Development and pilot testing of an equity-focused and trauma-informed communication intervention during family-centered rounds

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Purpose of the Study

The overall objective of this study is to test the feasibility, acceptability, and preliminary efficacy of an equity focused and trauma-informed clinician coaching communication intervention to improve child health and reduce the stress of hospitalization on Black and Latino(a/x) caregivers of hospitalized children. We will randomize 10 clinicians to either an intervention or waitlist control arm; clinicians in the intervention arm will receive the intervention immediately, while clinicians in the waitlist control arm will receive the intervention once we collect our primary efficacy outcome. We will include all clinicians to assess feasibility and acceptability data. We will audio record rounds for 3 Black and 3 Latino(a/x) caregivers per clinician (total n=60 caregivers, 30 in each arm).

Specific Aim 1: To co-develop and refine an equity focused and trauma-informed communication intervention for family-centered rounds.

The intervention will aim to improve communication with Black and Latino(a/x) caregivers of hospitalized children. We will combine previously successful clinician coaching interventions, our prior and ongoing research, and expertise in equity and trauma-informed literature to guide intervention development. We will create a manualized, intervention protocol that will undergo iterative user-testing with 20 Black and Latino(a/x) caregivers of recently hospitalized children and 10 clinicians to refine the intervention to meet the specific needs and preferences of caregivers and their clinicians.

Specific Aim 2: To assess the feasibility and acceptability of an equity focused and trauma-informed communication intervention.

We will test the intervention in a randomized pilot with 10 clinicians and 60 caregivers of hospitalized children in a two-arm trial with intervention and waitlist control arms. We will assess recruitment, enrollment, and data collection feasibility as well as intervention fidelity to evaluate feasibility of implementation and skill uptake using audio-recordings of rounds. We will develop a semi-structured interview and survey to assess acceptability as well as facilitators/barriers to implementation.

Specific Aim 3: To evaluate the preliminary efficacy of an equity focused and trauma-informed communication intervention on clinician-caregiver communication quality and caregiver stress.

Background & Significance

Hospitalized Black and Latino(a/x) children experience longer lengths of stay, higher healthcare costs, more medical errors, and higher readmission rates than their White counterparts. Although many factors likely contribute, racial/ethnic differences in clinician-caregiver (parent or guardian) communication may exacerbate these disparities. Across settings, including our preliminary work in the inpatient pediatric environment, Black and Latino(a/x) patients experience worse communication quality as evidenced by less patient and family-centered, empathic, and respectful communication as compared to White patients. Poor communication with clinicians can increase caregiver stress during the hospitalization with impacts on child health and future healthcare utilization. Despite evidence that

prior discrimination and trauma affect clinician-caregiver communication, current models of patient and family-centered care fail to incorporate equity and trauma-informed care into best practices. Currently, no prior investigator has tested an equity focused and trauma-informed clinician communication intervention to disrupt cycles of poor communication with Black and Latino(a/x) caregivers and lower the negative impacts of hospitalization on caregiver and child mental health.

Significance:

Hospitalized children from minoritized groups experience worse outcomes than White children:

Black and Latino(a/x) children disproportionately experience negative hospital outcomes compared to White children.7These inequities are not fully explained by patient pre-hospitalization risk, illness severity, or socioeconomic status8,9and likely reflect differences in inpatient healthcare quality. High quality communication is a fundamental aspect of high-quality healthcare that has well documented disparities in adult patients. Black and Latino(a/x) patients have been shown to experience worse communication quality as evidenced by less patient-centered language, engagement in decision-making, positive affect, and respect as compared to White patients.10-15 While fewer studies have been done in the pediatric population, in our preliminary study of audio-recorded family-centered rounds, coders rated medical team interactions as having lower respect and partnership in encounters with Black and Latino(a/x)caregivers compared to White caregivers in the hospital.5 Robust data links effective communication to important patient outcomes.16-22 As previously described,23 communication may directly or indirectly contribute to known inequities such as higher rates of adverse events, conflict with families, or readmission in Black and Latino(a/x)hospitalized children.24,25Thus, there is a critical need to address poorer communication quality in Black and Latino(a/x) caregivers to improve inequities in pediatric hospital outcomes.

Poor communication can be exacerbated by discrimination (past, present, and anticipated) and prior trauma

Past experiences of racism in healthcare settings affect subsequent patient-clinician communication.26,27 Patients who are primed to expect negative attitudes based on their individual or group experiences with doctors (and healthcare systems) may walk into the medical encounter with a high level of vigilance for cues of threat.28 This response to discrimination or fear of discrimination, called stigma induced identity threat, can reduce cognitive function,29,30 impair effective communication,26 activate a stress response,31,32 and lead to coping strategies such as disengagement or emotional activation.33 Clinicians may view these behaviors as “not caring” or “difficult” leading to a cycle of clinician disengagement, poor communication, and conflict.34-37 Similarly, a past history of trauma can affect caregiver communication, coping strategies, and behavior, especially in stressful situations such as a child’s hospitalization.34,38 Black and Latino(a/x) adults disproportionately experience trauma, including ongoing experiences of interpersonal or structural racism.39,40 To improve inequities in communication we will incorporate equity and trauma-informed strategies from the education and psychology literature that have been shown to blunt the stress response, improve cognition, and prevent further traumatization.38,41-44 Additionally, we will focus on communication skills of respect and partnership, given our preliminary study found racial and ethnic differences in these

domains, which are critical for establishing a therapeutic alliance.45-47Our research fills a critical gap by developing and testing an equity focused and trauma-informed clinician communication intervention that aims to disrupt cycles of poor communication and reduce caregiver stress by recognizing the role of past experiences in clinician-caregiver communication.

Poor communication worsens caregiver and child mental health and psychosocial outcomes

Child hospitalization is a stressful experience for caregivers that can elicit changes in cortisol secretion48 and an important opportunity for intervention.44,49,50 Hospitalization can have a lasting effect with almost a third of caregivers reporting symptoms of post-traumatic stress disorder after a child's hospitalization.51,52Hospitalization may be particularly stressful for Black and Latino(a/x) caregivers given that they are more likely to experience discrimination in healthcare settings26,53 and that discrimination is a particularly salient activator of the hypothalamic-pituitary adrenal (HPA) axis.54-56 Indeed, the experience of a daily act of discrimination or a microaggression can lead to changes in cortisol secretion.54,57 Importantly, supporting caregiver mental health and stressors in the hospital can lead to greater caregiver participation in the hospital, reduced healthcare costs, and improved child mental and behavioral health.58-62Conversely, when caregiver's report higher stress post-hospitalization their children are at increased risk for readmission and emergency room visits.63 Several studies have shown that empathic communication can lower caregiver stress and help with recovery from stressful situations including in pediatric medical encounters.64,65In this study we will fill a needed gap by evaluating the preliminary efficacy of an equity focused and trauma-informed clinician communication intervention to reduce activation of the stress response in a medical encounter amongst Black and Latino(a/x) caregivers of hospitalized children.

Design & Procedures

Setting and Population: All clinicians and caregivers of children admitted to the general pediatrics team meeting inclusion criteria will be invited to participate in studies for aim 1, 2, and 3. Dr. Katy Bartlett, MD, pediatric hospitalist and Division Chief of Pediatric Hospital Medicine, and Dr. Ann Reed, Chair of the Department of Pediatrics, have agreed to facilitate recruitment. The general pediatrics team takes care of children under 26 years old with a variety of acute and chronic conditions. This population notably excludes oncology, cardiology, and primary surgery patients.

Aim 1 Study Overview: We will use a combination of existing clinical guidelines, our prior and ongoing research, and expertise in equity and trauma informed care to guide intervention development. We will create a manualized intervention protocol, which we will then refine with interviews of caregivers of hospitalized children and clinicians (nurses, attending doctors, and resident doctors). A trained research assistant will assist with intervention development and refinement. Intervention development (3 months) and refinement (6 months) will take 9 total months.

Developing the Intervention (Aim 1): We will use previously successful clinician coaching communication interventions as a starting point to develop our equity focused and trauma-informed communication intervention. The intervention core components will be built based on our conceptual model and

include:(1) communication skills where inequities exist including techniques to show respect47 and build partnership 11,99 (2) trauma-informed approach using 6 guided principles of trauma-informed care34,38,44,100 and (3) equity focus including efforts to affirm caregivers to minimize stigma induced identity threat and promote belonging.28 These interventions will lower the caregivers physiologic stress response, improving cognition, minimizing negative coping, and disrupting reinforcing poor communication between clinicians and caregivers. Caregivers who are supported are then better able to attend to the physical and emotional needs of their children,58,101 resulting in improved child adjustment to illness and hospitalization.61 After completing training attendings will have the opportunity to practice these skills and receive feedback and support from the research team. The intervention's key processes will aim to improve child adjustment to hospitalization and caregiver stress symptoms in the hospital, at 30 days, and at 90 days post-discharge. We will create a manualized, intervention protocol, which will take 3 months.

Refining the intervention (Aim 1): The manualized intervention protocol will undergo iterative testing by clinicians and caregivers to determine acceptability.102 At each interview, we will talk through the protocol and describe and show what the intervention could entail. We will ask clinicians and caregivers for feedback on our proposed intervention. At the completion of the interview, participants will complete a demographic questionnaire, including questions about age, sex, race/ethnicity, language, and education; caregivers will also answer questions about their child's health, including reason for admission, past medical history, health insurance status, self-identified social economic status, and post-discharge support. Each interview will be 30-60 minutes long. Interviews will be transcribed by GMR transcription to assist with qualitative analyses. Findings from the interviews will be used to refine the intervention to be contextually relevant. Refinement will take place over 6 months.

Aim 2 and 3 Study Overview.

We will pilot a communication intervention using a randomized waitlist-control study design, in which the unit of randomization is the attending hospitalist clinician. Ten attendings (five in each arm) will be randomly assigned to either thecommunication intervention or waitlist control arm. Randomization will be computer-generated a priori by the statistical team and loaded directly into the study's tracking database; only personnel who are not blinded to study arm will have permission to access this part of the database. The training elements of the intervention will occur prior to a clinician's scheduled time on the general pediatrics team and will then be followed by coaching and professional feedback on the communication behaviors in at least 5 real-time encounters of family-centered rounds. As in prior studies, feedback will be brief (<20 min) and timely (within 48 hours).97,106 We will provide clinicians with illustrative examples from their encounters to prompt discussion and self-reflection.97In the intervention arm, following clinician didactic and feedback completion, a research assistant will recruit, consent, and enroll 8 caregivers of hospitalized children per clinician. In the control arm, 30 caregivers will be recruited (6 per clinician) before the clinician receives the didactic and practice feedback. The 5 clinicians randomized the control arm will undergo didactics and feedback once their pre-intervention audio-recordings are complete. The research assistant will assist with recruitment, consent, enrollment, and data collection. Assessing the feasibility, acceptability, and preliminary efficacy of the intervention will take 18 months.

Aim 2 Data Collection for Feasibility and Acceptability. Recruitment, enrollment, and data collection feasibility and intervention fidelity will be used to assess feasibility of implementation of the equity focused and trauma-informed communication intervention. For recruitment and enrollment feasibility, the research assistant will record the number of caregivers and clinicians eligible vs. number of caregivers and clinicians consented and enrolled to participate. We will define recruitment and enrollment as feasible if >50% of eligible clinicians and >50% of eligible caregivers are consented and enrolled. For data collection feasibility, the research assistant will obtain data from caregivers on hospital day 1 (optional salivary cortisol samples, audio-recording of family-centered rounds, and caregiver survey). We will define data collection feasibility as >80% completion of in-hospital measures. Fidelity will be assessed by coding transcripts of audio-recorded rounds to assess all components of the intervention were delivered to each caregiver. We will define fidelity as an average of >75% of intervention elements completed per encounter. Our team will review recruitment and follow-up rates weekly and identify strategies to improve recruitment, enrollment, and data collection. To test intervention acceptability, feasibility, and appropriateness we will survey clinicians using the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), & Feasibility of Intervention Measure framework of implementation success.107 Each measure has four-items that can be averaged together to create a 5 point scale. We will define intervention acceptability, feasibility, and appropriateness as successful if < 2 clinicians rate the measure as <3 on the averaged 5 point scale. Additionally, we will perform brief 15-30 minute interviews with clinicians to provide open-ended feedback on the intervention. Clinicians in both the intervention and waitlist-control arms will provide data on intervention acceptability, feasibility, and appropriateness following intervention didactic and practical feedback.

Aim 3 Data Collection PreliminaryEfficacy We will compare preliminary efficacy by exploring for differences in our outcome measures between the intervention and control arms.

Primary Outcome: Clinician Communication Behaviors: we will use validated instruments reported by Street et al to measure the count of medical team partnership-building and supportive talk statements. Respect will be measured as a global assessment of the encounter as we have done previously. Lastly, in interpreter-supported rounds we will calculate the average number of sentences before the team pauses for interpretation.

Caregiver Participatory Behaviors: validated communication measure that counts the number of times a caregiver asks a question, states a preference, or expresses an emotion per encounter. We will compare total caregiver participatory behaviors in the intervention and control arms applying codes to audio-recorded transcripts of rounds.

Caregiver-Reported Measures: We will survey families following rounds on hospital day 1 to collect measures of satisfaction, trust in doctors, and perceived communication quality.

Salivary Cortisol: Study has collected optional saliva samples from caregivers at two time points: 30-60 minutes before and 20-30 minutes after family-centered rounds (FCR). We will now collect 25 additional

cortisol samples from newly enrolled participants. Participants will be instructed not to eat, drink, or brush their teeth 30 minutes before sampling as this can affect cortisol levels. Samples will be immediately refrigerated and stored per Duke University Hospital Clinical Lab instructions (see letter of support). Testing will be performed by the Mayo Clinical Laboratories.

Unplanned readmissions will be collected through review of the electronic health record at 90 days or more after discharge.25Important confounders, such as clinician characteristics (gender, race, years in practice), caregiver demographics (age, gender, income, education, language, health literacy) patient characteristics (chronic conditions, prior hospitalizations, severity of current illness) and factors that affect cortisol levels will be obtained and considered as covariates in adjusted analyses.89

Selection of Subjects

Inclusion and Exclusion Criteria:

·Eligibility criteria for caregivers: Eligible caregivers will be adults (> 18 years of age), English or Spanish proficient, capable of providing informed consent, and identified as a primary caregiver (parent or guardian) of a hospitalized Black or Latino(a/x) child on the general pediatrics team. We will exclude caregivers of children undergoing evaluation for child abuse/neglect or other cases in which the medical team believes family-centered rounds are not appropriate.

·Eligibility criteria for clinicians: we will recruit clinicians, including nurses, attending doctors, and resident doctors, who provide hospital care to children at Duke Children's Hospital. For Aim 1, we will recruit nurses and doctors (attending or residents) who practice family-centered rounds to reach our target number of 10 clinicians. All participants must be able to consent to participate. For Aims 2 and 3 we will only include attendings doctors on the general pediatrics team.

·Eligibility criteria for children: Eligible children will be those admitted to the general pediatrics team during study enrollment who identify as Black or Latino(a/x). We will include children from 0-17 years of age. We will exclude children undergoing evaluation for child abuse/neglect or other cases in which the medical team believes family-centered rounds are not appropriate. We also exclude adults (18 years or older) admitted to the general pediatrics team.

Subject Recruitment and Compensation

Recruitment and Informed Consent: Recruitment for the study will occur on 4 inpatient units at Duke Children's Hospital (DCH) in Durham, NC. Staff will identify eligible patients through daily monitoring of inpatient team lists. Staff will approach potential participants to ask if it is acceptable if the PI (Dr. Parente) or research assistant comes to speak to him/her about a study for which he/she may be eligible, whenever possible. When staff is unavailable, study team will approach potential participants and will explain the informed consent to the caregiver and ask him/her to demonstrate sufficient

understanding of study participation before signing the form. Participants will also receive a copy of the informed consent for their own records.

The informed consent will be in the form of a packet, including a description of the study, the study purpose and procedures, all potential risks and benefits, amount and requirements to be met for compensation, and researcher contact information. Participants will receive $50 after completion of their interview (Aim 1), or if participating in the intervention trial after completion of hospital data collection. All participants will be required to provide written informed consent. All information will be written at a 4th grade reading level, due to differences in reading abilities of participants and variations in level of cognitive impairment. This reading level will support the autonomy of participants by allowing persons who have poor literacy skills to understand the informed consent. Because issues with reading may be present, participants will be given the option to have the informed consent read aloud to them by Dr. Parente or research assistant and to have a person of their choice present.

Enrollment:

·Enrollment of patients: At the time of admission, eligible caregivers will be provided information about the study (prepared by study staff) and asked by their child's medical team if they are willing to receive more information from the study team. The PI or research assistant will then meet with the potential participant to inform them about the study. If the potential participant is interested in participating in the study, the PI or research assistant will walk the participant through the informed consent, clearly explaining the study purpose and planned activities and will answer all questions. Finally, the PI or research assistant will obtain a signed informed consent and will provide the participant with a copy for their own records. The primary threat to attrition in this study is loss to follow-up. Participants will receive $50 each after completion of each of the two time points: interview (Aim 1, $50), hospital measures (Aim 2,3: survey, audio-recording, and cortisol sample, $50). Study will enroll an additional 25 participants to collect saliva samples, and complete audio recording.

·Recruitment and enrollment of clinicians: For Aim 1, intervention refinement, we will recruit attendings, nurses, residents, and interpreters who practice family-centered rounds at Duke. An email communication with a study information sheet will be sent to eligible clinicians to recruit for the interview. If a clinician is interested, a member of the study team will meet with them in-person to obtain written consent. Once consented, the team will work with the clinician to schedule an interview date in the future. Clinicians can withdraw from the study at any point.

For Aim 2 and 3, we will limit recruitment to the 22 pediatric hospitalists who serve as attendings on the general pediatrics team. With support from the Pediatric Hospital Medicine Division Chief (Dr. Bartlett) we will notify all potentially-qualifying clinicians about the study and ask if they are willing to receive more information. A preliminary survey of this group suggested 91% (20/22) would be interested in participating in a communication intervention, with majority interesting in receiving real-time feedback 77% (17/22). Clinicians in the waitlist-control arm (n=5) will not receive the intervention until audio-recordings of 8 encounters have been completed and 6 months from randomization have occurred. Clinicians will receive $50 at each time points; interview (Aim 1) completion of didactics and baseline survey (Aim 2 and 3) and at completion of 8 audio-recorded encounters (Aim 2 and 3).

In this study parents will provide consent for subjects under 18 years of age. To demonstrate sufficient understanding of study participation Dr. Parente or research assistant will use the teach-back method, where they will ask potential participants to recall or explain topics that were discussed in the informed consent, using their own words. These questions are meant to prompt a discussion. Similar to Kripalani et al. (2008),115 Dr. Parente or research assistant will ask the following questions to assess comprehension of informed consent: 1) This is a research study; do you have to participate?; 2) What would you do if you change your mind about participating in the study?; 3) There are some risks involved in this study. Can you tell me about the risks discussed? (If they do not remember, review them again); and 4) Do you still want to participate after hearing all the details? If a participant cannot demonstrate comprehension of consent or necessary cognitive ability for study participation or both as assessed by Dr. Parente or research assistant, he/she will not be included in the study.

Study Interventions

We will use previously successful clinician coaching communication interventions as a starting point to develop our equity focused and trauma-informed communication intervention. The intervention core components will be built based on our conceptual model:(1) communication skills where inequities exist including techniques to show respect47 and build partnership 11,99 (2) trauma-informed approach using 6 guided principles of trauma-informed care34,38,44,100 and (3) equity focus including efforts to affirm caregivers to minimize stigma induced identity threat and promote belonging.28 These interventions will lower the caregivers physiologic stress response, improving cognition, minimizing negative coping, and disrupting reinforcing poor communication between clinicians and caregivers. Caregivers who are supported are then better able to attend to the physical and emotional needs of their children,58,101 resulting in improved child adjustment to illness and hospitalization.61 After completing training attendings will have the opportunity to practice these skills and receive feedback and support from the research team. The intervention's key processes will aim to improve clinician-caregiver communication quality and caregiver stress. We will create a manualized, intervention protocol, which will take 3 months.

Risk/Benefit Assessment

All interviews with clinicians and caregivers will be limited to 60 minutes to protect against fatigue. Participants will be told that they may skip any questions, including those during the interview, on the demographic questionnaire, and on the data collection forms collected during the intervention. All data collected will be de-identified, where each participant will receive a three-digit identification number that will be used to label their audio recordings, transcripts, demographic information, and intervention data. Only Dr. Parente will have access to the key linking identification numbers to participant names.

Data management will strictly adhere to the Duke University Health System Institutional Review Board guidelines and federal privacy regulations. No identifiers will be used in reports, materials, or presentations that originate from this study. For publication purposes, only group data will be published. All data will be stored in a secure Duke University and Medical Center approved manner (secure drives,

identifiers separate, paper behind a minimum of two locks). More specifically, all recorded information will be transcribed into an electronic format. If any identifying information is shared in the interview, the information will be redacted from the electronic transcripts. All electronic data files, including all audio recordings, electronic versions of transcripts, and intervention data, will be stored only on a password-protected secure file server (located behind a firewall) using Duke University Department of Pediatrics on-site file server. Non-electronic files will be kept in a locked file cabinet in a locked office in Dr. Parente's office in the Duke Children's Health Center. In the event of a suspected breach, the Duke University Health System Institutional Review Board will be notified within 24 hours.

Following federal regulations for protection of human subjects, Dr. Parente is certified in Human Subjects Protection for Research by Duke University and the Collaborative Institutional Training Initiative (CITI). Dr. Parente has completed over 40 hours of Responsible Conduct of Research Training and has current CITI certification in biomedical and social sciences research. Dr. Parente's mentors and collaborators have also completed training in Human Subjects Protection for Research and CITI training.

Data Analysis & Statistical Considerations

Aim 1 Analysis:

Qualitative data will be analyzed using applied rapid qualitative analysis as has been shown to inform real-time intervention development. Data collection and analysis in this pragmatic approach aim to identify or broaden the understanding of key mechanisms, intervention elements, salient descriptors, or facilitators and barriers of a program to address time-sensitive research questions. The analysis will integrate all participants' perspectives, including caregiver and clinician perspectives. Findings from the interviews will be used to refine the intervention to be contextually relevant. We will have interviews transcribed and illustrative quotes will be selected.

Aim 2: This is a prospective waitlist-control pilot study to develop and test an equity focused and trauma-informed communication intervention. The goal of this intervention is to improve child and caregiver mental health following hospitalization through better quality communication between clinicians and caregivers of hospitalized children. We will randomize 10 clinicians to an intervention or waitlist group; clinicians in the intervention group will receive the intervention immediately, while clinicians in the waitlist group will initially serve as the control arm then receive the intervention to provide feasibility and acceptability data. Our outcome measures are as follows:

Feasibility: Feasibility will be assessed by computing the enrollment rate, plus a 95% confidence interval, and comparing that enrollment rate with a benchmark value of 50%. If we identify 160 eligible subjects we will be able to estimate a participation rate of 50% to within a 95% confidence interval of +/-8%. Feasibility will also be assessed by computing the rate of complete data collection and comparing that rate with a benchmark value plus a 95% confidence interval. Our benchmark values vary by time point, and are as follows if 80 caregivers participate, 80% for in-hospital measures (+/-17% for 95% confidence interval). Lastly, we will assess fidelity to the intervention by counting clinician communication behaviors during audio-recorded encounters of rounds to assess all components of the intervention were

delivered to each caregiver. We will define fidelity as an average of >75% of intervention elements completed per encounter.

Acceptability: To determine clinician acceptability of the tool, a mixed methods approach will be used in which quantitative data from self-report questionnaires are complemented by qualitative data from open-ended response items, and used in concert to further refine the intervention. Self-report questionnaires will include a 12-item survey with 5-point Likert scale response items as described by the tool developed by Weiner et al (2017) to assess intervention acceptability, feasibility, and appropriateness.107 Quantitative data from the self-report questionnaires will be summarized using means and standard deviations. The pattern of responses to individual items will also be considered: for example, any item with a response suggesting unacceptability will be flagged for discussion with the respondent. For the qualitative analysis, a directed content analysis approach will be used to identify themes.

Preliminary Efficacy Outcomes: Primary outcomes include clinician communication behaviors, caregiver stress, and caregiver-reported outcomes (satisfaction, trust, perceived communication quality). Secondary outcomes will include caregiver optional salivary cortisol before and after family-centered rounds,64 caregiver participatory behaviors on rounds,68 caregiver ability to correctly identify child's diagnosis,111and child 30- and 90-day unplanned readmission.25Preliminary efficacy will be evaluated based on differences in the primary and secondary outcomes comparing caregiver and child data between clinicians in the waitlist-control vs. intervention arm. We will use descriptive analyses (e.g., correlations, scatter plots, box plots) to assess the general relationship between the intervention and outcomes described above. These analyses will be conducted overall and stratified by race. Exploratory analyses will be conducted via generalized linear models, with the appropriate link function depending on the outcome of interest. We will account for the intracluster of multiple caregivers per each clinician in analyses.

Sample size: While the sample size chosen must reflect the pragmatics of recruitment during a short enrollment period, we will have adequate sample size to determine 1) whether study procedures can be feasibly implemented and 2) whether the intervention is acceptable to clinicians. The proposed sample and design compares favorably to standard approaches towards acceptability and feasibility testing of similar interventions.88This study will establish feasibility in a challenging population prior to launching a larger randomized clinical trial. Our sample size is not intended to provide a definitive assessment of the performance of the intervention; instead, our approach is exploratory and iterative.

Data & Safety Monitoring

All serious adverse events (SAEs), regardless of treatment group or relationship to the research, will be reported to the IRB within 24-hours in a full written report. The adverse event will be reported to the Duke IRB. SAEs will also be reported annually in the IRB application for continuation or termination of the research. All expected non-serious adverse events that occur at a greater frequency or severity than anticipated and all unexpected non-serious adverse events will be reported to the IRB within 15 working days and summarized annually in the IRB application for continuation or termination of the research. All expected adverse events will be reported annually to the IRB in the application for continuation or

termination. The PI and mentors of this proposal are versed in these reporting procedures as they are currently required for all research. All investigators and staff involved in this project have completed an extensive course and passed a certifying exam on the protection of human subjects in research.