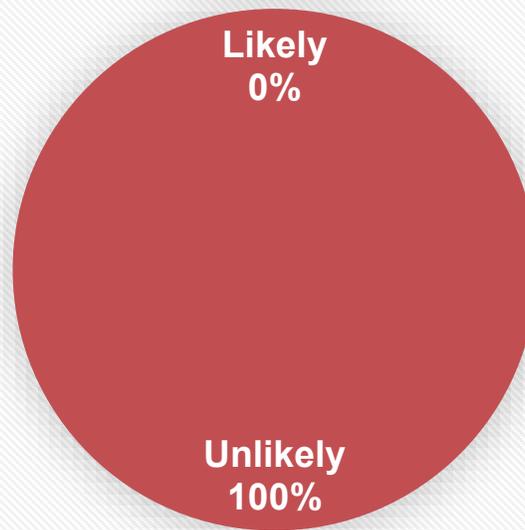
# Parent Perceived Risk for CMC Getting COVID at School



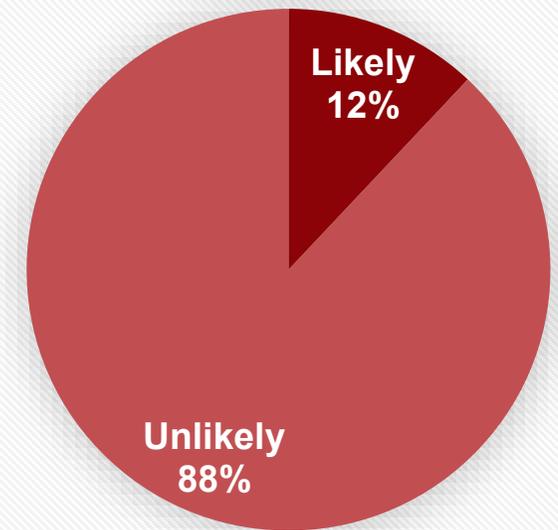
## In-Home Testing Cohort



## In-School Testing Cohort



## Non-testing (Survey) Cohort





Demographics, testing, and vaccine perceptions may be weaker drivers of in-person school

# In-home Testing Cohort – School Attendance



|                             | Not Attending | Attending | <i>P</i> |
|-----------------------------|---------------|-----------|----------|
| <b>Grade</b>                |               |           |          |
| <b>K-5</b>                  | 61%           | 74%       | 0.60     |
| <b>6-8</b>                  | 33%           | 26%       |          |
| <b>9-12</b>                 | 6%            | 0%        |          |
| <b>Race/Ethnicity</b>       |               |           |          |
| <b>White, non-Hispanic</b>  | 78%           | 67%       | 0.73     |
| <b>Black, non-Hispanic</b>  | 0%            | 10%       |          |
| <b>Hispanic</b>             | 11%           | 14%       |          |
| <b>Other</b>                | 11%           | 10%       |          |
| <b>Gender</b>               |               |           |          |
| <b>Female</b>               | 44%           | 33%       | 0.53     |
| <b>Non-English Language</b> | 17%           | 14%       | 1.00     |
| <b>COVID-19 Vaccine</b>     |               |           |          |
| <b>At least 1 dose</b>      | 28%           | 14%       | 0.43     |
| <b>None</b>                 | 72%           | 86%       |          |
| <b>COVID-19 History</b>     |               |           |          |
| <b>Ever Positive</b>        | 0%            | 11%       | 0.49     |
| <b>None</b>                 | 100%          | 89%       |          |

# Non-testing (Survey) Cohort – School Attendance



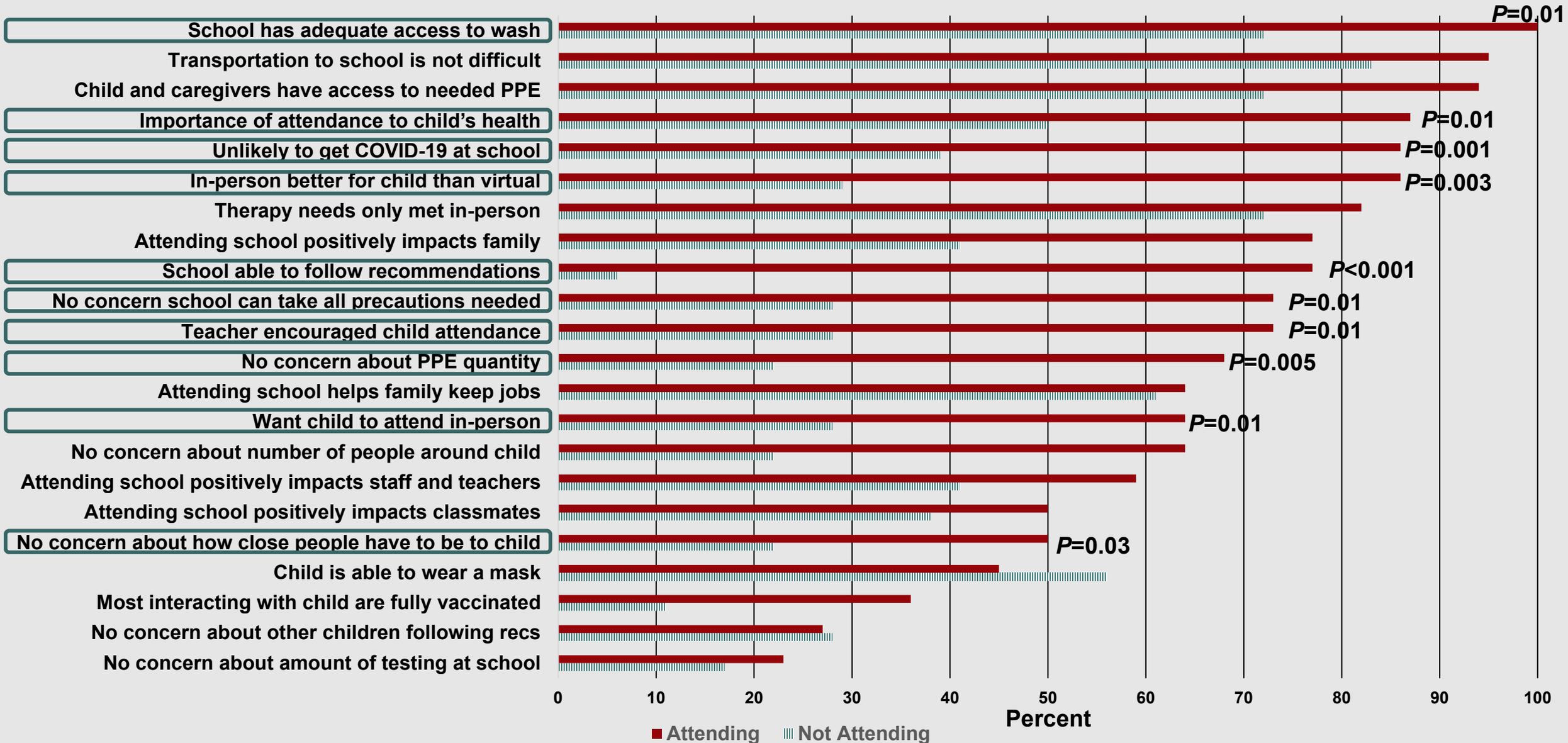
|                             | Not Attending | Attending | <i>P</i> |
|-----------------------------|---------------|-----------|----------|
| <b>Grade</b>                |               |           |          |
| <b>K-5</b>                  | 40%           | 44%       | 0.008    |
| <b>6-8</b>                  | 20%           | 26%       |          |
| <b>9-12</b>                 | 40%           | 30%       |          |
| <b>Race/Ethnicity</b>       |               |           |          |
| <b>White, non-Hispanic</b>  | 80%           | 79%       | 0.45     |
| <b>Black, non-Hispanic</b>  | 5%            | 5%        |          |
| <b>Hispanic</b>             | 7%            | 10%       |          |
| <b>Other</b>                | 9%            | 6%        |          |
| <b>Gender</b>               |               |           |          |
| <b>Female</b>               | 52%           | 52%       | 0.15     |
| <b>Non-English Language</b> | 9%            | 9%        | 0.94     |
| <b>COVID-19 Vaccine</b>     |               |           |          |
| <b>At least 1 dose</b>      | 45%           | 34%       | 0.007    |
| <b>None</b>                 | 55%           | 66%       |          |
| <b>COVID-19 History</b>     |               |           |          |
| <b>Ever Positive</b>        | 8%            | 14%       | 0.08     |
| <b>None</b>                 | 92%           | 86%       |          |



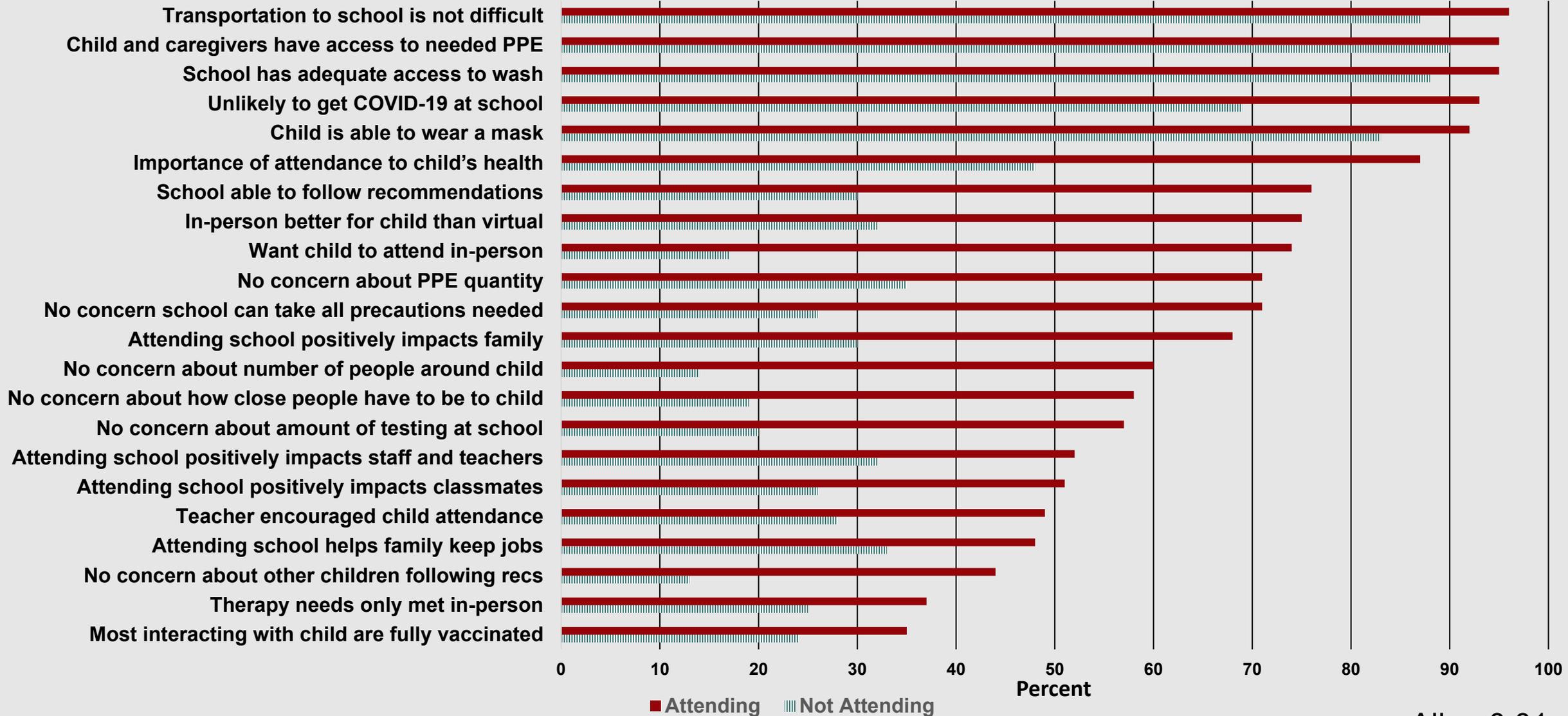
Demographics, testing, or vaccine perceptions may be weaker drivers of in-person school

**CMC school attendance and confidence in school mitigation plans strongly related**

# In-home Testing Cohort – School Perceptions



# Non-testing (Survey) Cohort – School Perceptions



All  $p < 0.01$

# Changing to In-Home Symptom Testing



|  | <b>Symptomatic</b> | <b>Surveillance</b> | <b>P</b> |
|--|--------------------|---------------------|----------|
| Desire child to attend in-person                         | 46%                | 55%                 | 0.39     |
| School able to follow recommendations to keep child safe | 88%                | 31%                 | 0.03     |
| School can take all precautions to stop COVID spread     | 88%                | 38%                 | 0.03     |
| No concern about PPE quantity                            | 88%                | 38%                 | 0.03     |
| Most or all interacting with child are fully vaccinated  | 63%                | 6%                  | 0.01     |

Two-thirds of families want to continue in-home surveillance testing

Less school mitigation confidence associated with continued surveillance testing

No associations with demographics, CMC COVID-19 vaccination status, or CMC history of COVID-19



# To support CMC attending school

- Schools likely need to...
  - Use recommended mitigation strategies
    - mask (PPE), vaccinate, distance, hygiene, etc
  - Communicate mitigation plans to families
  - Engage families
    - Teacher encouragement for CMC to attend assoc with 7x higher odds of in-person attendance ( $p=0.006$ )



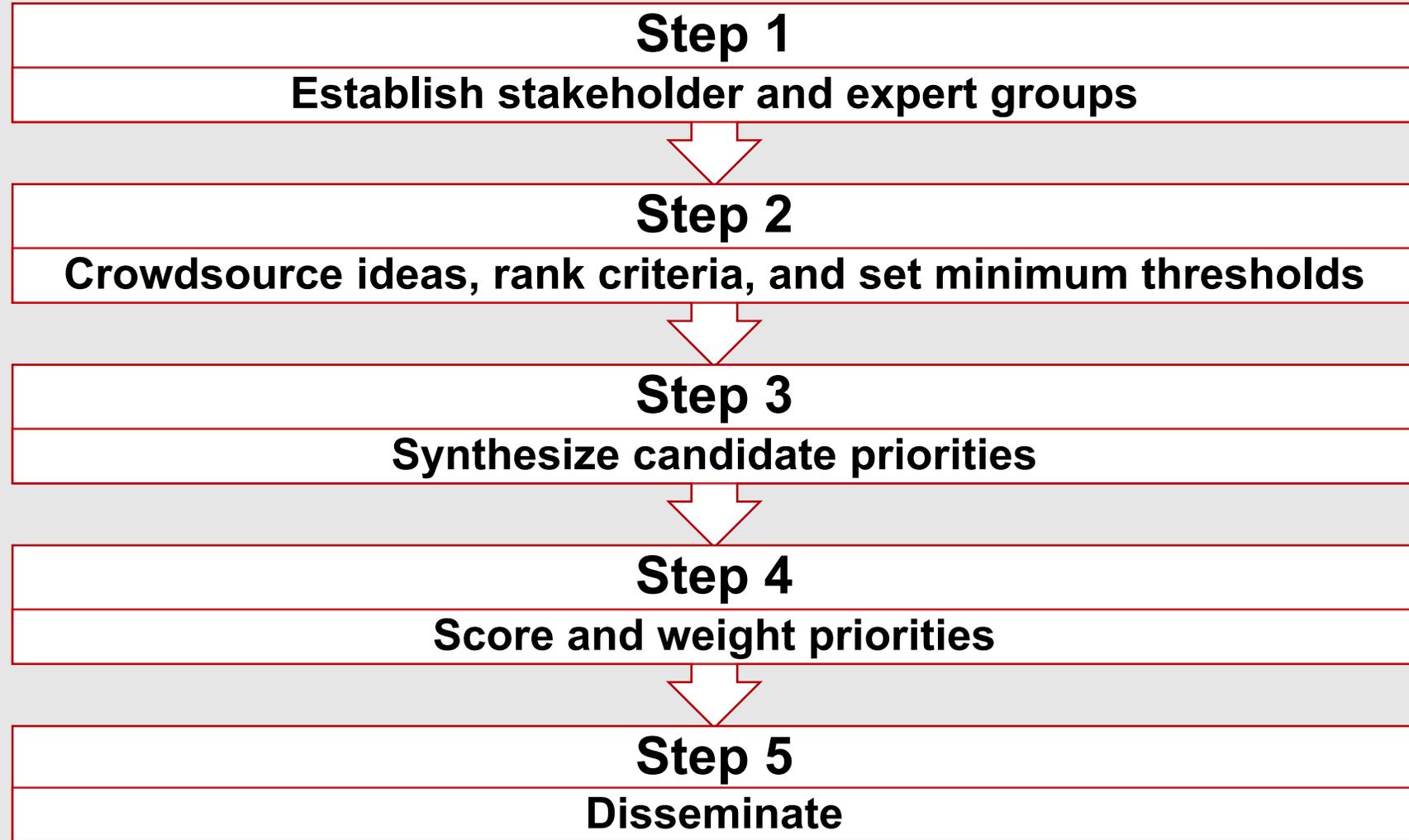
# Parents perception of schools

- Parents perceiving school not using mitigation strategies:
  - are less likely to have their child in school
  - also prefer more in-home (surveillance) testing
  
- *Could providing in-home tests to families concerned with school safety address concern & boost attendance?*

# Statewide Consensus Priorities



## *WI stakeholder consensus priorities for safe in-person school for CMC*





## Priorities for a Safe Return to School for Children with Complex Health Needs

Children with complex health needs have serious medical conditions and often rely on medical devices or people to help them with daily activities.

Safe in-person school attendance can be hard because these children are at higher risk of severe COVID-19, their daily care can include high-risk procedures, and physical distancing and mask adherence can be difficult.

The unique circumstances facing children with complex health needs require extra attention to support safe in-person school attendance.

In Spring 2021, 460 Wisconsin families, school staff, and clinicians sent us over 1,100 ideas on how to help these children attend school during the pandemic. The top 10 ideas shown below were prioritized by a team of 35 experts representing families, schools, clinicians and policymakers across Wisconsin.

As a central principle, the safety of children with complex health needs requires the safety of all children and staff at school. **Families of children with complex health needs should be supported to make the best decision for their child** with their health care providers and school staff when considering the risks of COVID-19.

**460**

families, school staff, & clinicians submitted ideas

**1,100+**

ideas were received

**35**

experts reviewed & prioritized the ideas

## IN FIRST WEEK

- >1000 views
- >650 unique users in 4 countries
- >200 downloads

## CURRENT RESOURCES

- Top 10 consensus priorities
- “1-pager”
- Family FAQ guide
- Healthcare provider template letter
- Social Media content
- *More on the way*

## PRIORITY SUMMARY

- Universal masks, vaccination, school testing
- Respiratory protection plans for staff
- Single use medical equipment
- Safety plans within IEPs, flexible curriculum
- Staff education on CMC, nurse available
- Healthcare team partner, transportation plan

# Challenges and Next Steps



## Challenges

- Low in-school testing enthusiasm
  - Enroll direct to symptomatic testing
  - Offer in-home (symptomatic) testing
    - This is what we hear parents want
  - Talking with additional schools
  - Talking with WI testing program
- Low (zero) case detection with asymptomatic testing
- Unknown impact of increases in other respiratory viruses

## Next Steps

- Finish data collection and analyses
- Longitudinal analyses
  - Repeated surveys, trends
  - $\Delta$  School perceptions associated with  $\Delta$  from surveillance to symptom testing
- Further develop and promote resource inventory



# Thank you! Questions?

**It's back  
to school time!**

View priorities for a  
safe return to school  
for children with  
complex health  
needs at

**reset4kids.org**



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

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

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

[reset@pediatrics.wisc.edu](mailto:reset@pediatrics.wisc.edu)



RADx-UP Presentation Return to School

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August 9, 2021

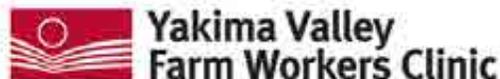
# Presentation Outline

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1. ROSSEY Overview
2. Aim 1: Key Stakeholder Interviews, Focus Groups & Child Interviews Update and Preliminary Themes
3. Aim 2: Testing Program (COVID-19 Testing + Health Education with Comic Books)
4. RADx-Up Return to School Diagnostic Testing Lessons and Next Steps

# Collaborators

- University of Washington School of Public Health and School of Medicine
- Fred Hutchinson Cancer Research Center and Center for Community Health Promotion
- Yakima School District
- Community Advisory Board (CAB)
  - Representing three school districts, Yakima Health District, and the Farmworkers' Clinic



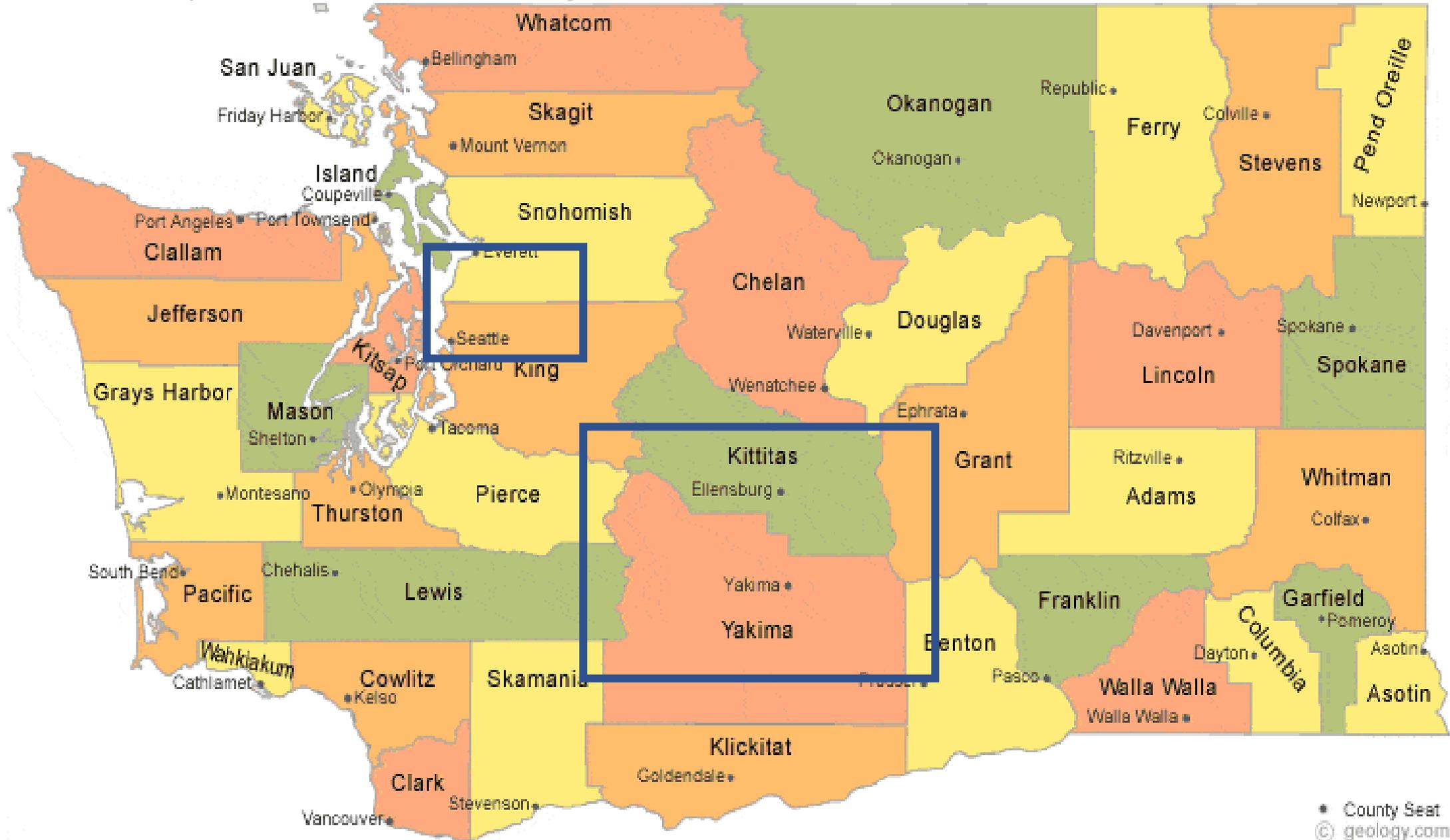
# Study Aims

**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 + risk communication)** on student attendance using a **cluster randomized controlled trial (RCT)** with two intervention arms: current learning model (comparison) and testing program.

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

# Map of Washington



# 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 residents are of Hispanic/Latino
  - Among these residents, 95% are Mexican-American



# Aim 1

Identify the rural Latino community's social, ethical, behavioral needs and resources for students to return to school and maintain onsite learning.

- Key Stakeholder Interviews (n=20)
  - Completed 19 interviews
  - Reached saturation
- Parent Focus Group (n=4)
  - 2 English (with 5 & 7 participants)
  - 2 Spanish (with 6 & 8 participants)
- Child Interviews (n=20)
  - 16 interviews completed, 3 scheduled, 1 pending



# Theme 1: COVID-19 pandemic on social, economic, & mental health

- The COVID-19 pandemic impacted families' social, economic, and mental health and required lifestyle adjustments to meet demands.
  - “Elders pa[id] the price” - unable to attend social gatherings, leading to further isolation.
  - Struggling businesses and loss of employment.
- Children's mental health issues
  - Lack of social interaction; Difficulties of remote learning; Loss of family members and/or teachers.
- Fatigue with mask wearing among families even after vaccination.
- “We're looking forward to a brighter next step.”

# Theme 2: Schools commitment to evolving needs of students

- Schools provided teachers and families with resources to adjust to the new learning mode
  - secured laptops and hotspots for children
  - created troubleshooting resources for parents
  - helped teachers familiarize with technology
  - weekly meal pick up for students
  - enhanced communication to increase sense of togetherness
- Created a safe environment for children to return to school
  - monitoring temperature
  - providing extra masks
  - hand sanitizers before entering schools and inside/outside each classroom

## Theme 2 cont.

- Teachers noted many homes were not good learning environments
  - lack of space for children to immerse in learning
  - distraction in the home environment
    - e.g. living room served many purposes
  - children being pulled in the middle of the classroom to finish chores
  - parents' limited technology literacy to help their children
- Concerns about widening learning gaps
  - some teachers went above and beyond meeting with parents to provide technical support to improve children's participation
- Even in the presence of resources, we heard disparities in the impact of policies among communities experiencing SDH

# Theme 3: Using testing for school reopening

- All participants were supportive of using testing as a way to return to schools
  - noted needs to educate families about the advances in testing technology (saliva testing, interior nasal swabbing)
  - the benefits of testing (for families more concerned about quarantining after positive test results)
  - dismantle stigma around positive tests
- Mixed opinions on how to implement testing in schools
  - provide testing to all students given many children are asymptomatic
  - should stay optional as it was within students' rights
- Most agreed that families will participate in testing
  - has become a familiar procedure during the pandemic

# Theme 4: Vaccine concerns

- Lack of education about the benefits of testing and discommunication in community.
  - negative perceptions from multiple sources (e.g., disproven scientific paper on vaccine side effects from measles, “bad” experiences with side effects being magnified)
  - long-term side effects
  - vaccine causing sterilization
  - mistrust for government and science – microchips in the vaccine
  - religiosity-related concerns – mRNA affecting the DNA that was created by God, vaccine using fetal tissue, vaccine being the mark of the devil/Satan (Patent #666)

# Child Interviews – Five main themes

- Quarantine and social distancing are difficult and often stressful
  - Took a toll on their “feelings and emotions”
- “A fear of what they put” in the vaccine
  - Getting the vaccine will get the “government to control”
  - “Vaccines will have magnets or chip”
  - “Getting the vaccine will only make me more sicker”
- Fear of side effects from getting the vaccine
  - J&J vaccine giving young adults heart problems and blood clots
- Family have a strong influence on them getting the vaccine
- Main motivation for getting tested is “wanting the pandemic to end”

# Aim 2 – Pilot



Aim 2 pilot study in May – June 2021 with one school then 4 additional during summer school to understand the implementation steps.

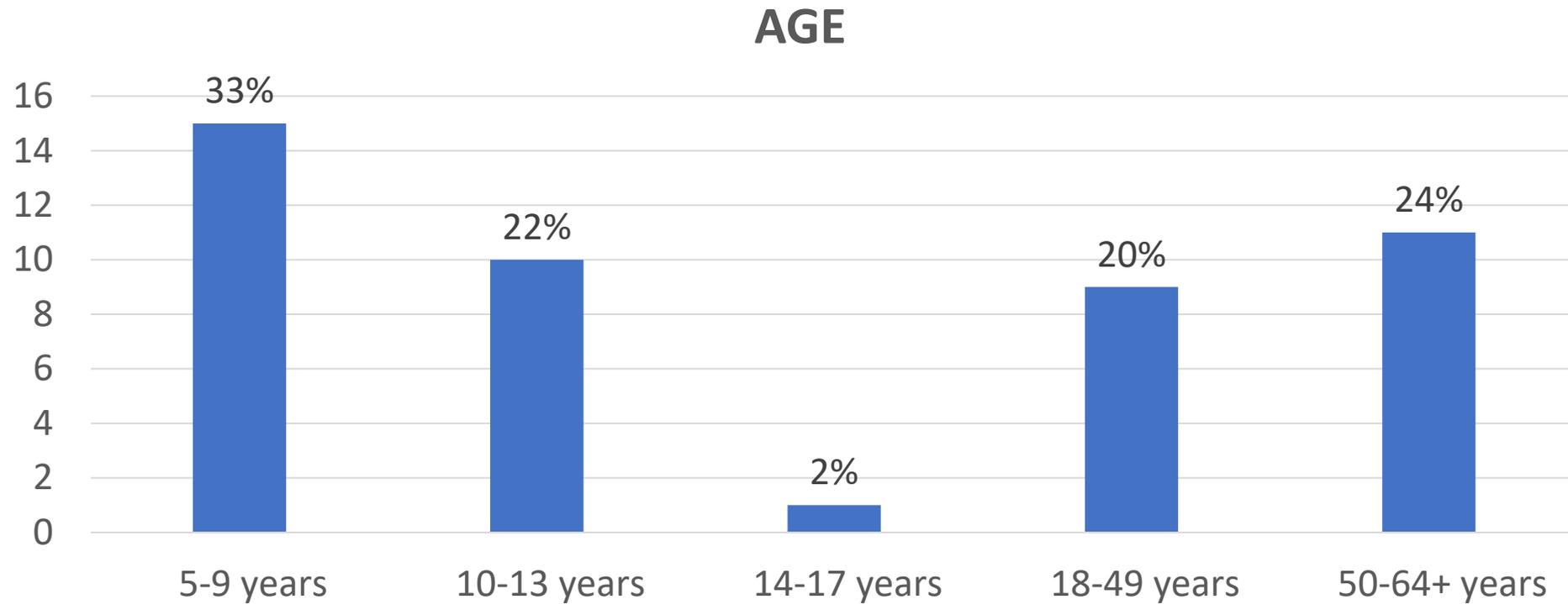
- 70 interested participants
- 46 total enrolled participants
- Discovery Lab School (K-8) participated as the spring pilot school
  - 24 / 27 enrollments did not continue after spring semester
- Extension of pilot to 4 summer school programs during a 6-week period (June 21-July 23)

# COVID-19 positivity rate



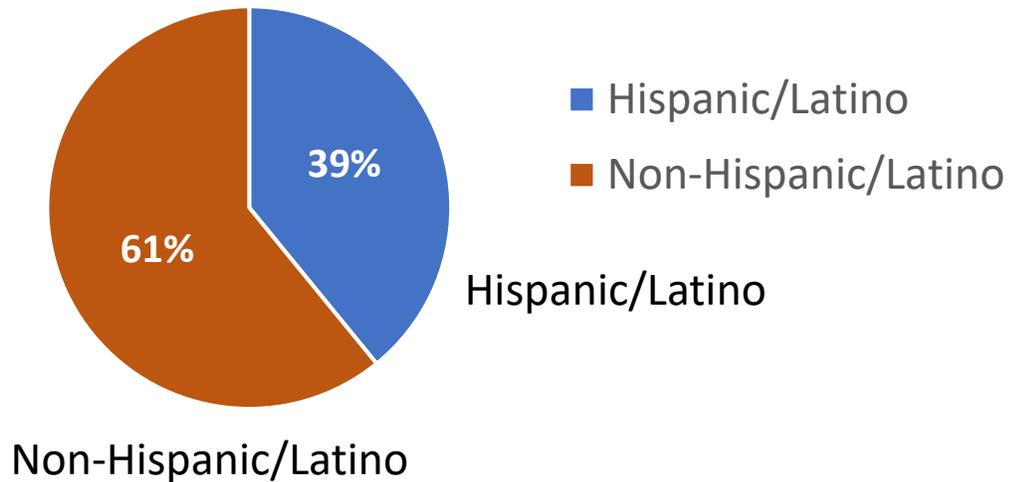
- 27 (59%) participants preferred home collection
- 3 COVID-19 positive cases (one family household)

# Pilot Demographics: Age (n=46)

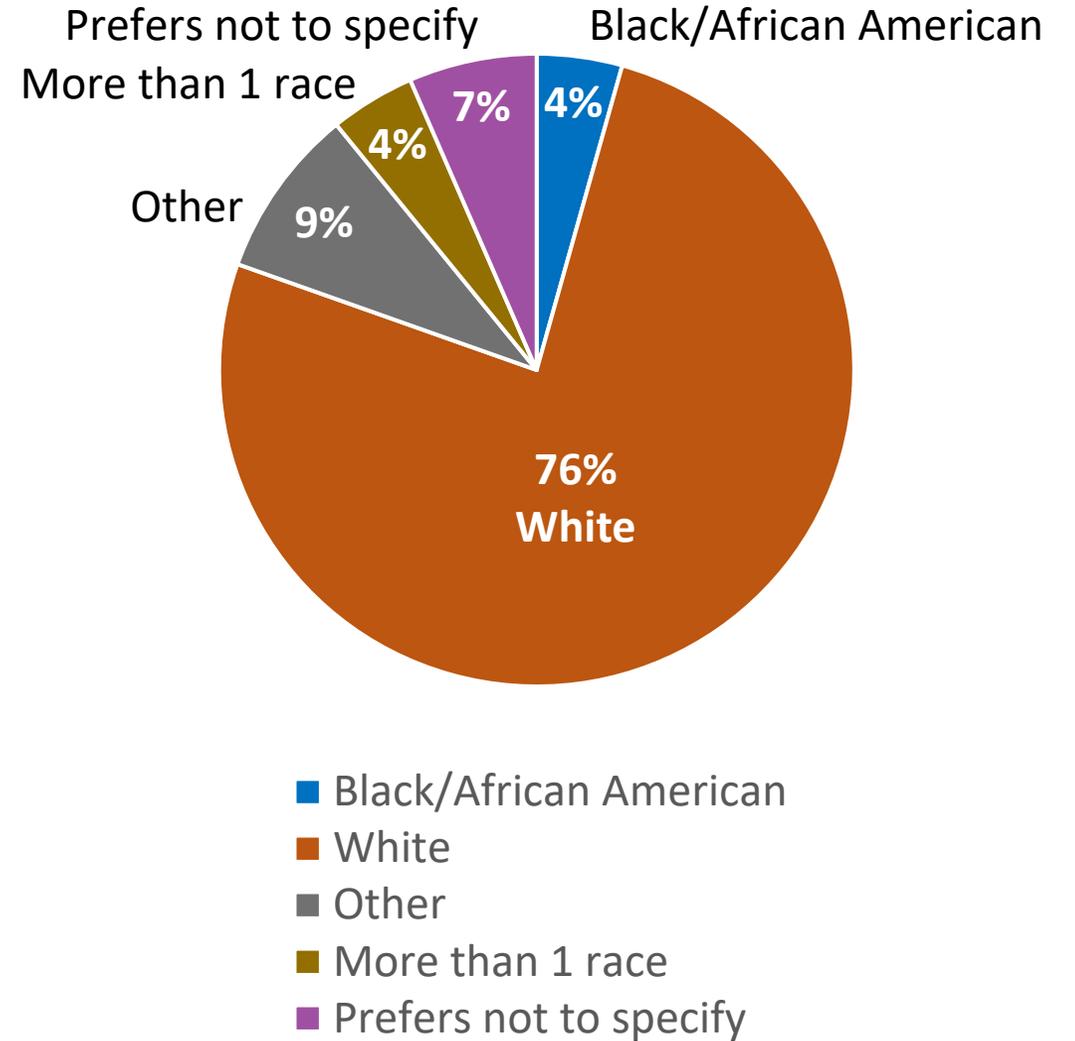


# Race/Ethnicity (n=46)

## ETHNICITY

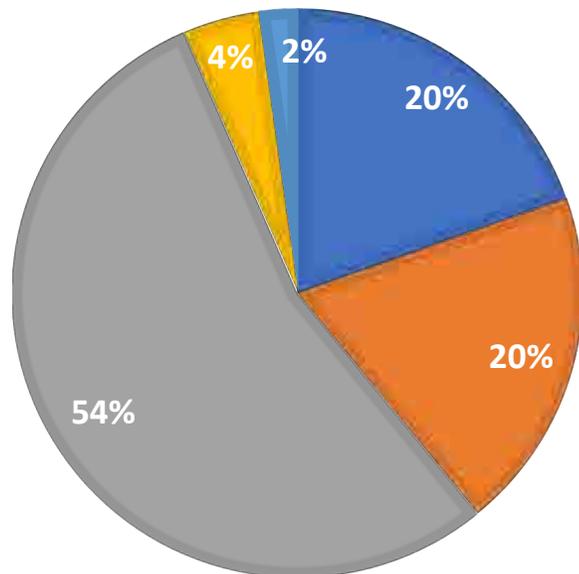


## RACE

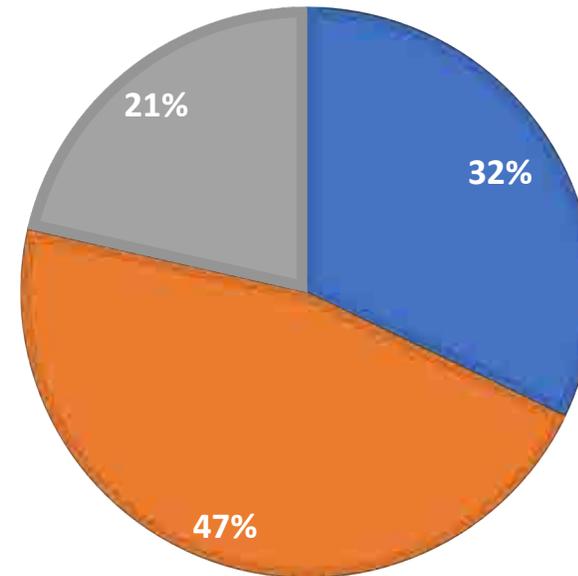


# Position and Grade Level

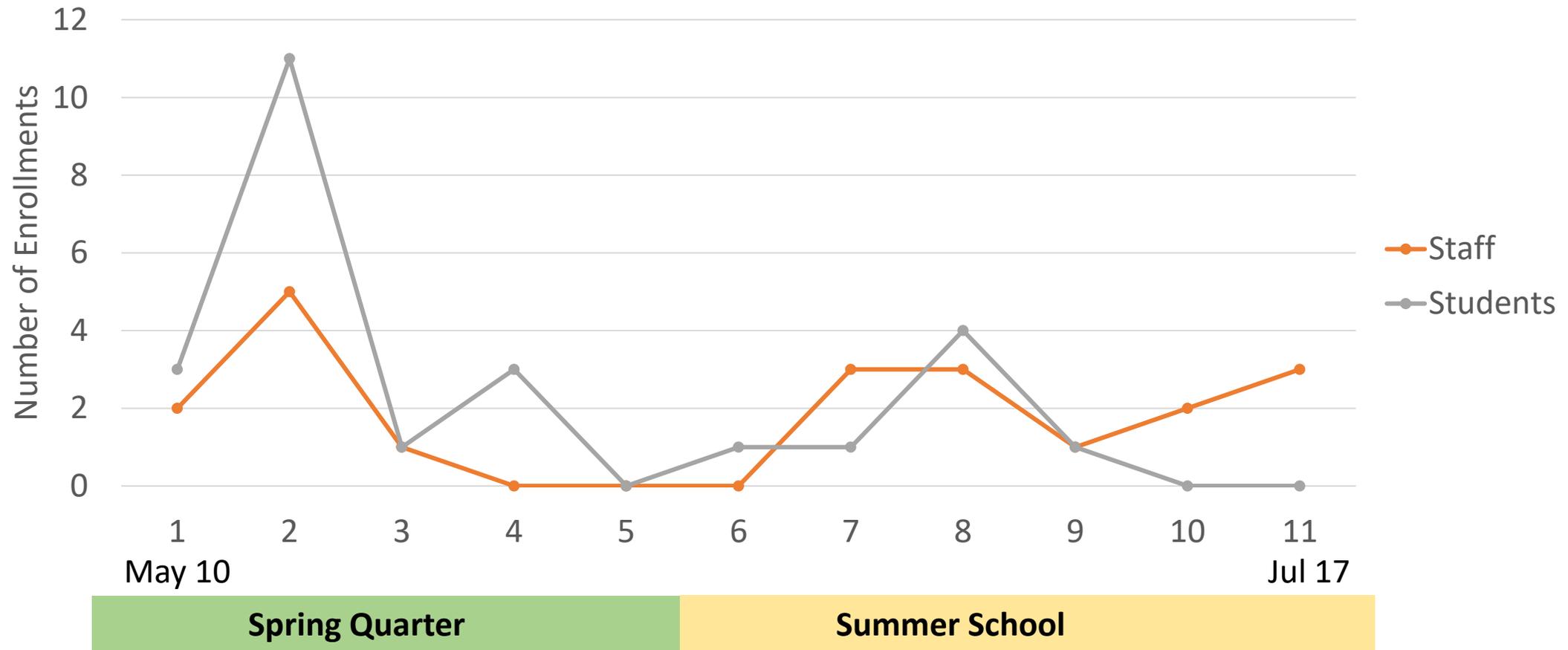
## POSITION IN SCHOOL



## GRADE LEVEL (STUDENTS ONLY)



# Enrollment Trends

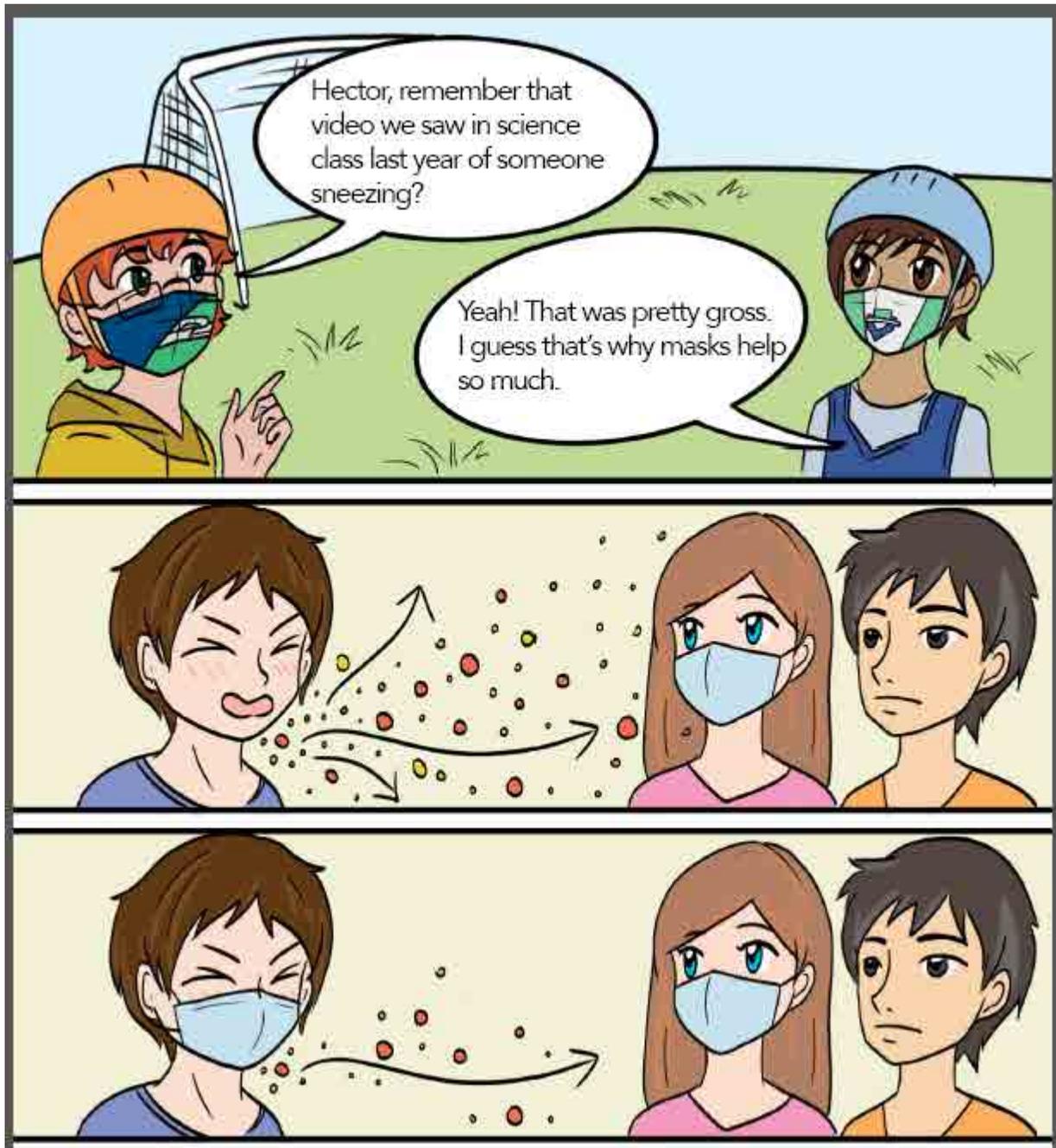


*\*Not including Role Not Specified (n=1)*

# Comic Book 1: Playdate during the pandemic



- Follows the main characters (siblings Hector, Mya, and Ava and their friend Aaron) and their experiences during the COVID-19 pandemic.



# Comics

- 3 comics tailored for students (masking, testing, vaccine)
- 2 comics tailored for parents (focusing on misinformation discovered from qualitative work)
- Messages infused with constructs from the Health Beliefs Model and the Self Determination Theory

# Key Take-aways From Pilot

- Recruitment and enrollment have been more challenging than anticipated
- Simplified consent forms and hands-on recruitment for Spanish speaking parents
- Logistics for multiple schools are manageable with trained staff
- Multiple recruitment strategies needed
- CAB's preference for parent-facing education tool on video format (rather than comic book)



# Next Steps

- Full trial enrollment starts on 8/25/21 (start of school year)
  - Goal of 900 children
- Address concerns for randomization in the trial design
- Will monitor testing fatigue during the full study period
- Strategies to address testing fatigue
  - Coordinate with school testing activities to avoid overlap
  - Education video to reframe the testing technology and burden of testing

# Questions



Thank you for your attention

Questions?

¿Tienen Preguntas?

# SARS-CoV-2 Screening and Diagnostic testing for return to K-12 schools

**Kanecia Zimmerman, MD MPH**

*Monday, August 9<sup>th</sup>, 2021*



**THE ABC SCIENCE**  
COLLABORATIVE

Learning | Informed Decision-Making | Research

# Agenda

- **Project Overview**
  - Project overview and scope
- **Recruitment – Testing Initiative**
- **Major Outcomes to Date**
  - Community Engagement and Education
  - Outcomes of testing program
  - Qualitative data
- **Lessons Learned**
- **Next Steps**



# Two major problems to solve:

With mitigation strategies in place (masking, hand hygiene, physical distancing), within school transmission is low and schools can safely reopen.

Even as schools are reopening:

- Black and Latino students have been less likely to return in-person to school compared to white students
- Quarantine requirements after exposure have led to prolonged periods of time out of schools (substantial individual and community risk:benefit)
  - Inherently worse among those with limited access/uptake of testing after exposure
  - Access to testing has been more limited in underserved communities.

# Overview: Project Scope and Goals

**Long-term goals:** to ensure the safe and equitable return of K-12 school children to US public schools, maximize access to in-person learning, and limit the spread of SARS-CoV-2 in Black and Latino communities.

- **AIM 1**: Assess the effectiveness of rapid, school-based SARS-CoV-2 **screening testing** in reducing within-school transmission and restoring trust among Black and Latino families.
- **AIM 2**: Assess uptake of school-based testing and time to safe school return after **exposure**.
- **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.

# Recruitment – Testing Initiative



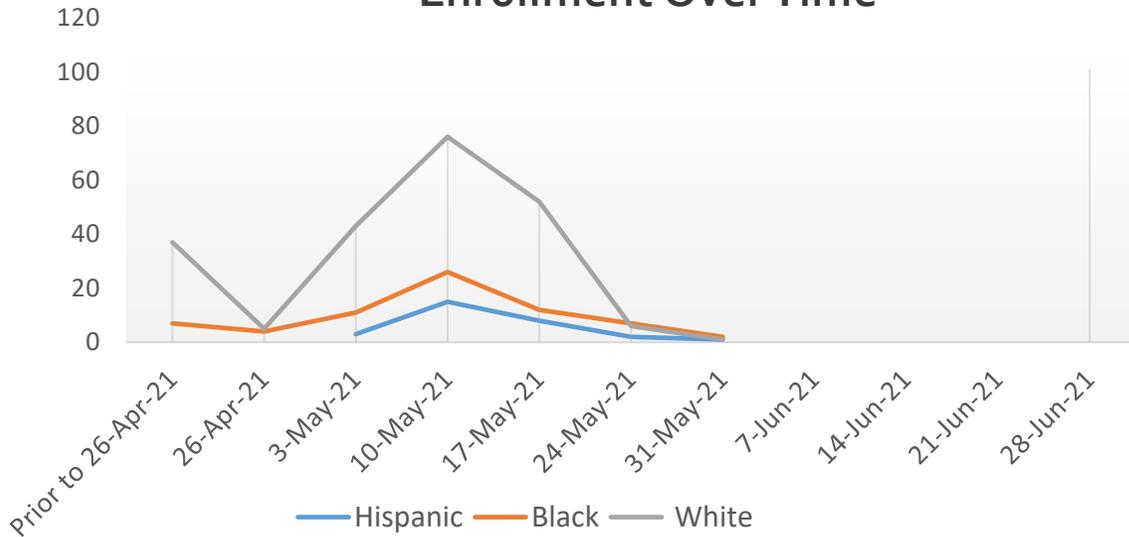
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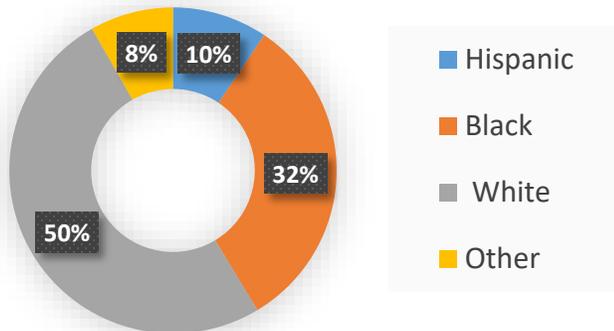
# Enrollment

## Enrollment by Race/Ethnicity

### Enrollment Over Time

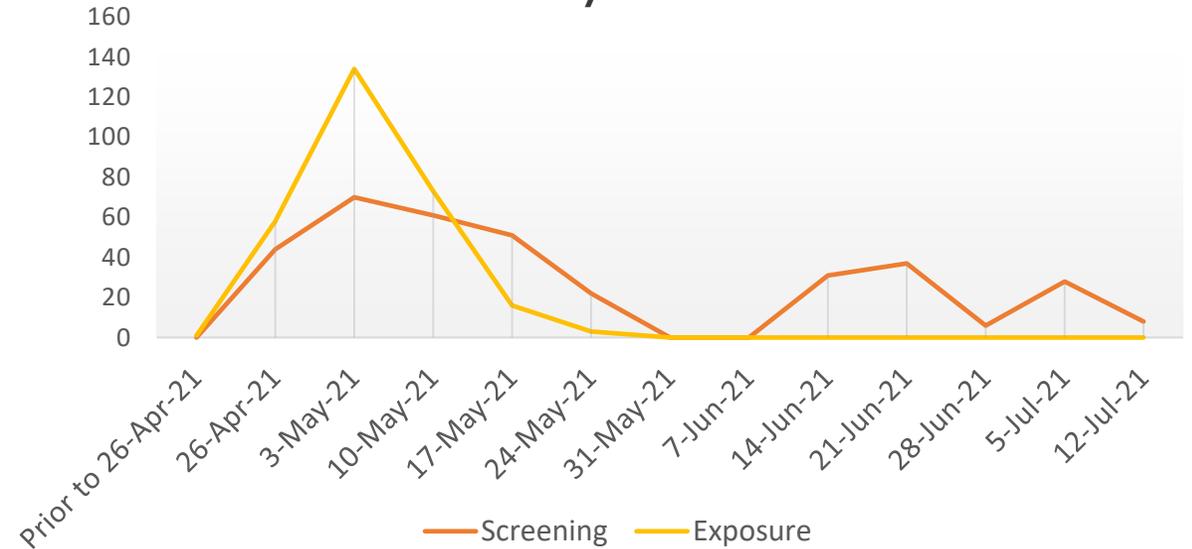


### Cumulative Enrollment

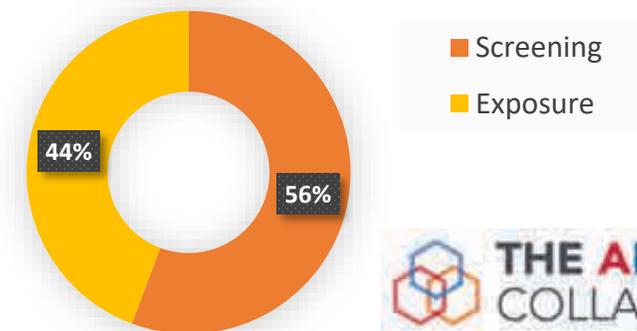


## Enrollment by Cohort

### By Cohort

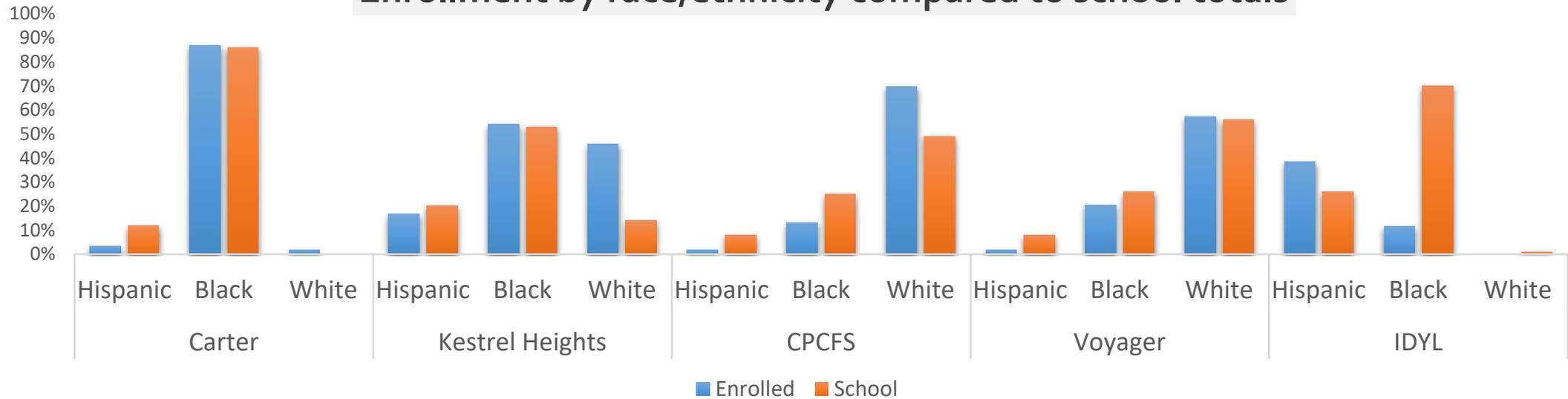


### Cumulative Enrollment

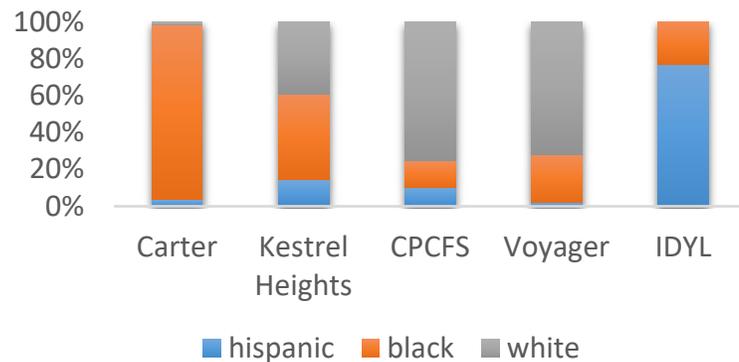


# Durham Charter Schools Enrollment

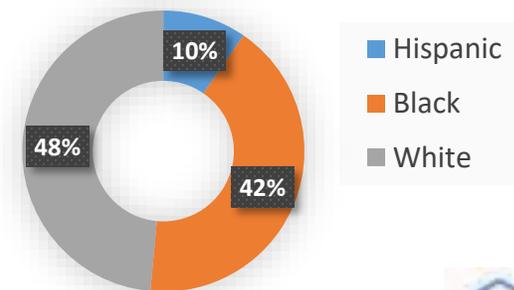
## Enrollment by race/ethnicity compared to school totals



## Enrollment by Race/Ethnicity

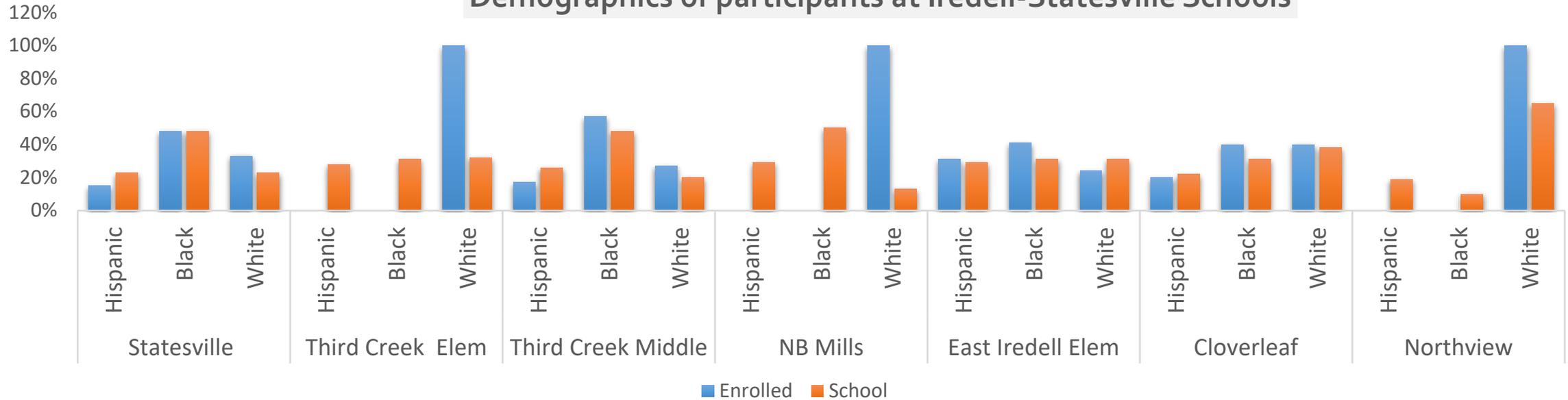


## Cumulative Enrollment by Race/Ethnicity

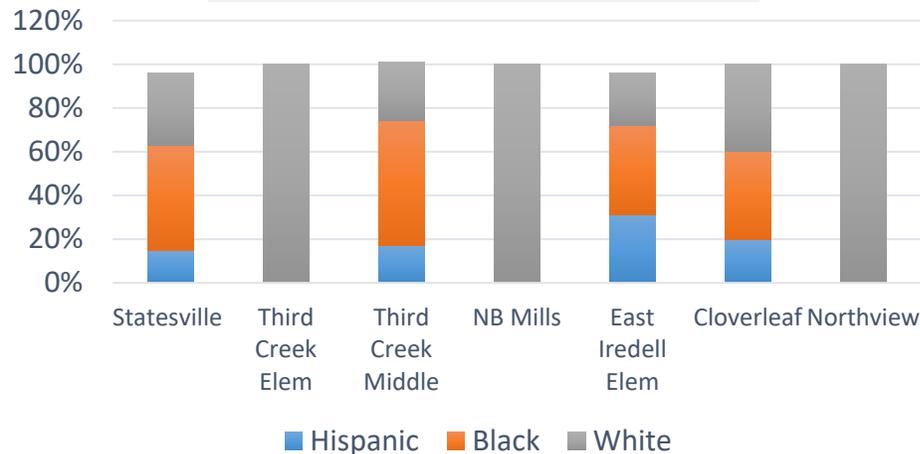


# Iredell-Statesville Schools Enrollment

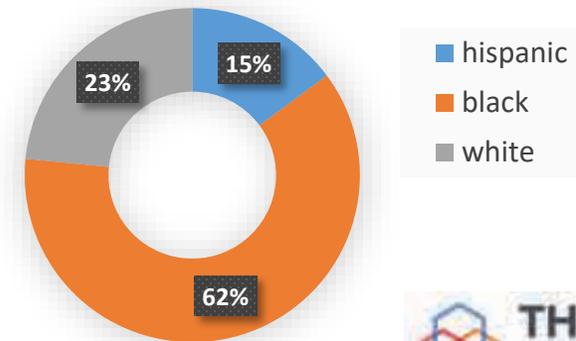
Demographics of participants at Iredell-Statesville Schools



Enrollment by Race/Ethnicity



Cumulative Enrollment by Race/Ethnicity



# Major Outcomes to Date



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# Major Outcomes: Community engagement and education

- Over 50 school board meetings to provide expertise and answer questions
  - ~60% k-12 masked in NC
  - ~20% unmasked but monitoring and providing data
- Hundreds of faculty to school leadership calls
- 10s of school/district-wide staff meetings
- Dozens of meetings with community members
- Extensive interaction with NCDHHS, DPI, General Assembly
  - NC legislation to require access to in-person school (March 2020)
- Extensive educational resources:
  - [Abcsciencecollaborative.org](https://abcsciencecollaborative.org)
  - Testing infographics/flowchart and decision tree
  - Vaccination videos
  - Lay summaries and reports
  - Media briefings on available data
  - "Year in Review"

# School Testing: Testing Results

## Key takeaways and findings from the testing initiative

### to date:

- None of the positive cases in the Durham Charter Schools were identified through the screening testing initiative; no effect on within-school transmission
- The **proportion of positive tests after initiation of the testing program dropped substantially**, suggesting that the **RTS program increased total testing access** and that testing access was not biased by concerns for test positivity.

Reported cases and secondary transmission in Durham Charter Schools prior to and during testing initiative

|        |         | STUDENTS       |                |                        |                | STAFF          |                |                        |                |
|--------|---------|----------------|----------------|------------------------|----------------|----------------|----------------|------------------------|----------------|
|        |         | Primary cases  |                | Secondary Transmission |                | Primary cases  |                | Secondary Transmission |                |
|        |         | Before testing | After testing* | Before testing         | After testing* | Before testing | After testing* | Before testing         | After testing* |
| SCHOOL | Carter  | 0              | 0              | 0                      | 0              | 0              | 0              | 0                      | 0              |
|        | CPSFC   | 1              | 4              | 0                      | 0              | 0              | 1              | 0                      | 0              |
|        | IDYL    | 0              | 0              | 0                      | 0              | 0              | 0              | 0                      | 0              |
|        | Kestrel | 0              | 0              | 0                      | 0              | 0              | 0              | 0                      | 0              |
|        | Voyager | 1              | 3              | 0                      | 0              | 0              | 1              | 0                      | 0              |

\*

Results of exposure testing after known COVID-19 exposure among students and staff in all ISS prior to and during the testing initiative

|               | Before Testing Program | After Testing Program | Totals   |
|---------------|------------------------|-----------------------|----------|
|               | N (%)                  | N (%)*                | N (%)    |
| Negative Test | 21(42)                 | 275 (91)              | 296 (84) |
| Positive Test | 29 (58)                | 27 (9)                | 56 (16)  |
| <b>Totals</b> | 50                     | 302                   | 352      |



\*cases not identified through OTA surveillance testing program; they were reported from external sources

# School Testing Results: Effect on Access

## Key takeaways and findings from the testing initiative to date

- The exposure testing program increased access to testing.
- The percentage of exposed students and staff tested after the initiation of the testing program increased by 29 percentage points. Only 8% of exposed individuals were tested prior to the testing program, whereas 37% of exposed individuals were tested after.
- Access to testing increased in both schools with high proportions of underserved populations as well as in schools where the testing program was expanded.

Table 7. Exposure testing access in all Iredell Statesville Schools\*

|            | Before testing program | After testing program | Total     |
|------------|------------------------|-----------------------|-----------|
|            | N (%)                  | N (%)                 | N (%)     |
| Not tested | 567 (92)               | 524 (63)              | 1091 (76) |
| Tested     | 50 (8)                 | 302 (37)              | 352 (24)  |
| Totals     | 617                    | 826                   | 1443      |

Table 9. Comparison of exposure testing access in pre-specified Iredell Statesville Schools\*\* vs other Iredell Statesville Schools with expanded testing

|   | Proportion tested before | Proportion tested after |
|---|--------------------------|-------------------------|
| Pre-specified Iredell Statesville Schools                     | 0.09929078               | 0.285371703             |
| Iredell Statesville Schools participating in expanded testing | 0.077731                 | 0.447433                |

\*Pearson  $\chi^2(1) = 155.0863$  Pr = 0.000

\*\*Pre-specified Iredell Statesville Schools include the seven (7) schools previously designated in the grant application to have high proportions of underserved populations

# School Testing Results: Effect on Quarantine Duration

## Key takeaways and findings from the testing initiative to date

- Duration of quarantine decreased after initiation of the testing program.
- This has a large impact on reducing the time missed from school due to quarantine and with-in school exposures.

Table 10. Days of quarantine in all ISS after in-school exposure\*

|                     | Before testing program | After testing program | Total    |
|---------------------|------------------------|-----------------------|----------|
|                     | N (%)                  | N (%)                 | N (%)    |
| Quarantine <10 days | 136 (22)               | 409 (50)              | 545 (38) |
| Quarantine ≥10 days | 481 (78)               | 417 (50)              | 898 (62) |
| Total               | 617                    | 826                   | 1443     |

Table 11. Days of quarantine in pre-specified ISS

|                     | Before testing program | After testing program | Total    |
|---------------------|------------------------|-----------------------|----------|
|                     | N (%)                  | N (%)                 | N (%)    |
| Quarantine <10 days | 32 (23)                | 196 (47)              | 228 (41) |
| Quarantine ≥10 days | 109 (77)               | 221 (53)              | 330 (59) |
| Total               | 141                    | 417                   | 558      |

# Qualitative Investigation: Phase 1

- Identify the preferences for and perceived outcomes of school-based SARS-CoV-2 testing among parents and caregivers of Black and Latino/a/x students and school personnel
- Describe factors influencing decisions to return to school among parents and caregivers of Black and Latino/a/x students

**Table 1.** Demographic characteristics of parents and caregivers of Black students

| Characteristic                          | No. (%)<br>n=6 |
|---|----------------|
| <b>Age</b>                              |                |
| 30-39                                   | 1 (16.7)       |
| 40-49                                   | 3 (50.0)       |
| 50-59                                   | 1 (16.7)       |
| 60-69                                   | 0 (0.0)        |
| 70-79                                   | 1 (16.7)       |
| <b>Gender</b>                           |                |
| Cisgender female                        | 6 (100.0)      |
| <b>Race</b>                             |                |
| Black or African American               | 6 (100.0)      |
| <b>Hispanic/Latino/a/x ethnicity</b>    |                |
| Hispanic/Latino/a/x ethnicity           | 1 (16.7)       |
| <b>Highest Level of Education</b>       |                |
| High school graduate/GED                | 2 (33.3)       |
| Technical/Vocational/Associate's degree | 1 (16.7)       |
| Master's degree                         | 3 (50.0)       |

**Table 2.** Demographic characteristics of school personnel

| Characteristic                       | No. (%)<br>n=7 |
|--------------------------------------|----------------|
| <b>Age</b>                           |                |
| 30-39                                | 1 (14.3)       |
| 40-49                                | 6 (85.7)       |
| <b>Gender</b>                        |                |
| Cisgender female                     | 6 (85.7)       |
| Cisgender male                       | 1 (14.3)       |
| <b>Race</b>                          |                |
| Black or African American            | 2 (28.6)       |
| White                                | 5 (71.4)       |
| <b>Hispanic/Latino/a/x ethnicity</b> |                |
| Hispanic/Latino/a/x ethnicity        | 1 (14.3)       |
| <b>Highest Level of Education</b>    |                |
| Bachelor's degree                    | 2 (28.6)       |
| Master's degree                      | 5 (71.4)       |
| <b>Position</b>                      |                |
| Teacher                              | 7 (100.0)      |
| <b>Grade levels taught</b>           |                |
| Kindergarten-3                       | 2 (28.6)       |
| 4-8                                  | 3 (42.9)       |
| 9-12                                 | 2 (28.6)       |

# Qualitative Investigation: School Personnel and Parent/Caregiver Perspectives

| School Personnel Perspectives   | Parent/Caregiver Perspectives  |
|---|--|
| <p><u>Suggestions for School Based Testing:</u></p> <ul style="list-style-type: none"><li>• Parental involvement and consent is needed</li><li>• The framing/presentation of the testing program to the school community is important for the acceptance</li><li>• Communication of clear expectations is important for acceptance</li><li>• Communications with parents about school testing should be science- and data-based</li><li>• Teacher involvement is important in designing the testing program to provide input on how best to minimize teacher burden and classroom disruptions</li></ul> | <p><u>Possible benefits of School-Based Testing</u></p> <ul style="list-style-type: none"><li>• Providing a safe school environment</li><li>• Providing families with peace of mind</li><li>• Reducing community spread</li></ul> <p><u>Concerns about School-Based Testing</u></p> <ul style="list-style-type: none"><li>• Logistics of the testing procedures</li><li>• Who is administering the test</li><li>• How students' privacy will be maintained</li><li>• Accuracy of home-based test results</li><li>• Some parents described experiences with school-based stigma or discrimination due to race prior to the pandemic</li></ul> |

# Qualitative Investigation: Main Findings

| School Personnel Perspectives  | Parent/Caregiver Perspectives  |
|--|--|
| <p data-bbox="147 376 937 419"><u>Suggestions for Return to In-School Learning</u></p> <ul data-bbox="112 451 1200 743" style="list-style-type: none"><li data-bbox="112 451 1098 494">• Schools need clear and consistent COVID-19 protocols</li><li data-bbox="112 522 1200 615">• Healthcare professionals should make contact with affected families</li><li data-bbox="112 644 1200 743">• Schools should develop plans for keeping students who test positive engaged during the quarantine period</li></ul> | <p data-bbox="1319 376 2091 419"><u>Facilitators for Return to In-School Learning</u></p> <ul data-bbox="1284 451 2372 793" style="list-style-type: none"><li data-bbox="1284 451 2155 544">• Providing school-based testing influences some parental/caregiver decisions</li><li data-bbox="1284 572 2372 665">• School personnel should be notified of students' test results because of the exposure risk</li><li data-bbox="1284 694 2321 793">• Teachers should prepare take-home materials and care packages for students who are diagnosed with COVID-19</li></ul> <p data-bbox="1319 822 2033 865"><u>Barriers for Return to In-School Learning</u></p> <ul data-bbox="1284 896 2372 1239" style="list-style-type: none"><li data-bbox="1284 896 2372 1043">• Decisions about returning to in-school learning were rarely impacted by experiences with stigma or discrimination prior to the pandemic</li><li data-bbox="1284 1072 2193 1165">• Concern about adherence to safety procedures by parents/caregivers, students, and schools</li><li data-bbox="1284 1193 2308 1239">• The potential for exposure for children and their families</li></ul> |

# Qualitative Investigation: Dissemination and Program Outcomes

## Dissemination of Findings

- **Health and education stakeholders** received a rapid analysis report that summarizes key points
- **Community stakeholders** received a rapid analysis report that summarizes key points
- **Participants** received a brief summary of the research findings, immediately prior to the release of the rapid analysis report
- **Education stakeholders** received a detailed report after the formal analyses using applied thematic analysis are complete

## Outcomes

- **Increased interest** in participating in future qualitative rounds
- Opportunity to **reimagine testing**
- Meetings organized with state officials on potential **ABC-NC Gov collaboration** related to school testing

# Community Response to our Work

*"I just personally want to say thank you to the entire ABC Science Collaborative Team. For over a year, you all have put in tireless hours for the people and schools in NC. Through your work, [School Name] has been open for 3 weeks successfully and has implemented all the health and safety protocols we learned through working with the ABC Science Collaborative team. While, I know it is a day-by-day effort, and staying diligent with the safety protocols, I know schools can open for students. Please know we value the partnership and will support any of your efforts and initiatives."*

*"Our daughters will return to school in-person in August. Only two of our four daughters are old enough to be vaccinated...we will continue to practice the 3W's as we re-introduce ourselves back into in-person everything. Thanks again for everything y'all are doing in the COVID world. You have no idea how much families like mine appreciate and value your work. It's literally keeping us safe, healthy and alive! Stay well!"*



# Lessons Learned

*School Testing and Postulates for Variable Recruitment*



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# School Testing Results: Key Takeaways

- In schools where screening testing was conducted, we found:
  - Enrollment was lower than expected
  - No positives
  - No secondary transmission in schools with mitigation strategies in place
- Offering testing after exposure is helpful – associated with increased testing uptake
- Able to make an impact on missed school days
- Dissemination and response to community requests are important
  - Can we reimagine our testing program in a way that is most useful for the community?
- Testing can be helpful in schools, but in this political climate, if our goal is safe return to in-person school, k-12 communities need:
  - **Access to the science** in order to weight risks and benefits of COVID-19 mitigation efforts (ex. masking/testing protocol)
  - **Advocacy** from those who understand what is happening on the ground.



# Postulates for variable recruitment

| Postulate  | Solution  |
|--|---|
| <p>School leaders and parents may have different goals as it pertains to testing and COVID-19 in general; Families on the fence may need evidence of benefit</p> | <ul style="list-style-type: none"> <li>Continued dissemination of testing results</li> <li>Concentration on areas where clear evidence of benefit</li> <li>Re-imagine testing program based on feedback from qualitative aims.</li> </ul> |
| <p>COVID-19 fatigue/substantial politicization</p>   | <ul style="list-style-type: none"> <li>Continued community engagement; boots on the ground to be able to relate to parents and other community members; changing COVID-19 dynamic (delta variant)</li> </ul>                              |
| <p>Concerns about privacy</p>  | <ul style="list-style-type: none"> <li>At home testing pilot</li> </ul>   |
| <p>Hesitancy from school leaders to push testing initiative (end of the year protocols)</p>  | <ul style="list-style-type: none"> <li>New school year, new variants, more children in schools may prompt school leaders to encourage testing</li> <li>Important to note that school leaders are facing many obstacles</li> </ul>         |
| <p>Parents who decided to return to school this spring may general represent a cohort that is less interested in testing</p>                                     | <ul style="list-style-type: none"> <li>Introduce possibility of testing to new cohort of parents with children returning to school (qualitative study suggests parents who were remote may be interested)</li> </ul>                      |
| <p>New state resources (from federal funds) to support testing in schools</p>  | <ul style="list-style-type: none"> <li>So far, schools remain interested in Duke collaboration (relationship and benefit beyond testing)</li> <li>Look to collaborate with the state</li> </ul>   |

# Next Steps



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# Next Steps

- Dissemination of findings through manuscripts (*Pediatrics* supplement)
- Continued dissemination to the public (lay summaries)
- Use data from qualitative evaluation (and available scientific evidence) to revamp testing programs --> expansion of testing opportunities in some partner schools
- Expand reach – collaborations with additional districts
- Collaboration with NCDHHS on state/federally-sponsored testing program
- Qualitative program: phase 2

# Thank you.

Study Email: [SchoolSETStudy@dm.duke.edu](mailto:SchoolSETStudy@dm.duke.edu)



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# School TLC Study

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

Dana Keener Mast, PhD, ICF

Jennifer Goldman, MD, CMKC

Jennifer Schuster, MD, CMKC



## RADx-UP Return to School Phase I and II Workshop

August 9, 2021



# Test Preference Study

Aim: Determine preferred testing strategy among students and staff

We collected a **nasal swab** and **saliva sample** from 135 study participants and asked,

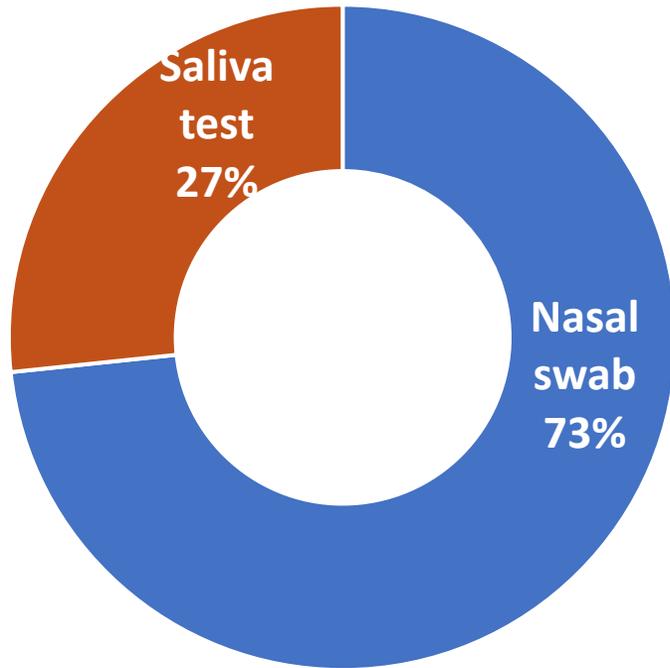
**“Which test did you like better?”**

## 135 study participants

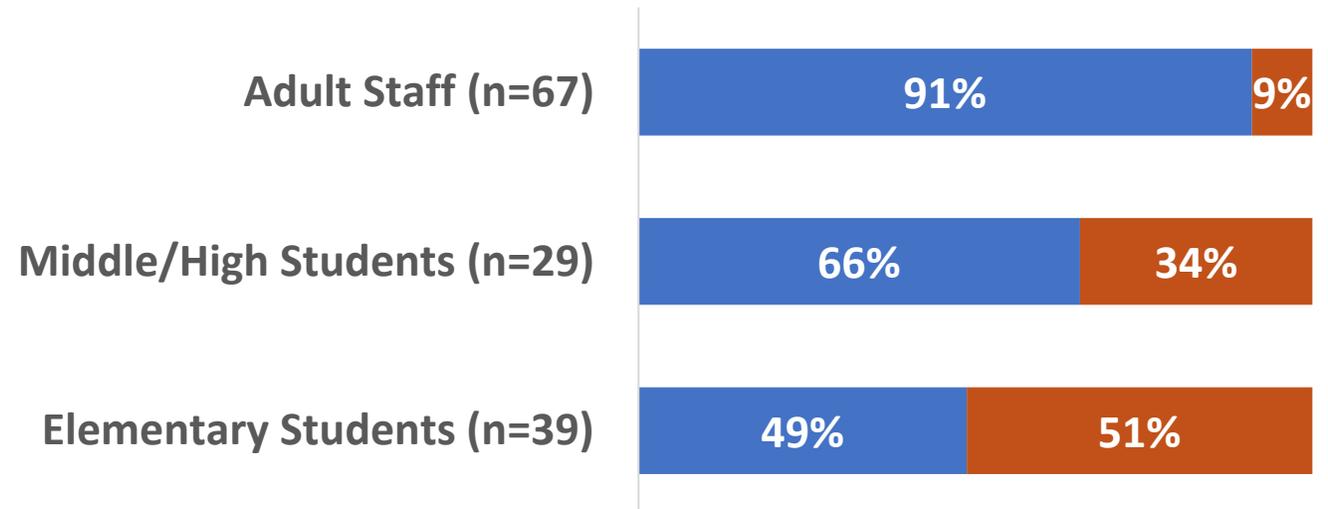
|     |                    |
|-----|--------------------|
| 50% | students           |
| 50% | adult staff        |
| 54% | female             |
| 32% | Hispanic/Latino    |
| 21% | Black non-Hispanic |
| 34% | White non-Hispanic |
| 13% | Other race         |

## Most participants preferred the nasal swab

Test preference **varied by age group**, with adults strongly preferring the nasal swab and elementary students split almost 50/50

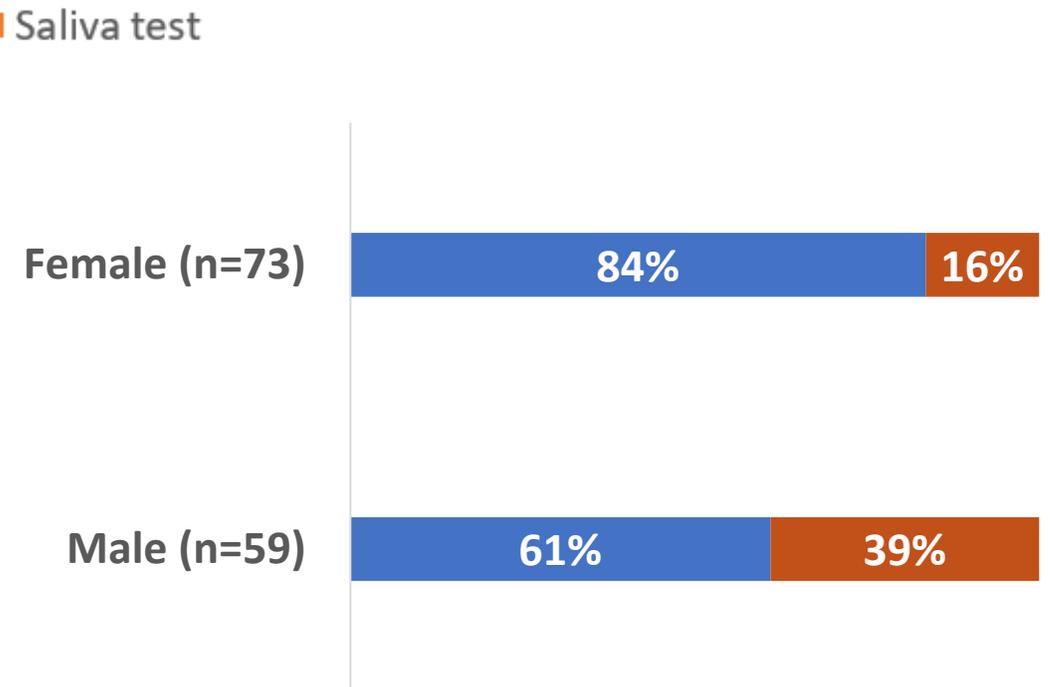
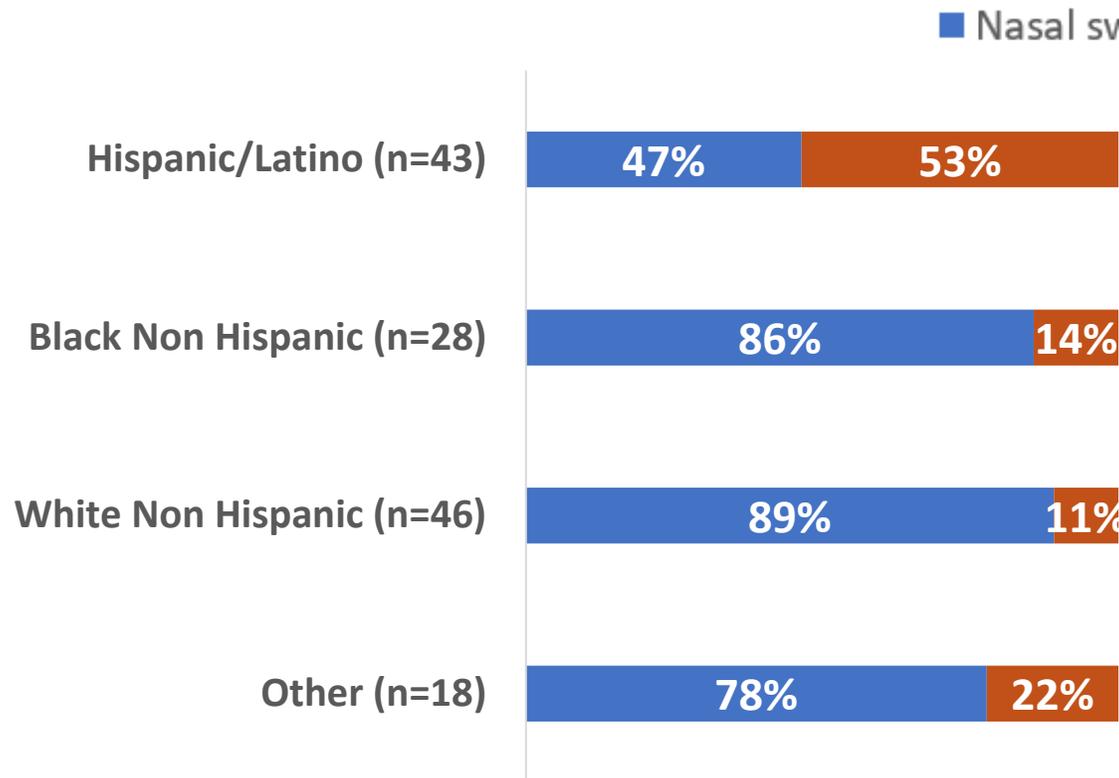


■ Nasal swab ■ Saliva test



Hispanic/Latino participants slightly preferred the **saliva test**-this group included more elementary students

Females had a stronger preference for the **nasal swab** than males



## Those who preferred the **nasal swab**... (n=99)



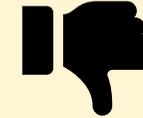
...liked the **nasal swab** better  
because



It was faster (60%)



It was easier (60%)



...did not like the **saliva test** as much  
because



It took too long (51%)



It was hard to do (49%)



It was gross (28%)

## Those who preferred the **saliva test**... (n=36)



...liked the **saliva test** better because



It was easier (39%)



Did not like the other one (22%)



It felt better (22%)



...did not like the **nasal swab** as much because



It was uncomfortable (44%)



It was painful (28%)

# Formative Needs Assessment

Aim: Identify attitudes, knowledge, and barriers that influence choice to enroll in testing and return to in-person learning

## Parent Survey

n=261

40 questions

Topics:

In-person schooling  
COVID-19 testing &  
vaccination  
School communications

## Parent Interviews

n=21

30 minutes

Topics:

In-person schooling  
COVID-19 testing &  
vaccination  
School communications

## Staff Interviews

n=10

30 minutes

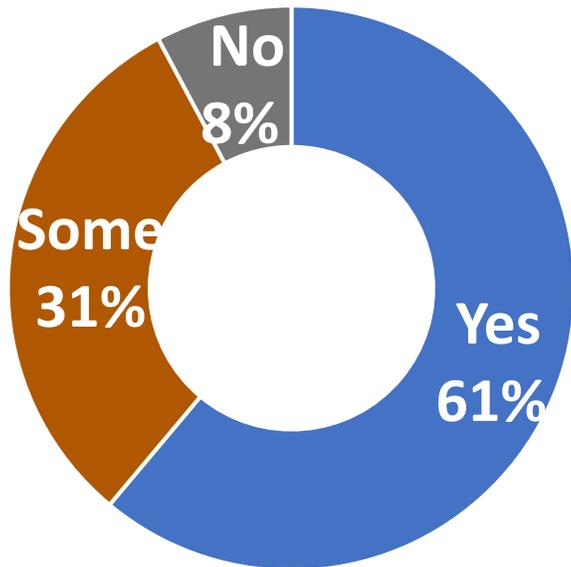
administrators, nurses,  
teachers, district staff

Topics:

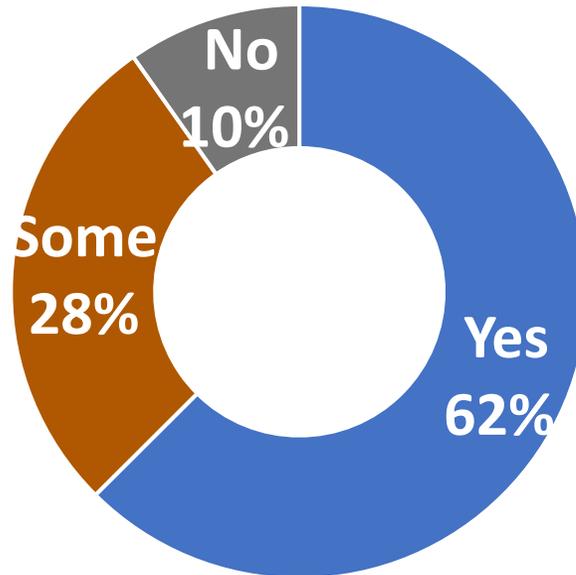
Needs, barriers, testing,  
school communications

## Parents largely support COVID-19 testing in school

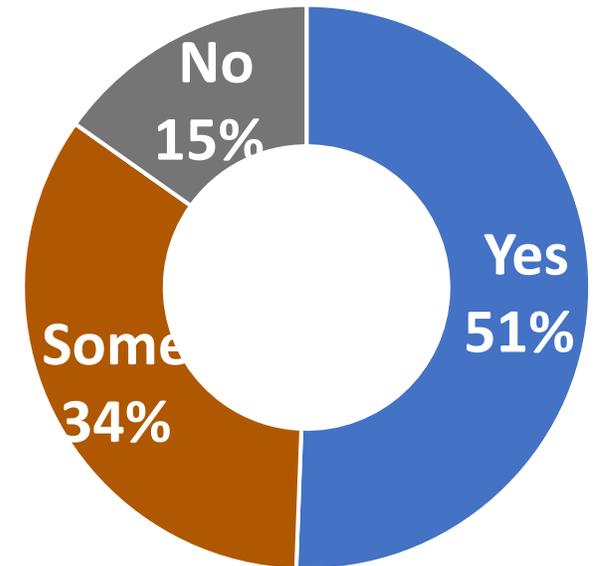
Do you like that your child's school offers COVID-19 testing at school?



Do you believe COVID-19 testing helps keep students and staff safe in school?



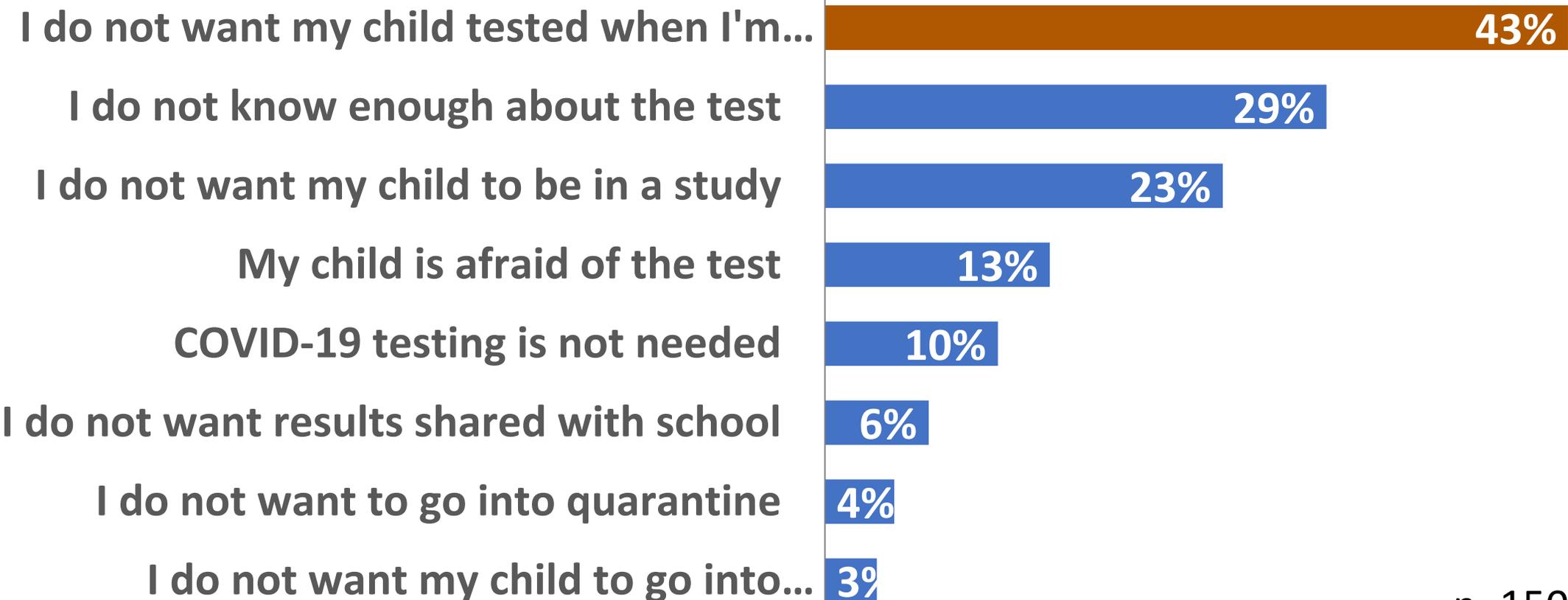
Does COVID-19 testing at school make you feel more comfortable with your child going to school in person?



Even so, less than 4% of students enrolled in testing in phase 1

## Not wanting child tested “when I’m not there” was the top reason for not enrolling child in testing

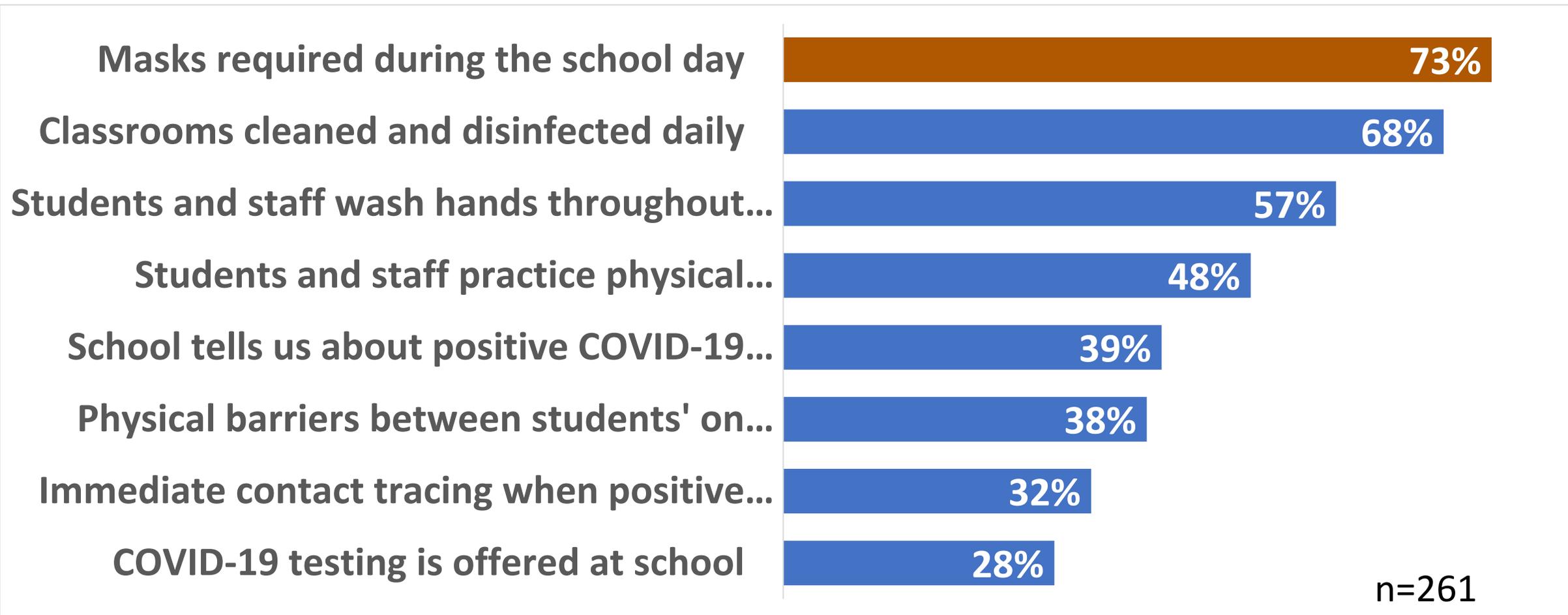
Please check all the reasons you chose not to have your child tested for COVID-19 at school?



n=150

## Nearly 3 out of 4 parents said that required masking is important to them while children are in school

Which of the following activities are important to you while your child goes to school in person?



# Lessons Learned from Testing in Schools



Opportunities to **connect directly with parents** is far more effective than email for increasing enrollment in testing.



Framing COVID-19 testing as a school **safety measure** was more motivating than promoting “free testing” or a research study.



**Strong relationships with school nurses** facilitated school communications, testing setup, symptomatic testing, and reporting results.



**Trusted school champions** were instrumental in recruiting staff and students for testing.



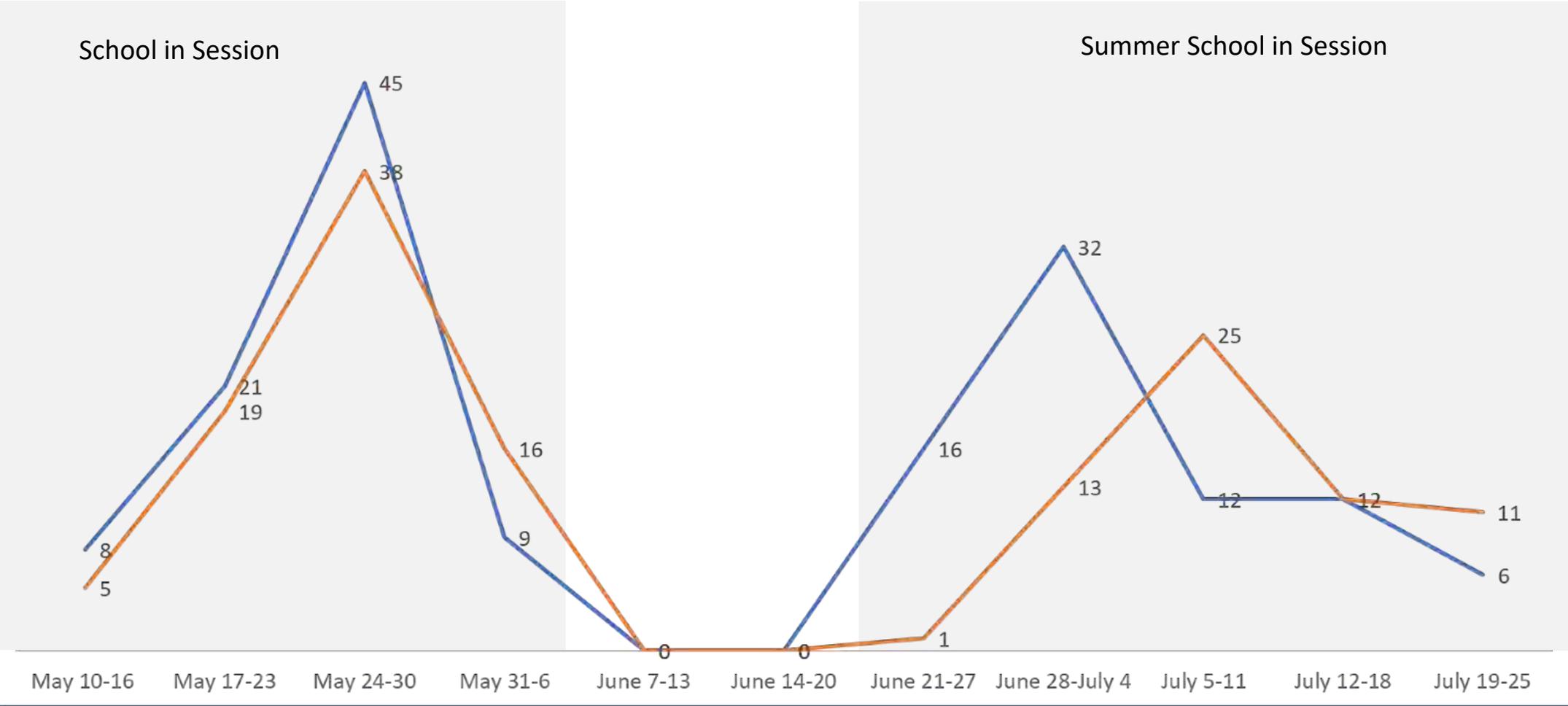
**Clear communication with school staff** about the who, what, when, and where of testing ensures families receive accurate information.



**Athletic coaches** were effective in encouraging parents to enroll students in testing.

# School TLC Study Phase 1 Weekly Enrollment and Testing

— New enrollments — New COVID-19 tests

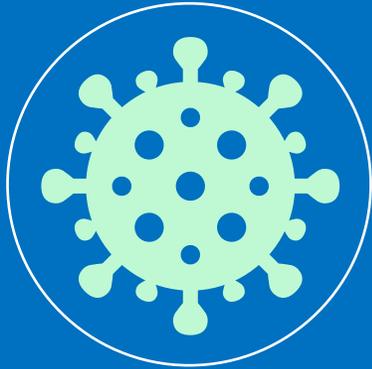


Total Enrolled = 152 Total Tested = 140

# Strategies to Address Testing Fatigue

- We have not done repeat testing to date, but will begin weekly testing in the Fall
- Surge in Delta variant is renewing commitment to COVID-19 mitigation
- Messaging “Help us keep kids safe and in school”

## Phase 2: Enhanced Intervention



### COVID-19 Testing

- Weekly screening
- Symptomatic testing
- Nasal swab



### Medical Consultation

- Monthly school walk-throughs and consults
- Bimonthly COVID-19 quick facts
- Family forums



### Tailored Communications

- Multicultural messaging
- Microsite communication resources hub
- Social media buys
- Targeting testing and masking behavior



## Phase 2: Comparative Outcomes Study

Aim: Determine how schools receiving enhanced intervention compare to schools receiving “testing as usual” on key metrics

### Metrics

Absenteeism

Case counts

Vaccination rates

Parent satisfaction

### Data Sources

Secondary district  
and school data

Repeated parent survey

# Safe Return to School for Children with Intellectual/Developmental Disabilities

Luther Kalb, PhD, MHS  
Director of Informatics  
Center for Autism and Related Disorders  
Department of Neuropsychology  
Kennedy Krieger Institute

Assistant Professor  
Department of Mental Health  
Johns Hopkins Bloomberg School of Public Health

Chair, National Research Consortium on MH-IDD  
Center for START Services  
University of New Hampshire



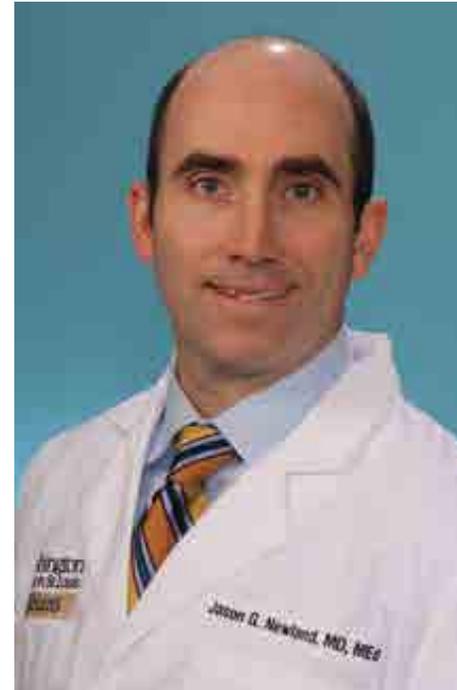
## Co-PIs

# COMPASS-T



**Christina A Gurnett, MD, PhD**

Ernest and Jane G. Stein Professor of Developmental Neurology  
Director of the Division of Pediatric and Developmental Neurology  
Co-Director of the IDDRRC Washington University in St Louis



**Jason Newland, MD, M.Ed.**

Professor of Pediatrics  
Pediatric Infectious Diseases  
Washington University, St. Louis



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# Impact of COVID-19 on persons with IDD

CNN health Food Fitness Wellness Parenting Vital Signs LIVE TV Edition Q

LIVE  
Watch winds from Hurricane Sally hit New Orleans

## Covid-19 has disproportionately impacted those living with developmental disabilities

By Naomi Thomas, CNN  
Updated 8:08 PM ET, Fri August 28, 2020



CNN Heroes: A lifeline for people with disabilities in Colombia 01:10

(CNN) — The coronavirus pandemic has had an especially harsh impact on people with



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# Impact of COVID-19 on persons with IDD

- Direct effect of COVID-19 on children's health
  - Fatality rate 1.6% for children with IDD vs <0.1% neurotypical children (Turk et al., 2020)
- Loss of Services (Constantino et al., 2020)
  - Therapy
  - Socialization
  - Healthcare
  - Detection of medical risk/neglect
  - Nutrition
- Impact on the well-being of families (Kalb et al., In Press) and Children (Vasa et al., 2020)



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# COVID-related Challenges in IDD

- Wearing a face mask
- Social distancing
- Hand hygiene
- Difficulty reporting symptoms
- Potential for multiple exposures (aides, therapists, bus drivers)



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# In Press

- Sherby, M., et al. for the COMPASS-T Study Group. SARS-CoV-2 Screening Testing in Schools for Children with Intellectual and Developmental Disabilities. *Journal of Neurodevelopmental Disorders*.



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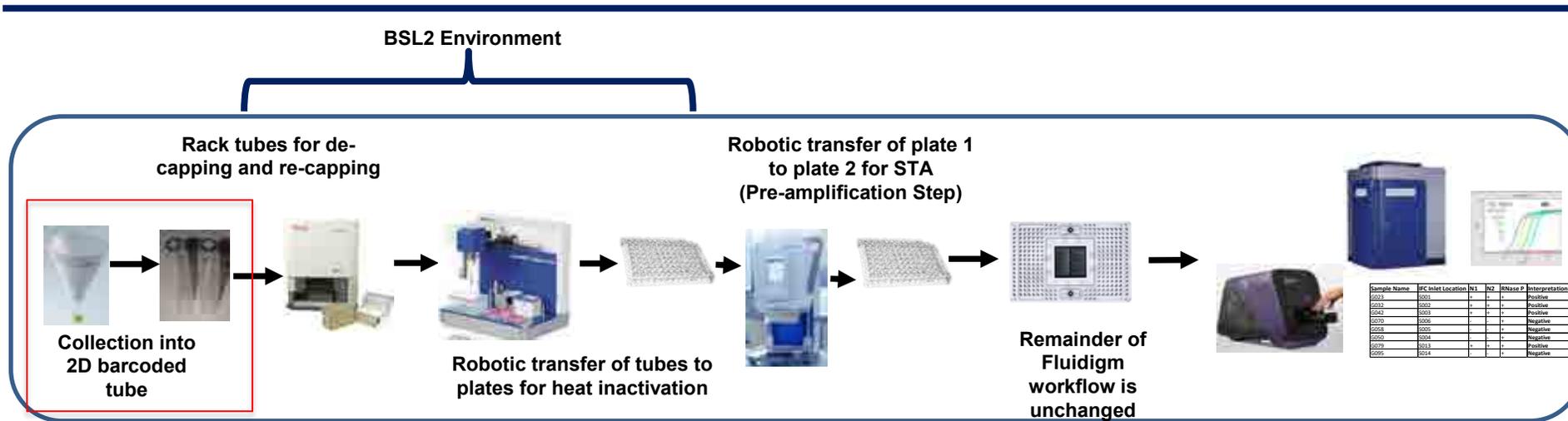
# Specific Aims

- To evaluate the impact of implementation strategies on the uptake of weekly SARS-CoV-2 testing in students with IDD and school staff through a blocked, randomized adaptive clinical trial.
- To assess perspectives among parents of students with disabilities who do not return to in-person instruction regarding the impact of COVID-19 and importance of SARS-CoV-2 testing and vaccine



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# PCR, Saliva-Based Testing



- 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



# Setting (N=500 students and staff)

Fairmount



Montgomery



LEAP

High School



# Picture of testing staff



# Study Goals and Timeline

April-June, 2021

- Management of IRB Reliance Across 3 sites (JHSOM, JHSPH, WU)
- Testing Preparation

July, 2021

- IRB Approval
- Begin conducting weekly asymptomatic COVID-19 testing

October, 2021

- Complete Fuzzy Cognitive Mapping; Launch Survey

January, 2022

- Randomize Schools To Customized Messaging Strategy



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# Outcomes

- Enrolled N=87 Staff, N=2 Students
- Completed N=347 Tests
- N=1 Positive Case

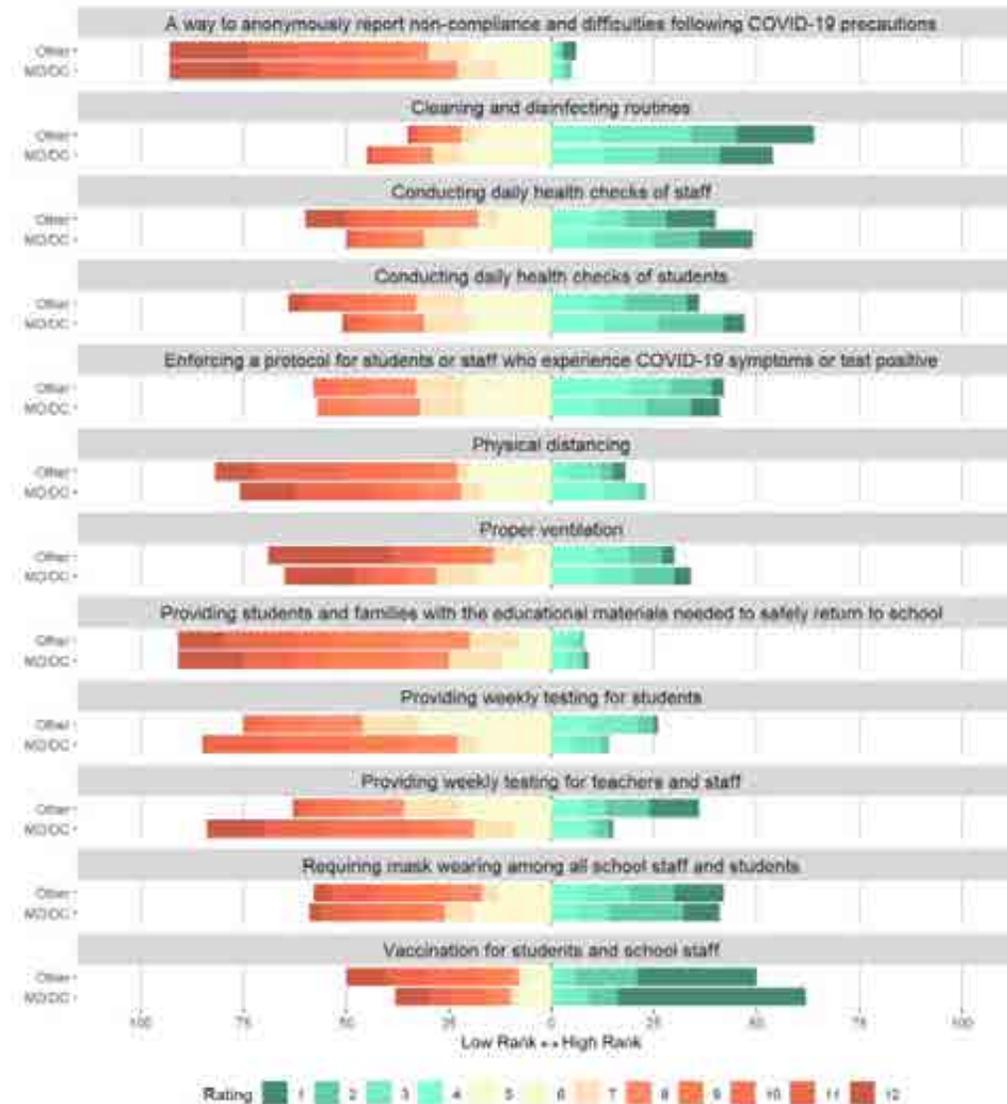


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# Challenges

- Teacher survey examining COVID-19 preventive strategies
- June, 2021
- N=230 (63% MD/DC, 37% MO)
- Testing is not highly rated

What strategies do you feel are most helpful to reduce the spread of COVID-19 at school? Rank the following



# Challenges

- Central IRBs should be taken into start-up consideration
- KKI Schools have *just returned* to in-school instruction
- Heavy staff turn over makes this “one more thing”; lack of incentive
- History of scientific misconduct at KKI (lead abatement study) and JHU (Henrietta Lacks)
- Lack of utility due to vaccines (and KKI requirements) as well as low regional positivity rate
- Parental concerns about managing positives tests among students as well as testing logistics



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# Immediate Solutions

- Met with Missouri and Maryland Community Advisory Boards
- Rolling out an advertisement campaign in September to promote upcoming study incentive (\$5 per test; \$200-250 max)
- New Flyers, Phone and Email Scripts
- Reporting results in Bi-Weekly Newsletter (parents/staff)
- Present at Back-to-School Night and Staff Professional Development Days
- Increase Age of Student Enrollment (from 17 to 22)



# Example of Study outreach



## THE INSTITUTE IS TAKING PART IN A STUDY THAT EXAMINES HOW WELL FREQUENT CORONAVIRUS TESTING WORKS AT PREVENTING COVID-19 OUTBREAKS AND ALLOWING IN-PERSON LEARNING TO CONTINUE.

Last spring, as communities implemented restrictions to limit the spread of the coronavirus, schools across the country shifted from in-person to virtual learning. It was a stressful change for many students, particularly those with intellectual and developmental disabilities, many of whom require hands-on instruction, speech and occupational therapies, and other specialized services throughout the school day.

For them, a full return to the physical classroom—five days a

### RESEARCH FRONTIERS



“We’re excited to add weekly testing to our COVID-19 safety toolkit so students with disabilities are able to more safely and fully return to in-person instruction,” says Dr. Linda Myers, the Institute’s vice president of school programs and one of the study’s co-principal investigators. “We are hopeful that the results of this study will be helpful for school communities across the country, as we continue to navigate the pandemic.”

“Routine testing is important, since many children with intellectual and developmental disabilities have difficulty with preventive measures, such as mask-wearing, hand hygiene, and social distancing,” explains Dr. Luther Kalb, director of the Informatics Program at the Institute’s Center for Autism and Related Disorders, and another co-principle investigator of the study. “This puts them at increased risk for contracting the coronavirus. Many of these children also have underlying medical conditions that put them at a higher risk for having poor outcomes if they develop COVID-19.”

To understand the best ways to prepare a child with intellectual or developmental disabilities for weekly testing, Kennedy Krieger conducted focus groups with parents of students attending Kennedy Krieger schools. Among other things, the focus groups revealed that preparing a child to receive a coronavirus test in the very environment in which the test will take place is extremely helpful.

Kennedy Krieger School Programs’ four schools, which serve



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# Long Term Solutions

- Tik-Tok Video
- Stickers
- Novel Messaging Campaign in January



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# Thank You

→ ↻ <https://sites.wustl.edu/safereturn/>

 Washington University School of Medicine in St. Louis

## Safe return to school for all



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# Acknowledgements

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



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John Foxe, Martin Zand, Stephen Dewhurst

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

# URMC / Mary Cariola Center Partnership



*Transforming lives of people with disabilities*

Mary Cariola Center (**MCC**) serves moderate-to-severe IDD children (**N=425**) via a large professional support staff (**N=450**). 70% of MCC students live in poverty, and 33% are from under-represented minority backgrounds. 100% are on federal food assistance programs.



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# Five Major Goals:

- 1) Virological Testing:** We will establish a nasal-swab FDA-approved testing regimen to monitor and identify disease outbreak in a school setting at ultra-high risk for COVID-19 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 Testing Unit:** 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.

# The Mobile Testing Unit

We will staff, equip and deploy a customized, disability-enabled, mobile unit to bring testing directly to the MCC community for optimal testing flexibility. A new van has been procured and we are working with Marketing to design a wrap similar to the UR Vision Van.



# Molecular Testing for SARS-CoV-w at the URM Central Laboratories

## UR Medicine Central Laboratory COVID-19 Testing Capacity and Modalities

| Assay   | Platform           | Manufacturer             | Capacity Tests/Day | Method | FDA Emergency Use Authorization |
|---|--------------------|--------------------------|--------------------|--------|---------------------------------|
| <b>TaqPath COVID-19 High-Throughput Combo Kit</b> | Amplitude Solution | Thermo Fisher Scientific | 3000-6000          | RT-PCR | YES                             |
| <b>cobas SARS-CoV-2</b>                           | cobas 8800 System  | Roche Molecular Systems  | 2000               | RT-PCR | YES                             |
| <b>Xpert Xpress SARS-CoV-2</b>                    | GeneXpert Infinity | Cepheid                  | 500                | RT-PCR | YES                             |

RADx-UP samples will be primarily tested on the Thermo Fisher Scientific Amplitude system:

- High-throughput with readily available testing reagents
- Three targets (N gene, ORF1ab gene, S gene) for higher specificity and lower risk for mutations affecting assay performance
- Automated, 3.5 hour run time



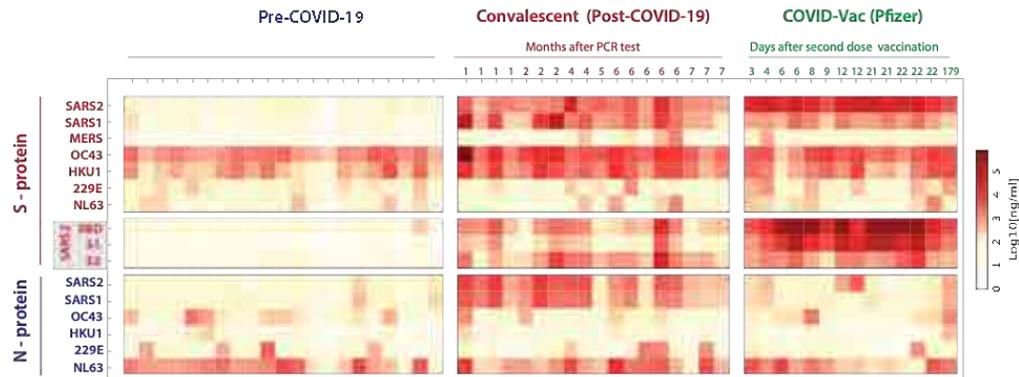
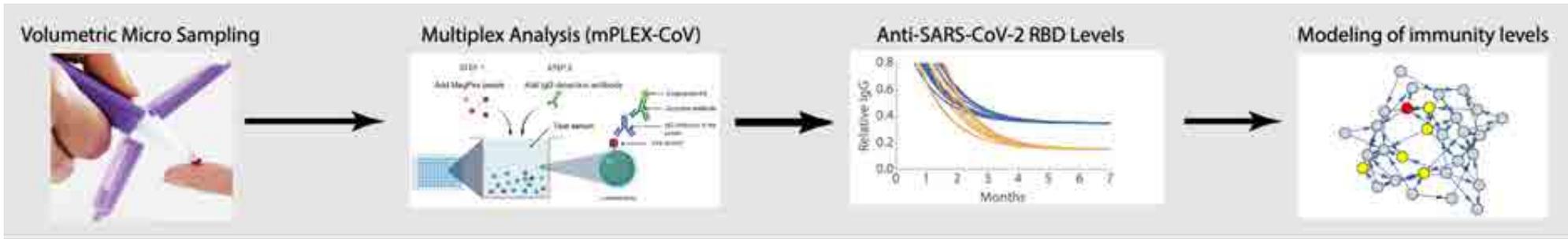
The UR Medicine Central Laboratory has tested over 750,000 respiratory specimens for SARS-CoV-2 since the beginning of the pandemic with an average TAT of 24 hours

**Clinical serological testing will be performed on the Abbott Architect platform using the SARS-CoV-2 IgG assay**



- Intended for the qualitative detection of IgG against the SARS-CoV-2 nucleocapsid protein
  - High sensitivity (~97%) and specificity (~99%)
- Assay: SARS-CoV-2 IgG assay
- Platform: ARCHITECT System
- Manufacturer: Abbott Laboratories Inc
- Capacity: High-throughput (500-800 per day)
- Method: Chemiluminescent microparticle immunoassay (CMIA)
- FDA Emergency Use Authorization

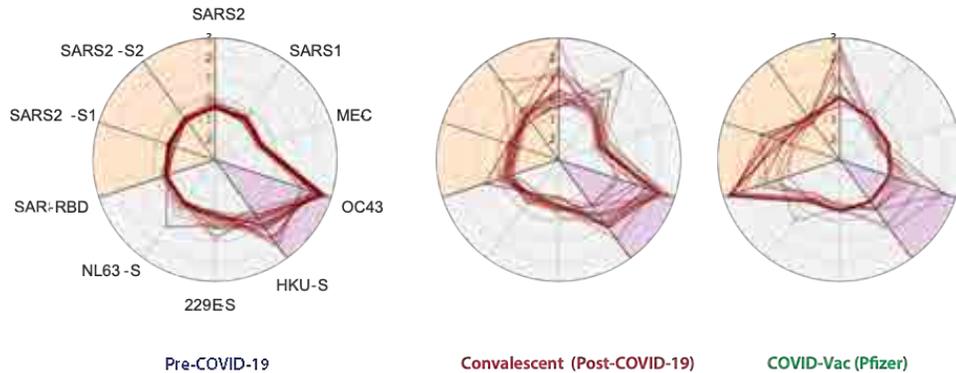
# Scientific Questions



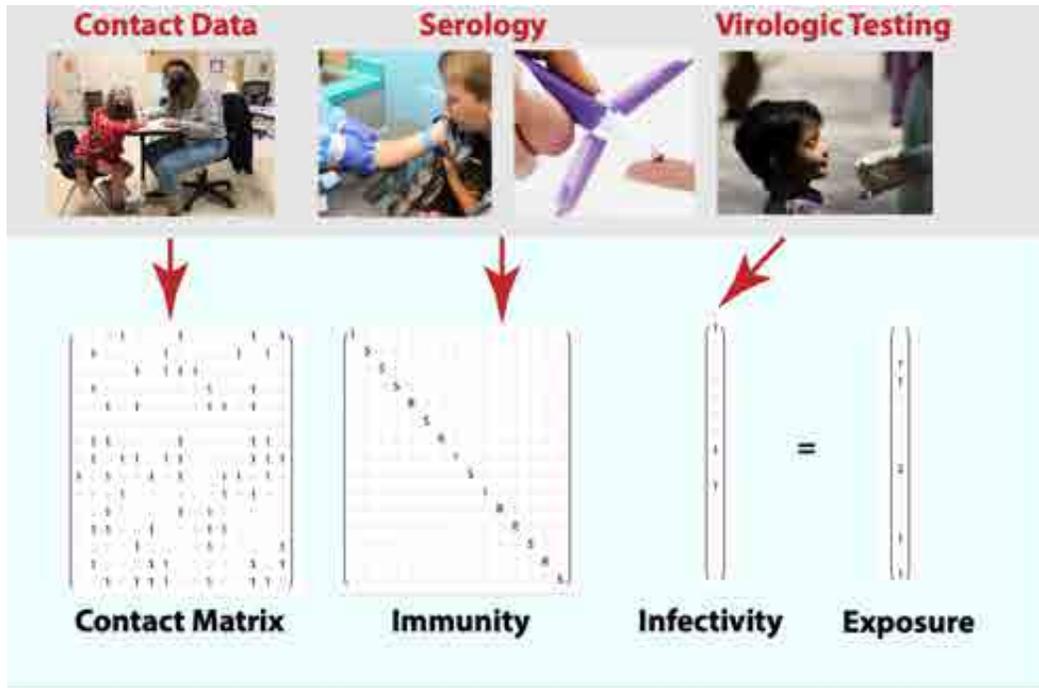
How does IgG antibody reactivity against SARS-CoV-2 change over time in teachers, staff, and IDD students?

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

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



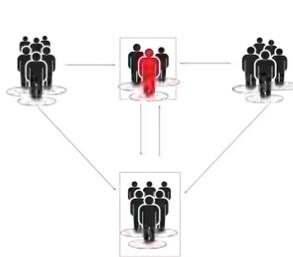
# Scientific Questions and General Deliverables



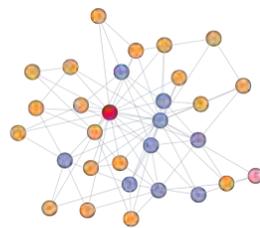
## Questions:

1. What testing patterns and frequency are needed to:
  - Detect asymptomatic SARS-CoV-2
  - Minimize risk of transmission of SARS-CoV-2
  - Monitor classroom immunity
2. What changes in contact, immunity, and classroom structure maximize student and staff attendance?
  - Class size
  - Contact patterns
  - Community prevalence of viral variants

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



**Agent Based Models**



**Stochastic  
Mobility Models**

**Deliverables** – Flexible models that could be adapted to different school staff and student configurations allowing “what if?” scenario modelling

# Major Outcomes to Date

- IRB approved 3/31/21
- Enrollment began 5/11/21
- Testing began 5/21/21
- Currently 147 participants enrolled - 124 Mary Cariola staff & 23 Mary Cariola students
- 592 RT-PCR tests processed- 509 negative SARS-CoV-2 & 83 awaiting results
- 211 Finger-sticks collected on 116 unique participants (89% staff and 11% students)
- 108 Serological test results



# Lessons Learned Regarding School Testing

We have experienced some issues in obtaining nasal swab specimens for PCR testing.

The issue arises mainly in the older students who are mostly able to walk, and move on their own. Distracting them to successfully collect nasal swabs has been challenging. Negative experiences from prior nasal swab specimen collection may also be a factor.

We have had better success at obtaining nasal swabs from Mary Cariola students who are younger and more “medically fragile”. They do not have the ability to stand up, push us away, dodge the nasal swab, etc.

Due to this discovery, the project team is considering the collection of saliva as an alternative to the nasal swab when that specimen is unobtainable. The Mary Cariola team has concurred that saliva collection for PCR testing could be more successful, since the kids often need help brushing their teeth and sometimes simply eating and drinking.



# Postulates for Variable Recruitment

We've implemented a number of different approaches to engage with Mary Cariola's parents and staff. Key lessons learned to date from the initiatives:

- Postcards sent in backpacks raise awareness but, with few exceptions, does not lead to action (i.e. calling about the study).
- Given the multiple competing priorities of their lives, many parents are not in a position to add one more task to their day (i.e. calling about study enrollment).
- The term research or study is a turn off to some parents so using that terminology early in the discussion may lead to a premature end to the conversation.
- Linking study outreach with existing events or activities is viable to both raise awareness and identify those interested in or potentially interested in enrolling. Individual outreach or conversations are important for many parents. For staff, engaging them through events (i.e. staff appreciation day) is a successful approach.
- Offering seasonal treats and T-shirts have a significant impact (i.e. ice cream trucks/shaved ice trucks)

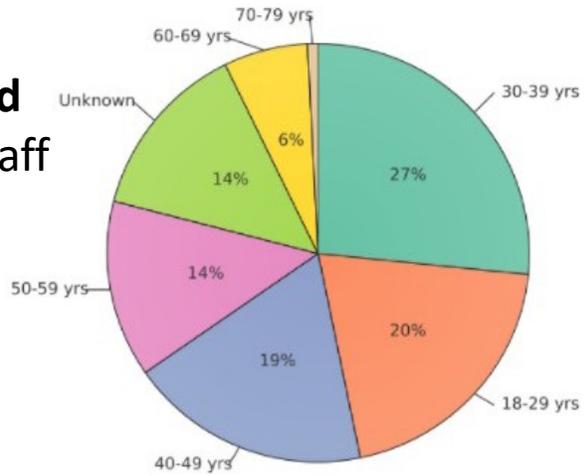


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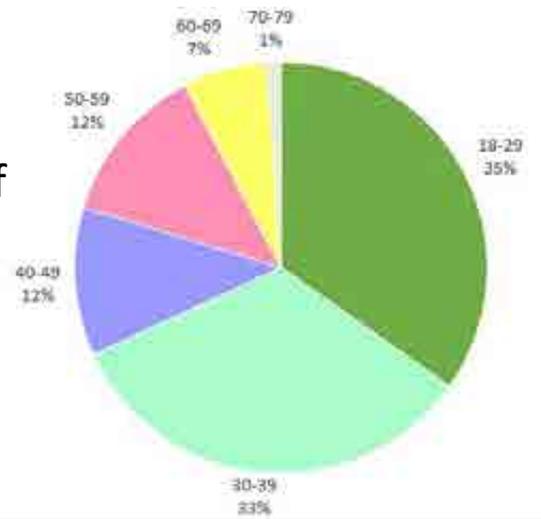
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# Representation for Recruitment for Mary Cariola Staff

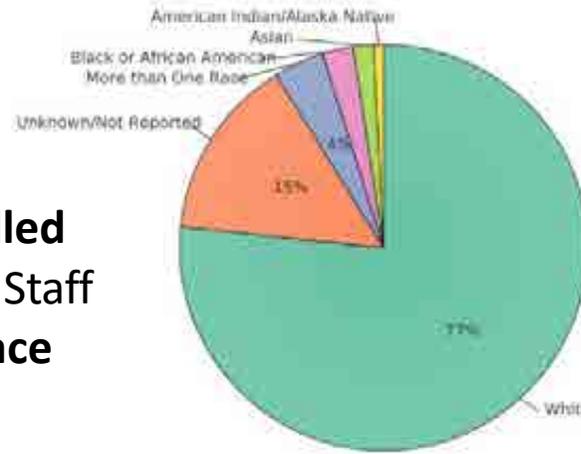
**Enrolled  
MCC Staff  
by Age**



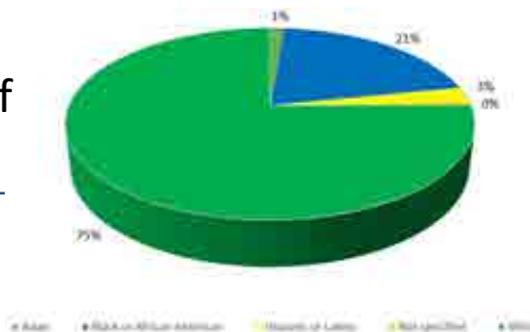
**Entire  
MCC Staff  
by Age**



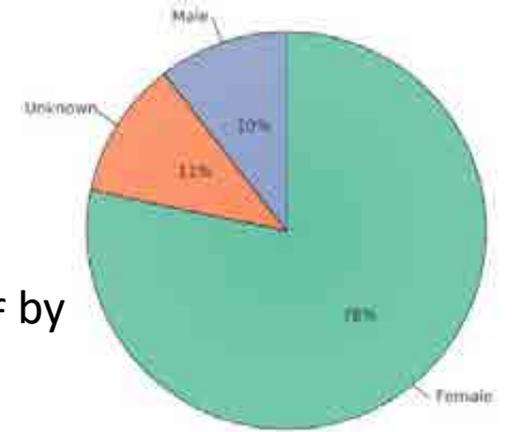
**Enrolled  
MCC Staff  
by Race**



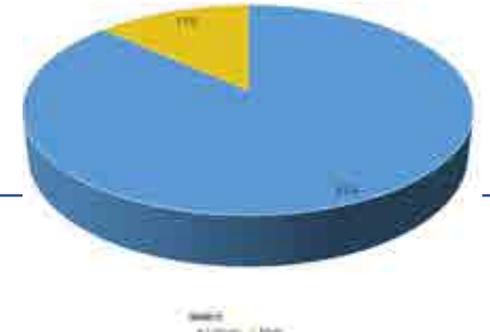
**Entire  
MCC Staff  
by Race**



**Enrolled  
MCC Staff by  
Gender**

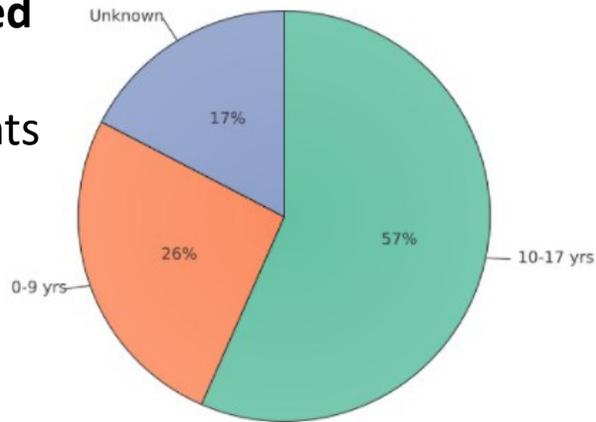


**Entire  
MCC Staff  
by Gender**

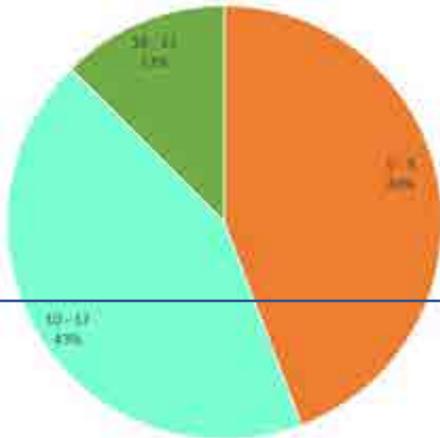


# Representation for Recruitment for Mary Cariola Students

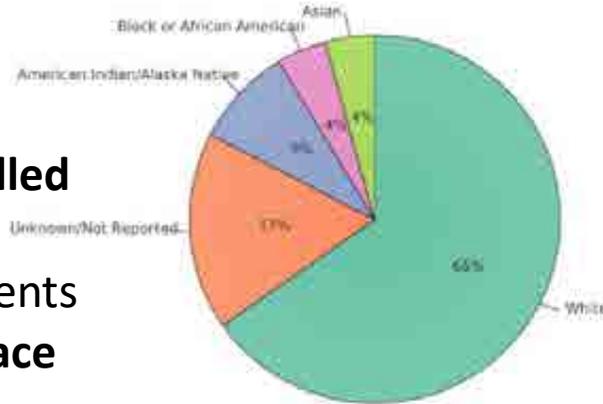
**Enrolled  
MCC  
Students  
by Age**



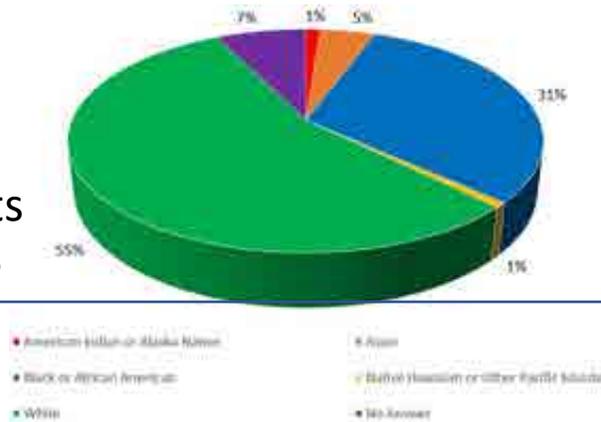
**Entire  
MCC  
Students  
by Age**



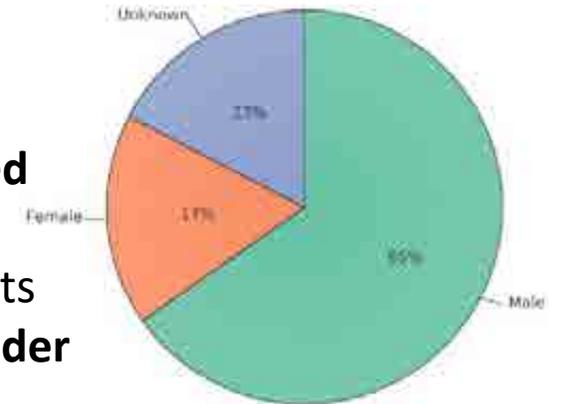
**Enrolled  
MCC  
Students  
by Race**



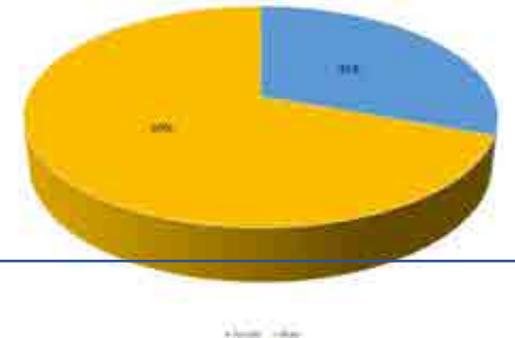
**Entire  
MCC  
Students  
by Race**



**Enrolled  
MCC  
Students  
by Gender**



**Entire  
MCC  
Students  
by Gender**



# Testing Fatigue

No Known Issues to Date

# Leveraging State Testing Resources

Developing Situation- Dr. Michael Mendoza from the Monroe County Health Department has informed the Mary Cariola team that it's unlikely that there will be a COVID vaccine for children under 12 before the Fall. Given the Delta Variant, there's a push for vaccination and mandated COVID testing in schools, which aligns well with our study as it offers free testing for participating Mary Cariola staff and students.



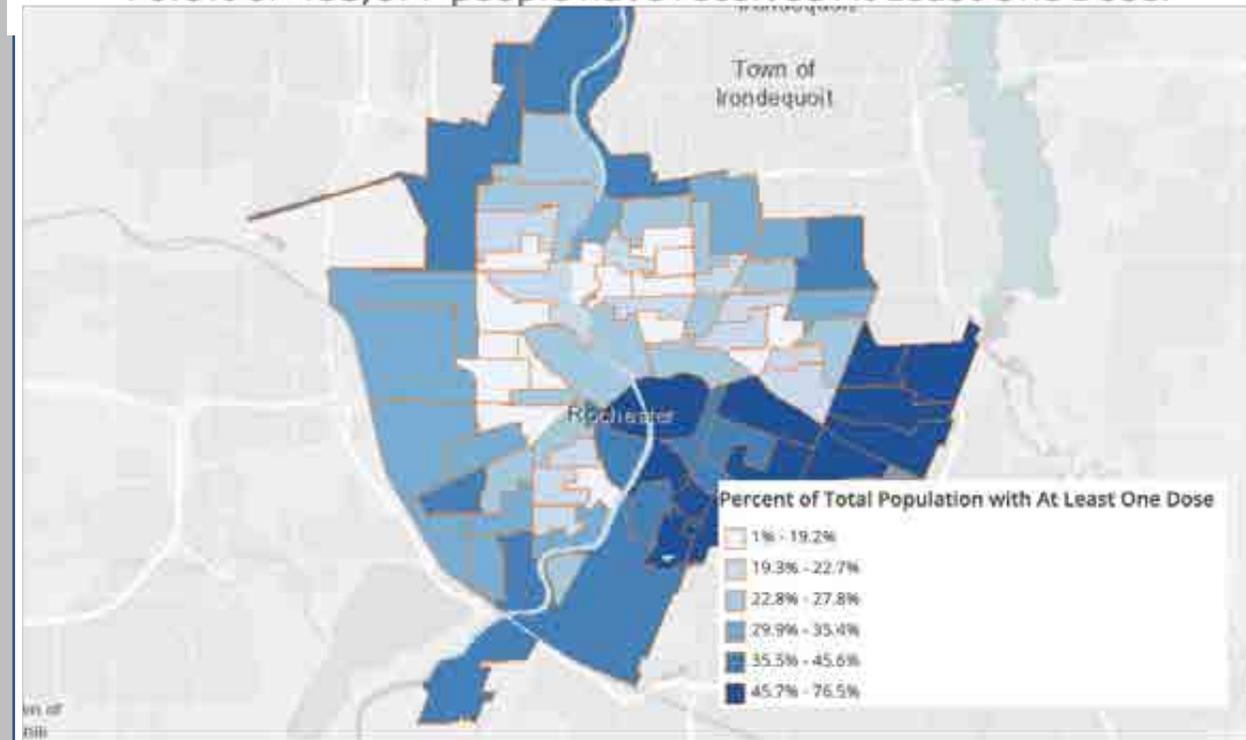
# Overcoming Testing & Vaccine Hesitancy; Measuring Impact

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 Vaccine Hesitancy

**Monroe | At Least One Dose | 453,677 people | 70.6%**

Of the 642,840 people 12 years of age or older in Monroe county, 70.6% or 453,677 people have received At Least One Dose.



# 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

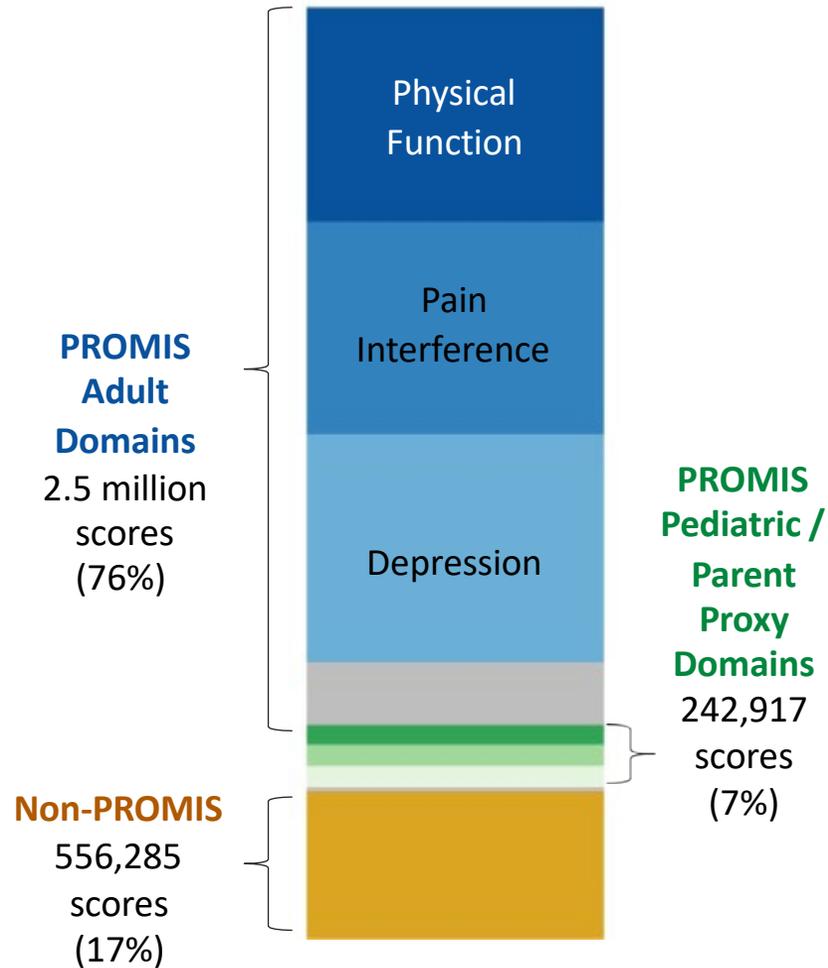
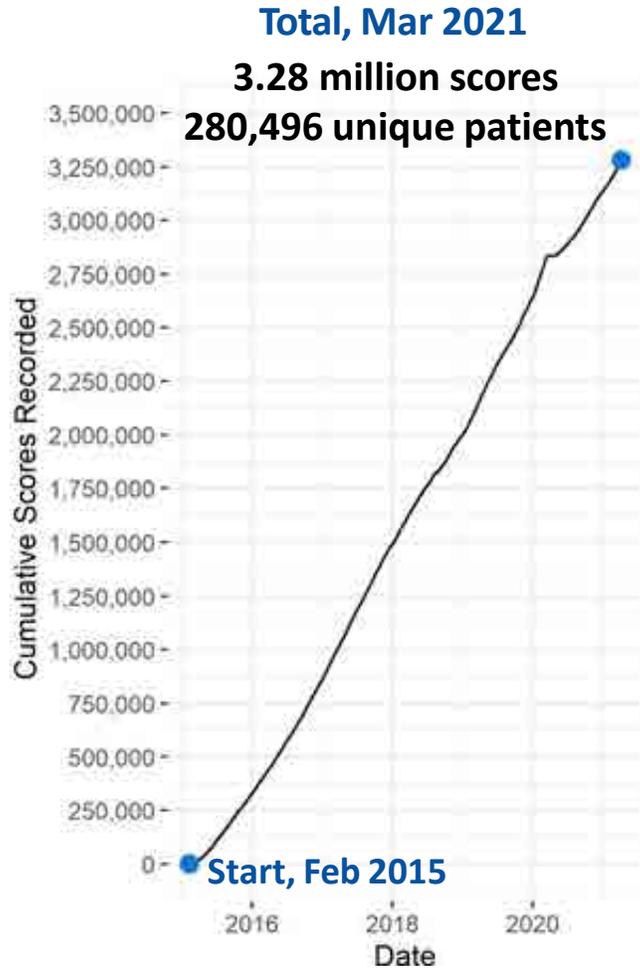
|                 |                        |   |
|-----------------|------------------------|---|
| Physical Health | Physical Function      | Upper Extremity Mobility<br>Physical Function         |
|                 | Physical Symptoms      | Fatigue<br>Itch<br>Pain                               |
| Mental Health   | Emotional Distress     | Anxiety<br>Depression                                 |
|                 | Psychological Function | Self-Efficacy   |
| Social Health   | Social Function        | Ability to Participate in Social Roles and Activities |
|                 | Social Relationships   |   |



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# UR Voice: Data Collection



## PROMIS CATs

**44 seconds**  
Median time to complete assessment

**4 items**  
Median items answered per assessment

**98.2% completed**



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# 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. **Agent-Based Modelling** – to derive high efficiency adaptive testing regimen.
5. **Use of PROMIS** – to measure impact rapidly (and scalably); *opportunities for machine learning*





Return to School Workshop

# Safe Return to School

Assessing Testing Strategies in Middle & High Schools

August 9, 2021

 Washington University in St. Louis

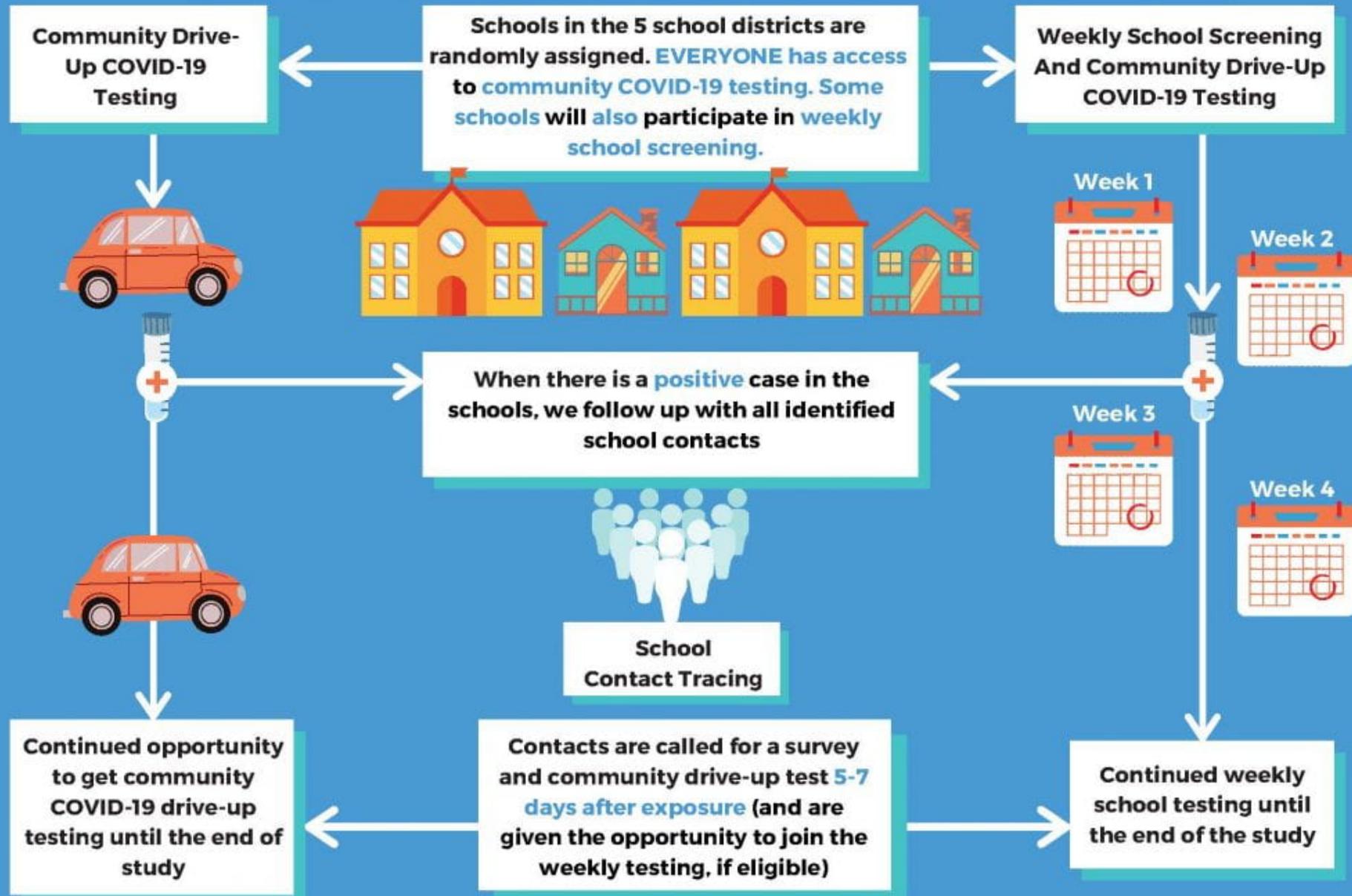




# Project Goals

- Determine the **best COVID-19 testing strategy** to limit COVID-19 transmission in middle and high schools
  - Provide easy access to free saliva-based testing to all of the school community (staff, students, household members)
  - Staff and students in some middle and high schools will be offered weekly testing
- Partner with our community in listening sessions to **better understand COVID-19 testing, vaccinations and in-person school**

# How does this research study work?



# Testing Results

389 tests amongst 289 people

39 positive tests

Both screening and community drive up testing available

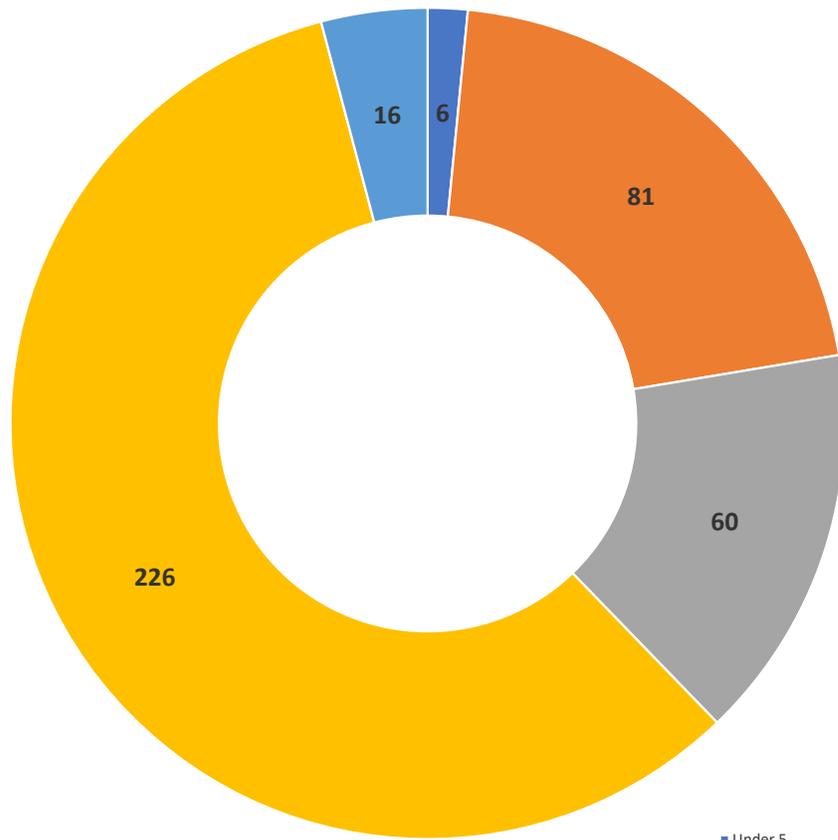


Cumulative  
Testing  
Numbers  
(Drive up +  
Surveillance)

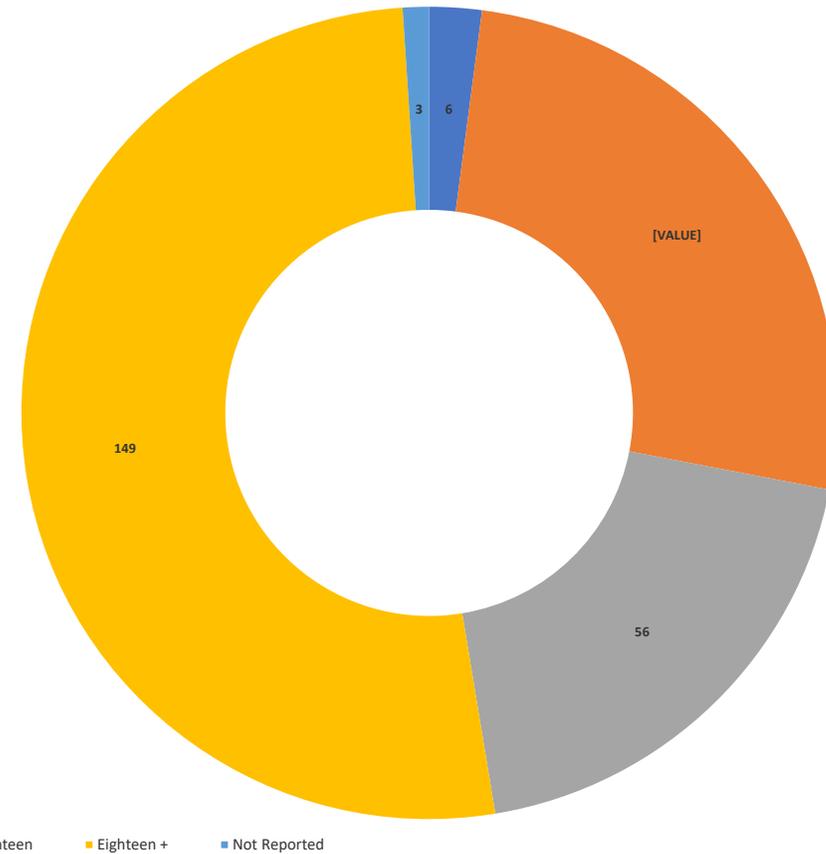
|                                  | Hispanic/Latino |      | Not Hispanic/Latino |        |      | Unknown/Not Reported |      |
|----------------------------------|-----------------|------|---------------------|--------|------|----------------------|------|
|                                  | Female          | Male | Non-Binary          | Female | Male | Female               | Male |
| <b>Black or African American</b> | 0               | 1    | 1                   | 115    | 75   | 1                    | 2    |
| <b>White</b>                     | 1               | 2    | 0                   | 38     | 24   | 0                    | 0    |

# Age Group Breakdown

Overall Tests

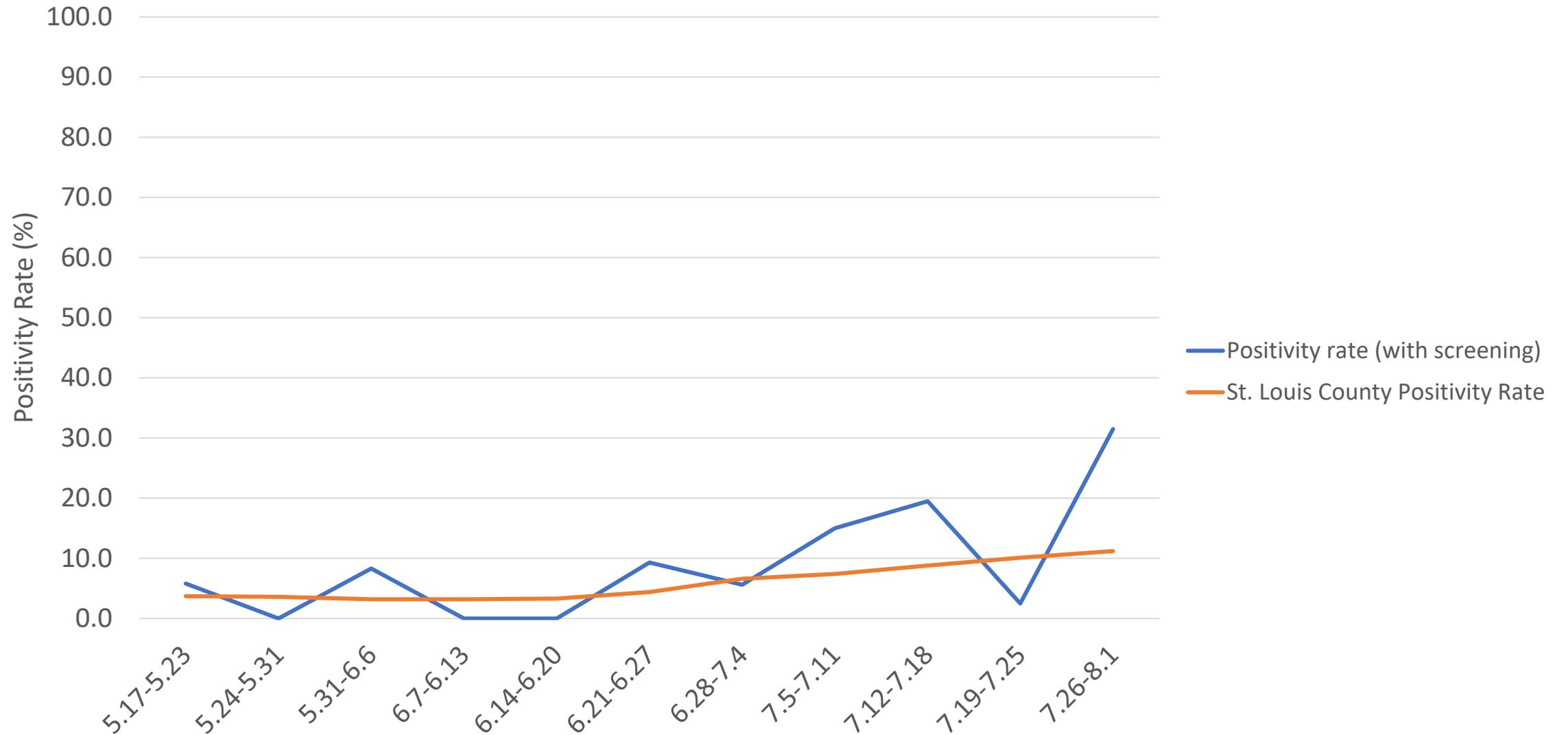


People Tested



■ Under 5 ■ Five - Eleven ■ Twelve - Seventeen ■ Eighteen + ■ Not Reported

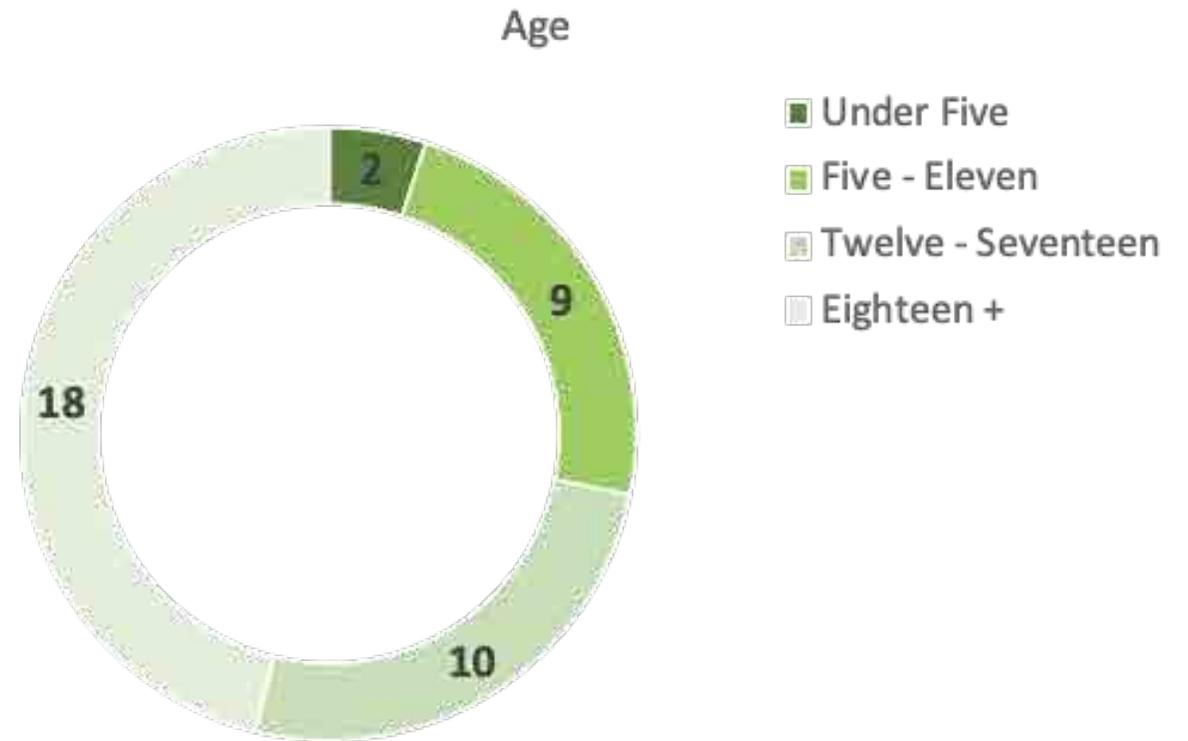
# Positivity Rate Including Weekly Screening



# Positive Test Breakdown



Of 28 positive tests eligible for vaccination, 4 were known to be fully vaccinated.



# Community Advisory Board

- **CAB Composition**
  - School district representatives
  - Community partners
  - Parents
  - Students
- Meets monthly
- Stipends provided
- **Working to expand participation among students and parents**

What COVID-19 testing strategy is best for our schools?

# YOUR INPUT NEEDED

Discussions for \_\_\_\_\_ of students in the \_\_\_\_\_ School District

- Session times and dates available in summer
- Receive a \$20 gift card for participation
- To sign up for a session, follow the link below

» <http://bit.ly/safereturn2school>

## Key Themes

- Lead with caring
- Go beyond testing and engage community
- Improved equity and systems change should be a priority
- Clarity, transparency, and simplicity is key in all aspects of communication
  - Clarify what is meant by “safe”
- Visuals help
- Engaging students requires a unique approach

# Qualitative Data Collection

- **Administrator Interviews**
  - Superintendents interviews complete (n=5/5)
  - School Principals recruiting and conducting interviews now (n=3/16)
- **Listening Sessions**
  - Parents/caregivers
  - Staff/Teachers
  - Students (n=3)
- Recruiting now



## Lessons Learned

- Relationships and trust are essential
- Continuous improvement and feedback to improve the process
- Ask and learn from the community
- Engaging CAB and Community Partners in recruitment is essential
- Participating in Back to School events and Professional Learning Meetings increases engagement

# Recruitment Challenges

- Summer schedules can be obstacles
- Difficulty in reaching students to become interested in testing
  - Recruitment video being developed
  - T shirts supporting the project
- Lack of trust in testing
- Continued testing awareness for the drive-up testing
  - Social media being utilized in the districts
  - New website being developed



# Next Steps

- School district meetings
- Back to school events
- Conduct listening sessions
- Expand Community Advisory Board
  - More Students and Parents
- Coordinate with community partners to support participants
- Promote vaccination



Ordinary people with extraordinary vision can redeem the soul of America by getting in what I call good trouble.



John Lewis  
July 17, 2020  
NY Times

**Thank You**