

ReSET Aim 1a: Restarting Safe Education and Testing for Children With Medical Complexity -Feasibility of In-home Cohort COVID-19 Testing Strategies, and Associations With CMC Parent Perceptions About In-person School Attendance

11/21/2022

NCT04895085

**University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research**

Study Title for Participants: Year 2: ReSET Study - Restarting Safe Education and Testing for Children with Medical Complexity

Formal Study Title: Year 2 ReSET Aim 1a: Restarting Safe Education and Testing for Children with Medical Complexity - Feasibility of in-home cohort SARS-CoV-2 testing strategies, and associations with CMC parent perceptions about in-person school attendance

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Invitation

We invite you and your child to take part in year 2 of the ReSET study, the COVID testing study that you began last summer. This research study is about the factors parents consider when deciding whether their child with medical complexity will stay at home or attend school during the COVID pandemic.

Your family's participation in this research study is voluntary. If you decide not to participate, the health care provided to you and your child by the University of Wisconsin-Madison (UW-Madison) and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) will not be affected in any way.

Year 2 study activities are very similar to those in year 1. This consent form will re-explain the study and highlight a couple of changes we are making from last year so you can decide whether to continue with the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

Why are researchers doing this study?

The purpose of this research study is to learn about the factors parents consider when deciding whether their child will go to school in-person or attend from home. We are also interested in learning whether access to in-home COVID testing is of value to parents and whether it affects decision-making about attending school.

This study is being done at UW-Madison, Department of Pediatrics. A total of 51 caregivers (plus their children with medical complexity) may participate in this study. This research is being funded by the National Institutes of Health. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen in this study?

COVID-19 TESTING and WEEKLY LOG

You will be asked to continue testing your child for COVID-19 using the BinaxNOW in-home test kits. In year 2, you will be asked to test your child if:

- 1) they have symptoms suggesting they may have COVID, and/or
- 2) they have been exposed to someone who has COVID.

In year 2, testing twice a week if your child does not have symptoms or has not been around someone with COVID is not a testing choice. Like year 1, you will report your testing activity (on paper or using the electronic survey) every Friday, even if you have not performed any tests that week.

You will continue testing your child in this fashion from now through the 2022-23 school year (ending in May or June 2023, depending on your child's school district). We will continue to provide the BinaxNOW test kits. To order more test kits, you can make a note on your weekly log (paper or e-survey) or email the study team at reset@pediatrics.wisc.edu.

The BinaxNOW in-home test kit is authorized under the Food and Drug Administration's Emergency Use Authorization. The test is allowed for over-the-counter, non-prescription use with or without symptoms. The test may be used with children two years and older with the help of sample collection by an adult, and the test may be self-administered by anyone aged 15 years or more.

What should I do if the test is negative?

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.

It is important to note that the COVID swab test tells you whether someone has COVID right now, at the time the test is done. It cannot tell you whether they have had COVID-19 in the past or whether they may be positive tomorrow. After someone is exposed to another person with COVID-19 it takes several days for them to show that they are infected by having a positive test. In the first few days after exposure, their test will be negative. Just before they develop symptoms their test usually becomes positive and stays positive for several more days.

What should I do if the test is positive?

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.

The PCR test detects genetic material that is specific to the virus within days of infection, even in those who have no symptoms. The test is done in a clinic, hospital, or community center. Study staff can assist you in arranging to obtain a PCR test. The PCR test results are generally available between 24 hours and 3 days after the test.

If your child's in-home test is positive, you are advised to restrict your child from school activities per public health guidelines until the results of the PCR test are known. If the PCR test comes back with a negative result and your child is attending school in-person, your child may return to school the next day (or if symptomatic, once symptoms resolve). If the PCR test comes back with a positive result, you are advised to keep your child at home per public health guidelines.

No matter what the results of the tests are, you should not assume that your child can relax the prevention measures they have been doing, such as frequent hand washing, wearing a face mask in indoor spaces that are not their home, covering their coughs, and sneezes, physical distancing, and staying home when possible. You (or your insurance company) will be responsible for costs related to any follow-up care.

If my child has a positive PCR, when should I resume testing?

Recommendations on when you can test for COVID-19 after a positive PCR have changed since last summer. In year 2, you can resume BinaxNOW in-home testing *21 days* after a positive result. It is recommended that you wait to do a PCR test for *90 days* following a positive PCR. If your child requires a PCR before 90 days (for example, if they require one for a hospitalization or procedure), follow the guidance of your healthcare provider.

Quarterly study surveys

You will continue to receive a survey link by email every three months in year 2. The survey asks questions about your perceptions about testing, in-school efforts to address COVID, and vaccinations. The surveys take about 15 minutes to complete and is done online.

At the end of the study

At the end of the study, you will be asked to complete your last quarterly survey. Study staff will instruct you to keep or destroy any remaining testing supplies.

How long will I be in this study?

This study is approximately 52 weeks in length.

Will being in this study cost me anything?

There is no cost to participating in this study.

Will I be paid or receive anything for being in this study?

You will receive a study stipend of \$200 five times over the year (approximately every 2-3 months). Participants who complete the entire study will receive a total of \$1000. Payment to subjects who complete a portion of the study will be prorated. Children will not receive compensation for their participation in the study.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Your responses to our interviews and surveys
- Testing information you share with us about your child

If your child has a PCR done, the testing lab will report the results to your local health officials, as required by law. The results are reported to the Wisconsin Department of Health Services in compliance with state statutes §252.05 using the Wisconsin Electronic Disease Surveillance System (WEDSS). 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.

How is being in this study different from my regular health care?

- Your child will continue to have their usual visits and contact with their Pediatric Complex Care team, their primary care provider, and their other specialists.
- This study is not part of your child's health care.

Do I have to be in the study? What if I say “yes” now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. You can also decide at any time to participate in just some of the study activities. For example, you may choose to do the COVID-19 testing but not complete the study surveys, or vice versa. If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study. Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you or your child have with healthcare providers at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you or your child. You and your child will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.

- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.

To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Ryan Coller, MD at UWHC Department of Pediatrics, 600 Highland Avenue, Madison, WI 53792.

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get a test for COVID-19. If you decide not to participate in this study, you have other choices. For example, you can contact your child's primary care provider or your Pediatric Complex Care team to learn how to arrange a COVID-19 test for you, your child or another family member. The BinaxNOW testing cards are also available over-the-counter for home use.

Will being in this study help me in any way?

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

What are the risks?

- You may find that answering some of the study questions stressful, upsetting, or embarrassing. You may choose to decline to answer any interview or survey question.
- You may experience distress if your child (or another family member) tests positive for COVID. The study team will guide you in finding the most appropriate plan of care for your child 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.
- There is a small risk that you or your child may find the nasal swab testing procedure unpleasant, burdensome, and/or anxiety-provoking. Study staff will ask how testing is going for you and your child and, if problems arise, will help troubleshoot solutions. You may also choose to switch from twice-weekly testing to symptomatic-only testing at any time or skip doing any of the testing.
- If your child tests positive using the in-home test, they will be instructed to get a PCR confirmatory test in a clinic or hospital. This test is typically done with a swab that goes deep into the nostril. Your child may experience discomfort during this procedure but the test only takes a few seconds.
- It is possible for the nasal swab test to give a negative result that is incorrect (false negative) in someone with COVID-19. If someone believes that they had a negative test result for COVID-19, they might stop following measures they would otherwise take to protect themselves from COVID-19 like frequent handwashing, mask-wearing, or social distancing. If this happens, and the test was wrong, relaxing these measures could make it MORE likely for the person to be exposed to COVID-19, or to expose someone else. That is why it is important to follow public health recommendations no matter what the results of the test show.
- There is a risk that your study information could become known to someone not involved in this study. This could happen if study staff are not careful with your study materials or if someone hacks into the University's computer systems. Study staff have many precautions in place to make this an unlikely event.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring the safety of this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative. The study team has a Certificate of Confidentiality from the National Institutes of Health for this study. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent.

Who at UW-Madison can use my information?

- UW-Madison regulatory and research oversight boards and offices
- Accounting and billing personnel at the UW-Madison
- Research support services staff at the UW-Madison and its affiliates

Who outside the UW-Madison may receive my information?

- The U.S. Food and Drug Administration (FDA)
- The study sponsor, the National Institutes of Health (NIH)
- A request for permission to share additional information with the NIH and the research group they have hired to oversee the data collection appears at the end of this consent form. Sharing this data is a separate permission.

Will information from this study go in my child's medical record?

- None of the information we collect for this study will go in your medical record or your child's medical record. The researchers are not required to release health information to you if it is not part of your medical record.
- Your child's medical record will not contain information about you or your child's participation in this study.

What if I have questions?

If you have questions about this research or you feel you have been harmed by participating in this study, please contact the Lead Researcher, Ryan Coller, MD at 608-263-9408. If you have any questions

about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

If you have questions related to performing the in-home testing, interpreting the test results, or following up on positive test results, contact the study team at 608-263-0740. If you have questions related to COVID symptoms, you may ask the study team, your child's primary care physician, or your Pediatric Complex Care team.

Authorization to communicate with you by email

We are requesting your email address so we can send you the weekly testing log and quarterly surveys. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the Lead Researcher, Ryan Coller, MD at 608-263-9408. You do not have to provide your email address to participate in this study.

- Yes, you may use email to contact me for this study.
- No, I do not want to be contacted by email.

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 _____

Agreement to participate in the research study

You are making a decision whether or not to have you and your child participate in this study. You do not have to sign this form. If you refuse to sign, however, you and your child cannot take part in this research study. If you sign the line below, it means that you have:

- read this consent and authorization form describing the research study procedures, risks and benefits
- had a chance to ask questions about the research study and your child's participation, and received answers to your questions
- decided to allow your child to participate in this study
- given authorization for the person's protected health information to be used and shared as described in this form

Printed name of child

**Printed name of parent or
legally authorized caregiver**

I am this child's parent
--- OR ---
 I am not this child's parent but
am the person legally authorized
to consent to the child's general
medical care

**Signature of parent or
legally authorized caregiver**

Date

Signature of Study Team Member Obtaining Consent

Date