REACH P2: Communication Coaching to Improve Patient and Clinician Satisfaction in Cardiology Encounters

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Protocol Title Communication Coaching to Improve Patient and Clinician Satisfaction in Cardiology Encounters

Purpose of the study

Aim 1: Determine the effect of a clinician communication coaching intervention versus control on an objective measure of the quality of communication (primary outcome) and patients' perceptions of the quality of patient-centered care (secondary outcome), both overall and within Black and White patients.
Hypothesis 1a: As compared to the control group, the intervention will improve objective measures of communication quality in encounters with both Black and White patients combined and in each race subgroup.
Hypothesis 1b: Black patients and White patients seen by clinicians in the intervention group will report improvements in the quality of patient-centered care compared to patients seen by control group clinicians.
Aim 2: Determine the effect of a clinician communication coaching intervention versus control on racial disparities in objective measures of communication quality (primary outcome) and in the quality of patient-centered care (secondary outcome).
Hypothesis 2a: Racial disparities in objective measures of communication quality will be reduced in encounters with clinicians in the intervention group as compared to encounters with control group clinicians.
Hypothesis 2b: Racial disparities in patients' perceptions of the quality of patient-centered care (IPC score) will be reduced among those having encounters with clinicians in the intervention group as compared to encounters with clinicians in the control group.

Research Abstract

We propose to conduct a cluster randomized controlled trial of a clinician communication coaching intervention in ambulatory cardiology practices. The aim is to determine the effect of a clinician communication coaching intervention versus control on an objective measure of the quality of communication and patients' perceptions of the quality of patient-centered care, both overall and within Black and White patients. We will recruit cardiology clinicians and randomly assign them to the intervention or control arms. We will enroll their adult patients pre-intervention and post-intervention

to obtain surveys and audio-recordings of encounters. The intervention includes face-to-face and/or video conference meetings, and audio recording their encounters in order to teach communication skills. We will analyze audio-recordings and patients' report of quality of communication. This is a minimal risk study.

Background and Significance

Racial disparities in clinician-patient communication contribute to disparities in the patient-centered care and health outcomes: Effective clinician-patient communication is associated with higher quality of care, patient satisfaction, greater adherence to treatment recommendations, and better health outcomes. Unfortunately, there are well-documented disparities in the effectiveness of clinician-patient communication. For example, studies in primary care settings have examined communication quality via analyses of audio recordings of medical encounters. In this work, physicians were more verbally dominant, less supportive, provided less information, expressed less positive affect, and used less patient-centered communication (e.g. partnership building, open-ended questions) with African Americans than with whites. Therefore, a strategy to improve patient-centered care and health outcomes is improving clinician communication in encounters with Blacks.

Effective communication can be taught: Most interventions to improve provider communication include monitoring (e.g., recording an encounter), practice and feedback. The content of the training tends to focus on improving clinicians' communication skills such as taking the patient's perspective, active listening, and engaging the patient to participate in the encounter – actions that are less common among clinicians interacting with Blacks. A systematic review of clinician communication interventions showed improvement in objective measures of communication behaviors (gathered more information, more engaged in the encounter, greater empathy) and improvements in patient perceptions of communication, including greater ratings of patient-centered communication. These data suggest that training may communication across domains where racial disparities in communication exist. Therefore, communication training may be one approach to reducing disparities in patient-centered communication and ultimately improving health outcomes for Blacks.

The cardiology encounter is a potentially high impact target for improved communication with a goal of reducing disparities for a number of reasons. First, compared to Whites, Blacks are 2 to 3 times more likely to die of cardiovascular disease. While the reason for these disparities are multifactorial, including differences in the social determinants, differences in the quality of care spanning stable low risk to lifethreatening cardiovascular issues contribute significantly to disparities. Blacks are less likely than whites to receive a range of cardiovascular treatments including angiograms, catheterizations, coronary bypass surgery, cardiac resynchronization therapy, automatic implantable cardioverter defibrillators, etc. Third, these disparities exist even when controlling for access to care, patient preferences, and appropriateness of therapies. Experiments using actors or clinical vignettes have indicated that providers are less likely to refer blacks than whites with same disease presentation for further evaluation or treatment and disparities are present even among those with similar insurance. This suggests that provider bias may contribute to disparities in communication and patient-centered care. Fourth, less than 1/3 of cardiology clinicians are aware of the existence of disparities. Awareness among clinicians is an important part of efforts to reduce and eliminate disparities. Fifth, cardiology encounters often involve recommendations to adhere to complex and life-long medication treatments; to undergo frightening, expensive procedures; and/or to make difficult lifestyle changes – all areas in which there are racial and ethnic disparities and in which effective communication is essential. Highly effective communication in the cardiology encounter may improve patient-centered care, leading to increased

adherence to cardiology treatments, acceptance of life-saving procedures, and implementation of effective preventive strategies.

Design & Procedures

We propose a two-arm cluster randomized controlled design, in which the unit of randomization is the clinician. Up to fifty cardiology clinicians will be randomly assigned to either the coaching intervention or to a control condition. We will recruit up to 50 clinicians to ensure that we have at least 40 clinicians with complete pre- and post-intervention measures. Although the unit of randomization is the clinician, the unit of evaluation is the patient: 10 patients per clinician (4 pre-intervention and 6 postintervention) who get cardiology care from the enrolled clinicians will consent to audio-recording of their encounters and to completing the surveys. The intervention will be delivered in the clinic or via video-conference (Skype or Facetime), providing individual coaching and professional feedback on the communication behaviors encounters. We will also measure Press Ganey scores by clinician pre- and post-intervention. We will ask that learners (i.e. medical students, fellows, interns, etc.) not be in the room during recorded encounters with enrolled patient participants.

Pre-Intervention

We will work with the Duke Division Chief of Cardiology to recruit clinicians across Duke's ambulatory cardiology clinics. Enrolled clinicians will complete a baseline and demographics survey. Then, for each enrolled clinician, we will recruit and enroll 4 of their patients for baseline measures. Patients will be consented prior to the encounter. After consenting, they will be asked to complete a survey on a tablet in an application that uses REDCap to obtain demographic and health information. We will seek the patient's permission to access their medical record to obtain information about their cardiology care and health status. Patients will audio-record the encounter on a tablet that saves the audio-recording directly to REDCap. The audio-recording is not stored locally on the device. After the visit, patients will complete a survey on the tablet in REDCap with questions to measure communication quality of their interaction with the clinician and will complete the Interpersonal Processes of Care Survey. If a patient cannot complete this survey after the visit, we will call the participant to complete the survey over-thephone, email the REDCap survey, or mail a paper copy to the patient. After patients complete the survey, their participation in the study is complete.

Randomization and Intervention

After 4 patients have been enrolled and successfully completed the baseline measures, the clinician will be randomized to either the intervention arm or the control arm. The intervention will contain elements of Motivational Interviewing coaching but also will teach providers how to address patient emotion and increase the efficiency of their visits. Clinicians randomized to the intervention will receive a tailored communication coaching intervention that includes didactic elements, audio recording encounters and providing feedback, and role-playing. They will receive a 'pocket card' that they can use to remind themselves about what they've learned in the coaching sessions.

The clinicians will meet in-person or via video conference three times with the coach.
Session #1: The first meeting with providers will give an overview of the study and communication techniques.
Then, clinicians will audio-record up to 3 clinical encounters with patients. These audio-recordings are the only data from the patients as patients do not complete surveys and we do not obtain any

information from their medical records. The consent process is outlined in the consent section below. The clinician uploads the audio-recording immediately to a shared Box folder and deletes the recording from the encrypted device, an iPod Touch.
The coach listens to the recordings then schedules a coaching session with the clinician. Session #2: The coach meets with the clinician to provide tailored feedback based on the audiorecordings. At the end of the session, the clinician will set a goal for a communication skill they will try to use in future encounters.
Clinicians then repeat this process by recording up to 3 new clinical encounters following the same procedures.
The coach listens to the audio-recordings and schedules another coaching session.
Session #3: The coach meets with the clinician to provide tailored feedback based on the audiorecordings. At the end of the session, the clinician will set a goal for a communication skill they will try to use in future encounters.

During the feedback sessions, coaches will debrief about the encounters, answer questions, and discuss difficult patient interactions. The audio-recordings will be saved to a Box folder that only the clinician, study coordinator, coach and data manager have access to. These intervention audio-recordings will only be used to tailor the communication coaching sessions. Clinicians in the control arm will not get communication coaching.

Follow-up

Clinicians in both arms will then move into the follow-up phase. Clinicians will complete the follow-up survey. Then we will recruit and enroll 6 of the clinician's patients for follow-up measures (these will be different patients than those who participated in the baseline measures). We will follow the same procedure as those patients enrolled at baseline. Patients will be consented prior to the encounter and after consenting, they will be asked to complete a survey on a tablet in REDCap to obtain demographic and health information. We will seek the patient's permission to access their medical record to obtain information about their cardiology care and health status. Patients will audio-record the encounter on a tablet that saves the audio-recording directly to RedCap. The audio-recording is not stored locally on the device. After the visit, patients will also be asked questions to measure communication quality of their interaction and to complete the Interpersonal Processes of Care Survey. If a patient cannot complete this survey after the visit, we will call the participant to complete the survey over-the-phone, email the REDCap survey or mail a paper copy to the patient.

Measures: Patients who participate pre- and post-intervention will be asked questions about their demographics, health, healthcare utilization, and questions specific to their encounter with the enrolled clinician. The patients' responses to survey questions will not be shared with the clinician.

Enrolled clinicians will be asked questions about their demographics, clinical care history, and a survey about their confidence to communicate about behavior change, outcome expectations that communicating about behavior change positively impacts patient behavior, and barriers to communication. Clinicians will complete the survey about the communication aspects again at followup.

Process Measures: To refine the intervention for future studies, participating clinicians will respond to questions about helpfulness, ease of use of the coaching intervention, the extent that they would recommend this training to a colleague.

Pilot: Prior to starting recruitment, we will do a small pilot test of the patient recruitment and data collection with up to 20 patients. The purpose is to ensure that the patients are able to use the tablet and the workflow is feasible within the clinic. We will follow the same patient recruitment plan and data collection process, including the inclusion/exclusion criteria. The patients will be patients who are attending their cardiology visit with the study co-investigator, Dr. Larry Jackson or with Dr. Kevin Thomas, a collaborator on the project. We will recruit additional cardiology patients with permission from their doctor. All of the patients' data, including survey responses and audio-recordings will be deleted within 60 days of collection. The only record of the patient's participation will be their signed consent form.

Selection of Subjects

In total, up to 720 people will consent to participate: 50 clinicians, up to 500 patients to complete the survey and audio-recording and another 150 patients to verbally consent to audio-recording the visit but no surveys. Up to 20 patients will consent to participate in the pilot.

Clinicians: Cardiologists who provide ambulatory cardiology care in a Duke cardiology clinic at least ½ day per week are eligible.

We will work with the Duke Division Chief of Cardiology to identify and recruit clinicians across Duke's ambulatory cardiology clinics.

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Patients: Patients must be at 18 years or older, identify as Black/African-American or White, can read and speak English, not hospitalized, capable of providing informed consent and be a new or return patient of an enrolled clinician. Patients who are accompanied by a third-party member that is not willing or able to remain in the waiting room during the patient's visit and 1) does not wish to be recorded; 2) a minor without a parent/legal guardian; 3) unable to consent will be excluded. There are two types of patient participants: those who participate pre-intervention or post-intervention and those who participate during the intervention. Both types of patients must meet this eligibility criteria.

For the pre-intervention and post-intervention phase, patients will be identified through the Maestro Care Report to identify enrolled clinician's patients who may be eligible. This report will be run by study personnel after the clinician has enrolled. We will oversample Black/African American patients and exclude patients at the eligibility screener to ensure that we achieve a sample of approximately 50% Black/African American. In order to avoid analytic issues related to correlated responses, we will select unique patients (i.e., if a patient has an encounter recorded at pre-intervention, he/she will be excluded from contributing an encounter at post-intervention). Thus, we will determine effects pre and post training of the clinician, not of individual patients.

Clinicians randomized to the intervention will identify up to an additional 6 eligible patients whose encounters will be recorded and used to guide the coaching session. These patients will not complete surveys and we will not record any information about them, other than the audio-recording. The clinician will be instructed to identify patients who meet the inclusion criteria and will obtain verbal consent, as outlined below.

Subject Recruitment, Consent and Compensation
Clinicians: We will work with the Division Chief of Cardiology to identify eligible clinicians.

The Division Chief of Cardiology will present the study at the Cardiology Grand Rounds and connect study investigators with the Clinic Leaders for each participating clinic. Study investigators will meet with clinic leaders to discuss best methods for recruiting (e.g., going to a staff meeting, email, etc.). The study will also be publicized on the Division internal website and the study team may make presentations at division conferences, with approval and support of the Division. Recruitment materials will be uploaded to the IRB once they are finalized. No recruitment will occur until these materials have been approved by the IRB.

For in-person clinician recruitment, study staff will meet with the clinician and obtain written consent or econsent via REDCap and ask the clinician to complete the baseline survey. To minimize the burden of the consent process on clinicians and to accommodate their schedules, clinicians may enroll with study staff in small groups, at faculty meetings, or individually. Clinicians will be offered the opportunity to ask questions in private and/or conduct consent in private.

For recruitment via email, Clinic leaders will send out an email introducing the PI and study coordinator. The PI will follow up with the clinicians and the study coordinator will send a link where clinicians can express interest or to opt out of the study. .Due to the possibility that clinicians may miss recruitment emails, the PI and CRC will contact the clinicians more than once in order to determine if the clinician would like to enroll or opt-out.
Patients: With a HIPAA Waiver of Authorization, we will run a report in Maestro Care report to identify eligible patients by clinician at pre-intervention and at post-intervention. At their visit, clinic staff (patient service associates, nurses, etc) will ask the patient if he/she is interested in a study looking at clinician communication. Interested patients will be referred to the study recruiter for screening and, if eligible, to conduct the informed consent process in a private location in the clinic. Patients who agree to participate will be consented at that time using the REDCap econsent. In addition, since family members and friends are often very active in patient's health care decisions, they will be approached for consent to allow us to code this comments during the clinic visit. If a legal guardian is present, study staff will obtain assent from minors accompanying an eligible patient. The study team member will be present during the consent process to answer questions. Patients will receive a copy of the consent form via email or a copy will be mailed to them. Patients who do not wish to participate will be recorded in the study's REDCap database as refusing participation. Up to 500 patients (10 per clinician) will be enrolled in order to produce audio-recordings of encounters, before and after intervention. These patients will receive $20 for completing the study (audio-recording and post-encounter survey).

Clinicians randomized to the intervention will identify and obtain verbal consent from up to an additional 6 patients to provide audio-recordings for the intervention feedback sessions. The study coordinator will provide the consent script to clinicians and ask that they follow it. Using this script, clinicians will introduce the study to eligible patients. The clinician will ask patients if they will allow for their visit to be audio-recorded as part of a study to understand the way the provider communicates. The clinician will obtain verbal consent from the patient. The clinician will make it clear that the audio recording is to observe the clinician and not the patient. The clinician also will let the patient know that if they refuse, it will not affect the care they receive. Only when the patient gives consent will the clinician turn on the audio-recorder. We request a waiver of written consent because it would not be

possible for clinicians to ask patients to sign a written consent form as it would interrupt clinic flow and make the study infeasible. We anticipate that up to 150 patients will verbally consent to allow for their visit to be audio-recorded. These patients will not be compensated for their participation. Patients who complete the pilot will not be compensated.

Risk/Benefit Assessment

The study involves minimal risk. The only risk to participation in this study is the potential breach of confidentiality during audio recordings and assessment. Some of the questions participants will be asked might make them feel uncomfortable. All participants may refuse to answer any of the questions and may stop their participation in this study at any time. Due to the sensitive nature of the survey questions, study staff will take every precaution to secure the privacy of participant information. As this is an NIH-funded study a Certificate of Confidentiality (COC) from the NIH has been issued to further protect the data. Potential benefits are that the clinicians might learn more effective ways to communicate with their patients. Information learned from this study may also benefit clinicians and patients in the future.

Costs to the Subject:

There are no costs to the participant as a result of participating in the study.

Data Analysis & Statistical Considerations:

General considerations: All variables will be described and explored using frequency tables, means, medians, standard deviations, histograms, box plots, and trajectory plots, both overall and within clinician. The primary analyses will be conducted on an intention-to-treat basis; clinicians and patients will be analyzed in the group to which they were randomized, regardless of clinician intervention adherence, using all available data. The main conclusions drawn from this trial will be based on the pre-specified hypotheses outlined below and will be tested with two-sided p-values at the standard 0.05 level. For all study outcomes, we will interpret differences between groups over time with reference to prior literature regarding clinically meaningful changes. Results from exploratory analyses will be interpreted with appropriate consideration for their exploratory nature. Statistical analyses will be performed using the latest release SAS for Windows (Cary, NC) and R/Rstudio.

The goal of the primary Hypothesis (1a) is to determine the efficacy of the clinician communication coaching intervention versus usual care on improvement in an objective measure of the quality of communication from baseline to post-training. Additionally, we are interested the intervention effect within Black patients and White patients separately. The quality of communication will be assessed at both baseline encounters and post-training encounters by a summary of clinician-encounter counts derived from the audio recordings. We plan to use mixed-effects models as our primary analytic strategy because they will appropriately account for the intracluster correlation of multiple patient encounters for each clinician and same clinicians followed over time. The mixed-effects model for Hypothesis 1a will have the following form: $\log(\square_{ik}) = \square_0 + \square_1(post) + \square_2(post*int_k) + \square_3(clinrace_k) + b_{0k}$ and b_{1kj}, where Y_{ijk} is the number of quality communication statements for patient *i* at time j clustered within physician *i*, and Y_{ijk} is assumed to be Poisson with mean and variance equal to $\square_{ijk}$. The fixed effects in the model include indicator variables for the post-treatment (*post*), intervention group (*int*), and clinician race (*clinrace*). The random intercepts, b_{0k} and $b_{1kj,}$ are normally distributed and account for dependence of encounters within clinicians, both between patients and on clinicians over time. PROC GLIMMIX (with

the quadrature option) in SAS (SAS Inc., Cary, NC) will be used to fit the mixed-effects Poisson model and test the primary hypothesis (1a). Specifically, if β_2 is positive and significantly different than zero, this provides evidence of improved communication quality among patients and clinicians in the intervention group as compared to the control group.

The secondary outcome, quality of patient-centered care, is a continuous measure assessed at baseline and post-training. However this is a patient-centered outcome (i.e., the patient's perception) and the same patients are not being followed longitudinally. Therefore, the patients' data collected in the baseline period will not be incorporated in the analysis.

Yik= $\beta_0 + \beta_1(\text{int}) + \beta_3(\text{clinsex}_k) + \beta 4(\text{clintype}_k) + b_{0k}$, where Y_{ik} is the IPC score for patient *i* clustered within physician *k*, and Y_{ik} is assumed to be normally distributed. The fixed effects in the model include indicator variables intervention group (*int*) and the clinician stratification variables. The random intercept, b_{0k}, is normally distributed and accounts for dependence of patients within clinicians. PROC MIXED in SAS (SAS Inc., Cary, NC) will be used to fit the mixed-effects model and test hypothesis (1b). Specifically, if β_1 is positive and significantly different than zero, this provides evidence of greater IPC among patients of clinicians in the intervention group as compared to the control group.

Hypothesis 1b will be repeated within Black and White patients separately with the goal to ensure that the intervention is effective in each subgroup (as an overall treatment effect can sometimes mask important heterogeneity). Relative differences in the intervention effect on reducing disparities will be addressed in Aim 2.

F.3 Aim 2 Analyses**:**

Hypothesis 2a: Racial disparities in objective measures of the quality of communication will be lower in encounters with clinicians in the intervention group as compared to encounters with clinicians in the control group.

Hypothesis 2b: Racial disparities in patients' perceptions of the quality of patient-centered care will be lower among those seen by clinicians in the intervention group as compared to encounters with clinicians in the control group.

A mixed-effects Poisson model will again be the primary modeling strategy for the objective communication outcome Aim 2 analyses. For this Aim, however, the model will include patient-race interaction terms and will have the following form: $\log(\beta_{ijk}) = \beta_0 + \beta_1(Black_i) + \beta_2(T2) + \beta_3(T2*Black_i) + \beta_4(T2*int_k) + \beta_5(T2*Black_i*int_k) + \beta_6(race_k) + b_{0k}$ and b_{1kj}, where Y_{ijk} is the number of quality communication statements for patient *i* at time *j* clustered within physician *i*, and Y_{ijk} is assumed to be Poisson with mean and variance equal to β_{ijk}. Again, the random intercepts, b_{0k} and $b_{1kj,}$ are normally distributed and account for dependence of encounters within clinicians, both between patients and on clinicians over time. In this model, $Black_i$ is the indicator variable for whether a patient is Black (value of 1) or White (value of 0).

Post-treatment, the Black-white mean difference among patients seen by usual care group clinicians is BWuc = exp(β0 + β1) – exp(β0), this represents the racial disparity in communication quality. The B-W

mean difference among patients seen by intervention group clinicians is BWint = exp(□0 + □1 + □2 + □3) - exp(□0 + □2).

Hypothesis 2a will be tested by $\square_5$ being significantly greater than zero, indicating a greater improvement in the number of quality communication statements for the intervention group versus the control group for Black patients as compared to White patients (i.e., the intervention group reducing the racial disparity). The estimated incident rate ratio, p-value, and 95% confidence intervals will be calculated via estimate statements in PROC GLIMMIX.

A similar linear mixed-effects model (rather than a Poisson) model will be used to examine the reduction in racial disparities of quality of patient-centered care and test Hypothesis 2b. Note that in a linear model framework, the coefficients will represent differences in means rather than rate ratios.

F.4 Missing Data: The survey data may contain missing values in any of the clinician-level and patientlevel variables due to drop-out, a missed interim assessment, or item non-response. In addition, there may be a rare instance of audio-recorder mechanical failure or of clinicians or patients turning off the recorder in the middle of the encounter. Our primary analysis technique, hierarchical models, allow for unbalanced or incomplete data and will be fit with maximum-likelihood methods to preserve the missing at random assumption. Additionally, we will thoroughly explore reasons for dropout, and depending upon the type and scope of missing data, variables may be multiply imputed as recommended by Panel on Handling Missing Data in Clinical Trials.[28] Note that if needed, we will utilize imputation methods that account for the multiple types of correlation inherent in the clustered data structure.

F.5 Power and Sample Size Considerations: The effect of interest for Aims 1 and 2 pre-post relative difference between the intervention and usual care groups; Aim 1 focuses on the overall difference and the difference within Black and White patients separately, while Aim 2 on the difference within Black patients compared to White patients. The sample size requirements are greatest for Aim 2; as discussed by Leon and Heo (2009), the needed sample size for the patient race-by-intervention group interaction is 4 times that needed for the overall test. For Hypotheses 1a and 2a, our sample size calculations are based upon the difference between two Poisson rates (incident rate ratio) in a cluster randomized design (i.e., patients clustered within clinician). Note that we are not explicitly accounting for the additional clinician-time correlation, so these calculations are conservative. Based on preliminary studies, the baseline mean number of quality communication statements is 1.0, and a conservative range of coefficients of variation (CV) is 0.2 to 0.5 to account for patients clustered within clinician. With a sample size of 240 patients (6 per clinician) and a type-I error of 5%, we will have 80% power to detect incident rate ratios of 1.5 to 1.8 for Hypothesis 1a in the overall test, 1.6 to 1.9 for Black or White patients separately, and 1.8 to 2.1 for Hypothesis 2a.

For hypotheses 1b and 2b, our sample size calculations are based upon the difference between two means in a cluster randomized design. Again, we are not explicitly accounting for the additional clinician-time correlation, so these calculations are conservative. We present a conservative range of intraclass correlation coefficients (ICC) to account for patients clustered within clinician. With a sample size of 240 patients (6 per clinician) and a type-I error of 5%, we will have 80% power to detect mean differences of effect size 0.37 to 0.44 for Hypothesis 1b in the overall test, 0.52 to 0.56 for Black or White patients separately, and 0.65 to 0.91 for Hypothesis 2b. PASS 15 was used for all calculations.

We plan to enroll approximately 2 clinicians per month and approximately 17 patients per month over 2 years.

Data & Safety Monitoring

The quality of data collection will be enhanced through extensive training of all personnel involved in data collection, with on-going quality assessments conducted while the project is in the field. Quality control checks will include feedback on protocol fidelity, interpersonal skills, and data entry and cleaning. We will also work with an experienced database manager who will oversee the operations, reconcile data from the various sources, conduct data quality assurance, provide reports to the study team, and conduct routine basic data analyses under the supervision of the study statistician. Reconciling differences in data reported from various sources will be on a case-by-case basis, ongoing as data is collected.

Privacy, Data Storage & Confidentiality

Data will be collected by trained research staff and/or entered directly by the participant. Data is collected in an application that stores the data directly in REDCap on a tablet provided by the study staff. Data is downloaded into password protected electronic files on a secure network server. All participants (patients and physicians) will be assigned a unique study number. All study files will be stored in personal locking file cabinets, located in a private and locked office on a badge-access only floor in Hock Plaza. Access to this file will be limited to study personnel. Patients will collect audio data by turning on the recorder during their office visit with their clinician in the exam room and the audio file is saved directly to REDCap through the tablet. The audio files will be downloaded into password protected electronic files on a secure network server. The intervention audio files are recorded on an encrypted iPod Touch and uploaded directly to a Duke Box account.

In the event of device malfunction, data will be collected via paper surveys. After the visit, study staff will enter data into REDCap.

Clinicians and patients will receive a copy of their consent form via email or by mail. As email is not a secure means of communication we have included this as a potential risk for loss of confidentiality in the consent form. Third-party individuals will receive a paper consent form.

Some audio-recorded conversations will be sent to DataGain. Inc in to be transcribed. We will obtain a RSSA. Audio files will be uploaded to the company website, https://transcription.datagainservices.com/enterprise via a password-protected account held by study staff. The audio file will be deleted from the website once the de-identified transcription document is uploaded.

Audio-recorded conversations will be analyzed by undergraduate research assistants in Dr. Sarah Gaither's Duke Identity & Diversity Lab. RAs will access de-identified transcripts and audio recordings via Duke Box. Only RAs who have undergone CITI training will participate in audio coding. A numerical coding system will be used for the audio files and transcripts so no names will ever be stored or linked. All RAs will sign a confidentiality agreement which states that if a research assistant personally knows one of the participants on the audio recording, they will skip coding that participant. The agreement also states that research assistants will not discuss the content of these videos with anyone outside of the lab

team. There will be a strict training and discussion surrounding the sensitive nature of these videos with each lab team member.

Data collected for the pilot will be deleted within 60 days of collection, except for the patients' consent form.

Data that is already being collected for routine use for Hospital Medicine through performance services will also be used (Press Ganey scores). This data is already available through performance services and has been obtained for the purpose of routine administrative activities within hospital medicine. The data is available at the provider level but does not include PHI.