Title: Year 2 ReSET Aim 1b: Restarting Safe Education and Testing for Children with Medical Complexity - SARS-CoV-2 testing in school with children and staff

Short Title: Year 2 ReSET Aim 1 (school cohort)
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BACKGROUND INFORMATION

The Coronavirus Disease 2019 (COVID-19), caused by the SARS-CoV-2 virus, is a worldwide pandemic that has resulted in large-scale quarantines in cities, states, and countries throughout the world. SARS-CoV-2 is a respiratory virus that is most commonly spread via contact with infective respiratory droplets and aerosols produced by coughing, sneezing, talking, and singing.

Children with medical complexity (CMC), i.e., children with multiple severe chronic conditions, high resource use, severe functional limitations, and substantial family-identified service needs, are a *medically vulnerable population* for the development of severe COVID-19. An illustrative CMC is born months premature with quadriplegic cerebral palsy, seizures, feeding and breathing tubes, 12 medications, and 8 specialists. Our research illustrates CMC as *a socially vulnerable population* in the US with over half living in poverty, 17% in rundown housing, and 14% food insecure - all substantially higher than non-CMC. CMC are also disproportionately from communities of color. CMC account for 1-5% of children, but > 1/3rd total child health spending, the majority being for hospital care. Medical fragility puts CMC at high risk for severe COVID-19 disease, including hospitalization and death.

Deciding to send CMC to school poses a major dilemma to families wanting to minimize severe COVID-19 risk. CMC require a mean of 52 hours/week for direct care, and even three feet of physical distancing is not possible with most daily needs, e.g., enteral tube nutrition and medications, respiratory medications, diapering/toileting, and direct mobility assistance (pushing a wheelchair). From our clinical experience, many families are opting to keep CMC out of school due to these concerns; however, the proportion of CMC attending school and the factors influencing parent decisions about return to school are unknown. Recent data from the Madison Metropolitan School District, with a 95% response rate, reported only 64% of parents of children in special education plan in-person attendance, with substantial variation across schools, and lower rates among underrepresented racial, ethnic, and income groups.

School personnel also face risks when CMC attend school. The daily number of staff exposures per CMC can be high because most CMC depend on others for every aspect of school attendance, e.g., transportation to, from, and within the school, medical care and therapy, meals, toileting, and instruction itself. Inability to maintain physical distancing during care places staff, CMC, and their families at risk. Moreover, wearing masks may be difficult or impossible for some CMC, and care can include aerosol-generating procedures that increase the risk for SARS-CoV-2 transmission (e.g., tracheostomy care, nebulizer treatments, suctioning, and positive pressure ventilation). Data from North Carolina suggests most secondary transmission at schools was from breaks in mask compliance, a high proportion of which came from children with special healthcare needs for whom mask compliance can be as low as 50% for children outside mainstream classes.

Despite these challenges, achieving in-person school attendance is critical for CMC. Compared to non-CMC, academic and social development for most CMC hinges on being at school. Severe intellectual and developmental disability impairs one's ability to engage with online platforms. Health-promoting services delivered at school, e.g., physical, occupational, and speech therapy, are likely less effective when delivered virtually. Parents of CMC, already disproportionately unemployed due to their child's care needs, experience added employment strain when their child is out of school.

In the Madison area, there are no schools catering exclusively to children with medical complexity. Moreover, researchers cannot learn about safe school attendance for children with medical complexity without learning about the whole integrated class (containing children with and without medical conditions). For these reasons, investigators are collaborating on this study with Waisman Early Childhood Program (WECP). WECP, housed within UW-Madison's child development center, is an ideal place to gain these early insights. It's a state-licensed program contracted with the Madison Metropolitan School District to provide year-round preschool in an inclusive setting for children with developmental disabilities. Up to 30% of WECP's students have diagnosed special needs, with individualized educational plans and physical, speech and occupational therapy embedded in a team-teaching curriculum. Learning from this population, and all children, will provide useful information about children with special healthcare needs and CMC.

STUDY OBJECTIVE

The study objective is to increase the safe return to school for CMC by 1) evaluating the feasibility of in-home COVID-19 testing strategies and 2) identifying parent perceptions of testing and school attendance. A related study (ReSET Aim 1a) will evaluate the same factors in home-based testing strategies in CMC exclusively.

STUDY DESIGN

This is a single site study taking place over 12 months (June 2022-June 2023) and involving approximately (50) families (parents and children) who were previously enrolled in IRB #2021-0488. Year 2 study design and procedures are similar to the activities in Year 1, the primary differences being 1) no in-school testing, 2) no study-provided PCR testing, and 3) no participation by school staff. New families who hear of the study from other families or school staff may contact us for more information/enrollment, but there are no plans to actively advertise/recruit new families.

COVID-19 TESTING DEVICE

BinaxNOW Rapid Antigen System (Abbott) is a point-of-care, lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs. Internal controls are built into the testing system and results are available in 15 minutes. To collect a nasal swab sample, the entire absorbent tip of the swab (usually ½ to ¾ inch) is carefully inserted into both nostrils. Swabs are then placed in the supplied card and extraction reagent is added. After 15 minutes, the results are read as the presence or absence of a blue line as compared to the control line. Test kits will be stored in study offices and shipped to families by UPS or given in person if the family is in clinic or hospital. The test procedure itself (swabbing the nose) poses no significant safety risk. Subjects were trained on the proper administration of the test during year 1 of the study.

Abbott's ABT BinaxNOW COVID-19 Ag Self Test is covered under the FDA's Emergency Use Authorization (EUA) for over-the-counter, non-prescription, and symptomatic or asymptomatic use. The test can be used with children two years and older with sample collection performed by an adult, and can be self-administered for all people aged 15 years or more. In this study, adult caregivers will be performing the tests on their child. Use of the BinaxNOW COVID-19 Ag Self Test in this study is consistent with the FDA's EUA recommendations.

The results of BinaxNOW tests performed at home will NOT be reported to the Wisconsin Department of Health Services as this is not required per state statutes §252.05. However, any confirmatory PCR results triggered by in-home study testing will be reported to the Wisconsin Department of Health Services using the Wisconsin Electronic Disease Surveillance System (WEDSS) by the party who performed the PCR. WEDSS is a secure, web-based system designed to facilitate reporting, investigation, and surveillance of communicable diseases in Wisconsin. It is designed for public health staff, infection control practitioners, clinical laboratories, clinics, and other disease reporters.

POTENTIAL RISKS AND BENEFITS

Potential Risks

Dislike of the nasal testing procedure. There is a small risk that some caregivers and children may find the nasal swab testing procedure unpleasant, burdensome, and/or anxiety-provoking. To address this issue, participants will be reminded that study participation is completely voluntary and they may choose to refuse nasal testing. If nasal testing is refused, participants may choose to stay in study but not participate in testing. Additionally, participants may consent to all or a portion of the study (e.g., weekly study staff contact and surveys but not testing, and vice versa).

The PCR confirmatory test (performed following a positive BinaxNOW system test in a clinic or hospital) is typically done with a swab that goes deep into the nostril. The child may experience discomfort during this procedure but the test only takes a few seconds.

Distress if the test is positive. Some participants may become distressed upon hearing their child or family member has tested positive for the virus. The study team will guide families in finding the most appropriate plan of care in the event

they become ill. Likewise, the study team will suggest where family members can seek care for COVID related-illness. They will also give guidance on how best to avoid spreading the illness to other members of your household and the community.

Ignoring COVID precautions with negative results. It is possible for the nasal swab test to give a false negative result. This may lead the family to stop following measures they would otherwise take to protect themselves from COVID-19 (i.e., frequent handwashing, mask-wearing, or social distancing), thus making them more likely to be exposed to COVID-19 or to expose someone else. Study staff will remind participants of the importance of following public health recommendations no matter what the results of the test show.

Distress experienced during or after completing research surveys/interviews. Some participants may find the completion of study surveys distressing. To protect against this distress, participants will be made aware that participation in the research study is entirely optional, has no effect on their children's medical care, that they may choose not to answer certain questions, and that they may end their participation at any time. If a participant expresses distress, the study staff will notify Dr. Coller. Participants will also be given the phone number (in the informed consent process) to contact Dr. Coller.

Detection of previously undisclosed dangerous or potentially dangerous situations or occurrences. It is possible that families may disclose information to our study staff that indicates they have been or may be subject to dangerous situations. Situations or occurrences that might be disclosed to or observed by the study staff and would require the staff to complete an incident report include but are not limited to child abuse, imminent threat to self, and imminent threat to others (even though our questionnaires will not specifically ask about these issues). General procedures we will take in these situations follow. Specifically, any suspected child abuse must immediately be reported to the Wisconsin Department of Child Protective Services (CPS) and, if any immediate danger is possible to the child, family or another individual, to the local Police Department. The social worker on call will be notified immediately if a participant discloses suicidal ideation or domestic violence. In any adverse situation possibly related to the research study, Dr. Coller and the IRB will also be notified.

Accidental disclosure of confidential material. It is possible that despite careful procedures to protect private information, there could be accidental disclosure of confidential information. To protect against accidental disclosure, study staff will store all electronic data on UW-maintained servers and UW-issued computers; paper data will be kept in locked cabinets in locked staff offices with access restricted to authorized study staff. Data containing identifiable information will be deidentified as soon as possible, and staff will use ID numbers on study materials when possible. In the event of a breach of confidentiality, we will notify the participant, Dr. Coller, and the IRB.

Potential Benefits
The results of the study may help researchers advance their understanding of in-home testing strategies for children with medical complexity.

STUDY RECRUITMENT AND WITHDRAWAL

Subject Identification
Approximately 50 families (parent and child) who participated in the first year of this study will be invited to participate in Year 2. Families new to the school or who initially decline participation and then reconsider may join at any time.

Subject Inclusion Criteria
In order to be eligible to participate in this study, children, parents and staff must meet the following criteria:

1. Parents and staff must be at least 18 years of age.
2. Parents and staff must be proficient in English.
3. Parents and staff must have access to a web-enabled device (phone, tablet, or computer).
4. Staff, parent and child must be residents of Wisconsin.

5. Child must be between 2 and 6 years of age and enrolled at WECP for the 2022 and/or 2023 school year.

Siblings who meet all inclusion criteria may be enrolled in the study. Parent will be asked to complete surveys for each child and will receive a stipend for each child. The study includes children of all developmental abilities, including those with special healthcare needs.

Subject Exclusion Criteria
Failure to meet all inclusion criteria.

Subject Recruitment
Families currently participating in the study will be sent a memo by email inviting them to participate in Year 2. The memo will contain a summary of the changes from Year 1 to Year 2, as well as the informed consent form (as an attached document). Parents will be invited to contact study staff with any questions. Families who do not respond to the email invitation to either join or decline the study will be contacted to learn of their decision.

New families who contact the study team through referral (by other families or school) will undergo a phone screening. If deemed eligible, an in-person or phone enrollment visit will be arranged.

Subject Withdrawal
Subjects are free to withdraw from the study at any time. Failure or refusal to participate in COVID-19 testing or the quarterly surveys will not result in study termination. As students matriculate or graduate from WECP, we will respectively enroll or disenroll them from the study.

STUDY ACTIVITIES

Phone Screening/Enrollment Visits
Parents/staff interested in the study will contact study staff for more information. The study will be explained in greater detail and staff will review eligibility criteria. Enrollment visits will be scheduled in-person or by phone per parent/staff preference. If a parent indicates their child has the capacity to give meaningful assent, an in-person enrollment visit will be arranged so that child has the opportunity to ask questions directly of study staff as well as have an in-person demonstration of the test kits that will be used in the study. This visit will be arranged at the beginning or end of the child's school day (e.g., drop off or pick up time).

Consent and Assent Process
Consent may be provided via DocuSign or by photographing and emailing the signed form. Caregivers may also choose to provide signed consent by meeting in-person at WECP. DocuSign (using the FDA Part 11 compliant functionality) will be used for those wishing to provide sign electronically. The research manager has obtained DocuSign access.

Given the very young age range and varying developmental capacities of the children involved in this study, child subjects will likely lack the capacity to give meaningful assent. Parent consent will be sought and explicit child assent will not be required. For children who are capable of discussing and understanding the study: 1) the child will be present during the in-person or remote consent/assent discussion, 2) staff will use the assent form as a guidance document for the oral description of the study, 3) the child will be given the opportunity to ask questions about the study, 4) oral assent will be sought and dissent will be respected.

In-home Testing and Weekly Testing Log
Families will be provided with BinaxNOW Self-Test kits for in-home use and instructions on how to use. Parents will be told that they may use the kits when their child is either symptomatic or when they have had a known exposure to someone with COVID.

Caregivers will be given the following instruction with regard to testing:

- If your child is symptomatic and the initial test is negative, test again using a Binax NOW test in 48 hours over 3 days. Report the test results in your weekly log.

- If your child is not symptomatic and the initial test is negative, test 2 more times using Binax NOW test kits at least 48 hours apart over 5 days. Report the test results in your weekly log.

- If your child is symptomatic and the initial test is positive, no need to repeat Binax Now test. Arrange to obtain a PCR test within 48 hours to confirm whether the in-home test was accurate. Report the test results on your weekly log.

- If your child is not symptomatic and the initial test is positive, no need to repeat Binax NOW testing. Arrange to obtain a PCR test within 48 hours to confirm whether the in-home test was accurate. Report the test results on your weekly log.

While false negative tests are possible with asymptomatic individuals, there will be no change in standard mitigation measures based on the test results (mandatory masks in school, social distancing, hand hygiene, etc.). If testing produces a positive result, the caregiver will be instructed to contact the study team immediately and then obtain a PCR (polymerase chain reaction) test within 48 hours. If needed, the study staff will assist the caregiver in making arrangements for this test. Study staff will not be performing PCRs. If the PCR returns as positive, the caregiver will be instructed to keep the child at home per public health guidelines and pause in-home testing for 21 days. In the event of a positive PCR, the study team will recommend that the participant not perform another PCR for 90 days. Study staff will be in close communication with Dr. Coller and Dr. DeMuri regarding families who test positive and/or are symptomatic.

In-home testing results will not be reported to school administration or state health agencies by study staff. Parents will be encouraged to share positive test results with the school as well as abide by CDC guidelines to prevent the spread of COVID-19, such as mask wearing, hand-washing, social distancing and quarantines.

Quarterly surveys
Approximately every 3 months (mon 3, mon 6, mon 9 and study end) the parents and staff will be asked to complete a survey regarding their perceptions about testing and school attendance (see Quarterly Survey). This survey, administered on REDCap, will take approximately 15 minutes to complete and may be self-administered online or by phone with the study staff.

Last study contact
On the day of their last weekly staff communication, caregivers will be asked to complete their last quarterly survey. Study staff will instruct them to keep any remaining testing supplies.

SUBJECT PAYMENT
Caregivers will receive a stipend of $50 each quarter (at months 3, 6, 9, and study end). Participants who complete the entire study will receive a total of $200. Payment to subjects who complete a portion of the study will be prorated. Children will not receive compensation for their participation in the study.

STUDY EVALUATIONS AND DATA TRANSFER/STORAGE

Subject ID assignment

Participants will have the same subject IDs as they had in Year 1. New participants will be assigned a subject ID sequentially.

Study Surveys and Trackers

Study surveys will be administered using UW-Madison REDCap. Study survey questions contain items derived from previously validated and published instruments. The year 1 Enrollment Tracker will continue to be maintained containing subject names, study IDs, addresses, telephone numbers, email addresses, and individual study activity progress across study milestones. The enrollment tracker will be housed in a secure UWBox folder, accessible to only those research staff with need to have access. Data collected on paper, such as the consent form should a participant choose not sign electronically, will be stored in a locked file cabinet in study staff locked offices until destroyed. Only study staff will have access to study data and access will be limited to only what is needed by study staff to perform their study role.

Collected data, such as test results and study surveys, will be coded to protect confidentiality. Codes to the direct identifiers, such as child and caregiver names, will be stored in a spreadsheet on the Department of Pediatrics HIPAA compliant secure file storage server with access limited to the PI and research manager.

As this is an NIH-funded study, a Certificate of Confidentiality applies, minimizing informational risks and confidentiality issues.

Following data analysis and study conclusion, data will be de-identified and remain housed on the Department of Pediatrics server, or will be de-identified and archived in UW REDCap. Note that UW Cybersecurity will set up and approve the Box account to be used for data storage.

A summary table of the data elements, collection, transfer, and storage follow.

Collected	Entered/Transferred	Stored/Access rights	Destruction
Subject ID Master List	Spreadsheet on staff computer	Stored in secure folder on UWBox; access restricted to authorized study staff.	List with identifiable data will be destroyed once study analyses are completed. De-identified data stored on Department of Pediatrics secure, restricted folder indefinitely.
Consent forms	If subject signs on paper, copy will be retained in locked staff office.	Hardcopy consents will be kept in locked cabinet in locked staff office with access restricted to authorized study staff.	Hardcopy consents will be stored and retained for at least 7 years after the completion of the study. Emailed photographs will be deleted once printed.
Study surveys	Entered on-line in REDCap	Stored in REDCap (maintained by UW-Madison IT staff on campus infrastructure). Access restricted to authorized study staff.	De-identified data set stored indefinitely in UW REDCap.
Study Staff Weekly Communication Log	Spreadsheet on staff computer	Stored on UWBox; access restricted to authorized study staff.	List with identifiable data will be destroyed once study analyses are completed. De-identified data stored on Department of Pediatrics secure, restricted folder indefinitely.
Positive PCR results – verbal report from parent	Recorded on study staff log	Documented in REDCap and in enrollment tracker on secure Box.	• Study staff's Log: identifiable data will be destroyed once study analyses are completed. De-identified data stored in UW REDCap indefinitely.

RADx optional component

The funding for this grant is part of a larger NIH funding project called RADX-Up. In accepting the grant, Dr. Coller and his team agreed to ask permission of subjects for the sharing of certain data with NIH and their contracted research group, the Duke Clinical Research Institute. The researchers hope to use this data to learn more about COVID-19 and

other diseases and conditions. Permission to share this data is voluntary and requires additional consent. If the caregiver does not consent to the sharing of data with the NIH, their responses to study surveys and testing data will be provided to NIH in an aggregated fashion (no identifiable data will be shared). If the caregiver consents to sharing their individual, identifiable data with the NIH, their name, date of birth, address, phone numbers, and email addresses will be shared with the NIH with their individual responses to their study surveys and testing data.

Parents will be presented with the following explanation of this data collection and asked whether they give consent to participate:

OPTIONAL STUDY ACTIVITIES - Consent to Share Your Re-SET Data with the National Institutes of Health

The following study activities are optional. You may still take part in this study if you say no to any or all of these optional activities. Participating in any of these activities will not help you or your child directly.

Dr. Coller and his research team received funding for the ReSET COVID testing study from the National Institutes of Health which funds a larger program called RADX-UP. The researchers overseeing RADX-UP are asking for your permission for us to share your Re-SET study data with NIH so they can learn more about COVID-19 and other diseases and conditions. The following consent form asks for your permission for us to share this study information. This is an optional, additional request. If you decline sharing your information with the NIH, your participation in the Re-SET study will not be affected.

What is the NIH and RADX-UP?
The NIH stands for the National Institutes of Health. The NIH is part of the United States Department of Health and Human Services. The NIH's purpose is to find new knowledge that will lead to better health for everyone. The NIH funded (provided support) for the RADx-UP program.

RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. RADx-UP is a health research program to learn more about COVID-19 disease. If you join RADx-UP, we will gather some data (information) about you. We will combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

What will you ask of me?
If you decide to join this study, we will gather data (information) about you and your child. If you choose to participate in this data sharing, Dr. Coller and his team will share the information collected in the study surveys with the NIH/RADX-UP team. Examples of the information that we may collect from your study surveys are, but not limited to:

- basic information about you and your child such as name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information including address history
- information about COVID-19 related to you and your child, including information about any symptoms and test results. If you had a positive COVID-19 test, we will ask information about contact tracing (people who may have come in contact with you while you had COVID-19). We will ask about your child's medical history and if they have or have not had vaccines and why.
- information about you and your child's health, education, family, home, relationships, and social life, among others.

What will you do with my data?
We will keep your data securely (which means with extra protection), along with the data from all the other people who take part in the RADx-UP program. Researchers will use the data to learn more about COVID-19 or other diseases and conditions.

The Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies.

The DCRI will build two RADx-UP databases (systems that hold electronic information).

The first database will only hold information that can identify you (called identifiable information). Examples are your name, address, email, and date of birth.

- These data will be kept at the DCRI. The DCRI will not share these data with the NIH.
- Only if you agree, by initialing below, the DCRI will keep information that can identify you in order to contact you for future research studies. If you do not agree, this information will stay with your study team, as applicable.
- These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of your data at the DCRI will be able to see this information.
- This database will contain the following identifiable information: name, date of birth, address, phone numbers, and email addresses of you and your child. This information will be paired with your responses to the study survey questions. Survey questions include information about your child's medical conditions, school attendance, health insurance type(s), vaccination status of you and your child, COVID testing history, your opinions about vaccinations and testing, household income, race, ethnicity, gender, your educational background, employment status, and marital status.

The second database will not hold information to identify you. It will hold all the nonidentifiable information you agree to give.

- You will be assigned a study code and you will only be identified in this database by this study code.
- It will not contain your name or other information that could easily identify you.
- We plan to transfer and keep these non-identifiable data in a secure database for COVID19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
- When using the data from this second database, researchers will only have access to your non-identifiable data and cannot link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.
- This database will contain the nonidentifiable information that you provide on the study surveys.

How will you protect my privacy?

Your privacy is *very* important to us. We will take great care to protect your privacy. However, there is always a chance that, even with our best efforts, your identity and/or information collected during this study may be accidentally released or seen by unauthorized persons. Here are a few steps we will take:

- Data will be stored on protected, secure computer systems. We will limit and keep track of who can see these data.
- Anyone who can see these data will have to use a password.
- We will take steps to protect your information from others that should not be able to see it.
- When your data are shared with other researchers, they will not have information that can identify you.
- This project has a Certificate of Confidentiality from the United States government. Certificates of Confidentiality protect your privacy by blocking the release of identifiable, sensitive research information to anyone not connected to the research except when you agree, or in a few other specific situations.

Optional:

I agree to let Duke Clinical Research Institute (DCRI) collect the following identifiable information: name, address, contact information, and date of birth, as stated above.

Yes, initials _____ No, initials _____

I agree to let the DCRI collect only my zip code and no other identifiable information as stated above.

Yes, initials _____ No, initials _____

I agree to be contacted for future research as stated above.

Yes, initials _____ No, initials _____

DATA ANALYSIS

In primary analyses, feasibility and school perception measures will be summarized with descriptive statistics. Differences by race/ethnicity and urban/rural category will be identified with t-tests or Wilcoxon rank-sum tests (continuous variables) and Chi-squared or Fisher's exact tests (categorical variables). Aim 1's design will allow us to conduct a couple of comparative analyses:

(1) We will evaluate whether statistically significant differences in feasibility or perceptions exist for in-home compared to school-based cohorts (see IRB ReSET Aim 1b)

(2) We will explore differences in perceptions associated with changes in community spread.

We anticipate the relatively small number of subjects and low COVID-19 rates will make sensitivity and specificity determination of BinaxNOW tests difficult; however, we will measure the number of positive and negative tests during the study period as well as the concordance of positive tests with PCR testing.

UNANTICIPATED PROBLEMS OR COMPLICATIONS

Study staff will report any unanticipated problems or complications to the principal investigator promptly. Weekly team meetings will review study issues such as any deviations from the protocol, subject complaints or questions, and positive test results. The principal investigator will provide guidance on these issues and determine whether such events are to be reported to the IRB in accordance with posted guidance. Should urgent issues arise, study staff will have access to principal investigator and/or research manager guidance at all times via email, texting and phone.

INSTITUTIONAL REVIEW BOARD

The UW-Madison Health Sciences Institutional Review Board (IRB) will serve as the IRB for this study.

PROJECT FUNDING

This project is funded by the National Institutes for Health.