

# Recommendations for SARS-CoV-2 Testing in Children With Disabilities and Medical Complexity

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abstract

Schools provide important services that cannot be provided virtually to children with medical complexity and children with intellectual and developmental disabilities, yet these children are among the most at risk from coronavirus disease 2019 (COVID-19). To keep schools open for children with medical complexity and/or intellectual and developmental disabilities during the COVID-19 pandemic, we implemented severe acute respiratory syndrome coronavirus 2 testing at 3 sites across the United States. We evaluated testing strategies for staff and students at each site, including specimen source (nasopharyngeal or saliva), test type (polymerase chain reaction or rapid antigen), and frequency and type (screening versus exposure/symptomatic) of testing provided. Among the greatest barriers to severe acute respiratory syndrome coronavirus 2 testing in these schools was the engagement of caregivers and challenges navigating legal guardianship for consenting adult students. Additionally, variability in testing strategies nationally and in the community, as well as surges in viral transmission across the United States during the course of the pandemic, led to testing hesitancy and variable participation rates. Essential to the successful implementation of testing programs is building a trusted relationship with school administrators and guardians. Leveraging our experiences with COVID-19 and forming lasting school partnerships can help keep schools for vulnerable children safe in future pandemics.



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This study is registered at Washington University in St Louis: Washington University in St Louis/Kennedy Krieger Institute study. Before enrollment, this study was registered at [www.clinicaltrials.gov](https://clinicaltrials.gov) on September 25, 2020 (identifier NCT04565509), titled "Supporting the Health and Well-being of Children with Intellectual and Developmental Disability During COVID-19 Pandemic" (<https://clinicaltrials.gov/ct2/show/NCT04565509?term=NCT04565509>). University of Wisconsin (identifier NCT04899245; May 25, 2021), titled "ReSET Aim 1b: Restarting Safe Education and Testing for Children With Medical Complexity: COVID-19 Testing in School With Children and Staff"; and (identifier NCT04895085; May 19, 2021), titled "ReSET Aim 1a: Restarting Safe Education and Testing for Children With Medical Complexity: Feasibility of In-home Cohort COVID-19 Testing Strategies, and Associations With CMC Parent Perceptions About In-person School Attendance."

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Children with intellectual and developmental disabilities (IDD) and children with medical complexity (CMC) are more vulnerable to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and, if infected, have a higher risk of developing severe symptoms compared with other children.<sup>1</sup> Despite this increased risk, it is essential that schools remain open in a manner that is safe for children with IDD and CMC. School closures during the coronavirus disease 2019 (COVID-19) pandemic have disproportionately impacted children with IDD and CMC and their families.<sup>2</sup> Many of these children access important support services, such as speech and physical therapy, psychological treatment, and other medical care, primarily through school.<sup>3</sup> Compared with parents of typically developing children, parents of children with disabilities experience more parenting stress and are further strained by taking on additional responsibilities to fill support roles when schools are closed. For example, parents of children with autism spectrum disorder reported higher stress, anxiety, and depression as a result of the pandemic compared with parents of typically developing children.<sup>4,5</sup>

Three projects in the National Institutes of Health Rapid Acceleration of Diagnostics-Underserved Population (RADx-UP) Return-to-School initiative implemented testing strategies to increase the safety of students and staff in schools for children with IDD and CMC. By addressing the unique challenges posed by the COVID-19 pandemic in the special school setting, our goal was to understand the best testing strategies to support keeping this vulnerable population safe at school. Our ultimate goal was to develop generalizable and scalable approaches that can be disseminated rapidly to facilitate school opening in future pandemics.

In this article, we describe our experiences implementing testing strategies in schools for children with disabilities across the United States during the COVID-19 pandemic (Table 1).

### UNIVERSITY OF WISCONSIN AND THE RESTARTING SAFE EDUCATION AND TESTING PROGRAM FOR CMC

The Restarting Safe Education and Testing (ReSET) program for CMC at the University of Wisconsin began in May 2021. The goal of the ReSET program was to evaluate the

feasibility of SARS-CoV-2 screening and symptomatic rapid antigen testing for CMC in home and school-based settings. Additionally, the program aimed to examine associations with responses to survey interviews at participant enrollment, surveillance testing, and symptomatic testing regarding school safety perceptions and practices. Using rapid antigen tests performed by caregivers in homes or by trained personnel at school, children received twice-weekly screening testing for 3 months and then families had the option to continue twice-weekly screening or to change to symptomatic/exposure testing. We used the BinaxNOW Rapid Antigen System (Abbot Laboratories, Chicago, IL), a point-of-care lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigen from anterior nasopharynx swabs.

As described previously,<sup>6</sup> enrollment populations included:

1. an in-home testing group recruited from our pediatric complex care program; and
2. an in-school testing group recruited from the Waisman Early Childhood Program (WECPP).

Housed within the University of Wisconsin's Waisman Center, the WECPP is a state-licensed program contracted with the Madison Metropolitan School District to provide year-round preschool in an inclusive setting for children aged 1 to 6 years with developmental disabilities. Up to 30% of WECPP's students have diagnosed special needs. During fall of the 2021–2022 academic year, the ReSET program began partnering with Syble Hopp School (SHS), a public school funded through Brown County to meet the needs of students aged 3 to 21 years with disabilities who resided in the 7 districts served in the region. The SHS implemented in-school symptom/exposure rapid antigen and polymerase chain reaction (PCR) testing sponsored through the Wisconsin Department of Health Services.<sup>7</sup>

Individuals in each arm of the study were contacted from May 3, 2021, to June 30, 2022. Overall, 51 out of 84 participants enrolled for in-home testing; 66 out of 83 participants enrolled for WECPP in-school testing; and 44 out of 126 participants consented to publish testing data from SHS in-school testing. This corresponds to

**TABLE 1** Characteristics of SARS-CoV-2 Testing Programs for Children With Medical Complexity or Intellectual and Developmental Disabilities

Study Location	Number of Participants	% of Students and Staff Enrolled	Number of Positives <sup>a</sup>	Sample Source/ Test Type	Testing Frequency/ Location	Duration of Testing
Wisconsin	161	137 of 267 (51%) students	82	Anterior nasopharynx/ antigen	Twice weekly	May 2021–June 2022
		24 of 26 (92%) staff				
SSD, St Louis	661	114 of 458 (25%) students	178	Saliva/PCR	Weekly	November 2020–May 2022
		547 of 575 (95%) staff				
KKI, Baltimore	327	277 of 605 (46%) staff eligible	42	Saliva/PCR	Weekly	July 2021–June 2022
		50 of 448 (11%) students				

<sup>a</sup> Positives do not include consecutive weekly repeat positive tests for a participant; cases of distinct reinfection are included.

enrollment rates of 61% for in-home testing, 80% for WECP in-school testing, and 35% for SHS in-school testing. The average number of tests per child per week was  $2 \pm 0.18$  (range = 0–6).<sup>8</sup> A total of 5796 tests were conducted, with 82 positive results, resulting in a 1.4% positivity rate. For both in-home and in-school testing cohorts, 76.9% of participants chose to opt in to twice-weekly screening, whereas the remainder opted for symptomatic/exposure testing. Notably, the in-school testing cohort had a higher opt-in rate of 87.9%.

### Important Findings

Overall, SARS-CoV-2 rapid antigen testing using nasopharyngeal samples in both in-home and in-school cohorts was feasible for CMC. Uptake into the program was high (eg, 70% approached/eligible were enrolled from the in-home and WECP cohorts). Dropout ( $n = 5$ ) was limited to those moving from the region and staff position changes. The rate of performed versus expected screening tests was high overall (85%) and similar between in-home (89%) and in-school (81%) cohorts. Reported testing problems from parents in the in-home cohort were rare and transient (eg, child resistance during 1 week that did not recur with future tests). The in-home, WECP, and SHS cohorts had overall positivity rates of 1.1%, 1.5%, and 5.5%, respectively. Nearly all positive tests were obtained from those with symptoms or known exposures.

Perceptions of school safety varied across testing cohorts (eg, those attending school reported more comfort with school safety measures). Over time, school safety perceptions increased across both cohorts. Although attendance increased over time from 40% of students with no in-person school attendance in spring 2021, 19% were still not attending in-person school by winter 2022.

### Identification of Barriers and Facilitators of Testing

The most common facilitator of testing as reported by parents was that the convenience of testing allowed their child to be diagnosed and treated earlier, and negative results reassured school staff that their child was safe to attend. A common barrier to testing was the need for officials to contact trace and the knowledge that, even if a child tested negative, they could become positive later. Collecting data from in-home testing was laborious and, because of geographical barriers, the ReSET program could only conduct PCR confirmation after positive rapid antigen in the school-based cohorts. Families shared that respiratory symptoms (which occur commonly in CMC, even when at their typical level of health) could still prohibit school attendance despite negative rapid antigen tests. Although this reality lowered the value of rapid antigen testing for some participants, it did not appear to reduce ReSET program participation. Finally, difficulty acquiring rapid antigen test kits because of the rapidly rising demand during the omicron surge threatened program sustainability.

### WASHINGTON UNIVERSITY IN ST LOUIS AND THE SPECIAL SCHOOL DISTRICT OF ST LOUIS COUNTY (SSD)

From November 2020 to June 2022, 6 schools in the SSD dedicated to educating children with IDD were invited to join a study for weekly SARS-CoV-2 screening testing. At these schools, ~600 teachers, staff, and administrators work with 716 students. SARS-CoV-2 screening used a saliva-based PCR test that was developed by Washington University investigators at the McDonnell Genome Institute in partnership with Fluidigm, and required only 0.5 mL of saliva.<sup>6</sup> The noninvasive nature of saliva collection facilitated use of this test in children with IDD because it minimizes aerosolization. Additionally, this saliva-based PCR test had 100% positive and 100% negative agreement with gold standard nasopharyngeal swab tests during validation in the US Food and Drug Administration submission. Results were typically returned to participants on the same day as the test.

One goal of the study was to investigate whether different messaging strategies would impact staff and student enrollment and participation in weekly SARS-CoV-2 screening testing. During the first phase of the study beginning in November 2020, general messaging was used to provide information about weekly testing at the schools via flyers, posters, and mailings. Subsequently, starting in January 2022, half of the schools were randomized to receive enrollment and testing participation messaging tailored to their school, including school name and images of people representative of the school's demographics. The other half of the schools continued with the general messaging strategy.

We enrolled 661 total participants in weekly testing, comprising 114 students and 547 staff. Each school was assigned a day of the week for test collection. During our study, we completed a total of 19 521 tests, of which 225 were positive, yielding a 0.2% positivity rate. Overall, 171 participants (25.8%) tested positive at least once during the study. Participants who had a positive result were notified via phone by a pediatric infectious diseases physician who answered questions and provided additional information that may impact the participant, such as eligibility for treatment.

### Important Findings

For the early SARS-CoV-2 variants (up through the delta variant in September 2021), in-school transmission appeared to be rare in these schools for children with IDD. Throughout the first 6 months of weekly testing, we identified only 1 case of definite in-school SARS-CoV-2 transmission.<sup>6</sup> After the 2021–2022 winter break and in the presence of the omicron variant surge, in-school transmission increased and we identified 41 school-based clusters of infection (2 or more linked infections). In addition, participation in screening testing increased with the rise in community positivity rates during the omicron variant surge. Overall, increased

community positivity appeared to impact participation more than any of the messaging strategies that were implemented.

### Identification of Barriers and Facilitators of Testing

One of the primary challenges in this study was difficulty recruiting students with IDD to participate in the testing. Each of the 6 SSD schools serves a wide geographic region, from which students generally arrive by bus. This method of transportation minimized in-person engagement with caregivers of students with IDD, which likely would have facilitated recruitment. Even when caregivers were engaged, many expressed a desire to be present during any testing procedure, which was a major barrier because most students are bused to SSD schools. Although we considered an alternative plan to allow in-home sample collection, the bus system, whose drivers were employed by a private company, would not allow transportation of potentially infectious saliva specimens; therefore, parents were not allowed to collect samples at home. Mobile collection services were not financially feasible for this study, and antigen tests that could be performed at home were not yet available at the start of the study.

The physical collection of saliva from students also presented a challenge for some children. For students who could not cooperate or were unable to place saliva into the collection device, modifications were made to allow study staff to collect specimens using a sponge or pipette.

### KENNEDY KRIEGER INSTITUTE (IN PARTNERSHIP WITH JOHNS HOPKINS UNIVERSITY)

Similar to the SSD study, the scientific goal of this project was to evaluate the impact of communication strategies on the uptake of weekly SARS-CoV-2 screening testing in students with IDD and their school staff through a blocked randomized trial. The study took place at 4 Kennedy Krieger Institute (KKI) schools located in the Baltimore and Washington, DC, areas, which have ~600 staff and 500 students in grades kindergarten to 12.

Over the course of almost 1 year from July 2021 to May 2022, SARS-CoV-2 testing was conducted weekly at the KKI schools. The SARS-CoV-2 test was identical to the saliva-based diagnostic test implemented at SSD in St Louis by Washington University. Study staff were present to collect samples in-person 4 days a week for 3 of the 4 schools. One school was located at a long distance; therefore, collection occurred only once a week. All samples were shipped to the Washington University laboratory for processing via FedEx, with results typically returning ~24 hours after collection. Results were returned to participants via e-mail. Positive results were managed by the KKI school medical director and KKI Infection Control Department.

Participant recruitment began in June 2021 for all 4 schools. Our recruitment efforts were extensive, including study flyers, incentives (\$5 per test; 1 per week), videos, dissemination of

overall results (positivity rates) in KKI's family and staff monthly newsletter, articles in institutional magazines, e-mails, presentations at staff meetings, and collaborations with a community advisory committee for additional recommendations. These recruitment efforts continued until January 2022, when schools were randomized into blocks to study the effectiveness of enhanced recruitment communication efforts. Two schools were selected for increased recruitment presence (eg, large billboards at the school entrance, study tablecloths on testing tables), whereas the other 2 schools only continued the preestablished baseline recruitment strategies. The goal of this communication randomization was to understand if providing more visual presence/advertising at the sites led to greater uptake in SARS-CoV-2 testing.

Between July 2021 and May 2022, a total of 50 students and 277 staff participated in weekly testing, resulting in a total of 6802 tests, of which 42 were positive, which yielded a 0.006% positivity rate. A total of 12.8% of all participants tested positive at least once during the study.

### Important Findings

Our data suggest that most enrollment, testing participation, and test positivity occurred during local community surges of SARS-CoV-2 infections, which corresponded with the omicron surge in December 2021 to February 2022 and the omicron BA2 surge in April to June 2022. Likely because of the impact of local viral variant surges on participation, preliminary data from the randomized trial suggested that the enhanced communication strategy did not significantly increase study recruitment or testing. Those results are being compiled and reported elsewhere.

### Identification of Barriers and Facilitators of Testing

During the course of this research, we identified systematic barriers that negatively impacted our ability to rapidly implement SARS-CoV-2 testing. The most notable barriers included regulatory requirements imposed by the institutional review board (IRB) reliance. Although funding agencies often require central IRB reliance, in its current state, this remains highly inefficient because local IRBs often impose additional local review that significantly slow a study. More work is needed to encourage local institutional IRBs to trust and rely upon a single central IRB as they are both designed and intended to be used.

Recruitment of consenting adult students with IDD who were aged >17 years was also challenging. For equity, this population should be included in studies. However, study teams need to be prepared to identify and address guardianship issues, gather appropriate guardianship documentation, and address concerns about cognitive limitations during consent.

Finally, testing access and logistics were significant barriers for individual communities. Although local testing is ideal, we had success with rapid turnaround of results using overnight shipping to a remote site (St Louis) for testing. Except for



a few unavoidable shipping delays, most test results were returned within 24 hours.

## DISCUSSION

Thorough preparation and planning are essential to keep students safe during the next surge or pandemic and to minimize the disruption of school services for children with IDD or CMC. Through these 3 RADx-UP Return-to-School projects, we have gained important insights into the implementation of SARS-CoV-2 testing in a research setting for children with IDD and CMC. Early implementation of both in-home and in-school testing during a pandemic can help minimize or avoid school shutdowns by providing multiple avenues for accessing testing, thereby reducing the spread of infection. Additionally, ongoing monitoring of the spread of infection through regular surveillance testing and symptomatic/exposure testing can help identify and isolate positive cases before spreading can occur.

### Recruitment of Students With IDD

Recruitment of students with IDD and CMC posed a significant barrier in all 3 of these studies. The ease of performing testing at school was offset by the difficulty in communicating with parents who were rarely present at the school and not always aware of the testing opportunities. Direct communication between school or research personnel and caregivers of children with IDD and CMC is limited in the school setting, particularly because most of these students are bused to specialized schools. In addition, many caregivers are already overwhelmed by caregiving activities, which minimized their interest in testing research. However, symptomatic/exposure testing during surges was often viewed by caregivers as an incentive for recruitment. Therefore, future pandemics would benefit from better integration of health care activities into the school setting because processes would already be in place for testing and students would be comfortable providing samples in this environment. It is also recommended that researchers work with parental advisory boards to gain their perspectives on the best way to gather caregiver input about research-related testing during future pandemics. This will help the research teams not only build trust, but also understand the feasibility and interest of caregivers concerning research engagement.

For students aged >18 years, legal guardianship and competency concerns also served as barriers to enrollment and participation in testing, and require early consideration in study design. Monetary incentives are a valuable research recruitment tool that also should be considered at study initiation.

### Access to In-Home and In-School Testing

Using feedback from survey interviews at participant enrollment, surveillance testing, and symptomatic testing, we determined that offering both in-home and in-school testing options could increase testing utilization by providing more

convenience to participants. However, systematically collecting results from in-home antigen tests and performing PCR confirmation, if needed, are logistically challenging and require more resources. Additionally, testing programs need dynamic plans, likely supported by public health departments or state departments of health, to maintain a reliable supply of rapid antigen test kits amid surges in public demand. Because of the success of some of these testing programs, caregivers of highly vulnerable students with IDD and CMC expressed an interest in extending school testing programs beyond SARS-CoV-2,<sup>8</sup> which may be advantageous for control of other transmissible illnesses, such as respiratory syncytial virus, influenza, and gastrointestinal viruses.

### Biospecimen Collection Methods

Sample collection methods need to be flexible for children with IDD and CMC because of their unique medical and behavioral health needs. Our 3 studies found that both anterior nasopharynx and saliva collection were suitable for this population, although modification of protocols was needed for some students. These modifications included training students to become more comfortable with the process, consistently pairing the same staff members with individual students, and using swabs or pipettes to collect saliva from students who were unable to provide saliva or cooperate with test instructions. Ideally, testing that utilizes multiple sample collection methods, such as anterior nasopharynx and saliva, maximizes testing uptake in these special populations.

### Focus on Targeted Symptom/Exposure Testing

Although these studies were not designed to evaluate the value of screening testing over targeted symptom/exposure rapid antigen testing, it was noteworthy that nearly all positive antigen tests were among symptomatic or exposed individuals. Antigen testing in schools may therefore be most efficient if focused on symptomatic/exposed individuals, perhaps because the sensitivity is too low for screening. Although implementation of weekly screening testing with highly sensitive PCR-based tests at SSD and KKI detected many asymptomatic cases and likely reduced transmission in schools, the enormous cost of testing and labor combined with the disruption of school activities likely limit widespread implementation even for shorter periods of testing in schools for children with IDD and CMC. Future development of economic models to justify use of screening testing in schools would need to account for the higher risk of serious infection in children with IDD and CMC.

### Relationship With Schools

To keep schools safe during a pandemic, preexisting relationships between the school or school system and academic partners are essential and provide many benefits. First, school staff should be involved in the study leadership and design, as exemplified by the community partners who were involved in

these 3 RADx-UP Return-To-School projects. This allows the research to be maximally responsive to local needs. Second, established champions within the schools (principals, school nurses, school data/research administrators) allowed us to rapidly implement testing in response to the pandemic. Third, community advisory boards, either already existing or formed specifically by the school or academic institution for the research activities, should be engaged, not only to help overcome study barriers (eg, recruitment), but also to interpret and disseminate findings. As with most school processes, we recommend that a testing strategy be prospective to avoid appearing reactionary. Following a prospectively established plan may improve participant engagement by reducing fear of a perceived major change or the appearance of a haphazard policy.<sup>9</sup>

## CONCLUSIONS

Detailed planning to keep students safe during the next surge or pandemic is essential to minimize the disruption of services for children with IDD or CMC and to keep this vulnerable population safe.

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## ABBREVIATIONS

CMC: children with medical complexity  
COVID-19: coronavirus disease 2019  
IDD: intellectual and developmental disabilities  
IRB: institutional review board  
KKI: Kennedy Krieger Institute  
PCR: polymerase chain reaction  
RADx-UP: Rapid Acceleration of Diagnostics-Under-served Population  
ReSET: Restarting Safe Education and Testing  
SARS-CoV-2: severe acute respiratory syndrome coronavirus 2  
SHS: Syble Hopp School  
SSD: Special School District of St. Louis County  
WECP: Waisman Early Childhood Program

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