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Version: 8

Date: May 27, 2021

Background and Rationale

Asthma is the most common chronic disease of childhood. Characterized by airway inflammation and bronchial hyper-reactivity, affected patients can experience symptoms such as cough, shortness of breath, exercise limitation, and wheezing.[1] Affected children are also at risk of developing acute exacerbations requiring healthcare utilization such as emergency department visits and/or hospital admission. An estimated 26 million Americans currently have asthma, including over 7 million children.[2] This leads to over 14 million outpatient visits, nearly 2 million emergency department visits, and over 400,000 hospitalizations each year with a disproportionate number of these coming from low-income and minority populations.[3-4] The estimated economic impact each year includes over $50 billion in direct costs with an additional $5.9 billion in indirect costs due to lost earnings.[5-8] Uncontrolled asthma is associated with higher medical expenditures and health care utilization, decreased work productivity, and missed school days.[9] There are multiple environmental factors that can trigger exacerbations including infections, weather changes, allergens, and airway irritants.[10-11] Several of these triggers can be found in the home environment and when identified, reduction or removal leads to improvements in asthma morbidity.[12] Current asthma guidelines recommend home environmental assessment and intervention as an important aspect of asthma management.[1]

The majority of research in asthma trigger reduction has focused on inner-city populations with less work done in rural populations. While there may be a similar rate of asthma between these two populations, rural children may have a higher rate of undiagnosed asthma and asthma morbidity, often due to lack of available care.[13-14] Nearly 50% of families living in rural areas have income less than 200% of the federal poverty level compared to 27% of those living in non-rural areas.[15] Approximately 20% of these families lack insurance and as a result are less likely to receive preventive medical care.[16] Less than 10% of physicians practice in rural areas and access to subspecialists is particularly difficult. When combined with the lack of insurance, rural populations are woefully underserved. Arkansas is a primarily rural state and also has large African American and other minority populations. In certain regions of the state, especially the Delta region, minority children with asthma suffered twice the mortality rate compared to the national average (45.0 vs 22.2 per 100,000) and had higher rates of asthma morbidity.[13]

Telemedicine (TM) has recently evolved to address some of these concerns. TM involves the use of telecommunication systems to deliver health care at a distance which can improve access to care while reducing costs. In studies of heart failure, TM led to similar outcomes as in-person or phone visits, while in diabetes, TM led to improved blood sugar control.[17-18] In asthma, TM programs have led to reductions in daily asthma symptoms and health care utilization.[19] To date, TM has not been utilized in asthma home assessment programs. As with clinical care, TM could improve the access to this important aspect of asthma care while decreasing the costs associated with in-person programs. In this project, we aim to determine the effectiveness of TM asthma home assessments/interventions in reducing triggers in a cohort of underserved

asthmatic children. Approximately 1500 children each year receive care at Arkansas Children's Hospital (ACH) for acute exacerbations of asthma. The majority of these children are African American and nearly 25% of these patients live below the federal poverty level. Given the burden of asthma in minority populations living in Arkansas, targeted home interventions could lead to significant reductions in asthma morbidity.

Hypothesis and Specific Aims:

Specific Aim 1: **Compare the effectiveness of TM home assessments/interventions versus standard of care education for the reduction of asthma related triggers.**

Hypothesis 1: TM home assessments/interventions will lead to greater reductions in asthma-related triggers compared to standard of care education.

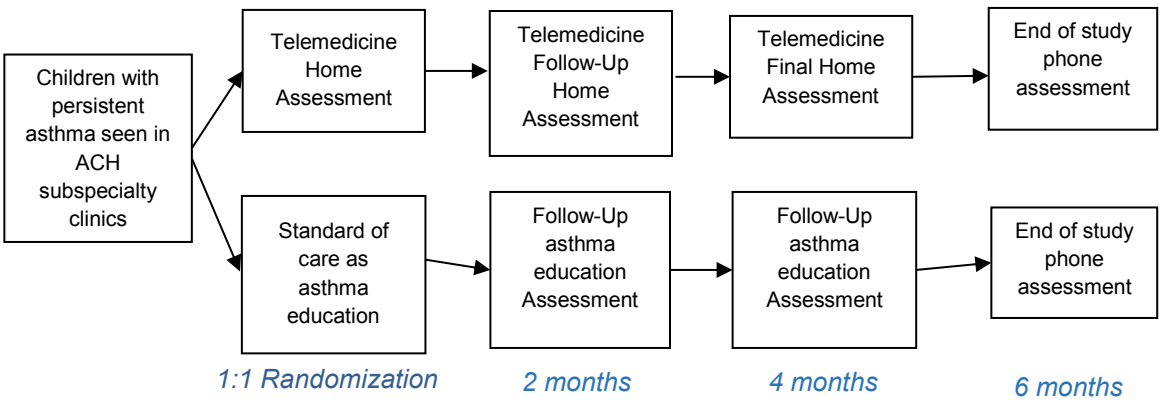
Specific Aim 2: **Determine changes in asthma morbidity as a result of asthma home assessments and related interventions.**

Hypothesis 2: TM assessments/interventions will lead to greater reductions in asthma symptoms and healthcare utilizations related to acute asthma compared to standard of care trigger education.

Study Design and Procedures

Design Overview: We will conduct a 6 month randomized pilot trial of 40 pediatric patients, ages, ≥5 and ≤18 years, with persistent asthma to compare trigger reduction performed through TM home assessments/interventions versus standard of care education. (**Figure 1**) For the proposed study, participants will be randomized to receive TM home assessments/interventions performed by a trained home visitor (HV) or standard of care asthma trigger education by the HV. Those who are randomized to TM home assessments/interventions will complete a baseline home assessment and two follow-up visits, occurring 2 months apart. Visits will assess the presence of potential asthma triggers in the home and frequency of asthma symptoms/exacerbations. TM participants will be provided education and materials necessary to reduce asthma triggers in the home. Follow-up visits will assess the interval change in presence of asthma triggers, change in daily asthma symptoms/exacerbations, and participant/family retention of education. For subjects randomized to receive standard of care asthma education, written and verbal information will be provided regarding identification and removal of potential asthma triggers in the home but no formal assessment of the home will be performed, nor will participants in this arm receive trigger reduction supplies. The **overarching hypothesis** is that utilization of telemedicine asthma home assessments/interventions will result in higher efficacy for trigger reduction, asthma outcomes, patient/family satisfaction, and retention of trigger education compared to standard of care asthma education.

Figure 1. Summary of Study Design



Study population: We will recruit 40 children (ages ≥5 and ≤18 years) with persistent asthma to participate in a prospective, randomized trial. Participants will be recruited from ACH locations including the emergency department, inpatient services, general, and/or asthma specialty (Allergy/Immunology, Asthma, Pulmonary) clinics.

Screening and Eligibility: A partial HIPAA waiver will be obtained to allow for access to identifiable health information in order to screen and recruit for this study. Patients will be pre-screened to determine age and persistent asthma diagnosis eligibility. The pre-screening process will involve the research staff reviewing the recruitment clinics, emergency department, and inpatient services daily EPIC schedules, to capture the age, diagnosis and potential participant's name, parent name, phone number and zip code. This information will be logged into a screening log in Excel. The screening log will be password protected and the research coordinator, study respiratory therapist and principal investigator will have access to this screening log. The research staff will call the potential participant/caregiver to provide a brief introduction (approximately 2 minutes) about the study. No additional PHI will be obtained during the introduction call. The purpose of the call is informative and to provide the potential participant/caregiver the opportunity to learn more about the research study during their scheduled clinic visit.

Patients identified as eligible for the study will be contacted and if interested in study participation, will be scheduled for a screening, enrollment, and initial demographic assessment visit to occur at the ACH campus.

Inclusion Criteria:

1) Age ≥ 5 years and ≤ 18 years
2) Have a diagnosis of persistent asthma as defined by national guidelines criteria[1]
3) Patient receives care in ACH primary care, in patient and/or specialty clinics

4) Patient has had at least one or more acute exacerbations of asthma within the 12 months prior to enrollment that led to an emergency department visit, hospital admission, or prescription for systemic steroids
5) English speaking participants/parents
6) Access to WIFI, smartphone or mobile device (tablet)

Exclusion Criteria:
1) Age <5 or >18 years
2) Non-English speaking participants/parents

3) Patients not receiving primary and/or asthma specialty care or inpatient services at ACH
4) Inability of patient or family to participate in TM evaluation due to lack of access to WiFi or smartphone or mobile device

Rationale for only enrolling participants with persistent asthma: Only children with persistent asthma will be recruited to participate in the proposed study because they require regularly scheduled, follow-up to monitor asthma control and prevention of future exacerbations.[1] Patients with intermittent asthma will not be recruited for participation because they typically are not at high risk of acute exacerbation nor require specialty care.

Recruitment: Potential participants will be recruited from ACH primary care or asthma subspecialty clinics through direct patient contact and advertising. These patients may also receive care in other ACH settings such as the emergency department, inpatient services or may be registered in institutional research participant databases, so we will recruit from these locations if needed to meet recruitment goals. Only one child per household who meets eligibility criteria will be enrolled.

We will utilize flyers, ACH/ACRI Intertube, and electronic signage to advertise the study. We will advertise via ACH/ACRI social media (i.e. Facebook, Twitter, and YouTube). The study will also be advertised via word of mouth. The advertisements will provide the contact information allowing parents/caregivers/potential adult participants to directly contact research staff. The clinics will be provided the study coordinator/respiratory therapist contact information to address any questions.

Screening, initial demographic assessment and informed consent: The informed consent/assent process will be carried out by trained research staff. All potential participants will be screened to ensure they meet inclusion and exclusion criteria as outlined above. After pre-screening, at or before the time of the potential participant's scheduled clinic visit, the research team will ask the parent/caregiver more detailed screening questions to determine eligibility prior to enrollment. The detailed screening may occur in person or via phone conversation from the research team's office or from a private, quiet area different from the research team's office. If eligible, informed consent/assent will be obtained from interested parents/caregivers/legal authorized

representative and patients. Adolescents who reach the age of maturity (turn 18 years of age) while enrolled during the study period will be re-consented. The research staff will contact the parent/caregiver/legal authorized representative prior to the participant's age of maturity and a time will be scheduled to re-consent the participant using the IRB approved Informed Consent document. In addition to survey and home assessment data, we will obtain consent from caregivers and adult participants to access participants' health record to assess and monitor healthcare utilization for asthma. In the event a parent/potentially eligible participant agrees to participation at a later time after the eligibility screening, the informed consent interview and initial demographic assessment can be completed at an ACH campus location. During the consent/assent process, the participant will be given a copy of the consent document and asthma trigger education materials. Participant identification and enrollment will take place until we meet our enrollment goal.

Randomization: Subjects will be randomized 1:1 into 2 groups. One group will receive TM home assessments/interventions for identification and reduction of asthma triggers in the home while the other group will receive standard of care asthma trigger education. Randomization will occur at the time of enrollment visit after consent and assent is obtained and initial demographic assessment is complete. All participants will receive the same asthma education and trigger reduction materials. For those randomized to TM, participants will receive TM assessment of their home as well as an Asthma Home-Assessment kit that will provide supplies to reduce asthma triggers in the home.

The Role, Qualifications, and Expectations of the Home Visitor (HV): The Home visitor (HV) is a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. The HV is in a unique position to partner with families due to living in the area they are serving or having similar cultural backgrounds. The person acting in this role will be responsible for performing standard of care trigger education and asthma TM home assessments to aide in the identification and reduction of exposure to indoor asthma triggers. The goal is to establish a trusting partnership with participants and family members by providing education and tools to maximize asthma control and management as well as model appropriate behavior standards and core values as exemplified by Arkansas Children's mission and vision statement. For the purpose of this pilot project, the HV will enter into a contract agreement with UAMS or the Arkansas Children's Research Institute (ACRI) for the period of the pilot project. A minimum of a high school education, with a Bachelor degree in a health or social science related field preferred. In addition, one year of experience in some type of home visiting related to health care. Asthma specific training will be provided in the amount of 10 hours by a Certified Asthma Educator. The HV will receive CITI training as well. The education materials are provided by the Association of Asthma Educators and a certificate of completion is awarded after post testing. The HV will be expected to carry out the asthma home assessment via TM consistent with the procedures listed below.

Study Procedures, Outcome Measures, and Longitudinal Assessments: For the proposed study, participants will receive home assessments for identification and reduction of asthma triggers via TM or standard of care asthma trigger education. Eligible subjects will undergo a total of 4 visits including an initial, in person screening/enrollment and initial demographic assessment visit, lasting approximately 1-2 hours. After enrollment and randomization, each TM participant will receive three home assessments including an initial baseline home assessment and two follow-up assessments, each 2 months apart (+/- two weeks). The home assessment visits will last approximately 90 minutes. During the TM home assessment, a home environmental asthma trigger assessment checklist (heat) will be utilized to identify potential asthma triggers in the subject's home. TM participants and their household will receive education and supplies, at the time of enrollment, for reduction of any identified triggers as well as education and supplies for general cleaning of the home. The Asthma Home Kit supplies provided to participants will include: Quickie 45TRI automatic sponge mop, child resistant roach and mice bait stations, zippered mattress covers, zippered pillow covers, trash can with lid, trash bags, anti-microbial sponges, rubber gloves, non-toxic all-purpose cleaner, Borax powder, scrubbing pads, Quickie home pro cleaning cloths, broom/dust pan, dusting spray, and paper towels. Each kit will contain labeled instructions on the proper use and/or storage of each item.

For those receiving standard of care education, each subject will receive the same education given to TM subjects for identification and reduction of asthma triggers, but will not receive TM home assessments or trigger reduction kits. Standard of care subjects will be contacted again at 2 months and 4 months (+/- 2 weeks) to assess retention of education materials and to provide additional asthma education and trigger reduction info. All participants will then receive a phone follow-up at 6 months (+/- two weeks) from the time of enrollment.

Dust samples will be collected from all subjects in both study arms. We will use the Dustream collector (Indoor Biotechnologies) to collect the dust specimens. Subjects will receive a dust collector kit that attaches to a vacuum cleaner. All participants will receive written instructions at the time of enrollment but will also be contacted by TM to assist with proper collection of the dust samples. These samples will be mailed to the study team using pre-paid postage and packaging through the USPS. One sample will be collected from the main living area and another sample will be collected from the participant's sleeping area during the baseline visit. A second set of dust samples will be collected at the 4 month visit for both groups.

Each participant will be contacted by phone at 6 months for an end of study visit. This phone conversation should last approximately 15-30 minutes. In the event the participant is no longer available on the day of the scheduled follow-up visits or 6-month phone contact, three attempts will be made to complete study procedures/ end of study phone call. If the research staff are unsuccessful after the third scheduled visit or phone call attempt, an email will be sent to the parent/caregiver asking that he/she contact the research staff via return phone call.

Telemedicine Home Assessment:

Interactive Video (IAV) will be utilized to complete the TM home assessment. This mode of communication allows for real-time audio and visual interaction between individuals in two different locations. The participant will be located in their primary resident, while the HV will be at an office location that allows for patient privacy. This would include a room with IAV set up and the ability to close the door for privacy. The interaction will be in real-time interactive video via a secure link with ACH. The research staff will provide the participant/parent written instructions on how to connect via IAV. Participants may use their own smart phone, tablet, or lap top that has Wi-Fi/data capability. The device must be mobile so the HV can see all parts of the home that are being assessed. The participant/parent/caregiver will use the ACH secure link: asthma.research.space@archildrens.org to connect with the HV via teleconference. The participant/parent/caregiver will also be given a second means of a secure connection. He/she can click to join the link for audio/video using *Chrome browser only* at:https://telehealth.archildrens.org/invited.sf?secret=0BpuE4x3LrLOFIAS5mlN2Q&id=138052178.

At the start of the TM assessment, the HV will review the home assessment process and answer any questions posed by the participant/parent. The steps for the TM home assessment 1st Visit include:

1. Ask the participant/parent to remove and inspect items in the kit. These items should be visible to the HV. In addition, the HV will have a sample kit to help participants/parent find and visualize each item. The HV will review recommendations for use and storing of all items, emphasizing those that should be kept away from children.
2. Device positioning to allow performance of the home assessment
3. All data to be collected during the assessment will be reviewed and participants will verbalize understanding prior to collection.
4. Each visit will cover the following topics and items:
    - Education topics: basic facts of asthma, triggers, medication/inhaler technique
    - Environmental Assessment
    - Asthma Control Test (ACT) and other surveys
    - Reduction strategies for identified asthma triggers

Standard of Care Asthma Education:

At each visit, the participant/parent will be contacted to cover the following topics and items:

- Education topics: basic facts of asthma, triggers, medication/inhaler technique
- Asthma Control Test (ACT) and other surveys
- Reduction strategies for identified asthma triggers

Outcome Measures:

Outcomes of patients receiving home assessments/interventions via TM will be compared to patients receiving standard of care trigger education. (**Table 1**) The **primary outcome** will be the mean difference in dust mite levels found in home dust samples at 4 months compared to baseline and between TM and standard of care groups. Other outcomes will be any change in the home environmental asthma trigger assessment score (heat) as a result of trigger mitigation performed at each home visit (TM group), changes in ACT score, comparison in number of exacerbations requiring a healthcare utilization or prescription for systemic steroids, and patient/household family retention of education provided during visits (both groups). We will measure study satisfaction among all participants and telemedicine-specific satisfaction among TM participants.

Table 1. Summary of Outcome Measures

	Baseline	2months	4months	6months
Dust Mite Levels	X		X	
Asthma Control Test (ACT)	X	X	X	X
Healthcare Utilization	X	X	X	X
Satisfaction Survey	X	X	X	X
Information Recall Survey		X	X	X

Primary Outcome Measure: The primary outcome measure will be the mean difference in dust mite levels found in home dust samples at 4 months compared to baseline and between TM and standard of care groups. Dust mites (*Dermatophagoides farina* and *Dermatophagoides pteronyssinus*) are one of the most common triggers for asthma and are commonly found throughout homes. ELISA testing can be utilized to quantify household dust mite levels with levels ≥ 2 mcg/g considered positive.[20] Prolonged reductions in household dust mite concentrations are associated with improved asthma outcomes.[21]

Secondary Outcome Measures:

Asthma Control Test (ACT): The ACT is a validated 5-question (≥ 12 years of age) or 7-question (<12 years of age) survey used to assess asthma control. ACT is used for symptoms monitoring as per guidelines[1] and has been identified as an appropriate asthma control composite score in clinical research.[22]

Healthcare Utilization: At baseline, participants will be surveyed to determine the number of acute exacerbations he/she has experienced in the past 12 months resulting in hospitalization, emergency room/sick visits, or systemic steroid use. At each study time point, participants will record acute exacerbations resulting in hospitalization, emergency room or sick visits, or systemic steroid use since the previous asthma education session/TM home assessment visit.

Visit Satisfaction: We will administer ACH's outpatient satisfaction survey, supplied by National Research Corporation, at the completion of each visit for both groups. For TM

participants, we will administer the telemedicine patient satisfaction survey[23] that will ask respondents to assess four areas regarding the effectiveness and quality of care received via TM: 1) risk and benefits, 2) effectiveness, 3) efficiency, and 4) future adoption.

Education Recall: Participants and household parents/caregivers will be administered a questionnaire at each follow-up visit and again via phone call at 6 months to assess recall of education provided during each home assessment.

The ACT, healthcare utilization, visit satisfaction and education recall questionnaires will be completed via a mobile link and take approximately a total of 20 minutes to complete.

Participant Withdrawal

Since participation is strictly voluntary, participants may withdraw at any time. Participants will only be replaced if withdrawal occurs prior to the beginning of the first home assessment. Participants may be withdrawn due to non-compliance with study related procedures. Data from the baseline assessment or the subsequent data collection time points for participants who withdraw or who are lost to follow-up will be analyzed.

Risks and Benefits

A potential risk to study participants is the potential for loss of confidentiality. Measures to protect confidentiality will be implemented according to UAMS/ACH/ACRI policies. There are no significant risks to participants regarding the home assessment products being used. All products utilized in cleaning of the home or with the reduction in asthma triggers are non-toxic. The pesticides in the bait traps should not be handled by young children or pregnant individuals during their first trimester. We recommend the participant/household family member read all labeled warnings prior to opening the package. There are no significant risks associated with use of telemedicine as the connection is via secure link with ACH.

There could be no direct benefits to the study participants. Potential benefits to participation include improved education of participating subjects and family members in regards to identification and removal of asthma triggers. Participants in the TM group will be provided supplies to assist with reduction in home asthma triggers throughout the study period. This may improve the participant's asthma morbidity leading to decreased healthcare utilization. Knowledge gained from the study could also potentially benefit patients in the future.

Participant Incentives

Participants will receive $25 for each completed visit for a total of $75 during the enrollment period. The monetary incentives will be issued via ClinCard. ClinCard is an electronic debit card method that allows participants to have access to their study incentives immediately at the conclusion of the home assessment. The participant pays

no fees to access funds that are securely loaded to their unique debit card. The research staff will assist the participant to create a username and the participant is navigated via www.myclincard.com to select their unique 4-digit PIN. ClinCard is used for in-store and online purchases. It's accepted at ATM locations. The use of ClinCard eases the administrative cost and burden associated with incentive processing. In the event a debit card is lost or damaged, it can be replaced at no cost to the participant. Any existing balance on the previously issued card will automatically transfer to the newly issued debit card. UAMS ClinCard administrator will conduct the research staff ClinCard training prior to study enrollment. The initial debit card will be issued to the parent/adult participant during the consent interview. At the conclusion of each visit, the research staff will load the $25 incentive onto the debit card.

An alternate incentive payment method will utilize UAMS accounts payable. The research staff will submit the participant incentive via invoice or Workday to UAMS accounts payable. Accounts payable will approve the invoice/requisition and submit a paper check to the participant via the address listed on his/her W9. This process could take upwards of three weeks to process and USPS mail the participant his/her check.

Data Handling and Recordkeeping

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. All study participant material will be assigned a unique identifying number. Only study staff will have access to the code and information that identifies the participants in this study. Questionnaires, consent and assent forms will be stored in a binder in a locked protected file in a locked office on ACH campus. Only study personnel will have access to these forms. All participant materials will be recorded in a REDCap database utilizing the unique subject identifier to protect the confidentiality of the individuals. Maintaining a link to identifiers until after data analysis is complete allows for rechecking of data to ensure data integrity and improved study design. For dust samples, only the unique identifying number will be used to identify subject samples during shipping to the processing lab. Samples will be discarded after lab analysis. At the end of the study, documents will be archived according to UAMS/ACH/ACRI policies regarding destruction of research records. Electronic records will be stored on the ACRI/UAMS servers which are password protected.

Data Analysis

Sample size:
Analysis for the primary endpoint: The primary outcome measure is level of dust mite allergens as measured by the MARIA™ test data. Using a one-way analysis of covariance, we estimated that a sample size of 20 in each of the two groups will yield at least 96% power to detect a 4 μg/g difference between group means assuming a common standard deviation of 2 and a two-sided significance level of 5%.

Analysis for the secondary endpoint: To evaluate the secondary outcome variables, the distribution for each outcome (i.e. home environmental asthma trigger score (heat), ACT score, healthcare utilization, visit satisfaction, and education recall) will be first assessed with summary statistics and graphical measures. It is anticipated that the distribution for some of these variables will be positively skewed. In cases of non-normal data, a logarithmic or square root transformation will be applied to normalize the distribution of the data. Secondary outcomes will be assessed for significant differences between groups and from baseline to 4 months and 6 months using a univariate repeated measure analysis of variance that will include a time x group interaction.

All tests will be two-sided and assume a significance level of 5%. All statistical analyses will be performed using SAS software version 9.4 (SAS Institute Inc., Cary NC, USA).
Missing data and general considerations: All reasons for drop out and missing data will be documented and reported. Subjects will be replaced if the dropout rate exceeds the estimate of 10%.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and UAMS research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board to conduct the study.

At the time of the detailed screening, the parent/caregiver/adult participant will indicate "Yes" on the eligibility document acknowledging verbal consent to complete the eligibility screener. The formal consent of each subject, using the IRB-approved consent form, will be obtained before the participant is submitted to any study procedures. All participants for this study will be provided a consent form describing the study and providing sufficient information in language suitable for participant to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study.

The consent process will take place in a quiet, private room and participants may take as much time as needed to make a decision about their participation. Participant privacy will be maintained and questions regarding study participation will be answered. No coercion or undue influence will be used in the consent process. Assent will be obtained from capable participants 7-17 years of age. This consent form must be signed by the participant or legally authorized representative, and the individual obtaining the consent. A copy of the signed consent will be given to the participant, and the informed consent process will be documented in each participant's research record.

CONFIDENTIALITY: The participant's records will be kept confidential with the exception of the Office for Human Research Protection (OHRP), UAMS IRB and other institutional oversight offices. The participant will be made aware that the Investigator

and HV are considered mandated reporters. As a mandated reporter the investigator and HV might be required to report any child abuse or neglect, as well as any intention of study participants for self-harm or harm of others. The Investigator and HV, if ordered to do so by a court of law, may also be required to disclose information the participant has provided.

Dissemination of Data

We will protect the rights and privacy of all human subjects who participate in this research. The proposed research will include data from 40 children participating in the trial. The final dataset from the trial will include demographic, medical, and survey data from participants. The final dataset will be stripped of identifiers prior to release for sharing. Sharing of data will be accomplished by publication in the scientific literature, presentation at national scientific meetings, as well as communicating our findings to the public through the ACRI and UAMS Translational Research Institute websites.

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