Supporting the health and well-being of children with intellectual and developmental disability during COVID-19 pandemic

Short title: Children with IDD during COVID

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A Introduction

The COVID-19 pandemic resulted in school closures that negatively impact children. In December 2019, a novel coronavirus, now termed SARS-CoV-2, was identified to cause a severe acute respiratory syndrome (SARS) in Wuhan, China.[1] The virus quickly and inexorably spread to six continents, and in the US alone has now caused over 4.5 million infections and 150,000 deaths.[2] Without proven treatments or an effective vaccine, the actual timetable for when this crisis will end is unknown. Non-pharmaceutical public health interventions, including social distancing, limiting gatherings of individuals, and face coverings, are the key strategies being used to limit ongoing transmission of SARS-CoV-2. In March, as the cases began to rise in the US, schools were closed and virtual learning commenced. While this temporarily reduced the spread of disease, the negative consequences of school closures include an increase in adverse child experiences such as child abuse and neglect, food insecurity, and lack of essential services that are particularly acute for children with IDD.[3]

Individuals with IDD are disproportionately affected by the COVID-19 pandemic. Children less than 17 years of age with IDD are much more likely to become infected and have a greater case-fatality rate than children without IDD.[4] Children and adults who live in residential facilities have a 5–fold higher rate of COVID-19 and a 6% greater case fatality.[5] Furthermore, individuals with IDD have additional disparities including higher rates of obesity and cardiovascular disease which are both significant risk factors for severe COVID-19, higher rates of poverty with household income less than $15,000, lack of internet access, and inadequate transportation.[6]

Children with IDD rely on schools for many services besides an educational curriculum. Schools provide an opportunity for socialization, work skills development, and receipt of therapy services that are not available outside the home. Furthermore, reports have suggested children with IDD have experienced behavioral and developmental regression, resulting in significant struggles for the families. Ensuring a safe return to school for this vulnerable group of children is essential and will require the successful implementation of new mitigation strategies including readily available SARS-CoV-2 testing and vaccinations.

Purpose of the Study Protocol

Access to COVID-19 diagnostic testing for children with IDD and their teachers is a critical step toward ensuring a safe return to school. Children with IDD are likely at higher risk of contracting and transmitting SARS-CoV-2 as they are often unable to wear a face covering, maintain social distance, and practice effective hand hygiene. Throughout the pandemic, access to SARS-CoV-2 testing and timely results reporting have remained a major barrier to safely reopening the workplace and schools. In underserved communities, these barriers are magnified due to lack of access to testing sites within close proximity.[7] Since many children with IDD live in poverty and lack transportation, access to an easily administered test within the school setting is essential for the safety of the child and school staff.

Safe return to school relies on convenient access and use of SARS-CoV-2 testing. However, reports suggest that SARS-CoV-2 testing is not supported by all individuals. Lack of trust in the healthcare system due to centuries of systemic racism and discrimination on the basis of disability may result in poor participation by this population. Refusal of testing is also possible when individuals do not have a social or financial safety net to provide for their families if they are subsequently unable to work due to being quarantined. The stigma of SARS-CoV-2 infection, fear of a positive test and the implications to their health, lack of health insurance, and risk of deportment also contribute to test refusal.[8]

Understanding the barriers to and optimal approaches for implementing testing of children with IDD in the school setting is essential and is likely to inform the best strategies for vaccine delivery to this vulnerable population of children with IDD.

B Background

Children with IDD have an increased risk of COVID-19 and are at particularly high risk for severe disease. Additionally, children with IDD are more adversely impacted by the loss of access to critical school-based services including nutritional, social, therapy and healthcare services. Because mitigation strategies such as masking, social distancing and effective hand hygiene cannot be reliably performed by many children with IDD, a safe school environment for children with IDD, their teachers, and caregivers will require frequent SARS-CoV-2 virus testing. The best implementation strategies to achieve SARS-CoV-2 testing in children with IDD in a school setting are unknown. Geographic, socioeconomic, and racial differences in public attitudes toward COVID-19 prevention for children with IDD are also unknown. By identifying the most effective methods for SARS-CoV-2 testing in children with IDD, we will establish a blueprint for wide adoption of school testing that will also guide future COVID-19 mitigation strategies, such as vaccination.

Overview. The primary goal of this study is to enable successful implementation of saliva-based SARS-CoV-2 testing for children with IDD and staff so that schools can operate as safely as possible. Utilizing community partners within the St. Louis region and nationally, our multidisciplinary research team will conduct a cluster randomized adaptive trial of different strategies to maximize delivery of weekly SARS-CoV-2 tests to this vulnerable population. Over the course of the study, we will perform a minimum of 52,000 diagnostic tests on saliva. As testing capacity expands locally and nationally, widespread use of testing within a school setting may become an essential tool to mitigate the impact of COVID-19, therefore we will assess national attitudes toward SARS-CoV-2 testing and the COVID-19 pandemic to guide sustainable testing and vaccination strategies.

Saliva-Based Diagnostic Testing. Investigators at Washington University (WUSTL) recognized early on in the pandemic that establishing rapid and widespread SARS-CoV-2 testing is essential to safely resume social and commercial activity. Therefore, the McDonnell Genome Institute (GTAC@MGI) deployed its expertise in high-throughput sequencing capabilities, enhanced technology development, and large-scale data processing to develop a saliva-based SARS-CoV-2 diagnostic test [Washington University SARS-CoV-2 Ultrasensitive-High-Throughput-Saliva assay (WUSC2-UHT-S)]. To address the limited supply of swabs and reagents needed for RNA isolation and the need for safe and acceptable collection method for use in children, we developed methods to detect virus directly from saliva. The non-invasive nature of saliva collection also facilitates its use in community settings, such as schools because it does not require special training to collect and minimizes aerosolization. In addition, saliva contains more viral particles than nasopharyngeal (NP) samples. Because it contains an inhibitor of reverse transcriptase that prevents detection of RNA genomes like SARS-CoV-2.[9-11], the WUSC2-UHT-S test includes novel treatment steps to allow viral detection directly from saliva without the need for RNA-extraction.[12] This is a major advantage of this new method. Because NP swabs and RNA-extraction reagents have become difficult to procure during the pandemic because of demand, removing these steps makes the assay robust to supply chain disruptions. In addition, saliva samples can sit for 5 days at ambient temperature without impacting assay sensitivity. This dramatically simplifies transport, storage, and handling of samples.

The WUSC2-UHT-S test is processed and run at GTAC@MGI on the WUSTL campus with a turn-around time of less than 3 hours. The test had 100% positive and 100% negative agreement with gold standard NP swab tests during validation and in the FDA submission. Application of microfluidics and adaptation of our existing sample-handling robotics has resulted in a capacity to test 4000 samples

per week as of August 1, 2020. With capital investments already allocated by WUSTL, GTAC@MGI should reach a throughput of 20-30,000 samples per week by Fall 2020. . Through a commercial partnership, the technology has been implemented commercially (Advanta Dx SARS-CoV-2 RT-PCR Assay) and will soon be available nationwide.

Point of Care Testing. GTAC@MGI is also investing in additional technology to allow the same test chemistry to be used at point of care (POC) through a CLIA-waived device operated by a laptop or mobile device. The new device can process this assay anywhere in <30 minutes. Importantly, this new device requires only 1 uL saliva which is obtained by touching a small plastic loop to the tongue. Prototypes of the Rapid Genetic Detection (RGD) readers are already in use in the Barnes Jewish Hospital Emergency room for rapid triage of incoming patients into a COVID-19 ward. The RGD has also been used at a St Louis nursing home facility previously devastated by COVID-19 that now has patients in recovery. The RGD has received FDA approval and is considered an innovative alternative approach that is low cost, alleviates the need to transport samples, and provides immediate on-site test results.

Summary Table of Results		Gold Standard (Nasopharyngeal Swab)		
WU-RADx-0v3 Assay 1-Pot Saliva Assay on Prototype Devices		**Positive**	**Negative**	**Total**
	Positive	19	1	20
	Negative	0	18	18
	Total	19	19	38
Positive Agreement		100% (19/19)		
Negative Agreement		94.7% (18/19)		

Point of Care Testing. Left, RGD reader connected to a cellphone. Reaction Kits are shown as well as the microliter "loop" used to acquire the saliva (simply by touching the tongue, no scraping required). Right, results from 38-patient trial, showing overall 97% accuracy in blind testing.

SARS-CoV-2 Testing Capacity and Process. Our overall strategy builds upon testing and associated informatics infrastructure that is rapidly being ramped up to test thousands of WUSTL staff and students every week. As the current project leverages existing infrastructure, we will be able to rapidly role out a similar test for the SSD.

Strategy for Sample Collection and Processing. We will use a standardized sample collection kit developed for WUSTL. Kits contain barcoded sample collection tube, CLIA/CAP compliant label, and ziplock biohazard bag. 500 uls of saliva will be collected from each subject in the classroom under the supervision of a trained research coordinator. For students unable to spit because of poor motor control, we will use disposable transfer pipette under the tongue to collect a sample. Some will also have the option of providing the sample at home and bringing it to the school. We will provide what is needed to obtain the sample at home. If a participant becomes symptomatic while at school, the research coordinator and/or school nurse will be able to obtain additional samples from those individuals in addition to their weekly testing.

Scanning of corresponding barcode and data-entry into a HIPAA compatible Research Electronic Data Capture (REDCap) database will occur at time of collection (or return of sample), and will include all information needed for eventual National level reporting and contact tracing (e.g. demographics, communal housing status, pregnancy status, etc.).[19] Labeled samples are transferred to a ziplock bag which is externally sterilized with an alcohol wipe, then sent to Vault or couriered *en masse* to GTAC@MGI on the WUSTL medical campus. Limit of detection on this assay is <10 particles/ul, with no cross reactivity to any other viruses tested to date. Leveraging the rapid run-time, sample collection to return of results is expected to be <2-3 d at Vault or <24 hours at GTAC@MGI. Since our

POC test has received FDA approval, we will use it, as the results return within 30 min on-site and at less cost.

Return of Results. Results from the diagnostic test will be transferred into a study-specific REDCap database for research and communication to the RADx-UP Coordinating and Data Collection Center (CDCC), and provided as a HIPAA compliant report to the requisitioning physician (Drs. Newland or Fritz). Under their guidance, research coordinators will return results to parents/guardians using standardized algorithms developed by Dr. Newland that provide training on appropriate responses reporting to the appropriate health department, referral for medical monitoring and care, as well as referrals for social supports (e.g. food aid or financial assistance). Dr. Newland will coordinate with the health department and the school medical staff to ensure appropriate contact tracing and quarantining. Contact tracing will be done by our trained research coordinators. To remove administrative burden from the schools, reporting to state and county agencies will be handled directly by the Consortium Data Reporting Unit (CDRU)(see below) and medical team. The CDRU, which has extensive experience developing similar reporting systems, will adapt an existing pipeline.

Implementation Research for Diagnostics in a Pandemic. The application of implementation science tools to promote the use of a new diagnostic method, particularly in the face of a worldwide pandemic in which both the speed and scale required are unprecedented, represents a remarkable opportunity to demonstrate their effectiveness in a public health emergency. The Center for Dissemination and Implementation (CDI) in the Institute of Public Health at WUSTL is a national and international leader in this field of research.[13] The CDI is directed by Dr. Elvin Geng, a member of our Scientific Advisory Board (see below), who also coordinates the Washington University Network for Dissemination and Implementation Research (WUNDIR).[14] This university-wide, transdisciplinary network of over 80 researchers meets regularly to develop new and ongoing research efforts including an Agency for Healthcare Research and Quality funded R01 study of the de-implementation of antibiotics led by three investigators on this proposal, Drs. Newland (co-PI), McKay (co-I), and Powell (co-I) (NCT04366440). In addition, the Brown School at Washington University, whose mission is to advance social work, public health, and social policy, is on the front lines of social change both regionally and nationally. By engaging with investigators in their Health Communications Research Laboratory (HCRL) and Evaluation Center, we have access to the highest caliber investigators for this community-engaged research.

Community Partner Program

Special School District of St Louis County. Our primary community partner for COVID-19 testing in Aim 1 is the Special School District (SSD) of St Louis County. IDDRC@WUSTL investigators have a long-standing relationship with SSD and have worked closely with them on past and current projects,[15-17] including the Center for Disease Control-funded Autism and Developmental Disabilities Monitoring (ADDM) Network and the Study to Explore Early Development (SEED). St Louis County consists of more than 20 communities surrounding the city of St Louis City (**Figure 2**) that together have a population of 996,945 and are economically (9.8% poverty rate) and racially diverse (65.5% White, 24.4% Black,

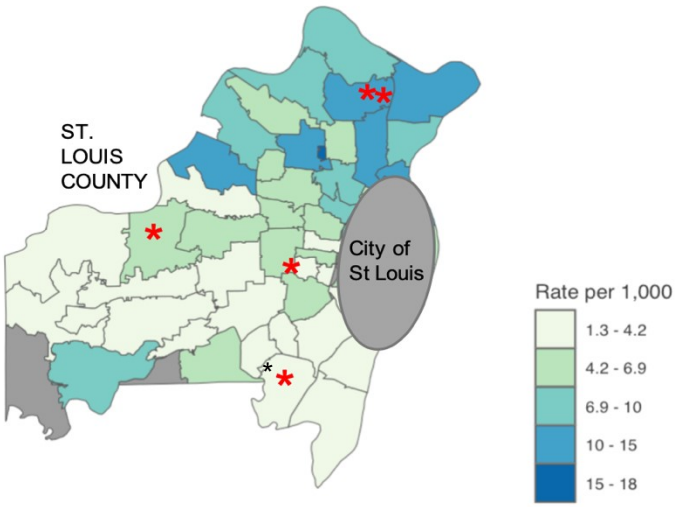


Figure 2: Community Partner for the IDDR COVID-19 project. Special School District of St Louis County (non-gray) and the 6 special education schools (red) where the project will take place, and corresponding SARS-CoV-2 infection rate by ZIP code (as of 6/16/20).

4.5% Asian, and 2.1% Hispanic). Nearly 10% speak a non-English language. The SSD provides special education and related services for more than 23,000 students within 22 school districts in St Louis County. While the vast majority of students receive special education and related services in their home school in the district in which they live, 909 children with disabilities are educated in one of the District's six special education schools, of which 48% of students are Black. Students served by the SSD make up approximately 20% of the total population of students with disabilities in the state of Missouri.

Table 1: Racial demographics of students in Special School District of St Louis schools	
	Number (%)
Black	440 (48.4%)
White	403 (44.3%)
Asian	18 (4.4%)
Multiracial	27 (2.9%)
Hispanic	20 (2.2%)
Total	909

This project will leverage six racially diverse special education schools at SSD that serve 909 children age 5-21 years (**Table 1**), and employs 590 teachers, staff, and administrators. Children who attend these schools are bussed from their homes daily. The students' medical needs are complex, including 54 with non-progressive neuromuscular disorder, 8 with progressive neuromuscular disorder, 90 with permanent orthopedic disabilities, 42 receiving gastric-tube feedings, and 11 with tracheostomies.

Our partners at the SSD of St Louis County include Superintendent Elizabeth Keenan, PhD; Kelly Grigsby, PhD, Executive Director of Schools and Programs, and the principals of each school where the project will take place. The SSD project co-leads are Maureen McCoy, Area Coordinator for Nursing and Health Services, and Matthew Traughber, PhD, Evaluation and Research Administrator. The SSD also has a Parent Advisory Council, and an active Family and Community Resource Center that is led by Michelle Levi Perez, who is also a member of our Community Advisory Board (see below).

The School Project Implementation Team will consist of Maureen McCoy and Matthew Traughber, Michelle Levi Perez, a nurse from each school, principals (or designee) from each school, as well as Drs. Newland, Gurnett, Fritz, Morris, and 4 research coordinators employed by Washington University embedded within the SSD. This team will meet weekly throughout the study to discuss any concerns as they arise. The research coordinators will work closely with teachers and administrators at each of the six schools to solve local problems, with oversight by the School Project Implementation Team. The SSD is an equal partner in the decision-making structure of this project, therefore any modifications of the proposal will require approval of (a) Maureen McCoy and Matthew Traughber, if minor, or (b) the SSD Executive Leadership Team, if deemed major.

University Centers for Excellence in Developmental Disabilities (UCEDDs). Our national community partner for Aim 2 is the Association of University Centers on Disabilities (AUCD), which sponsors a network of 67 University Centers for Excellence in Developmental Disabilities (UCEDDs) that are housed in every US state and territory.[18] Intellectual and Developmental Disabilities Research Centers (IDDRCs), which are funded by NICHD, are closely aligned with the UCEDDs. Centers work with people with disabilities and their families, state and local agencies, and community providers to provide training, technical assistance, community service, research, and information sharing, with a focus on building capacity of communities. The national network of UCEDDs is authorized by law and their core funding is administered by the Office of Intellectual and Developmental Disabilities (OIDD). Thus, the UCEDDs are an ideal partner for this project. The nationwide reach of the UCEDDs will allow us to assess and disseminate successful strategies for reducing healthcare disparities in SARS-CoV-2 testing in schools and communities across the US. We will initially partner with two UCEDDS: The University of Missouri-Kansas City Institute of Human Development (IHD)(directed by co-I George Gotto) and the Maryland Center for Developmental Disabilities (MCDD)(directed by co-I Maureen van Stone) at Kennedy Krieger Institute (KKI) led by Co-I and CEO Dr. Brad Schlaggar.

The KKI School Program uniquely comprises 4 publicly funded nonpublic schools providing special education and related services to >480 children from across the state of Maryland. We will leverage

the UCEDDs large network of professional and community partners to distribute a national survey in Aim 2, and to disseminate results of our study for impact on local and national policy.

Consortium Data Reporting Unit (CDRU)

The CDRU will coordinate the submission of common evaluation metrics on SARS-CoV-2 testing and implementation outcomes to the RADx-UP CDCC. The CDRU will be led by Albert Lai, the Deputy Director for the Institute for Informatics and the Chief Research Information Officer for the School of Medicine at WUSTL. We will comply with data sharing as mandated by the NIH and follow the guidance provided by the CDCC for data acquisition, collection and curation, including appropriate consent for data sharing and implementation of the schemas proposed under the ABOUT ML effort. The CDRU will also coordinate data safety monitoring board (DSMB) activities with the CDCC and ensure compliance with federal, state, and local requirements on testing, reporting, and surveillance policies. The CDRU will also work closely with the CDCC to employ a common set of tools to promote collection of comparable data on social determinants of health, including measures from the PhenX Toolkit. Effective implementation strategies for rapid adoption will be disseminated through the CDCC as well as by IDDRC/UCEDD community partners to spread best practices nationally.

Community and Scientific Advisory Board

We have already convened our Community Advisory Board (CAB) to discuss this proposed project on July 9, 2020, with the goal of assimilating their perceptions of barriers and facilitators of school-based COVID-19 testing for children with IDD. During the hour-long conversation led by Co-PI Christina Gurnett, the CAB strongly encouraged our team to consider: (1) effective communication strategies tailored to the culture and demographics of each school, (2) providing resources to parents if their child tests positive for COVID-19 ("a big blanket that will catch you"), and (3) contingency plans based on infection rates in the community and transmission within the school. Given the fluidity of the pandemic and its effect on our community, the CAB will meet quarterly (Sept, Dec, Mar, Jun).

CAB. The CAB consists of members of our IDDRC CAB, the Institute of Public Health/Institute of Clinical and Translational Science CAB, and several community members who were asked to join due to their expertise in educational settings (e.g. as school nurses) or healthcare in underserved populations. The CAB is comprised of representatives of our parents of children with IDD, child advocates, teachers, school nurses, medical providers, and leaders of community health organizations. Many of our board members have completed a 15-week training through the Community Research Fellows Training program (https://beckerguides.wustl.edu/fellows), and have participated in other COVID-19 CAB meetings, including those discussing return of genetic results to vulnerable infected patients, and vaccine recruitment strategies. Thus, our CAB is actively committed to improving public health through research participation.

Community Advisory Board:

- Michelle Levi Perez, Family and Community Resource Center, Special School District of St Louis County
- Will and Tricia Bolster, Autism Speaks St Louis, Chairman of the Board, IDDRC@WUSTL Board
- David and Mary Steward, IDDRC@WUSTL Board
- Pat Fox, Missouri Family Partnership, Bureau of Special Health Care, Dept of Health and Senior Services
- Diane Southard, Community Support Southwest Regional Director, National Fragile X Foundation, mother of four children with special needs
- Judy Bentley, Founder, Community Health in Partnership (provides healthcare for uninsured and underserved populations)
- Linda Neumann, Consultant, Former Lead Nurse, Webster Groves School District
- Felice McClendon, Byrne Criminal Justice Innovation Project Manager, Urban Strategies
- Stacey G Newman, Director and Founder of ProgressWomen.com, Retired Missouri State Legislator
- Doug Lindsay, Keynote Speaker, Workshop Designer, and Personal Medical Consultant, survivor of rare disease
- Sherrill Jackson, CPNP, President and Founder, The Breakfast Club, Inc, Retired Certified Pediatric Nurse Practitioner
- Nancy Spargo, Dennis Lane, Maxine McBride Jackson
- Krista Peyton, St Louis Housing Authority, General Counsel

SAB. Our Scientific Advisory Board (SAB) is comprised of local experts in infectious diseases, genetics, community outreach and engagement, social determinants of health, and implementation science with local expertise to guide the clinical trial. Due to the rapid timeline for achieving results, the SAB will meet monthly during the start-up period of this project (Sept-Nov 2020), then quarterly.

Scientific Advisory Board:
- ❖ Katie Plax, MD, Ferring Family Chair in Pediatrics, Medical Director of the SPOT (Supporting Positive Opportunities with Teens)
- ❖ Cynthia Rogers, MD, Assoc Prof of Child Psychiatry
- ❖ Hillary Babcock, MD, MPH, Medical Director, Occupational Health, BJC and St Louis Children's Hospitals
- ❖ Elvin Geng, MD MPH, Director, Center for Dissemination and Implementation
- ❖ Alex Ramsey, PhD, Assist Prof of Psychiatry, expert in organizational psychology
- ❖ Joseph Dougherty, PhD, Professor of Genetics

Human Subjects Unit (HSU)

The HSU be supported by Drs. DuBois and Balls-Berry who bring extensive knowledge of research ethics, community engagement, and social science research methods. Dr DuBois also leads the Bioethics Research Center (BRC), a Clinical & Translational Science Award (CTSA) core that provides consultative services on demand. The HSU will provide three services for the proposed project:

1. Ethical Guidance. First, the HSU will provide the project team with consultation access to either of the two faculty who will respond to requests within 48 hours. HSU faculty and staff will conduct literature reviews and consult with stakeholders or experts as needed to address ethical questions. Second, a HSU faculty member will attend all meetings of the CAB and SAB to provide "embedded ethics" services [20] which we have used previously and will adapt for this project.[21]
2. Cooperation with the Social, Ethical, and Behavioral Implications (SEBI) RADx-UP Program. Dr. DuBois will serve as a liaison to this SEBI program (NOT-OD-20-119) program, and will participate in calls and coordinate activities that require multi-site collaboration. Dr. DuBois spent 6 years on the NIH Societal and Ethical Issues in Research (SEIR) study section, has been engaged with the CTSA ethics network since its inception, and currently chairs the External Scientific Panel for the NHGRI Center for ELSI Resources and Analysis. He is in an excellent position to serve as a liaison for SEBI work.
3. Formative Ethical Evaluation. We will support the community-based participatory research activities by holding Community Engagement Studios described by Joosten et al. but modified for a virtual Zoom platform.[22]. This approach encourages respect, facilitates recruitment, increases trust, and buy in from communities, and makes communities more willing to engage.[23]

The Consolidated Framework for Implementation Research (CFIR) will be used to evaluate facilitators and barriers, and identify strategies to increase participant adoption of weekly SARS-CoV-2 testing. This framework is widely accepted and allows systematic assessment of contextual factors important for implementation. CFIR has 39 constructs in five domains: innovation characteristics (e.g. saliva-based test), outer setting (e.g. home, culture challenges), inner setting (e.g. school culture), participant characteristics, and process (e.g. planning and stakeholder engagement).[24] Furthermore, implementation strategies are linked to barriers and facilitators in CFIR domains.[25] Our implementation experts (Drs. Newland, McKay, and Powell) along with Dr. Fritz have extensive experience with this framework and in conducting successful clinical trials in settings outside of healthcare. [26-33]

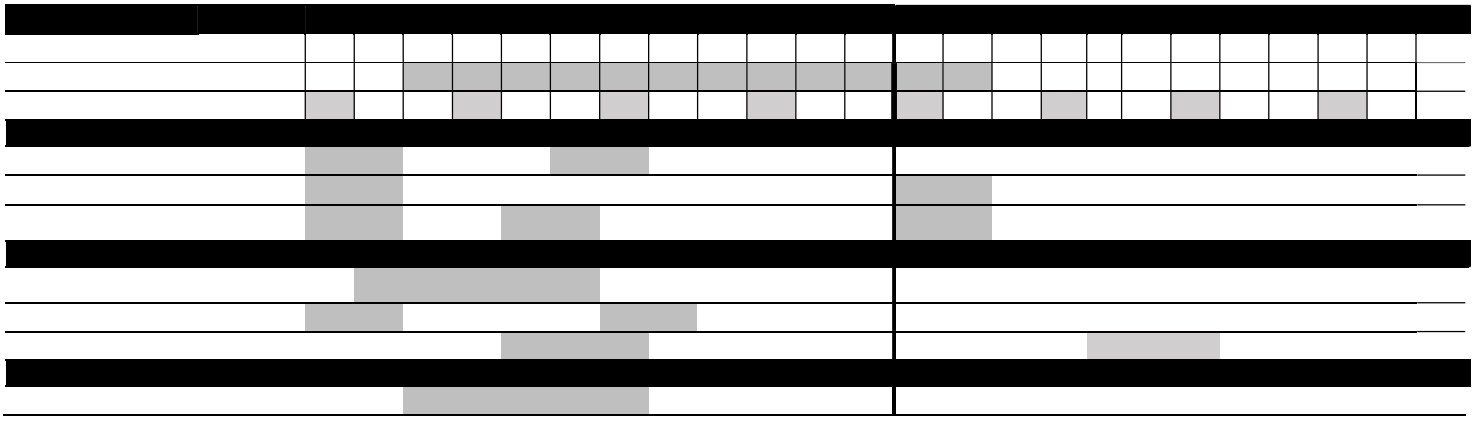
Dissemination Plan for the Entire Project

Community Conversations. We will employ a World Café process to share qualitative and quantitative data from the FCM, FG, and survey findings to our key stakeholders of parents/guardians and school staff. In our experience, these conversations spur creative thinking that will lead to the identification of parent-driven strategies that draw upon the ideas, insights, relationships, and resources of the wider community to generate creative solutions to issues.[61,62] Individuals who participated will be invited to attend these zoom meetings. Following each Community Conversation, researchers from UMKC and KKI will organize the developed strategies and share them with the full research team for final review and dissemination.

Sustainability. The SARS-CoV-2 testing paradigm described here is designed to be acceptable and sustainable, particularly as schools are increasingly recognized as sites of essential health care delivery. Further, the relationships built across the research team, AUCDs and IDDRC, CAB, SAB, and our community partners will be maintained through the regular meetings and reports as described above. Thus, we are prepared to pivot the same team and network to enhance adoption of vaccines or other therapeutics for this vulnerable population and have laid the groundwork for those efforts through the aims described here.

Data sharing and dissemination. We will deposit the IDD-specific measure that we develop to identify barriers and facilitators to COVID-19 testing and vaccination into the PhenX Toolkit. FG, FCM, testing and survey results will be shared through the RADx-UP CDCC, and participants with COVID-19 complications such as MIS-C will be entered into national registries. Results of the national survey will be widely disseminated to our community partners to guide local policy and decision-making. Academic manuscripts will be submitted simultaneously as preprints on MedRxiv to facilitate rapid dissemination of relevant data while under peer review. Finally, as we proceed through this adaptive clinical trial, we will share the most effective messaging and implementation strategies developed through this project with the national IDDRC and AUCD network to enhance diagnostic testing uptake for children with IDD and school staff nationwide. We anticipate that our results will serve as a template to aid enhanced diagnostic testing, and eventual vaccination, for this uniquely vulnerable population.

Description of milestones and timeline completion



		Year 1												Year 2											
	Site(s)	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A
Diagnostic Testing	SSD		R_1						R_2																
CAB and SAB Mtg	WUSTL																								
Aim 1: Determine the most effective messaging and implementation strategies to maximize SARS-CoV-2 testing with IDD and school staff using an adaptive trial design																									
Messaging: Develop and test entere	SSD																								
FGs: Parents	SSD																								
FGs: Staff	SSD																								
Aim 2: Assess national perspectives among parents of children with IDD and school staff regarding the impact of COVID-19 and the importance of SARS-CoV-2 testing																									

FCM: Parents	SSD KKI	
Local Survey	SSD KKI	
National Survey	All	
Dissemination and Utilization		
Community conversations	SSD KKI	

C Study Objectives

AIM 1: Determine the most effective implementation strategies to maximize SARS-CoV-2 testing for children with IDD and school staff using an adaptive trial design.

AIM 1.1: Develop messaging and implementation strategies for parents/guardians and staff based on the local identification of facilitators and barriers to weekly SARS-CoV-2 testing in a school setting.

AIM 1.2. Evaluate the impact of implementation strategies on the uptake of weekly SARS-CoV-2 testing in children with IDD and school staff through a cluster randomized adaptive clinical trial.

AIM 2: Assess the local and national perspectives among parents/guardians of children with IDD and school staff regarding the impact of COVID-19 and the role of frequent SARS-CoV-2 testing.

D Study Design

AIM 1: Determine the most effective implementation strategies to maximize SARS-CoV-2 testing for children with IDD and school staff using an adaptive trial design.

Our first practical goal is to test all students and staff weekly for SARS-CoV-2 in the SSD schools so that they can operate as normally and safely as possible. Beyond the weekly monitoring, we will also provide prompt testing to any staff and students who develop COVID-19 like symptoms. Over the course of the study, we will perform at minimum 52,000 diagnostic tests on saliva. Those with negative test results will continue to attend school, while those with positive results can rapidly be home-quarantined, undergo contact tracing, and be referred for additional medical and social services as needed.

Study Setting and Populations. All research activities for this aim will occur among the students, parents/guardians, staff (teachers, aides, nurses, administrators) of our primary community partner, SSD. SSD has six schools that only serve only children with IDD. All students (5-21 years old) and school staff are eligible for inclusion in the study. Individuals will be excluded if they (or their parents/guardians) do not provide consent or are unable to provide saliva for testing.

Table 2: Students and Staff of Special School District of St Louis County Schools Based on Location

	Ackerman Elementary	Litzsinger Elementary	Neuwoehner High School	Northview High School	Southview Elementary	Southview High School	Total
Students	222	164	141	207	75	100	909
Other Staff	89	73	66	73	49	50	400
Administrators	2	2	2	2	2	1	11
Nursing Staff	2	7	6	3	4	3	25
Teachers	29	24	31	33	18	19	154
Total	244	270	246	318	148	173	1499

Recruitment and Consent for AIM 1. Informational emails and zoom meetings will occur at each site to recruit staff and students for the study. Informed consent will be obtained from the parents/guardians or school staff by the research coordinator after discussing the benefits and risk of the study. Children 8-17 years of age who are developmentally able will provide assent. Children age 5-7 will not be providing assent due to their age and development. The consenting/assenting process will be done virtually, in person or by phone.

Research Design. A cluster randomized adaptive trial with 2 phases will be conducted at six schools dedicated to children with IDD (**Figure 3**). An adaptive trial provides the capability to assess multiple interventions and modify the trial based on data obtained during the trial. Adaptive trial designs have been used in a wide range of studies from improving adoption of suicide risk screening to optimizing use of mosquito nets to prevent malaria.[34,35] Based on our initial focus group (FG) and prior work, messaging that educates the participants about COVID-19, explains the benefits of frequent SARS-CoV-2 testing will likely have the greatest impact on the participation of students, parents/guardians and staff of the SSD schools in SARS-CoV-2 virus testing. Additionally, we will utilize FGs and surveys to develop/enhance messaging and other implementation strategies to maximize testing of children and school staff.

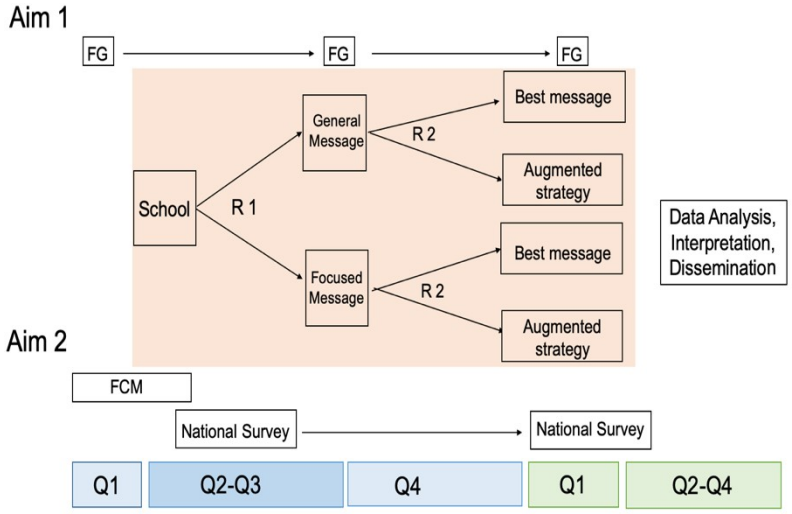


Figure 3: Research design and study aims. Clinical trial is in orange box. Timeline is indicated at the bottom. FG=focus groups, R1=Phase 1 randomization, R2=phase 2 randomization, FCM=fuzzy cognitive mapping.

Each school will be randomized 1:1 at the beginning of the study to one of two messaging strategies (Phase 1) that are informed by FGs involving parents/guardians and staff. Messaging strategies will include either (a) a general message that is inexpensive and easy to disseminate or (b) focused message that address specific concerns of the different communities. Messages may target groups being tested (staff versus students) or sociodemographic or racial differences between schools depending on the FG input. Analysis will occur after 5 months of weekly testing to determine which of the two initial messages is correlated with the highest uptake of testing among eligible subjects. After the testing begins, additional FGs will be conducted to assess factors that promote or discourage testing. After 6 months, each school will be randomized a second time to either the best initial messaging strategy (general v. focused) as determined by the analysis or the best message plus an augmented messaging or implementation strategy (Phase 2) to further promote the adoption of

testing. Such strategies might include a specific type/role of person delivering the message or the type of content (factual versus narrative). Other implementation strategies will be informed by the barriers and facilitators identified based on the CFIR domains and results of focus groups and surveys in Aim 2. For example, if participants feel there is a lack of communication regarding the importance of testing, local consensus discussions may be added as an additional strategy.[25]

AIM 1.1: Develop messaging and implementation strategies for parents/guardians and staff based on the local identification of facilitators and barriers to weekly SARS-CoV-2 testing in a school setting.

Focus Groups to capture stakeholder perceptions. To develop effective messaging strategies for recruitment, we will use the CFIR domains to understand local views on: 1) SARS-CoV-2 testing and COVID-19 (e.g. risk, symptoms); 2) facilitators and barriers to testing; and 3) messaging and implementation strategies to encourage the adoption of weekly testing for children and staff. The Brown School Evaluation Center will collaborate with the CAB to develop FG and interview guides. FGs will be conducted with parents/guardians and school staff using a virtual Zoom platform. A total of 21 staff FGs will occur across three time points (pre-, midpoint, and post SARS-CoV-2 testing). Twenty-four parent/guardian focus groups will occur over two time points (pre- and post SARS-CoV-2 testing). Recruitment of stakeholders will occur via their school with the assistance of the School Project Implementation Team, CAB, and SSD Parent Resource Center. FGs and interviews will be conducted by Evaluation Center team members who are experienced qualitative methodologists. FGs (8-10 participants/FG) will last approximately 60 minutes and will be recorded and transcribed. Parents/guardians and school staff will receive $20 gift cards per FG. **Recruitment and Consent for AIM 1.1.** The SSD will share project description through multiple methods (e.g., email, electronic platforms, meetings) with parents/caregivers and school staff. One of the methods will be to share project description handout. (ProjectOverview).

SSD will share recruitment flyers for discussion sessions through multiple methods (e.g., email, electronic platforms, meetings) with parents/caregivers and school staff (DSRecruitmentFlyerParents or attachment: DSRecruitmentFlyerStaff).

Individuals interested in participating in discussion sessions will contact the research team to enroll.

Within approximately 2 business days of contacting research team, interested individuals will be:

a. Emailed project description (ProjectOverview)
b. Emailed consent cover page and consent information sheet (DSConsentCoverPage and DSConsentInformationForm)

Within approximately 1-2 business days after initial contact the research team will follow-up with a phone call (DSInfoPhoneScript)

a) If agree to participate, research team will follow up with discussion session information email and/or phone call (DSConfirmation and DSDemographicForm)
b) Reminders will be sent between 2-7 days prior to the discussion session date via email and/or phone

Participants that attend discussion sessions will provide verbal consent at the beginning of the session. Discussion sessions will be conducted virtually (via Zoom) with approximately 1-15 participants. Sessions will be led by at least one facilitator and at least one note taker. Facilitators will use a guide to assist with facilitating the discussion session: (DSGuide).

Message Development. The Health Communication Research Laboratory (HCRL) will use an iterative process of environmental scan and pre-testing of initial message concepts to translate well-received concepts into prototype messages. We will rely heavily on input from the FGs and our CAB, which has already emphasized the importance of trust. The HCRL will conduct an environmental scan of communication messages about SARS-CoV-2 testing, including headlines, taglines, and calls to action designed for a variety of audiences, further differentiated for delivery on specific platforms (e.g., policy briefs, report, social media, schools, etc.). Results of this environmental scan, as well as conversations with our CAB and data collected in the FGs by the Brown School Evaluation Center, will be used to create an initial set of 30 messages focused on promoting SARS-CoV-2 testing. Messages will be pre-tested among a variety of audiences, including the CAB and key stakeholders. Pre-testing identifies messages that are truthful, interesting, original, informative, clear and easy to understand, emotionally evocative, memorable, stimulate self-reflection and are perceived by audiences as personally relevant.[37,38] Participants will evaluate these messages through cognitive response interviews, paraphrase tasks, thinking exercises and thought listing,[39] and their reactions and responses will be captured for analysis (described below). These methods not only assess participants' understanding of content, but also capture the natural language they use to express questions about and barriers to frequent SARS-CoV-2 testing, identify points of confusion, and reveal how this information is processed cognitively, emotionally and for personal relevance.

Participants (n=15) will be key influencers or stakeholders such as parents, teachers, and school administrators, and we will recruit at least 5 participants from each subgroup. Pre-testing will be iterative in blocks of five participants, as recommended for user-centered design.[40,41] After each block, content is revised before the next iteration of testing. The Brown School Evaluation Center will assist in recruitment and participants will receive a $20 gift card for their time.

AIM 1.2. Evaluate the impact of implementation strategies on the uptake of weekly SARS-CoV-2 testing in children with IDD and school staff through a cluster randomized adaptive clinical trial.

Clinical Trial Data Collection. Demographic data will be collected on each participant who consents to weekly SARS-CoV-2 testing in the cluster randomized adaptive trial and stored in a REDCap database. This will include age, gender, race/ethnicity, insurance status and type, medical conditions, number of individuals in the home, income and educational level, type of work, and all county-level reporting data required for the SARS-CoV-2 diagnostic test. The number of missed days of school or work will be recorded as well as the reason for the absence. Additionally, if a student or staff is infected with SARS-CoV-2, the following data will be obtained: signs and symptoms, duration of symptoms, possible exposure(s) and location of exposure, contacts of the student or teacher, and outcome of the infection (e.g. resolution, hospitalization, complications, and death). We will also collect the mitigation strategies (e.g. social distancing, school schedule, PPE use by staff, etc.) being employed at each school and whether masks are provided and worn by students participating in the study.

Primary Outcome. Adoption of diagnostic testing for each participant will be the primary outcome for this study. Adoption, a common implementation outcome, will be defined as the ratio of the total number of tests to the number of weeks during the study period. For example, in Phase 1 the analysis will occur at 20 weeks.

Secondary Outcomes. Acceptability, feasibility and appropriateness will be secondary outcomes assessed for each strategy through validated surveys prior to each randomization and at the conclusion of the study.[51] Secondary clinical outcomes will include the number of missed school or work days, the percentage of students or staff who test positive for SARS-CoV-2, and number of possible SARS-CoV-2 transmission events per student or staff within the school setting.

AIM 2: Assess the local and national perspectives among parents/guardians of children with IDD and school staff regarding the impact of COVID-19 and the role of frequent SARS-CoV-2 testing.

As testing capacity expands locally and nationally, the next major roadblock is gaining widespread acceptance of testing so that even the most vulnerable students can resume access to special education and related services. We will take two separate approaches to gain broad insight into the stakeholders' perceptions of the pandemic, the need for and barriers to frequent testing, and attitudes toward future COVID-19 interventions, such as vaccination. First, to understand the conceptual and causal relationships that parents attribute to issues surrounding SARS-CoV-2 testing strategies, we will utilize Fuzzy Cognitive Mapping (FCM) to understand how stakeholders make complex decisions. Custom IDD surveys along with standard PhenX surveys will also be deployed through email and captured via REDCap. Second, we will deploy national surveys through AUCD and additional community partners. These nationwide surveys will allow us to assess geographical, sociodemographic, and racial differences in attitudes that will inform the feasibility and sustainability of strategies to resume safe special education and related services for children with IDD, including vaccination strategies for this vulnerable population.

Recruitment and Consent for AIM 2.

The team will share recruitment flyers for focus groups through multiple methods (e.g., email, electronic platforms, meetings) with parents/caregivers (KKI and KC family recruit flyer B).

Individuals interested in participating in focus groups will contact the research team to enroll. Informed consent will be sent via email/mail, if preferred by the interested potential participant for review prior to the focus group (informed consent KKI and KC).

Participants that attend focus groups will provide verbal consent at the beginning of the session after the consent has been reviewed with all. Focus groups will be conducted virtually (via Zoom) with approximately 1-10 participants. Facilitators will use a guide to assist with facilitating the focus groups. (Fuzzy cognitive mapping script).

Participants will receive a $20 gift card for their time.

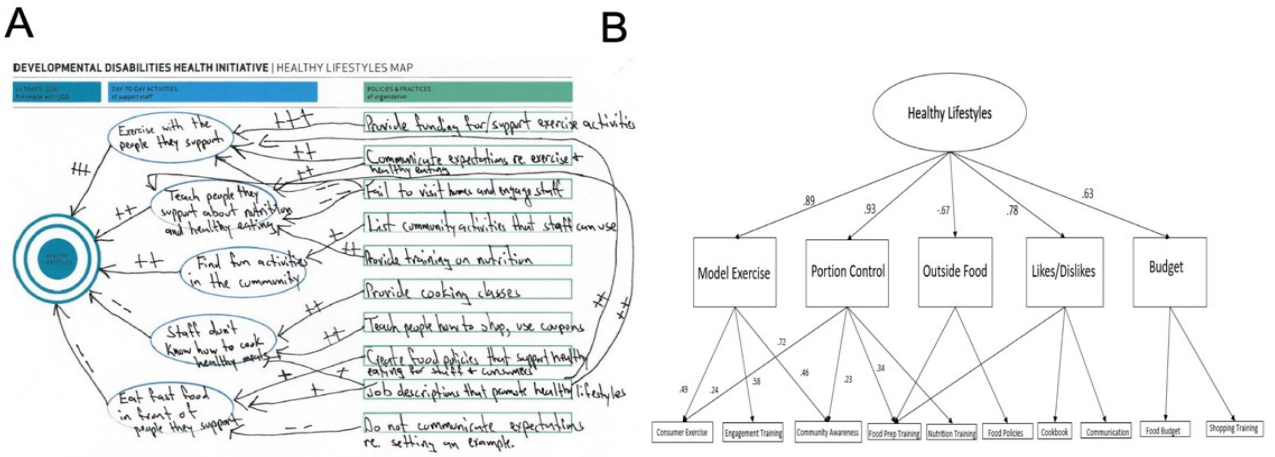


Figure 4: Fuzzy Cognitive Mapping (FCM). A. Individual hand written FCM. B. Synthesized and modeled FCM.

Fuzzy Cognitive Mapping to Understand Decision-Making. FCM is a reliable knowledge-based model that facilitates democratic discourse to understand how stakeholders make decisions.[52-54] We have demonstrated its effectiveness in our prior study of veterans' participation in higher education.[55] This methodology is highly participatory and fosters social learning among participants. For the current project, we anticipate that FCM will generate community-specific, testable strategies to address factors impacting the uptake and effectiveness of SARS-CoV-2 testing. The FCM sessions will take place with 10 groups of 10 parents/guardians (100 total). The sessions will be organized at the community level in partnership with the six SSD of St Louis County schools and the 4 Kennedy Krieger School Programs schools. Leadership from each school will work with our team to recruit parents/guardians who are representative of the gender, ethnic/racial, and social/economic diversity in the school. FCM sessions will take place in an online Zoom format using a program called Draw Chat and all sessions will be recorded. This whiteboard program allows collaborators to work on a document in real time via audio and video conference systems. Each participant will have their own template to draw their own maps (**Figure 4A**). The UMKC UCEDD has extensive experience in leading FCM sessions and will provide written instructions, a tutorial, and will work with the MCDD team to implement this at KKI. In each FCM session, participants will be asked to list up to five important facilitators and five barriers to COVID-19 testing in children with IDD. Participants will apply directional (arrows) and weighted (e.g. negative to positive) connections that quantify the relationships between the items on their maps. A facilitated discussion of the ideas presented on the maps will then take place (Petri & Corwin, 2015). A minimum of three members of the research team will be present for each FCM session.

National Surveys to Assess COVID-19 Impact and Mitigation Strategies. Because there are no accepted measures for understanding parent or school staff concerns around COVID-19 or any IDD-specific measures regarding SARS-CoV-2 testing and vaccination, a series of surveys will be developed to evaluate stakeholders' perceptions and impacts of the COVID-19 pandemic, acceptability of COVID-19 testing, perceptions of risk and appropriate strategies to mitigate risk, and acceptability of and attitudes toward COVID-19 vaccinations. The team at KKI has substantive and methodological expertise with survey-based research, including assessing the impact of COVID-19 on mental health.[59,60] Custom surveys will be deployed across two stakeholder groups: parenst/guardians and school staff.

The initial local and national survey will be informed by the FGs that take place prior to onset of the trial in Aim 1. For parents, we expect items to assess domains such as: 1) trust in the healthcare systems, 2) transportation, 3) beliefs about COVID-19 testing and vaccines, and 4) access to social and community resources in the event of exposure and quarantine. For school staff, we expect items

to address: 1) concerns about infection; 2) conditions that facilitate and/or inhibit testing; 3) perceptions of hybrid educational models; and 4) trust in educational leadership. Both surveys will build on extant resource that are not currently tailored to the IDD population (see below for details).

After baseline data from our survey is collected, we will conduct preliminary psychometric analyses to revise our custom measure. Both reliability (Cronbach's α) and validity (correlations between our novel measure and standard COVID-19 measures, as listed below) will be evaluated. We will also integrate results from the FCM to ensure items comprehensively cover parental concerns. Ultimately, this effort will yield the first, IDD-specific measure that identifies barriers and facilitators to COVID-19 testing and vaccination. This revised measure will be launched at the end of the trial across our national network of partners (**Table 3**). This national survey will allow identification of regional populations that may face major barriers to testing or vaccination.

Beyond our custom survey, we will also use several NIH-recommended parent-report surveys from the PhenX Toolkit during each survey administration. This includes the *Psychological Stress Associated with the COVID-19 Crisis Scale*. This measure includes standard demographics and social determinants of health, the Perceived Stress Scale, exposure to COVID-19, impacts of COVID on daily life and work as well as disruption to sleep and exercise. We will also deploy the *COVID impact questionnaires* developed as part of the NIH Director's Environmental Influences on Children's Health Outcomes (ECHO) initiative, which addresses multiple research questions in school-age children and their parents/guardians. These specific ECHO questionnaires assess the impact of COVID-19 on child and family life. In total, these external surveys were selected to ensure we are following recommended measurement protocols, promote future data sharing efforts (i.e. through the CDCC), and validate our novel measure.

Table 3: Community Partners Who Will Distribute IDD Focused COVID-19 Survey

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

Contingency Plans for the Entire Project

If in-person school is suspended at the SSD schools, we will partner with a local community-based health organization (FQHC), Affinia Healthcare. Affinia offers school-based health care services at Normandy High School, Lift for Life Academy, and Confluence Aspire Academy, as well as the Flance Early Learning Center which also serve a large number of children with IDD. Affinia provides care to

>43,000 people annually, 88% of whom have an income below 100% of the federal poverty level and 67% of whom are African American. Affinia has provided no-cost SARS-CoV-2 tests to more than 10,000 individuals from underserved communities in St. Louis that have been devastated by COVID-19. Even if schools are closed at the beginning of the school year, access to repeated testing through our research study may be sufficient for school leadership to resume services for at least some students with IDD at either SSD or Affinia-affiliated schools.

We envision POC testing within the school as being a long-term sustainable solution to mitigate the effects of the COVID-19 pandemic, with utility either as a screening tool for asymptomatic children to determine prevalence within a school, or as a diagnostic test that can be performed by a school nurse for mildly symptomatic children with COVID-19-like symptoms. We expect the POC test to cost <$5 per test which makes it feasible in the school setting, provided that our study demonstrates acceptability of school-based testing by both parents/guardians and school staff.

E Study Procedures

This research study will occur at six schools that are a part of the Special School Districts in St. Louis, MO that serve children with intellectual and developmental disabilities (IDD). Additionally, surveys, focus groups, and fuzzy cognitive mapping sessions will be conducted at these six schools and at schools within the Kennedy Krieger School Programs in Baltimore, MD. Finally, a national survey will be administered to families, teachers, and staff of the 67 University Centers for Excellence in Developmental Disabilities (UCEDD) which is sponsored by the Association of University Centers for Disability (AUCD).

The primary goal of this project is to identify the best messaging and implementation strategies to maximize SARS-CoV-2 testing for children with IDD and their teachers to help ensure a safe school environment. Additionally, we will understand nationally the perceptions of COVID-19 and identify facilitators and barriers to help with the adoption of testing in other parts of the US and the necessary strategies to address other mitigation strategies including vaccination. The first aim will involve focus groups of parents/guardians, teachers, and school staff to identify the barriers and facilitators of testing, impressions of COVID-19, and best messages and implementation strategies for improving testing and vaccinations. A formal process for developing the message will be performed using focus group data and involving key stakeholders to test the messages. Additionally, in the first aim we will conduct a cluster randomized adaptive clinical trial. The six schools will be randomized initially to either a general message or focused message to promote the adoption of weekly SARS-CoV-2 testing by the students and teachers. A second randomization will occur for the 6 schools and phase 2 of the study will start at 7 months. In the second phase, each school will be randomized to either the best message determined from phase 1 analysis or the best message plus an augmented strategy.

For aim 1, focus groups will be conducted and recorded. Participants will provide consent prior to participating. The recorded focus groups will be transcribed and the analyzed using NVIVO. The community advisory board and key stakeholders will pre-test the general and focus messages. Following the development of the messaging which will also be informed by FCM and the local surveys done in aim 2, each school will be randomized to either the general of focused message. Testing will commence and adoption of the weekly testing by the students and teachers will be assessed through a REDCap database. Once consented, testing will be completed weekly unless the student or teacher has tested positive for SARS-CoV-2 in the previously 12 weeks. After 12 weeks has past since the student or teacher's most recent positive SARS-CoV-2 test they will begin weekly testing. When a student or teacher tests positive for SARS-CoV-2 during weekly testing they will then wait 12 weeks to continue their weekly testing. To assess transmission in schools a REDCap

database will be used to examine the percentage of students or staff who test positive for SARS-CoV-2 each week, prevalence and incidence of COVID-19 within the school, create an epi curve, and obtain symptomology. Research coordinators will return results to parent/guardian using standardized algorithms for both positive and negative test results developed by Dr. Newland that provide education on appropriate responses including criteria for immediately contacting the appropriate health department, referral for medical monitoring and care, as well as further referrals for social supports as needed (e.g. food aid). Dr. Newland will coordinate with the health department and the school medical staff the appropriate contact tracing and quarantining that is required.

Each school will be randomized 1:1 at the beginning of the study to one of two messaging strategies (Phase 1) that are informed by FGs involving parent/guardians and staff. Messaging strategies will include either (a) a general message that is inexpensive and easy to disseminate or (b) focused message that addresses specific concerns of different groups. Messages may target groups being tested (staff versus students) or sociodemographic differences between schools depending on the FG input. Analysis will occur after 5 months of weekly testing to determine which of the two initial messages resulted in the highest percentage of eligible testing to be performed. After the testing begins, additional FGs will be conducted to assess factors that promote or discourage testing. After 6 months, each school will be randomized a second time to either the best initial messaging strategy (general v. focused) as determined by the analysis or the best message plus an augmented messaging or implementation strategy (Phase 2) to further promote the adoption of testing. Additional messaging could be the type of person delivering the message or the type of content (factual versus narrative). Other implementation strategies will be informed by the barriers and facilitators identified based on the CFIR domains and results of focus groups and surveys (Aim 2).

For Aim 2, FCM sessions will occur by zoom with 10 groups of 10 parents that are from the St. Louis Special School District schools and the Kennedy Krieger School Program. The program Draw map will be utilized in real time to help create the map and the audio from these session will be recorded. In each FCM session, participants will be asked to list up to five important facilitators and five barriers to COVID-19 testing in children with IDD. Participants will apply directional (arrows) and weighted (e.g. negative to positive) connections that quantify the relationships between the items on their maps. A facilitated discussion of the ideas presented on the maps will then take place (Petri & Corwin, 2015). A minimum of three members of the research team will be present for each FCM session. Qualitative analysis with coding and network mapping are then performed followed by confirmatory factor analysis.

Additionally, in Aim 2 local and national surveys will be constructed and administered. For parents, we expect items to assess domains like: 1) trust in the healthcare systems, 2) transportation, 3) beliefs about COVID-19 testing and vaccines, and d) access to social and community resources in the event of exposure and quarantine. For school staff, we expect items to address: 1) concerns about infection; 2) conditions that facilitate and/or inhibit testing; 3) perceptions of hybrid educational models; and d) trust in educational leadership. Both surveys will build on extant resource that are not currently tailored to the IDD population (see below for details).

The second aim involves FCM and the administration of local and national surveys. FCM will involve in-person sessions at the 6 schools in aim 1 and Kennedy Krieger Schools. These sessions will help identify important factors that will support SARS-CoV-2 testing and other mitigation strategies including vaccinations. Since no accepted measures have been developed for understanding parent and school staff concerns for children with IDD around COVID-19, local and national surveys will be conducted. Custom surveys will be deployed across two stakeholder groups: parent/guardians and school staff. We will administer the survey at baseline and during the trial across school settings (St. Louis and Baltimore). A national survey will also be administered across the UCEDDs. Psychometric analysis will be performed to help identify the questions for a national survey at the end of the study period. In addition to the custom surveys, NIH recommended parent-report surveys from the PhenX

Toolkit will be used. The surveys to be used include the *Psychological Stress Associated with the COVID-19 Crisis Scale* and *COVID impact questionnaires.*

After baseline data from our survey is collected, we will conduct preliminary psychometric analyses to revise our custom measure. Both reliability (Cronbach's α) and validity (correlations between our novel measure and standard COVID-19 measures, as listed above) will be evaluated. We will also integrate results from the FCM to ensure items comprehensively cover concerns parental concerns. Ultimately, this effort will result in the first, IDD-specific measure that identifies barriers and facilitators to COVID-19 testing and vaccination. This revised measure will be launched at the end of the trial across our national network of partners (Table 3). This national survey will allow identification of regional populations that may face major barriers to testing or vaccination.

Beyond our custom survey, we will also use several NIH-recommended parent-report surveys from the PhenX Toolkit during each survey administration. This includes the Psychological Stress Associated with the COVID-19 Crisis Scale. This measure includes standard demographics and social determinants of health, the Perceived Stress Scale, exposure to COVID-19, impacts of COVID on daily life and work as well as disruption to sleep and exercise. We will also deploy the COVID impact questionnaires developed as part of the NIH Office of the Director Environmental Influences on Children's Health Outcomes (ECHO) initiative, which was developed for school age children and their parents/guardians. This survey assesses the impact of COVID-19 on child and family life. These broad surveys were selected to ensure we are following recommended measurement protocols, promote future data sharing efforts, and validate our novel measure.

F Statistical Plan

AIM 1.1: Develop messaging and implementation strategies for parents/guardians and staff based on the local identification of facilitators and barriers to weekly SARS-CoV-2 testing in a school setting.

Focus Group Analysis. A directed thematic analysis of the qualitative data will be conducted.[36] Transcripts will be independently coded by the qualitative leads and research assistants. Coders will discuss codes to resolve discrepancies and analyses will be based on consensus codes. NVivo will be used for the analysis.

Message Development Analysis. Qualitative analysis methods will be used to identify specific content revisions. Audio recordings of pre-testing interviews will be transcribed, reviewed for accuracy, and analyzed using a hybrid deductive/inductive thematic approach.[42,43] A *priori* codes will come from health communication and behavior theories.[44-46] Emergent codes will be added after reviewing representative transcripts.[47] The HCRL will code transcripts and results will be discussed with the larger study team to challenge perceptions and explore potential negative responses.[48-50] At the conclusion of the pre-testing activities and qualitative analysis, the HCRL will use these findings to create prototype messages to support SARS-CoV-2 testing.

AIM 1.2. Evaluate the impact of implementation strategies on the uptake of weekly SARS-CoV-2 testing in children with IDD and school staff through a cluster randomized adaptive clinical trial.

Sample size calculation. Assuming the percentage of testing in the group of general message (P0) is 0.60 and the intracluster correlation (ICC) is 0.05, 64 participants per school with 3 schools per group will achieve 80% power to detect a 25% difference between two groups when the percentage of

testing in the group of focused message (P1) is 0.85 using the two-sided Z-Test at the significance level of 5%.

Analyses. The generalized estimating equation (GEE) model with appropriate link function (e.g. identity for primary outcome, logit for test positive) will be used to analyze the cluster randomized trial data at the end of phase 1 and again at the end of phase 2, in which the correlation among the participants within each school need to be considered. The autoregressive of first order as working correlation structure will be used and the participants with missing values will be excluded from GEE analysis. The GEE model will include the group indicator and other factors including race/ethnicity, insurance state, age, gender, underlying diagnoses. Least square means for each outcome per group will be estimated and the standard errors will be calculated with the use of GEE sandwich method when accounting for within-school correlation. All analyses will be conducted using SAS at the two-sided 5% significance level.

AIM 2: Assess the local and national perspectives among parents/guardians of children with IDD and school staff regarding the impact of COVID-19 and the role of frequent SARS-CoV-2 testing.

Fuzzy Cognitive Mapping (FCM) to Understand Decision-Making.

Analysis. Using the added directional and weighted relationships, the maps from multiple responders can be integrated to show a dynamic display of direct and indirect effects. An item level analysis will be used to code the mapping data.[56] An adjacency matrix will then be created for each map representing a network-type diagram or graph, directed (with arrows) or non-directed (without arrows). We use the directionality of the connecting arrows and the strength score assigned to each connection to develop the adjacency matrix and merge individual matrices into one data set for export to R for the final analysis. Confirmatory factor analysis (CFA) will be employed to examine latent constructs within the mapping data (**Figure 4B**). As a part of the structural equation modeling family, CFA plays an essential role in model validation.[57,58] CFA will allow us understand the relationships between the mapping concepts and the underlying factor structure supporting SARS-CoV-2 testing strategies among children with IDD. The data will also be analyzed using FCMapper that aggregates maps and uses the values of weight and direction of the relationships between major and minor factors to provide if-then scenarios for hypothesis generating and simulated testing.

The informatics team at WU will deploy the electronic surveys via REDCap. KKI will assist with survey development and dissemination. Best practices will be used throughout to ensure responses are valid. Survey data will be analyzed using a series of descriptive, bivariate, and multivariate methods to understand unadjusted and adjusted associations between beliefs about testing and vaccines, COVID-19 related stressors, and Aim 1 outcomes.

Data Management.

All data, including FG transcriptions, will be managed utilizing REDCap and stored on secure servers.

G Study Monitoring

Study Monitoring Plan

The proposed study will evaluate the impact of messaging and potentially other implementation strategies to maximize the adoption of frequent SARS-CoV-2 testing for students with IDD and their teachers. Frequent testing has been a recommended strategy by experts to help prevent outbreaks of COVID-19. Performing the test does not provide any risk to the participants, as it is saliva-based. For

this reason, a Data and Safety Monitoring Plan, rather than a formal board is appropriate. Monitors for this study will include the co-PIs, Drs. Gurnett and Newland, independent monitors, Drs. David Hunstad (Division Chief of Pediatric Infectious Diseases) and Greg Storch (Pediatric ID physician and virologist), and the trial statistician, Esther Lu, PhD. The co-PIs will monitor the number of SARS-CoV-2 tests being obtained at the schools, rate of SARS-CoV-2 positivity in all schools, and the number of potential transmission events within the schools on a continuous basis and is responsible for providing the monitors with new safety information relevant to the study. This group will meet quarterly during the testing phase of the study and will review interim and cumulative data for the measures mentioned. Interim reports will be developed for these meetings by the trial statistician. Ad hoc meetings may occur at the request of the monitors or the WU HRPO.

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Data Points

Focus groups and the FCM sessions will be recorded and transcribed. Local and national surveys will be developed and administered using REDCap.

For the **students/parents/guardians and teachers** in the randomized clustered adaptive clinical trial we will collect:
Age
Gender
Race/ethnicity
Insurance status and type
Medical conditions
Number of individuals in the home
Income and educational level of parent/guardians or teachers
Type of work
County-level reporting data required for the SARS-CoV-2 diagnostic test

Information collected from the schools
Mitigation strategies utilized (e.g. social distancing, school schedule, PPE use by staff, etc.)
Whether masks are provided and worn by students participating in the study.
Number of days of missed school work
Reason for missed days
Percentage of students and teachers that are SARS-CoV-2 positive
Number of SARS-CoV-2 transmission events by the students or teachers.

Student or staff is infected with SARS-CoV-2, the following data will be obtained:
Signs and symptoms
Duration of symptoms
Possible exposure(s) and location of exposure
Contacts of the student or teacher
Outcome of the infection (e.g. resolution, hospitalization, complications, and death)