MRSA Eradication and Decolonization in Children (MEDiC) Protocol

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1.0 Background

The term Methicillin-resistant Staphylococcus aureus Skin and Soft Tissue Infections (MRSA SSTI) is used to describe cellulitis, boils, myositis, and abscesses caused by MRSA. Methicillin-*susceptible* Staphylococcus aureus (MSSA) causes similar disease, but the rapidly increasing incidence of MRSA in otherwise healthy children has been largely explained by a community-acquired MRSA, and specifically the MRSA clone USA 300. USA 300 has been linked to both aggressive disease and frequent recurrence with studies reporting recurrence rates as high as 72%. The current US incidence of pediatric hospitalizations caused by MRSA SSTI has been estimated to be more than 45 per 100,000 children, with many children requiring surgical procedures to drain pus caused by the infection.

Because frequent recurrence of MRSA SSTI is believed to increase suffering, health care utilization, and cost, there has been an emphasis on developing strategies to decrease the rate of recurrence. MRSA colonization (presence of bacteria on the skin and in the nose) has been demonstrated to be one risk factor for SSTI. So most strategies to prevent recurrence have included *decolonization* of patients. Strategies to prevent hospital acquired MRSA infections have included topical mupirocin ointment in the nose to eliminate nasal carriage and chlorhexidine or bleach baths to eliminate skin carriage. The reported success rates of such protocols vary. Prevention of community acquired MRSA has been studied to a much lesser degree. One small, randomized controlled trial of adults and children with Staphylococcus aureus infection (MRSA and MSSA) has shown a short lasting effect (4 months) of a decolonization protocol on bacterial eradication (defined as no presence of bacteria on the skin or in the nose), and an even shorter lasting effect (1 month) on SSTI recurrence. Decolonization of all members of the household was more effective on SSTI recurrence than decolonization of the index patient only. The effect of decolonization on patient-centered outcomes such as quality of life and school or work attendance has not been assessed.

In this study, we intend to compare two therapies for MRSA SSTI (abscess surgery and hygiene education compared to abscess surgery and hygiene education followed by decolonization) to determine which is the more effective treatment for MRSA SSTI. We will focus on patient-centered outcomes as described by the families of MRSA infected patients. Such outcomes are likely to include quality of life, side effects, and school and work attendance. The hypothesis is that treatment with decolonization will decrease the rate of SSTI recurrence and improve overall patient-centered outcomes. The rationale is that negative outcomes such as recurrence may be avoided through the use of readily available prevention strategies, however, it is important to determine how burdensome those prevention strategies are for patients and families.

2.0 Rationale and Specific Aims

The past two decades have seen a dramatic increase in skin and soft tissue infections (SSTI) caused by antibiotic resistant bacteria Methicillin-resistant *Staphylococcus aureus* (MRSA). The shift from hospital-acquired infections to community-acquired infections has resulted in many otherwise healthy children being affected. Recent estimates are that the US incidence of hospitalizations caused by MRSA SSTI is > 45 per 100,000 children, with many children requiring surgical procedures to drain pus caused by the infection.

Treatment of MRSA SSTI usually involves abscess surgery (incision and drainage), but recurrence of infection can be as high as 72%. Decolonization protocols are, therefore, sometimes recommended to eradicate the bacteria and decrease recurrence. These measures can be burdensome for the patient, consisting of regular bleach baths or chlorhexidine body washes, and/or daily nasal antibiotics. The Infectious Disease Society of America supports decolonization, but acknowledges that the recommendations are based on limited, non-MRSA specific data. One small, randomized controlled trial of children with Staphylococcus aureus infection (MRSA and non MRSA) has shown a short lasting effect (4 months) on skin colonization (presence of bacteria on the skin), and an even shorter lasting effect (1 month) on SSTI recurrence. The effect of decolonization on patient-centered outcomes such as quality of life and school attendance has not been assessed.

To accomplish this the research aims for this proposal are:

Aim 1. Explore MRSA abscess-related outcomes that are important to both patients and their families and explore patient/family perspectives on the study design via a Patient Advisory Board (PAB).

> **Sub Aim 1a) Hold sessions with families from the Pediatric Surgery clinic and Emergency Medicine Department to gather this patient-centered information.**
>
> **Sub Aim 1b) Analyze PAB session results and incorporate patient/family input in tools to be used in Aim 2.**

Aim 2. Compare the effectiveness of two interventions for MRSA SSTI, specifically abscess surgery and hygiene education versus abscess surgery and hygiene education followed by decolonization in children 3 months to 18 years of age who present to the Emergency Department as well as the Pediatric Surgery Clinic and Operating Room.

> **Sub Aim 2a) Compare the two interventions on rate of self-reported MRSA SSTI recurrence and repeat surgery over a 12 month follow-up period.**
>
> **Sub Aim 2b) Compare the two interventions on patient-centered outcomes such as quality of life and school attendance as well as others informed by Aim 1 over a 12 months follow-up period.**
>
> **Sub Aim 2c) Determine the burden and patient preferences regarding the decolonization protocol on families.**

The proposed research will be conducted as a randomized controlled comparative effectiveness trial over three years. Aim 1 will be carried out over a six months period. For Aim 2, recruitment and randomization will be done over a period of approximately 12 months and will be followed by a 12 month long evaluation period. Interviews as well as recruitment and randomization will be carried out in the pediatric surgery outpatient clinic and over the phone for patients of the Emergency Department at Riley Hospital for Children in Indianapolis, IN. Evaluation will be done by trained research assistants through phone interviews (or data collection via US post and/or online via secure email link to REDCap) at approximately 6 weeks, 6 months, and 12 months.

3.0 Inclusion/Exclusion Criteria

Eligible participants will be the following:

- Children/youth ages 3 months up to 18 years seen in the Riley Pediatric Surgery Outpatient Clinic for a follow up visit within a maximum of 90 days of the incision and drainage of a culture-confirmed MRSA abscess (regardless of where the abscess was drained)
- Children/youth ages 3 months up to 18 years who had an incision and drainage of a culture-confirmed MRSA abscess in the Riley Emergency Department or Riley Operating Room within a maximum of 90 days of enrollment (though target enrollment is the two weeks prior to enrollment)
- Household members of the patient who are between the ages 3 months up to 64 years

In order to enroll, the parent or legal guardian of the eligible patient must consent to the patient's as well as the parent's own participation and the patient, if age seven and older, must assent to participate.
The following children will be excluded due to the risk of a more complicated course:

- Children in need of additional abscess surgery at the time of follow up
- Children with documented immune deficiency
- Children who are previous burn victims and required specialized burn care
- Children with another medical condition may be excluded at the discretion of PI, e.g. for a condition that would be adversely affected by bleach baths.

The following children will also be excluded:
- Children <3 months of age
- Children with self/parent-reported history of sensitivity to chlorine bleach or mupirocin
- Children whose siblings/families have already been recruited into the study

The following family members will be excluded:
- Family members with a self/parent-reported history of sensitive to bleach or mupirocin or other condition that would preclude a bleach bath.
- Family members who cannot understand the verbal and written instructions.
- Families without a bathtub in their home and pregnant and nursing mothers will also be excluded.

For the Patient Advisory Board (PAB), the following inclusion criteria apply:
- Parents/legal guardians of children ages 3 months to 18 years who have undergone an incision and drainage procedure at Riley for an abscess (regardless of MRSA confirmation)
- Children and youth ages 9-18 who have undergone an incision and drainage procedure at Riley for an abscess.

4.0 Enrollment/Randomization

In-person recruitment will be done in the pediatric surgery outpatient clinic located in the Riley Outpatient Center Riley Hospital for Children, Indiana University Health, Indianapolis, Indiana. The Pediatric Research Network (PResNet) RAs will have access to the clinic schedule available in the pediatric surgery office. The electronic medical record of patients scheduled for "follow up of abscess incision and drainage procedure" will be accessed to determine whether the patient's culture from the day of their procedure grew MRSA. Eligible families will be approached in the outpatient surgery exam room as they wait for their appointments (or after the appointment ends). Families interested in participating will be consented before and/or after completion of their follow-up appointment.

Recruitment will also be done via phone for patients who had an incision and draining procedure of a culture-confirmed MRSA abscess in the Riley Emergency Department (ED), Riley Operating Room (OR), or IU Health North Operating Room (OR). The PResNet RAs will have access to the electronic medical record and/or queries of patients who underwent incision and drainage in the ED and OR (under a waiver of authorization for recruitment). PResNet will send a recruitment letter to those eligible patients who have a culture positive for MRSA and then attempt to contact them via phone for consent and randomization. Parents of children and youth who are in the Emergency Department (ED) for an incision and drainage procedure will be verbally consented for a swab of the boil to send to a lab for detection of the presence of MRSA in order to identify eligible patients for the study. Children ages seven and older will also be verbally assented for the swab. Anyone contacted by phone who meets screening will have the option to meet an RA at Riley or in another private space to consent/assent and complete baseline data collection in person.

In an effort to increase enrollment, an RA will attempt to approach families who are in the hospital after an incision and drainage procedure to introduce the study and answer any questions in person. Families will have the option to consent to participate while their MRSA result is pending and then be enrolled once a positive MRSA result is documented in the EMR.

For all patients, the initial contact about the study will be from someone recognized as part of the healthcare team, either in person or via phone or letter (or in the discharge instructions).

The unit of randomization will be the household of a child. Randomization will be done in REDCap. Half of the households will be assigned to hygiene education, and the other half will be assigned to hygiene education followed by decolonization. We will also attempt to stratify enrollment by clinical site of incision

and drainage, Riley ORs and Riley Emergency Department. In an effort to boost enrollment, families who are already doing bleach baths (or intend to) may be placed in the bleach bath/Mupirocin arm (rather than excluding them).

Potential participants may also receive a recruitment flyer from clinic or hospital staff and providers, or from a PResNet RA to alert them to the possibility of receiving a call about the study if they are identified as eligible (via + MRSA lab result).
For those who decline enrollment, we will collect age and demographic information as well as the reason for non-enrollment.

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PResNet is a pediatric practice-based research network located within Children's Health Services Research (CHSR), Department of Pediatrics, at the Indiana University School of Medicine. PResNet research assistants (RAs) are IUPUI Human Subjects certified and have reviewed HIPAA policies. PResNet RAs have also undergone additional training for the unique challenges in consenting/assenting potential pediatric subjects, active listening skills, and child development. Additionally, PResNet has bilingual RAs who can recruit Latino participants. PResNet RAs have recruited thousands of pediatric subjects over the last 9 years with very high recruitment rates.

Potential PAB participants will be identified by hospital and clinic physicians and staff, including review of the medical records or queries of potentially-eligible patients, who will introduce the PAB to the potential participants (in person, by phone, or via letter). Study staff will follow up with interested families to explain the PAB and invite eligible families to the next PAB session.

5.0 Study Procedures

AIM 1. Explore MRSA abscess outcomes important to patients and their families through a Patient Advisory Board (PAB) and incorporate results in outcomes tools to be used in the randomized comparative effectiveness trial

In order to ensure we are measuring outcomes that are important to patients and their parents we will invite families who have experienced an incision and drainage procedure in the pediatric surgery clinic or Emergency Department to participate in a Patient Advisory Board (PAB) for the study. The Patient Advisory Board meetings will consist of informal and interactive discussions facilitated by design researchers. The meetings will allow participants to contribute as much or as little as they feel comfortable doing. One Patient Advisory Board will be comprised of parents or legal guardians of children ages 3 months to 8 years old who have undergone an incision and drainage procedure at Riley for an abscess. The other Patient Advisory Board will be made up of children 9-18 years old who have undergone an incision and drainage procedure at Riley for an abscess and their parents or legal guardians. The meetings will last up to 4 hours and will focus on study acceptability, recruitment, and patient centered outcomes. Participants will be compensated for their contribution to the study with a $20 per hour payment in the form of a gift card. No more than two family members will be compensated for participation, e.g. one parent and one child who participate can each be paid $20 per hour or two parents who participate can each be paid $20 per hour. The Patient Advisory Board may also reconvene if additional patient input is needed during the study.

AIM 2: Compare strategies of care for MRSA SSTI, specifically abscess surgery and hygiene education versus abscess surgery and hygiene education followed by decolonization, on outcomes such as SSTI recurrence and repeated surgery, and patient-centered outcomes such as quality of life, side-effects and school absence

This part of our study is a randomized comparative effectiveness trial. Recruitment, randomization, and collection of outcomes will be done by PResNet.

The interventions will be targeted to all household members for whom consent can be obtained. All participants will receive written instructions for the intervention to which they are randomized. A registered nurse in the pediatric surgery clinic will be available to review instructions and answer any questions about MRSA. The instructions for the diluted bleach bath and Mupirocin administration will also be publically available in an online video.

Intervention number 1, Hygiene education
Participants will receive specific hygiene instructions according to existing recommendations from the Ryan White Center for Pediatric Infectious Disease, Riley Hospital as outlined here:

- Take daily showers or bath with soap
- Clean hands with soap and water or with hand sanitizers when hands are dirty, and after each bathroom break or diaper change
- Don't share towels, wash cloths, clothing, toothbrushes, or razors within the family or with friends
- Discard lotions in jars (can be easily contaminated with MRSA when someone puts their hand in a jar)
- Keep all wounds including cuts and scrapes clean and covered until healed
- Avoid other person's dirty bandages or uncovered wounds
- Encourage athletes or health club members to shower before and after all practices and competitions, and wipe down equipment surfaces before and after use
- Uniforms and practice jerseys should be washed after each game or practice. Sports equipment should be washed/cleaned weekly
- Wash all towels, wash cloths, sleepwear, underwear, and linens in hot water with laundry detergent once weekly and dry with hot air in a dryer

Intervention number 2, Hygiene education and Decolonization
Participants in this intervention group will receive the same hygiene instructions as the participants in the first intervention group. In addition, intervention number 2 will include the following for all consented household members:

- Twice weekly 15 minute soaks in diluted bleach water (a cup of 6% sodium hypochlorite [Clorox; The Clorox Company] for a standard 50 gallon tub of water, or a teaspoon for each gallon of water used) for the duration of 6 weeks
- Application of 2% mupirocin ointment by the use of clean swab to the bilateral anterior nares twice daily for ten days

At the time of enrollment, those randomized to intervention 1 will receive written hygiene instructions and a form to document outcomes, such as missed school or work. Those randomized to (or placed in) intervention 2 will receive a "kit", which will include a bucket for measuring the water, two cups to be used for measuring bleach, Clorox bleach, mupirocin ointment, double sided q-tips for application of mupirocin, hygiene instructions, as well as a form to document outcomes. Participants will also receive a link to an online video demonstrating the accurate process for preparing the diluted bleach bath and administering the mupirocin. (www.youtube.com/watch?v=3RbtyLT071M&feature=youtu.be) For each intervention arm, the above materials will be sent via mail after enrollment or provided in person by a research assistant.

Outcomes Measures

The patient-centered outcomes we plan to measure are summarized below.

The results of PAB sessions performed during aim 1 of this study will further inform some of the patient-centered outcomes measures.

Recurrence of SSTI
• Percent of participants with recurrence of skin and soft tissue infection by parental report at 6 weeks, 6 months and 12 months.
Repeat surgery
• Percent of participants with repeat incision and drainage procedure by parental report at 6 weeks, 6 months and 12 months.
Adherence to intervention
• Participant adherence to intervention measured on a 5 point scale by parental report at 6 weeks • Household adherence measured on a 5 point scale by parental report at 6 weeks • Have you tried anything outside the protocol to reduce the risk of MRSA recurrence? If yes, then what? (6 weeks)
Side effects
Percent of participants with side effects from intervention by parental report at 6 weeks and 6 months.
Participant time committed to intervention
Estimated weekly time to adhere to intervention by parental report at 6 weeks
Quality of Life
• Participants' quality of life measured by parent-proxy report (or youth tool) of the PedsQL 4.0 (Pediatric Quality of Life Inventory) at recruitment, 6 weeks, 6 months, and 12 months. • Impact on free time measured on a 5 point scale by participant (age>=13) and parental report at 6 weeks
Impact on school attendance
• Participants' school attendance by parental report at 6 weeks, 6 months and 12 months
Impact on parents' work attendance
• Assessment of parents' work attendance by self report at 6 weeks, 6 months and 12 months
Other Patient Centered Outcomes
• Participant's level of pain and discomfort at incision site via NRS at enrollment and 6 weeks. • Participant's level of knowledge on what MRSA is and how to prevent its recurrence at enrollment, 6 weeks, 6 months, and 12 months. • Additional measures as suggested by Aim 1

Data Collection and Study Tools

In order to evaluate the outcomes identified above, data will be collected by RAs in person or by phone at enrollment, and through phone interviews at approximately 6 weeks, 6 months and 12 months as time allows within the study period. RAs will be trained to perform phone interviews to assess recurrence, adherence, side effects, quality of life and school/work attendance. When requested by the participant, data collection tools/questions may be mailed via US post and/or emailed via secure link to REDCap. For all practical outcomes, such as missed school and work, participants will have forms to help them document these outcomes to aid in recollection at follow up.

The data collection for specific outcomes is outlined below:

<u>*Recurrence of skin and soft tissue infection*</u>

An RA will contact a parent of participants by phone at approximately 6 weeks, 6 months and 12 months. Participants will be asked whether they have had a recurrence of MRSA SSTI since the previous contact. If the answer is yes, they will also be asked if and where medical care was sought, and if any interventions (surgery, antibiotics) were needed. In cases for which antibiotics were prescribed, the name of antibiotics and duration of course will be recorded.

Repeat surgery
In a continuation of the questioning as shown above, an RA will contact a parent of participants by phone at approximately 6 weeks, 6 months and 12 months. They will be asked whether participants needed another incision and drainage procedure for MRSA SSTI in the same or another body location. If the answer is yes, they will also be asked in what facility that was done and whether antibiotics was prescribed or not. In the cases for which antibiotics were prescribed, the name of antibiotics and duration of course will be recorded.

Adherence to intervention
An RA will contact a parent of participants by phone at approximately 6 weeks after study randomization. The RA will ask parents of participants about adherence to interventions. The RA will initiate the conversations by saying "we are very interested to know what people think about the protocol". For any of the interventions experienced (hygiene measures, mupirocin to nose, and bleach bath) participants will then be asked to report adherence. Adherence will be reported on a 5 point scale for child and other family members: We followed the instructions as recommended – always, sometimes, never.

For the purpose of analysis "always", "never omitted more than one time/dose/bath in a row" and "never omitted more than one day/week in a row" will be considered adherent to treatment.

RAs will also ask: "Have you tried anything outside the protocol to reduce the risk of MRSA recurrence? If yes, then what?" This should capture any patients in the control arm who may be using decolonization regimens outside their designed protocol.

Side effects
An RA will contact a parent of participants by phone at approximately 6 weeks after randomization. The RA will ask parents of participants about side effects to interventions, for example: "Did any family member experience side-effects from the intervention? All parents will also be asked: "Dry skin and irritation in the nose or runny nose are sometimes reported in families, have any of your family members experienced those symptoms?

Participant time committed to intervention
An RA will contact a parent of participants by phone at approximately 6 weeks after randomization. If participant report that they adhere to the protocol, the RA will ask parents to estimate the amount of time (in hours) per week they estimate the intervention took for all family members combined.

Quality of Life
Impact on quality of life will be measured by the use of Peds QL, Pediatric Quality of Life Inventory. [22] The Peds QL was developed to measure health-related quality of life (HRQOL) in healthy children and adolescents and those with acute and chronic health conditions. The RA will administer the 23-item parent proxy report of the Pediatric Quality of Life Inventory in person or by phone at recruitment and at recruitment, and over the phone at approximately 6 weeks, 6 months, and 12 months. Participants 13 and older will be able to give self-report.
We will also assess the impact of the protocol on free time. RAs will ask participants (13yrs and older) "How much has the diagnosis of MRSA impacted your ability to do the things you like to do in your free time?"

Impact on school attendance
An RA will contact a parent of participants by phone at approximately 6 weeks, 6 months and 12 months. Parents of participants will be asked whether their child have missed any school days due to MRSA SSTI. Parents will be asked about number of school days missed.

Impact on parents' work attendance
An RA will contact a parent of participants by phone at approximately 6 weeks, 6 months and 12 months. Parents of participants will be asked whether they have missed any workdays due to their child's or their own MRSA SSTI. Parents will be asked about number of work days missed.

Medical data that cannot be collected directly from the parent of the patient, such as infection site, size of boil, location of reoccurrence may be collected via review of medical record.

Study Timeline

	Year 1				Year 2				Year 3			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Aim 1 – PAB Sessions												
Aim 2 – Recruitment												
Aim 2 – Data Collection												
Statistical Analysis												
Manuscript Preparation												

6.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Oversight for the conduct of the study will be provided by the study PI, Dr Paul Musey, with input and advice from his mentorship panel. He will take primary responsibility for overseeing data collection and verification and review of cumulative adverse events. While adverse events are not anticipated, a process has been established for continuous review of data and patient safety. The PI and his study team (PResNet RA and PResNet Study Coordinator) will conduct quarterly review meetings of the data. Other members will be included in these meetings at the discretion of the PI. Quarterly meeting summaries will include the number of patients recruited, rate of recruitment refusal, and subject attrition. Additionally the research team will report (1) all causes of mortality and (2) morbidity (hospitalizations, ER visits, and other injuries/problems resulting from the study protocol). Any adverse events occurring will be documented and reported according to Human Research Protection Program (HRPP) at Indiana University policies and procedures. This (de-identified) summary may be submitted to the Patient Advisory Panel (PAB) of the Patient Engagement Core. Cumulative adverse events and study progress summary will be communicated to the IRB at the time of continuing review.

7.0 Study Withdrawal/Discontinuation

Participants are always free to discontinue any therapy if they find it intolerable at any time.
Participants will be encouraged to contact PResNet RA should they decide to do so.
At every follow up point, PResNet RAs will attempt to make contact using each phone number up to three times. If they cannot make contact at that point, they will attempt to contact them by email or physical mailing address if those are available. Should those measures fail, the patient will be considered lost to follow-up. When assessments begin, RAs will explain to parents how long the interview should take. If a parent has to interrupt and end an interview, RAs will attempt to schedule a follow-up appointment at which they can continue from where they left off. Should they not be able to re-contact that parent, that patient will be considered lost to follow-up, but that data which has been collected will be used.

Participants are also able to leave the PAB at any time.

8.0 Statistical Considerations

Based on previous published studies we estimated the risk of recurrence in the hygiene education group to be 50%. REF We then determined our sample size to ensure adequate power to detect a 50% relative reduction in SSTI recurrence in the hygiene and decolonization group at 12 months ($\alpha = 0.05$ and $\beta = 0.8$). We used the formula for sample size calculation for dichotomous outcomes $((2(Z\,\alpha + Z\,\beta)^2 \times P\,(1-\underline{P})) / ((P_c-P_I)^2)$ where $\underline{P} = (P_c-P_I)/2$, P_c is the expected proportion of events in hygiene intervention group, and P_I is the expected proportion of events in hygiene and decolonization group. We determined our needed sample size in each group in our study to be 59. Assuming a 20% drop-out rate at 6 weeks, and another

10% at each subsequent follow up, we will aim to enroll 95 households/adolescent-parent pairs in order to achieve a final study group size of 59 participants in each of our intervention groups.

9.0 Privacy/Confidentiality Issues

Several measures will be taken to protect patient confidentiality. Identifying information collected on paper forms will be entered into REDCap and stored in a locked file cabinet in the PI's or PResNet's office and access to them will be restricted to study personnel only (i.e., only the PI, PResNet study coordinator, and RAs will have keys to the file cabinet). All data provided by participants (e.g., responses to questionnaires) will be entered into REDCap. Identifiable database records will be destroyed at the end of the study or as soon as the law allows.

10.0 Follow-up and Record Retention

Tape recordings of the PAB meetings will be housed in a locked file cabinet in a locked office and/or stored as a digital file on the PResNet server or in the REDCap (Research Electronic Data Capture) database system. The servers hosting REDCap are administered and supported by Indiana University's University Information Technology Services (UITS) and are physically located in IU's secured and environmentally structured data center on the Bloomington campus. To comply with HIPAA guidelines, physical, administrative, and technical safeguards and on ongoing risk management framework have been implemented and documented to ensure the security and protection of the study data within the data center, the servers, and the database. Access will be granted only to the PI and the study personnel to perform transcriptions. Tape recordings are identified by the aforementioned code number assigned by study personnel to each patient. There is no other identifying information contained on the tape recordings. The duration of the study is three years. All data provided by participants (e.g., responses to questionnaires) will be entered into REDCap. Data records will be destroyed through shredding 7 years after completion of the project.