VIVID

Educational **V**ideos to Address Racial Disparities in **I**mplantable Cardioverter Defibrillator Therapy **V**ia **I**nnovative **D**esigns

STUDY PROTOCOL

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PROJECT LEADERSHIP

Study Principal Investigator:

Kevin L Thomas MD
Assiociate Professor of Medicine
Division of Clinical Cardiac Electrophysiology
Duke Clinical Research Institute (DCRI)
200 Morris St.
Durham, NC 27701
Email: kevin.thomas@duke.edu

Study Funder:

Patient Centered Outcomes Research Institute (PCORI)
1828 L Street, NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700 | Fax: (202) 355-9558
info@pcori.org

Clinical and Data Coordinating Center:

Laura Webb
Project Leader
Duke Clinical Research Institute
200 Morris St.
Durham, NC 27701
Phone: (919) 668-8977
Email: laura.webb@duke.edu

INVESTIGATOR AGREEMENT

I have read the VIVID study protocol Version 27February2020, including all appendices and I agree that it contains all necessary details for my staff and I to conduct this protocol as described. I will personally oversee protocol conduct as outlined herein.

I will provide all study personnel under my supervision with copies of the protocol and access to all information provided by PCORI or DCRI. I will discuss this material with personnel to ensure that they are fully informed about the conduct of the protocol and the information being collected from patients enrolled in the VIVID study. I am aware that, before commencement of this study at my clinical facility, the local (or central) institutional review board must approve this protocol. I agree to make all reasonable efforts to adhere to the VIVID study protocol.

I, or my designee, agree to be present at all site visits and investigator meetings. In addition, I will ensure the presence of relevant study personnel under my supervision at these visits and meetings.

I agree to provide all subjects with a signed copy of the informed consent form, as required by government and International Conference on Harmonization regulations. I further agree to report to the DCRI any protocol deviations in accordance with the terms of this protocol, Good Clinical Practice Guidelines, and applicable regulatory requirements. All information pertaining to the protocol shall be treated in a confidential manner.

_____ _____

Principal Investigator Name (print) Signature

_____

Date

BACKGROUND

Utilization of implantable cardioverter defibrillators (ICD) is lower in black indiviudals than white individuals after adjusting for health system related and socioeconomic variables. [1, 2] Racial and ethnic disparity in ICD utilization is particularly disconcerting given the abundance of data on its efficacy in the primary and secondary prevention of sudden cardiac death (SCD) and the higher relative rates of SCD in black populations. Since its approval in 1985, the ICD has become the standard of care for patients with potentially lethal ventricular arrhythmias.

Racial differences in patients' willingness to accept a recommended invasive cardiac procedure may contribute to racial differences and potentially disparities in care. [3] Thus, patient education and reducing communication barriers between patients and physicians are important considerations in assisting patients with medical decisions. The quality of the doctor-patient interaction may influence both doctors' recommendations and patients' refusals, and it may be that communication is better when health care provider and patient race is concordant. [4 5] Race-concordant physician visits are associated with higher levels of positive patient affect, greater length of time spent with the patient and reduced physician verbal dominance. [5, 6] Conversely, patients not of the same race as the physician receive less information, possibly because they are less likely to engage in communication behaviors, such as asking questions or expressing concerns that indicate desire for additional information. [7] Ultimately, willingness to accept a doctor's recommendation may be influenced by the patient's knowledge and familiarity with suggested treatment options and the effectiveness of the doctor-patient communication.

The multiple and complex factors underlying racial disparities in cardiovascular procedures provide a range of levels for intervention: patient-level, physician-level and hospital systems-level. Patient-level interventions that provide appropriate educational materials may encourage patients to participate actively in their health care and improve medical decision-making. The format of educational materials affects patient knowledge and satisfaction with treatment. In a randomized trial of an educational videotape versus 'usual care,' ischemic heart disease patients who viewed a videotape on their condition and treatment choices were significantly more knowledgeable about their disease state than those who received standard physician counseling. [8]

A key purpose of patient education is to increase patients' confidence in making decisions that are congruent with their personal values. [9] One means of assessing whether a patient feels informed about treatment alternatives and their risks and benefits; has clarity about their personal values; and feels supported in choosing a course of action is the decision conflict scale.[10] This tool has been used in numerous studies where patients face treatment decisions and are required to balance the known risks and benefits along with scientific uncertainty in choosing a course of action. One study, evaluated the effectiveness of educational videotapes for assisting newly diagnosed hypertensive patients (n=217) in the decision to start drug therapy for reducing blood pressure.[11] The researchers found that patients who watched the videotape had a significantly lower decisional conflict (30.3 vs. 36.8, adjusted 95% CI = -7.4 to -0.6, P = 0.021) and greater knowledge of their condition (75% vs. 65%, adjusted 95% CI = 6%- 13%, P < 0.001) compared with corresponding controls.

SIGNIFICANCE

Although it is clear that racial disparities in ICD therapy exist, no one has systematically studied reasons for these disparities or interventions to eliminate racial disparities in ICD implantation. Consequently, factors explaining this finding remain incompletely elucidated, but are likely similar to those seen in other cardiovascular procedures including influences at the patient, provider, and health system levels. In part, race-related patient preferences have been implicated.[12-16] Members of certain racial groups may systematically prefer less intervention. Studies have shown that blacks are more likely to refuse an invasive cardiac procedure than whites.[14, 15,17-19] Disparities that arise from patient preferences may be worthy of remediation. For example, it is important to consider reasons for a given preference of care and to distinguish between preferences that represent deeply held beliefs that are based on codified cultural or religious traditions from more transient beliefs that are based on unequal access to health care information or health myths. Although it is always useful to *understand* patient preferences, it is important to note that patient preferences should not be regarded as sacrosanct and that some preferences may be appropriately amenable to intervention and change.[20] Recently, there has been a growing realization of the need to differentiate between patient preferences that are grounded in ethnicity or culture,(long-standing cultural traditions or deeply held and well-codified beliefs about health and medical treatment) from those grounded in modifiable perceptions or even misleading information (urban legends or myths that arise from unequal access to health care information). For example, Jehovah's Witnesses may choose not to have curative surgery because they are unable to receive blood transfusions, due to their religious beliefs. By contrast, some black individuals choose not to have potentially curative lung cancer surgery because of the myth that the surgery and the concomitant exposure of the tumor to oxygen may cause the cancer to spread.[21] Thus, understanding the root causes of patient preferences is important when determining the appropriateness of an intervention and when tailoring interventions that address underlying patient beliefs. Unfortunately, data suggest that patients are frequently misinformed or not fully informed when making health care decisions.[22] Lack of understanding of a recommended procedure is a strong predictor of patient refusal, while clarity of information and hearing from others who have accepted similar recommendations are important in influencing decisions.[22-24, 26, 27] At the provider level, racial disparities exist, partly, because of conscious or unconscious racial bias. In some instances, doctors do not offer or prescribe the same services for black patients that they do for white patients. [23, 28] Although most doctors strive to keep their clinical work free of bias, social psychology research documents that bias can occur without intention or recognition, and that certain situational factors, e.g., working under time pressure, can boost the effects of racial or gender stereotypes.[23, 24] Studies have documented suboptimal communication between health care providers and ethnic minority patients. While the issues that limit provider/patient communication are not unique to racial and ethnic minority patients, they limit communication to the greatest degree among such individuals and therefore contribute to racial and ethnic disparities in care.[25] In fact, some individuals prefer providers of the same racial or ethnic background. Racial concordance among black health care providers and patients appears to be a strong predictor of patients' satisfaction with care, trust, and intent to follow recommendations.[26] The theory underlying race-concordance research is that racial/ethnic disparities in health may be ameliorated as a result of increased mutual respect, trust, communication, and satisfaction, which may exist more in race-concordant patient-provider relationships.[27]

OBJECTIVES

Using patient-centered racially distinct educational videos on SCD and ICD therapy, we will compare in black patients the effect of the video intervention vs. health care provider counseling (usual care) on 1) patient knowledge of SCD and ICD's, 2) the decision for ICD implantation and associated decisional conflict, and 3) ICD receipt within 90 days. We will also explore the influence of racial concordance between provider and patient video participants on the decision for ICD implantation, associated decisional conflict, and ICD receipt at 90 days.

Primary Outcome: 1. The decision for ICD implantation at 7 days among patients randomized to the video intervention compared with health care provider counseling (usual care) .

Additional Outcomes: 1. The effect of racial concordance on the decision for ICD implantation 2. Changes in patient knowledge (pre and post intervention). 3. Changes in decisional conflict (pre and post). 4. ICD receipt within 90 days of the decision for ICD implantation. 5. In-depth qualitative interviews of 90 patient participants that will focus on: a) knowledge of SCD and ICD therapy b) influences on the decision to accept or decline an ICD, c) impact of the video on the decision (critique of the video content) d) barriers to ICD placement following the initial decision. Lastly, study coordinators will assess the time spent with patients by providers in each arm of the study.

METHODS

ELIGIBILITY AND CONSENT

Inclusion criteria:

1) Non-hospitalized patients with ejection fraction ≤ 35%
2) New York Heart Association class I-III heart failure
3) Age > 21
4) Eligible for an implantable cardioverter defibrillator (ICD) for the primary prevention of sudden cardiac death
5) Self-identified race as black
6) Provision of informed consent to participate in the study.

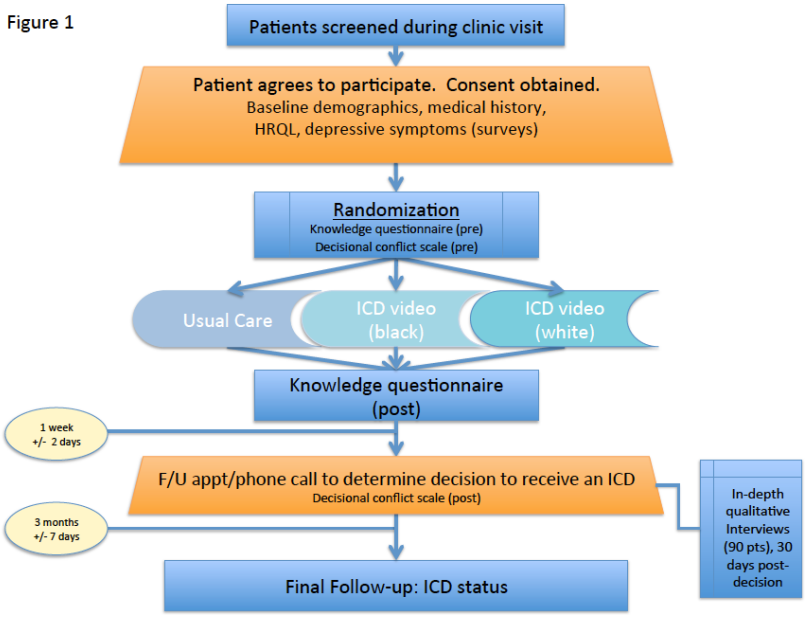
Exclusion criteria:

1) Life expectancy < 12 months
2) Listed for Orthotropic Heart Transplantation (OHT)
3) Transplant (OHT) or OHT imminent within 12 months,
4) History of ventricular fibrillation or sustained ventricular tachycardia without reversible causes
5) ICD already implanted
6) Myocardial infarction within the last 40 days
7) Coronary revascularization within the last 3 months
8) Patients who are unable to understand the study procedures due to cognitive or language barriers
9) Inpatients will be excluded from the study because decision-making processes are thought to be appreciably different in inpatients as compared with outpatients.
10) Plan for subcutaneous ICD (Sub-Q ICD)

SCREENING, ENROLLMENT, AND CONSENT PROCESS

Figure 1: Study Processes

Figure 1



Study processes are outlined in Fig. 1. Patients will be screened for participation/eligibility by the Research Assistant (RA), prior to the patients scheduled visit to the electrophysiology clinic. An introductory letter will be sent to potential patients by mail from their provider and research team. At the electrophysiology clinic visit, the RA will approach the patient about participation in the project. At that time (baseline visit), the RA will review study procedures and begin the consenting process. The consent process will include a full explanation of the research protocol and aims, as well as use of the iPad technology for the patient to review and sign the consent. The patient will also review and sign a medical release form, to facilitate patient follow-up, if the patient is not available via phone. In certain U.S. states, the patient will also review and sign a bill of rights statement. Following the consent and other document(s) signature process, the patient will provide baseline demographics (age, gender, payer status, household income, education, distance from health care facility, method of transportation, current employment status and a number of other social determinants), followed by administration of the Health Related Quality of Life Survey (HRQOL) SF-12v2, a depression assessment PHQ- 2, knowledge questionnaire and the decisional conflict scale (DCS), on the iPad. The patient will then be randomized on the iPad to one of three study arms (see below). The patient will view a video (per randomization) or consult with their provider to discuss the ICD procedure. After exposure to their assigned arm (video or usual care), patients will be administered the same knowledge questionnaire on the iPad, prior to the conclusion of the visit. Using the iPad at the end of the visit, the RA will note the length of time the patient spent with the provider.

BASELINE VISIT DATA

Following consent and other processes on the iPad, the RA will collect baseline visit data from the patient's medical record, including medical history, heart failure classification (NYHA), etc. The baseline data will be entered into the Data Collection Form (DCF). The DCF is an electronic web-based form in the Registry System, used at the DCRI for data collection.

RANDOMIZATION AND BLINDING

Participants enrolled in the study will be randomized on the iPad to 1 of 3 arms, A) video with black participants, B) video with white participants, or C) usual care (UC): health care provider counseling (Figure 2). For the outcomes not based on racial concordance, patients in ARM A and ARM B (video arms) will be combined and compared with UC. Study participants will be blinded to differences in the 2 videos.

Arm A: white video
Arm B: black video
Arm C: Health care provider consult only (usual care)

Figure 2: Form and Content of Information Conveyed in 3 Study Arms

	Arm A	Arm B	Arm C
	White ICD Educational Video	Black ICD Educational Video	Usual Care
Video featuring predominantly Black patients & health care professionals		**X**	
Video featuring predominantly White patients & health care professionals	**X**		
Chapter 1: Introduction	**X**	**X**	
Chapter 2: SCA and the heart's electrical system	**X**	**X**	
Chapter 3: Are you at risk? The importance of ejection fraction	**X**	**X**	
Chapter 4: Therapies to prevent SCA and ICDs	**X**	**X**	
Chapter 5: Making the right decision for you – a patient's perspective	**X**	**X**	
Chapter 6: Living with an ICD	**X**	**X**	
Health provider driven discussion (standard of care)			**X**

DATA SUBMISSION AND SITE TRAINING

For each patient enrolled, the RA will be responsible for submitting the iPad data and entering the baseline visit data via the DCF within a short period of time. Data submission for both the iPad and DCF will be essential to facilitate patient follow-up. All sites will be trained on the VIVID Protocol, use of the iPad and Registry System, and the site materials. The DCRI study team will ship all site materials, including the iPad, and provide the site team with access to the Registry System.

POST-INTERVENTION VISIT ACTIVITIES

Outcomes Call Center (OCC)
Following the baseline visit, the DCRI OCC interviewing team will contact patients at two intervals: one-week post intervention and 90-days post-intervention to ascertain information regarding ICD decision/implantation and to administer questionnaire(s) (see Figure 3). Medical record abstraction will be performed to determine ICD implantation among patients who cannot be reached at 90-days. For those individuals who did not receive an ICD we will seek to understand reasons for non-ICD implantation utilizing chart review and telephone interview.

At study enrollment patients will be asked if they would like to participate in an in-depth qualitative interview. Qualified patients who would like to be considered for qualitative interviews may be contacted by a team member to schedule a convenient time to complete the interview (see section on in-depth interviewing below).

Figure 3: Activities included in 1-Week and 90-Day Post-Intervention Follow-Up Interviews

1 Week Post-Intervention	90 Days Post-Intervention
Ascertain decision regarding ICD implantation Administer DCS Administer knowledge questionnaire Reassess patient interests to participate in in-depth interview • Patient information will be made available to qualitative research team member for potential follow-up contact (assuming eligibility criteria are met)	Ascertain whether ICD was implanted Offer patients with discordant ICD decision/implantation opportunity to complete in-depth interview or those who were initially unsure in their decision. • Patient information will be made available to qualitative research team member for potential follow-up contact (assuming eligibility criteria are met)

IN-DEPTH INTERVIEWS

To better understand patient decision-making processes regarding whether an ICD is right for them, we will invite some VIVID study participants to complete one or two in-depth interviews (IDIs) by telephone. During the interviews, we will ask participants about factors that were important to them in the decision-making process (see Interview Guide). These interviews will last between 45 and 90 minutes and participants will be compensated for their time. Not all VIVID study participants will be asked to complete these in-depth interviews. Rather, we will purposively select participants to ensure that we interview a diverse sample of patients. Sampling, interviewing time points, interview content, and compensation information is provided in Figure 4.

RECRUITMENT

Our goal is to recruit up to 90 VIVID participants – 30 who initially accept the ICD, 30 who initially refuse, and 30 who are undecided. Beyond this initial screen, we will select participants within each category to ensure that we have gender, age, and educational diversity. For example, if we have already interviewed 20 highly educated males, we will not contact the next highly educated male. All of this screening will take place *before* any member of our team contacts a participant.

All participants who indicate a willingness to be contacted for an interview will be eligible for both the 1st follow-up qualitative interview at 1-week and the 2nd follow-up interview at 90 days. Participants who complete the 1st follow-up interview will be flagged in the call-center system. The call center will see these flags when they complete their call at 90 days and confirm that the participant is willing to complete the 2nd interview. The call center can relay this information to the interview team, who will then schedule the 2nd interview with the participant. If not enough participants who completed the 1st follow up interview make a final decision about ICD implantation that is discordant with their original decision, the study team will follow up with participants who made a discordant decision and who agreed to be contacted for an interview, but who were not contacted for the 1st follow-up interview.

Figure 4: In-Depth Interview Design

	Round 1 Interviews	**Round 2 Interviews**
Sampling	Up to 90 IDIs, stratified by initial ICD decision: • 30 Acceptors • 30 Refusers • 30 Unsure Within each group, patients will be purposively samples to ensure we speak to a diverse range of participants (e.g., based on region, gender, education level, etc.)	Up to 60 follow-up IDIs, to be completed with a sub-set of patients. Follow-up interviews will be completed with three groups of patients (with their consent): • Patients who were originally unsure about ICD implantation • Discordant Cases - Patients who originally accepted ICD but had not had it implanted at -day follow-up - Patients who originally rejected ICD but had it implanted at 90-day follow-up
Interview Time Points	Consenting patients will be contacted within a few days of their 1-week follow-up to schedule a time to complete the IDI	Consenting patients will be contacted within a few days of their 90-day follow-up to schedule a time to complete the IDI
Content	- Examine thoughts and opinions regarding educational component (health care provider counseling, video only) - Explore considerations important to ICD decision-making process - Interview Guide, for use by the DCRI Team	- For patients originally unsure about an ICD, better understand processes/considerations that ultimately led them to accept or refuse the ICD - For discordant cases, examine factors that led to shift in initial acceptance/refusal decision.
Duration	Between 60-90 minutes	Between 30-45 minutes
Compensation	Patients will be compensated $50 for their time.	Patients will be compensated $25 for their time
Consent	The original consent form includes a description of IDI opportunities. At one-week/90-day telephone call, the interviewer will ask the participant if he/she is interested in completing an IDI (see In-Depth Script Language). Interested patients who also meet inclusion criteria may then be contacted by the IDI	

	interviewer, who will further describe the interview and answer patient questions (see Information Sheet, which interviewer will discuss by phone and send to participant by email or traditional mail). Telephone interviews will be scheduled for participants who wish to complete the interview.

INTERVENTIONS

BLACK INDIVIDUAL FOCUSED ICD EDUCATIONAL VIDEO

(25 minutes):
The patients and health care professionals in the video will be predominantly black. This video will be available on the iPad, if the patient is randomized to watch this video. For site training, the video is available on YouTube. Enter "ICD YouTube" into web browser. Click on the ICD – YouTube link that states: African American by Duke Clinical Research Institute. Additionally, we have both videos in DVD format if preferred by sites.

Chapter 1 Introduction

Chapter 2 Sudden cardiac arrest (SCA) and the heart's electrical system.
Indicates normal components of electrical system (SA node, AV mode, is bundle)
Discusses ventricular arrhythmias

Chapter 3 Are you at risk? The importance of ejection fraction (EF)
Discusses the association between EF and SCA. Ejection fraction as a measure of heart function

Chapter 4 Therapies to prevent SCA and implantable cardioverter defibrillators (ICDs)
The efficacy of medical therapy (b-blockers and ace inhibitors in prevention of SCA in patients with left ventricular dysfunction. Describes the ICD and how it works and the implantation procedure and potential complications

Chapter 5 Making the right decision for you: a patient's perspective
Patients will discuss their decision-making process regarding ICD placement.

Chapter 6 Living with an ICD
Patient testimonial about what a shock feels like. How is life different with an ICD.
Details about remote monitoring and device follow up.

The video will consist of patient testimonials, educational segments with visual animation, physician commentary, and narration.

WHITE INDIVIDUAL FOCUSED ICD EDUCATIONAL VIDEO

(25 minutes):
Same content as above with predominantly white participants. This video will be available on the iPad, if the patient is randomized to watch this video. For site training, the video is available on YouTube. Enter "ICD YouTube" into web browser. Click on the ICD –YouTube link that states: Caucasian by Duke Clinical Research Institute. Additionally, we have both videos in DVD format if preferred by sites.

USUAL CARE

Health provider driven discussion, which is the predominant counseling mode utilized at participating sites.

STUDY INSTRUMENTS

KNOWLEDGE QUESTIONNAIRE

We constructed a 13-item knowledge assessment tool to determine participants' knowledge of SCA, associated risk factors, and ICD therapy (Aim 1) (Appendix A). Potential answers for each question are True, False or Don't Know; for the purposes of the final results "don't know", answers will be scored as incorrect. A group of health care providers, ICD patients, and general public members has reviewed this tool for clarity, accuracy and relevance of content. Additionally, our stakeholder advisory panel reviewed the content and approved the final version of this tool. To assess the change in knowledge, the same questionnaire will be administered immediately before and after the intervention. Additionally, participants will be contacted at 1-week post intervention, and the same questionnaire will be administered to assess retention of information.

DECISIONAL CONFLICT SCALE

Since there is no existing decisional conflict scale (DCS) for assessing decisional conflict associated with ICD implantation, we have modified a previously validated DCS used for decision-making in breast cancer screening, influenza vaccination, and coronary revascularization procedures. This tool was also developed with the assistance of our patient, provider and general public focus groups and our stakeholder advisory panel. This DCS was tested in our pilot study and performed well. The DCS will measure the effect of the video on decisional conflict and the decision for ICD placement. The overarching goals of the DCS are to assess overall decisional conflict measured through five subscales: 1) informed subscale 2) values clarity subscale, 3) support subscale, 4) uncertainty subscale and 5) effective decision subscale. Prior to the intervention and at 1-week post intervention, participants will be asked to give their decision for ICD implantation (yes, no, unsure) followed by the administration of the DCS. Respondents will be asked to reflect on their decision and respond to the DCS questions using a 5-point Likert scale. Responses to each statement are scored 0 (strongly agree) to 4 (strongly disagree). Total scores range from 0 to 100, with higher scores indicating greater decisional conflict (Appendix B). We will compare the delta change pre to post DCS scores across study arms. To determine the effect of racial concordance between video participants (physicians and patients with ICD's and their families in the video) and study participants we will compare the delta change in pre and post DCS scores, decision for ICD implantation, and ICD receipt within 90 days of the decision in racially concordant intervention compared with racially discordant intervention.

IN-DEPTH INTERVIEW GUIDE

The Round 1 in-depth Interview Guide is designed to elicit patient perspectives on the educational information they received regarding the ICD, including information that was reassuring, concerning, confusing, etc. Patients randomized to a video arm will be asked specific questions about the video component. All patients will be asked questions regarding the conversation they had with their provider. In addition, patients will be asked a series of questions to better understand factors and individuals important to their ICD decision. The guide

draws from questions used in previous qualitative studies on ICD decision-making [29, 30] and has been reviewed by the grant's advisory council.

STATISTICAL ANALYSIS

SAMPLE SIZE AND POWER CALCULATIONS

We will randomize self-identified black outpatients with primary prevention indication for ICD in a 1:1:1 fashion to watch a video with white participants, a video with black participants, or a health care provider counseling (usual care). Approximately 480 patients will be enrolled from up to 15 active sites across the Unites States.

Power calculations for this study were based on the assumption of 160 patients in each of the following three treatment arms:

A. video with predominantly white participants (N = 160)
B. video with predominantly black participants (N = 160)
C. usual care (N = 160)

The sample size has been determined to provide a reasonable level of confidence for detecting clinically important differences in decision ICD implantation outcome between groups if such differences indeed exist. We also have substantial power for comparison of additional outcomes. In the pilot study **60%** of black patients in the video group said yes to ICD placement compared with **43%** in the UC arm. We estimated a 15-20% increase in the proportion of patients accepting ICD implantation in the video group could change practice patterns. Similarly, a 15-20% higher acceptance for ICD implantation in the racially concordant video group compared with the discordant group would be meaningful. Based on the proportion of patients indicating yes to ICD therapy in each arm of the pilot study and estimating an effect size of 17-20% to achieve 90% power, the sample size in the UC and each video arm should be between 160 (17%) and 115 (20%). Using the same proportions of yes responses from the combined video groups (60%) an absolute difference of 20% would imply that the proportion of yes responses in the concordant video is 70% and 50% in the discordant video. For these proportions, to achieve 90% power, we need 148 subjects in each video group to detect 20% absolute improvement in concordant video group compared to discordant video group. Thus a total sample size of 480 (160 black video, 160 white video, 160 UC) provides excellent power for the decision for ICD implantation.

We will conduct Round 1 in-depth interviews with 30 patients who originally accept, refuse, and are unsure about ICD implantation, for a total of 90 interviews. This sample size is expected to be sufficient to achieve thematic saturation in the qualitative data[31]. Patients participating in an in-depth interview will be purposively selected to ensure we collect a wide range of experiences from a diverse subset of individuals (e.g., education, gender, region, etc.). Round 2 interviews will be conducted (with their consent) with up to 60 participants who completed the first interview. The 30 individuals initially unsure about ICD implantation will be invited to complete a follow-up interview, to better understand what factors ultimately influenced their final decision. Additionally, any Round 1 interviewee whose 90-day ICD status differed from their 1-week decision (i.e., acceptors who did not have device implanted at 90 days and rejecters who did have device implanted at 90 days), will also be invited to complete an additional interview to understand factors that led to ultimate outcome.

The primary outcome will be the decision for ICD implantation at 7 days. Other outcomes include: the effect of racial concordance on the decision for ICD implantation, changes in patient knowledge (pre and post intervention), decisional conflict, and ICD receipt within 90 days of the decision for ICD implantation. The in-depth interviews will focus on: 1) knowledge of SCD and ICD therapy, 2) influences on the decision to accept or decline an ICD, 3) impact of the video on the decision (critique of the video content) 4) barriers to ICD placement following the initial decision. Lastly, study coordinators will assess the time spent with patients by providers in each arm of the study.

Analysis Plan: For the primary outcome, the proportion of patients saying "yes" to ICD will be compared between patients receiving the ICD video intervention (arms A + B) and patients receiving standard of care (arm C). The two proportions will be compared with the Pearson chi-square test. We do not expect small counts in light of the pilot study results but, if necessary, the Fisher Exact Test will be used. In addition to p-value we will provide estimates of proportions with their confidence intervals (exact confidence intervals will be used if needed).

EFFECT OF RACIAL CONCORDANCE

As a secondary outcome, we will compare the proportions of individuals saying yes to ICD implant in the racially concordant video (A) and the racially discordant video (B). The two proportions will be compared with the Pearson chi-square test. We do not expect small counts in light of the pilot study results but, if necessary, the Fisher Exact Test will be used. In addition to p-value we will provide estimates of proportions with their confidence intervals (exact confidence intervals will be used if needed). At an interim analysis based on the rate of patient accrual and projected sample size, the effect of racial concordance on the decision for ICD implantation \was changed from a co-primary outcome to a secondary outcome.

KNOWLEDGE QUESTIONNAIRE

To test the hypothesis that a patient centered educational video can improve patients' knowledge of SCD and ICDs we developed a questionnaire to assess knowledge of SCA and ICD therapy. This short (13-item) questionnaire comprises true/false statements designed to measure participants' comprehension of SCD, associated risk factors, and treatment options including ICD therapy. Possible scores vary from 0 to 13, with a higher score indicating better knowledge. Potential answers for each question are (true, false or don't know); "don't know" answers will receive a score of 0 while correct true and false responses will receive a score of 1. In the pilot study the test had excellent reliability with a correlation coefficient of 0.9. To assess the change in knowledge, the same questionnaire will be administered immediately before and after the exposure to the video or UC. Additionally, participants will be contacted at 1-week post enrollment, and the same questionnaire will be administered to assess retention of information.
Analysis plan: To determine the effect of the video on knowledge of SCD and ICDs: The pre/post intervention *mean* change in correct responses will be compared between combined video groups (N=320) and usual care group (N=160). Comparisons of these continuous measures will be performed with a two-tailed t-test (or Wilcoxon rank sum test if substantial departure from normality is noted).

Outcomes: Mean and standard deviation of correct answers on the knowledge questionnaire pre and post intervention in the combined video group with UC.

Sample size and power estimation: Sample size and power estimates are based on the findings from the pilot study results for black participants. In the pilot study, among black patients, there was an improvement in the number of correct responses on the knowledge

questionnaire from baseline to post intervention in both the video and the UC arms, mean standard deviation (SD) 8.4± 2.7 to 10.8± 2.1(video group), 7.4±3.9 to 9.7±2.9 usual care (p-value comparing video and UC NS). Based on these data and considering two-tailed equal variances t-test and 0.05 type I error, a sample size of 480 patients will have 99% power or higher to detect a mean test score difference between arms of 1.5 with SD equal to 2.5, 3.0, or 3.5. For a mean difference between video and usual care arms equal to 1.0, power remains at 99%, 93%, and 84%, respectively across SD of 2.5, 3.0 or 3.5.

DECISIONAL CONFLICT SCALE

We will use the DCS to measure decisional conflict. The scale measures a person's perception of the difficulty in making a decision, the extent to which they feel uncertain about treatment options, are knowledgeable about the risks and benefits of options, clear about personal values, and supported in decision making; the scale has demonstrated good reliability (Cronbach' s alpha coefficients > 0.78) and predictive validity. Higher scores indicate greater decisional conflict and patients experiencing decisional conflict are more likely to change their minds, delay decisions, express regret, and fail knowledge tests. Patients will be administered the DCS *pre* intervention at the baseline enrollment visit, and post intervention, 1-week post enrollment. Respondents will be asked to reflect on their decision and respond to the DCS questions using a 5-point Likert scale. Responses to each statement are scored 0 (strongly agree) to 4 (strongly disagree). Total scores range from 0 to 100, with higher scores indicating greater decisional conflict. ***Analysis Plan:*** To determine differences in decisional conflict, each group' s scores will be compared using independent samples t -test at two time points or Wilcoxon rank sum test if substantial departure from normality is noted. The first comparison will be within group (pre and post intervention) followed by 2) between group differences in the change scores using analysis of covariance (ANCOVA) that adjust for baseline scores. All quantitative tests will be two-sided and conducted at the 5% level of significance. Due to the secondary nature of these comparisons, there will be no adjustment for type I error. However, it is important to note that all these group comparisons are pre-specified and results of all attempted comparisons will be reported.

Sample size estimates:
In the pilot study, among black patients, the mean and standard deviation DCS scores for UC and video groups were 36.0 ± 3.2 and 33.7 ± 4.3 respectively. Based on these data and considering two-tailed equal variances t-test and 0.05 type I error, a sample size of 480 patients will have 99% power or higher for a mean DCS difference between arms of 3.0 across standard deviations of 2.5-5.0. For a mean difference between video and usual care arms equal to 1.0, SD 2.5, power remains at >99%.

ICD IMPLANTATION RATES

Compare the proportion of patients with an ICD implanted within 90 days of study enrollment in UC vs. combined video group.
Analysis Plan: To determine the differences in implantation rates in video versus UC arms, proportions will be compared with the Pearson chi-square test.
Outcomes: Proportion of patients with an ICD implanted between groups (video combined N=320, UC N=160).

IN-DEPTH INTERVIEWS ANALYSIS

All audio recordings of in-depth interviews will be transcribed and redacted to remove any identifying information. The qualitative research team will then engage in an iterative, robust process to code and analyze interview transcripts:

CODING

Each interview transcript will be coded with both structural (question-based) and thematic codes using qualitative research software, NVivo 10. Specifically, we will first assign structural codes throughout the text of each transcript to delineate each question and corresponding response based on our interview guide. Next, we will create a thematic codebook based on the substantive content of the transcriptions and the research objectives. Researchers will read the first three transcripts and then discuss and develop an initial set of codes. These will be compiled in a codebook that contains the code name, definition, details concerning when to use and not use the code and example text to which the code has been applied. Working independently, two members of the research team will use the codebook to apply the codes to the transcripts and use Holsti's method[31] to assess inter-coder agreement. Any discrepancies in coding application will be discussed and resolved by the research team, and revisions made to the codebook as necessary. This process will be repeated in sets of 3-5 transcripts, with modifications to the codebook and recoding of the transcripts as needed to capture any additions or refinements. Interview questions and/or probes may also be modified or added depending on initial findings to ensure research objectives are met (18 months).

QUALITATIVE ANALYSIS

Applied thematic analysis will be used to analyze the coded interviews. Analysis may include running queries or generating code reports, completion of inter-coder reliability assessments, development of code summary tables or memos, and potentially any second-pass coding required. Interim results will be shared and discussed with the VIVID team to inform the future direction of the research.

ANTICIPATED SITE REGULATORY AND PERFORMANCE COMMITMENT

Enrollment is anticipated to take approximately 18 months. The study will enroll 480 patients from 12 active study sites, averaging 27 patients a month for a mean of 40 patients enrolled per site.

SITE COMMITMENT

Sites will be expected to:

1) Sign a site agreement with DCRI, which includes site payment benchmarks, specifying IRB fees and site payment information.
2) Obtain IRB Approval prior to enrolling any patients and maintain approval throughout the study.
3) Screen patients, and obtain informed consent and contact information from all patients, via the provided iPad
4) Have institution Wi-Fi access and ability to use the iPad to submit signed informed consent, patient contact information, and questionnaires to DCRI
5) Use a web-based EDC system to submit the DCF.

SITE REGULATORY AND PERFORMANCE REQUIREMENTS

Once regulatory requirements are met, training is completed, and the site agreement has been executed, the site will be activated for enrollment. All active sites are responsible for obtaining and maintaining IRB approval from their local or central IRB. In addition, sites are expected to follow Good Clinical Practice (GCP).

Failure to comply with the regulatory or performance requirements above will result in an internal review by Dr. Thomas and the DCRI Study Team.

ETHICAL AND REGULATORY CONSIDERATIONS

RISK/BENEFIT ASSESSMENT OF QUALITATIVE INTERVIEW

There are no physical risks involved in this study. There is a very small risk that interview responses could inadvertently be disclosed outside the study in an identifiable way. We believe these risks to be minimal. As described in the next section, we will take several steps to protect the privacy of our participants and minimize any risks to confidentiality.

There is also a risk that some participants may feel uncomfortable answering questions regarding their ICD decision. To reduce this risk, the participant will be able to skip any interview questions they do not wish to answer and can stop participating at any time. Some participants may also seek interviewer input regarding the "right" decision. To minimize this risk, the interviewer's introductory script will include information about his/her limited role and credentials (e.g., not a medical doctor or expert in the field, role only to understand how patients think through these topics).

This research is not expected to provide direct benefits to participants. However, by soliciting feedback about the ICD decision-making process, we hope our findings will better enable prospective recipients of ICDs to receive the information most helpful to informing their treatment decision.

PRIVACY, DATA STORAGE, & CONFIDENTIALITY

We will take many steps to maintain the privacy of our research participants and the confidentiality of the information they share. In particular, we will assign a code number to all interview materials. The only connection between the code number and direct identifiers will be a password-protected linkage file, stored at the Duke Clinical Research Institute (DCRI) and accessible only by study personnel. The linkage file will be kept separate from interview data, and will be destroyed upon completion of the project.

We will follow the data storage procedures described below, as well as assure compliance with the VIVID research data security plan regarding the iPads, iPad security and data transmissions:

- Paper study records will be stored in locked areas accessible only by the study team. Only key-card access is permitted within the DCRI. Secured waste receptacles are available on each floor for expired confidential printouts; this waste is shredded weekly.
- Electronic data will be stored on secure computers at the DCRI. The following describes DCRI data storage and security procedures, which are designed to maintain the confidentiality of research data. By restricting access to these confidential data, the

DCRI Network Infrastructure serves as the principal means of safeguarding this information from improper use or disclosure.

- The DCRI has extensive electronic data safeguard procedures in place. All data are securely stored on Unix servers (currently, Solaris 9 and 10 operating systems) that are behind the Duke Protected Health Information (PHI) firewall.
- At point of entry at the firewall, policy directs the denial or acceptance of certain types of Internet traffic from specific sponsors or sources. Connections to certain sites are also restricted. The router has access lists and commands to deny or permit traffic. Internal network software continually monitors the Intranet for the presence of virus' or worms and electronically quarantines any infected device.
- All users are required to have strong passwords, changed every 90 days, and not reused for 3 years. The system tools enforce the strong password provision at the time of password creation. Access to data is based on a person's role and need to know. All file and directory access is controlled by groups and users rights. Users must have the proper access rights to read, create, and modify files. All work areas are secured with electronic key access. Secure recycling is provided on each floor for sensitive paper disposal.
- The Unix servers are physically located in a secure IT server room with emergency power, non-liquid fire suppression, and authorization-based limited access. Server room access includes an audit trail.
- All users are authenticated, authorized, and accounted on the DCRI domain. Remote Access at the DCRI is granted one of two methods and only for DCRI authenticated individuals. The first method is a VPN (Virtual Private Network) connection (Firepass from F5). A VPN allows users to form an encrypted network connection via the Internet backbone. The Firepass VPN software checks the client's internal virus protection software and will not allow inadequately controlled clients to access the DCRI. The second method is Citrix access (Cisco Systems). Citrix clients use an ICA (Independent Computing Architecture) client. Once again, all connections are encrypted. Client and server data is secure while the connection is maintained. These technologies are in place at DCRI and are fully functional. Wireless (Wi-Fi) access to the DCRI is only available under the VPN or Citrix routes.

Reports, articles, and presentations of the study findings will include aggregate results only, and we will apply significant attention to ensuring that responses cannot be attributed to a particular panelist through direct or indirect inference.

ALTERNATIVES TO THE IPAD AND PROCEDURES

Patients who appear uncomfortable with the iPad consent process may, at the site's discretion, be offered supplemental consent discussions and support to ensure comprehension and agreement with participation. However, consent signature will still occur via the iPad so that data collection proceeds as outlined above. No alternative methods for consent or data collection will be available. Thus, patients who are not willing or able to sign the consent using the iPad will be unable to participate.

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APPENDIX A: KNOWLEDGE QUESTIONNAIRE

	True	False	Don't Know
1. A sudden cardiac arrest is the same as a myocardial infarction (heart attack).			
2. Conditions that place a person at risk for sudden cardiac arrest include all of the following: history of a heart attack, family history of cardiac arrest, weakened heart muscle.			
3. Ventricular tachycardia and ventricular fibrillation are abnormal heartbeats (rhythms) that can lead to sudden cardiac arrest and possibly death.			
4. Sudden cardiac arrest causes more deaths each year than breast cancer and AIDS combined.			
5. An ICD could save me from sudden cardiac arrest.			
6. If I have an ICD, I no longer have to take my medications.			
7. The ejection fraction is a measure of how fast my heart beats when it is in an abnormal rhythm.			
8. An ejection fraction less than 30% puts me at risk for sudden cardiac arrest			
9. Having an ICD placed requires me to have open-heart surgery.			
10. The ICD procedure carries some risks such as: puncturing a hole in the heart or lung, infection, stroke and bleeding.			
11. Once I have my ICD implanted, I have to avoid strong magnets or metal detectors in airports.			
12. If your heart rhythm is ventricular tachycardia or ventricular fibrillation (abnormal heart rhythms originating from the bottom chambers of the heart), the ICD device should respond with a shock to the heart.			
13. My ICD needs to be checked every 3-6 months to ensure it is working properly and to check the battery status.			

APPENDIX B: DECISIONAL CONFLICT SCALE

Which treatment option do you prefer?

a. ICD placement with medications
b. No ICD, continue with medications only
c. Unsure

Now, thinking about the choice you are about to make/just made, please look at the following comments about your decision regarding placement of an implantable cardioverter defibrillator. Please answer how you feel about these comments by CIRCLING THE RESPONSE that best shows how you feel about the decision you are about to make/have just made.

1. I'm aware of the therapies available to protect me from sudden cardiac arrest.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
2. I feel I know the benefits of an ICD.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
3. I feel I know the risks and potential complications of having an ICD implanted.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
4. I am clear about which benefits of the ICD matter most to me.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
5. I am clear about which risks and potential complications of the ICD matter most.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
6. I am clear about which is more important to me (the benefits or the risks and potential complications of and ICD)	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
7. I have enough support from others to make a decision.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
8. I am choosing without pressure from others.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
9. I have enough advice to make a decision.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
10. It's clear what decision is best for me.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4

11. I feel sure about the decision.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
12. This decision is easy for me to make.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
13. I feel I have made or will make an informed decision.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
14. My decision shows what is most important to me.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
15. I expect to stick with my decision.	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4
16. I am satisfied with my decision	Strongly agree 0	Agree 1	Neither agree nor disagree 2	Disagree 3	Strongly disagree 4

APPENDIX C: VIVID QUALITATIVE INTERVIEW GUIDE
APPENDIX D: PROPOSED VIVID CALL CENTER SCRIPT
APPENDIX E: VIVID STUDY INFO SHEET

The above appendices are included separately.