

The overarching goal of Rapid Acceleration of Diagnostics - Underserved Populations (RADx-UP) is to understand the factors associated with disparities in COVID-19 morbidity and mortality. RADx-UP lays the foundation to reduce disparities for underserved and vulnerable populations who are disproportionately affected by, have the highest infection rates of, and/or are most at risk for complications or poor outcomes from the COVID-19 pandemic. The RADx-UP Return to School Diagnostic Testing Initiative aims to increase COVID-19 testing access and uptake for underserved and vulnerable populations to safely return children to in-person school. Specifically, the projects will:

- Provide evidence for the effectiveness, sustainability, and scalability of COVID-19 testing approaches (i.e., FDA-authorized/approved diagnostic testing, screening, and/or surveillance testing) and mitigation strategies (e.g., masking, physical distancing, vaccination, as applicable)
- Discuss the qualitative data related to social, behavioral, and ethical implications of implementation of COVID-19 testing within identified communities.

Workshop Goals

- Assemble RADX-UP Return to School awardees/investigative teams with others conducting school-based research on COVID-19 diagnostic testing to learn from each other and define the current state of their research projects supporting the safe return of children to in-person school.
- Use this knowledge and experience from the research projects to:
 - Identify common themes, highlight shared research milestones and opportunities that can complement and innovate to expedite the translation of research results into knowledge, tools, and procedures to improve the health of school communities
 - Identify the addressable gaps needing informative future research directions
 - Review and evaluate the research projects to facilitate analysis of research questions and potentially inform school policy at the local and community levels, as appropriate

Opening Remarks:

Presentation Title	Presenter Names	Institution
Welcome and Overview of RADx-UP and the RADx-UP Return to School Diagnostic Testing Initiative	Eliseo Perez-Stable Alison Cernich Sonia Lee	National Institutes of Health

Dr. Eliseo Perez-Stable, Director of the National Institute of Minority Health and Disparities (NIMHD) welcomed participants to this Workshop. He described the Return to School effort as part of RADx-UP, one of the first actions taken by Congress in response to the pandemic. RADx-UP funded their first efforts the end of September 2020 with a focus on underserved and vulnerable populations. The RADx-UP effort is designed as a consortium wherein funded projects work together to tackle persistent disparities, utilizing FDA/EUA authorized tests and standardization across efforts.

Dr. Alison Cernich, Deputy Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and Dr. Sonia Lee, Program Official, described the goals of the Return to School Initiative, and provided an overview of the awarded projects, including the budget, number of projects awarded in Phase I and II, geographic distribution of the sites, vulnerable and underserved populations included, and school settings.

Dr. Lee introduced the presentation from Dr. Shamez Ladhani, National Infection Service, Public Health England, London, UK; Senior Lecturer, St. George’s University, London, UK; Pediatric Infectious Diseases Consultant, St. George’s University, London, UK.

Presentation Title	Presenter Names	Institution
COVID and Children	Shamez Ladhani	Public Health England

Providing the perspective of the school experience in the United Kingdom, Dr. Ladhani centered his presentation on the question of whether children will be a source of transmission once they return to school. Key points of the presentation: keeping children in school as much as possible is essential; while children are as likely as adults to contract COVID-19, children have a robust antibody response to the COVID-19 virus; outbreak risk in a school setting is correlated with the community risk of contracting COVID-19; there have been low secondary cases in school indicating little evidence of in-school transmission; the U.K. does not require masking but does utilize other layered mitigation strategies.

Presentations from Department of Health and Human Services Partner Programs

Presentation Title	Presenter	Institution
Supporting Implementation of Screening Testing in K-12 Schools	Angelica O’Connor	Epidemiology and Laboratory Capacity, Centers for Disease Control and Prevention

Ms. Angelica O’Connor, Program Advisor, provided an overview of the CDC’s ELC Program, which provides trained personnel to perform testing in school settings and vendors that can provide a full range of services. COVID-19 testing is considered a good alternative to other mitigation measures which may not be implementable in the school setting (e.g., distancing). Although the overall guidance for the ELC Program has not changed, some flexibilities considered on a case-by-case basis as part of a larger testing effort for schools include: diagnostic testing, testing at school events, prevention and mitigation strategies such as Personal Protective Equipment (PPE), portable HEPA filters, and vaccination.

Presentation Title	Presenter	Institution
Operation Expanded Testing (ET)	Matthew Humbar	Department of Health and Human Services

Dr. Matthew Humbar from the Testing and Diagnostics Working Group provided an overview of ET, a no-cost testing solution for K-8 schools and congregate settings. The program is a public-private partnership with privately run lab networks and continues to work on enrollment of districts into the program, testing logistics, community outreach, and regulatory issues with the states and specific

school districts. Thus far, ET is successfully implemented in several states, with over 4000 tests conducted at 1000 enrolled sites.

Presentation Title	Presenter	Institution
Increasing Community Access to Testing (ICATT)	Joseph Miller	Food and Drug Administration

Dr. Joseph Miller, Program Lead, provided an ICATT overview, which includes pharmacy partnerships to support testing with a focus on vulnerable communities, a Surge Testing Program to provide resources to state and local health departments to support testing in COVID-19 outbreaks, Pop-up Testing at Events, and school testing programs (including underserved community K-12 schools, community colleges, and summer camps). When choosing school districts, the program considers high social vulnerability, high pandemic vulnerability, high degree of child poverty, and immediacy for testing support. The program also conducted an evaluation to optimize the testing process and the program impact on enabling and sustaining in-person learning. The program is working to expand the sites and develop best practices to guide the school testing program.

Presentation Title	Presenter	Institution
RADx-UP Coordination and Data Collection Center (CDCC)	Michael Cohen-Wolkowicz	Duke Clinical Research Institute

Dr. Michael Cohen-Wolkowicz, Principal Investigator of the RADx-UP CDCC, discussed the CDCC guiding principle, science with the communities that are served at the center and the services and the support being provided around them. The CDCC has 4 cores that serve the RADx-UP projects: Administrative Core, COVID-19 Testing Core, Community Engagement Core, and the Data Science and Biostatistics Core. The CDCC also has the goal of translating the utility of new testing technologies to communities. CDCC accomplishments include transitioning 15+ projects from Non-FDA/EUA to FDA/EUA tests, collection of harmonized Common Data Elements, and overall support of all RADx-UP projects.

Lightning Presentations from Project Investigators

Dr. Chris Lindsey, Program Official, introduced the project Investigators and moderated the Lightning Presentations.

Presentation Title	Presenter	Institution
Project Safe Schools	Emily Haroz	Johns Hopkins University

Dr. Emily Haroz discussed her team’s study: testing within the White Mountain Apache Tribe and Navajo Nation communities. The study will determine the effectiveness of the schools’ selected testing approaches (school rapid antigen test, home rapid antigen test, front-end PCR tests) with a longitudinal observational cohort using convergent mixed-methods design. To date, 540 people participated in testing (289 school staff and 217 students). Teacher/staff uptake (measured by consent forms) was 80% and student uptake increased through end of 2020-2021 school year/summer school. Zero cases were detected which is representative of low community transmission rates. The project developed COVID-19 testing toolkits with resources for other schools that this project cannot directly support. Finally, as there are not universal mask mandates in Arizona, the research team will track school-specific masking protocols (and effect) in real time.

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ReSET: Restarting Safe Education and Testing for Children with Medical Complexity	Ryan Collier	University of Wisconsin-Madison
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Dr. Ryan Collier's project focused on students and children with medical complexity (CMC) and aims to: 1) determine the feasibility of home and school-based testing; 2) predict in-person schooling attendance; and 3) develop consensus priorities for safe in-person school. The project team used the BinaxNOW rapid antigen platform (testing conducted twice per week) for an in-home testing cohort and in-school cohort. The research team is compiling demographics, testing and vaccine data as it relates to going back to school, and perceptions around school and school safety. Schools were successful in returning CMC families to school when using recommended mitigation strategies (PPE, distancing, hygiene, etc.), communicating plans to families frequently, and engaging families and students through teachers.

Presentation Title	Presenter	Institution
ReOpening Schools Safely and Educating Youth- ROSSEY	Linda Ko	University of Washington

Dr. Lindo Ko's study aims to: 1) Identify rural Latino community's social, ethical, behavioral needs and resources to bring student back to school; 2) evaluate effectiveness of a testing program on student attendance using a cluster randomized control trial; and 3) assess implementation outcomes of testing program with school stakeholders, parents, and children. The project has completed 19/20 parent interviews, 4 focus groups with parents, and 16/20 child interviews. All stakeholders were supportive of using testing to reopen schools and noted the need for high content communication regarding testing updates. Initial data reflected mixed opinions of how to implement testing strategies to open schools. Most agreed that families needed to be involved/participate in testing; the school and medical support team also needed to address stigma around having a positive test.

Presentation Title	Presenter	Institution
SARS-CoV-2 Screening and Diagnostic Testing for Return to K-12 Schools	Kanecia Zimmerman	Duke University

Dr. Kanecia Zimmerman noted that even as schools are reopening, Black and Latino students are less likely to return to school. She also provided evidence that quarantine requirements after exposure have led to prolonged periods of time out of school. The project team hosted hundreds of faculty and school calls and created educational resources available on the project website to respond to these school/community needs. Initial project findings included: 1) very low positive rates in screening test protocols (10 case out of 643 tests – screening and exposures); 2) when masking and physical distancing are in place, in-school transmission is very low; 3) presence of a testing program for individuals exposed to COVID-19 increased overall testing access rates; 4) duration of quarantine decreased after initiation of testing program with a large impact on reducing time missed from school; 4) strong community engagement and communication is paramount.

Presentation Title	Presenters	Institution
Schools TLC Study Support for Safe return to In-Person School: COVID-19 Testing, Learning and Consultation	Dana Keener Mast, Jennifer Goldman, Jennifer Schuster	ICF, Children's Mercy Hospital

Drs. Keener Mast, Goldman, and Schuster described their project to determine the preferred testing strategy among students and staff among three Kansas City public schools. Findings indicate that most people preferred the shallow nasal swab due to ease of test administration (versus saliva-based testing). Parent and staff surveys and interviews indicate support for COVID-19 testing and masking in schools to increase safety and comfort with sending children back to school.

Presentation Title	Presenter	Institution
Safe Return to School: WashU IDDRC and KKI	Luther Kalb	Kennedy Krieger Institute

Dr. Luke Kalb emphasized how implementation of COVID-19 mitigation strategies are more difficult with children with Intellectual and developmental disabilities (e.g., masking compliance, maintaining hand hygiene). He also noted that regular care is needed for these individuals in the school setting which makes distancing difficult. To date, the project has enrolled up to 93 people. Recruitment challenges are being encountered because of perceptions of the limited value of COVID-19 testing at the time of report. New messaging campaigns and increased outreach and community efforts are underway.

Presentation Title	Presenter	Institution
COV-IDD: Testing for COVID-19 in children with intellectual and developmental disabilities (IDD)	John Foxe	University of Rochester

Dr. John Foxe introduced the collaboration of his project with the Mary Cariola Center which serves moderate to severe IDD children. Important components of the project include a mobile testing unit, quick turnaround of test results, and inclusion of serology testing to identify variants. The current enrollment of staff and students is 147 individuals. Overcoming testing and vaccine hesitancy is a major issue in this project. In the fall, the team will develop and test strategies to increase understanding, enable communication, and provide on-the-ground education to increase enrollment.

Presentation Title	Presenter	Institution
Safe Return to School: Assessing Testing Strategies in K-12	Jason Newland	Washington University in St. Louis

Dr. Jason Newland described the goal of his project: determining the optimal COVID-19 testing strategy in St. Louis area middle and high schools. The project community partners have conducted listening sessions to better understand community concerns regarding COVID-19 testing and vaccines. The project also implemented 389 tests among 289 people, including whole-family testing of students. Initial lessons learned encompass how community relationships and trust are essential (e.g., Community Advisory Board) with continuous feedback loops, as well as integrated events with the schools to engage and promote testing, as well as vaccination.

Closing Remarks and Adjournment

Drs. Lee and Cernich closed the Workshop by thanking all of the presenters, schools, communities, and attendees. Dr. Cernich emphasized the community-engaged projects' importance in returning and retaining children in in-person learning environments and the importance of building research evidence for the effectiveness, sustainability, and scalability of COVID-19 testing approaches and other mitigation strategies (e.g., masking, physical distancing, vaccination).