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## “It's Not Broke, So Let's Not Try to Fix It”: Why Patients Decline a Cardiovascular Implantable Electronic Device

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### Abstract

**Background**—Few patients decline therapy of a cardiovascular implantable electronic device (CIED), and little is known about the characteristics or reasoning of those who do. Our objective was to describe the reasons why patients decline CIED implantation using qualitative methods.

**Methods**—Qualitative, engaging thematic analysis. Three patient focus groups led by 2 trained facilitators and 1 semistructured interview guide.

**Results**—Of the 13 patients, 2 were women and all were white (median age [range], 65 [44–88] years). Five themes emerged: 1) don't mess with a good thing, 2) my health is good enough, 3) independent decision making, 4) it's your job, but it's my choice, and 5) gaps in learning. Most patients who decline CIEDs are asymptomatic. Other reasons to decline included feeling well, enjoying life, acceptance of the future, desire to try to improve health through diet and exercise, hearing of negative CIED experiences, and unwillingness to take on associated risks of CIED implantation. A medical record review showed that clinicians understand patients' reasons for declining CIED treatment. However, focus group data suggest that gaps in patients' knowledge around the purpose and function of CIEDs exist and patients may benefit from targeted education.

**Conclusions**—Patients decline implantation of CIEDs for various reasons. Most patients who decline therapy are asymptomatic at the time of their device consult. Focus group information show data suggestive that device consultations should be enhanced to address gaps in patient learning and confirm knowledge transfer. Clinicians should revisit treatment options iteratively.

### Keywords

decision making; ethics; implantable cardioverter-defibrillator; refusal; treatment imperative

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## Introduction

Each year, approximately 400,000 cardiovascular implantable electronic device (CIED) implantations take place in the United States, [1] adding to the several million patients who already have these devices. Despite the indication, CIEDs may improve quality and prolong lives, and despite the benefits of CIED therapies, some patients decline implantation.

Previous studies have identified several characteristics and underlying values that motivate patients to accept or decline CIED implantation. Patients who accept CIEDs value longevity and view devices as a means of delaying death. [2] Alternatively, some patients who decline CIEDs believe that the treatment is merely prolonging the end-of-life process. In addition, when a patient decides to accept or decline CIED implantation, the patient may believe he or she is choosing between quality and quantity of life. [3]

Several authors have articulated a distinction between passive and active decision makers and draw correlations between these decision-making styles and the final outcomes. [2, 4] Passive decision makers rely heavily on their physicians, friends, and family for advice, sometimes even leaving the final decision to others. [2] Less engaged in the process, passive decision makers view decision making as obvious and easy. [4] Active decision makers seek advice and further education from other physicians, family, print materials, and the Internet and make decisions independently. [5] It is common for active decision makers to take more time to weigh costs and benefits.

One study found that the majority of passive decision makers accept implantable cardioverter-defibrillator (ICD) implantation when offered. [2] Furthermore, active decision makers may be more likely to decline CIEDs than passive decision makers. [2] In the present study, we used qualitative methods to examine the perspectives and experiences of patients who decline implantation of a CIED.

## Methods

Patients at Mayo Clinic in Rochester, Minnesota, who underwent consultation and declined implantation of a CIED were recruited for study participation. Eligible patients were identified through Mayo Clinic Rochester's Sudden Cardiac Arrest (SCA) database. Patients were listed in the SCA database if they had received an echocardiogram at Mayo Clinic Rochester showing an ejection fraction of 35% or less. If a patient met the clinical criteria for device implantation, follow-up was coordinated by Registered Nurses in the Heart Rhythm Service. Follow-up included scheduling an appointment for the patient to be re-evaluated or sending a letter to the patient's primary physician offering device consultation. Once a patient was offered CIED and verbally declined the SCA database was updated along with the patient's medical record.

Patients in the SCA database who resided in Olmsted County, Minnesota, who declined a CIED were eligible for study participation. Eighty-four patients were recruited by phone to participate in the study. Of those invited, 20 did not respond, 24 declined to participate, 13 reported never having a device consultation, 9 mentioned consenting to device implantation, 3 did not show up for the focus group, and 2 declined because of health (ie, hearing

impairment and physical illness). Verbal consent was obtained by phone. Confirmation letters were sent to patients who agreed to participate in the study.

Three 90-minute focus group meetings were held at Mayo Clinic. Each focus group meeting was held in the same conference room on the Saint Marys campus. The dates of each focus group and the number of patients were as follows: July 2009, 5 patients; August 2011, 3 patients; and May 2012, 5 patients. Focus groups were chosen to allow for nuanced discussion and to encourage self-disclosure. The groups were designed to be small, to allow patients to fully express themselves in a comfortable setting while important themes could still be captured. [6] [7] Furthermore, there are no exact sample size requirements for qualitative research; rather, the purpose of the study, the richness of the data, and the resources available to the researchers guide accrual. [7, 8] The study was conducted over a three-year period to reach sufficient data saturation. [6, 8]

Each focus group was facilitated by 2 trained moderators (A.L.O., K.M.S., S.K., or P.S.M.) using the same semistructured interview guide with questions based on current literature (see Appendix). Initial questions asked patients to explain their personal and health histories. Patients were then asked about their medical eligibility for a device and how the subject was approached by their health care team. Several questions asked patients to pinpoint the people, values, or other factors that influenced their decisions. Later questions explored patients' advance care planning and the advice they would give to other patients, families, or clinicians.

The conversation of each focus group was audio recorded and transcribed by a professional transcriptionist. Transcripts were verified and deidentified before analysis. Three analysts (A.L.O., K.M.S., and R.J.T.) independently read each transcript and used open coding to isolate themes according to guidelines of thematic analysis. [7] [9] [10, 11] Transcripts were read word for word and were analyzed by hand. Analysts marked sections of the text that formed the basis for their original preliminary codes. The analysts also met to discuss codes, categorize findings, write a codebook, and establish descriptive themes to report. Instances of disagreement were resolved by consensus. Final codes were standardized and discussed until they were approved by all 3 analysts. Five codes formed the basis of the findings.

To address the perspectives of clinicians, we reviewed notes in the electronic medical record relating to the discussion surrounding device implantation. Clinical notes marked "device consult" were qualitatively reviewed for major themes. Themes established the basis of our findings and allowed us to compare clinician notes with patients' memories of the consultation.

Patients were offered lunch, parking, and a remuneration of \$50 on completion of the session. This research study was carried out independent of any CIED manufacturer and was approved by the Mayo Clinic Institutional Review Board in accordance with federal regulations.

## Results

Overall, 13 patients enrolled into the study; 2 were women (median [range] age, 65 [44-88] years). All patients were white and 10 were married (see Table). Eleven identified themselves as Christian. A review of clinical notes pertaining to device consultation in the patients' medical records showed that clinicians accepted patients' decisions to decline CIED therapy. According to the medical record, several clinicians presented the idea of CIED implantation more than once to the patient, and in most cases, clinicians included statements indicating that sufficient education was provided. Statements such as "All questions were answered" were common. Five major themes emerged from the analysis of focus group transcripts: 1) don't mess with a good thing; 2) my health is good enough; 3) making independent decisions; 4) it's your job, but it's my choice; 5) gaps in learning; and 6) clinicians' perspectives.

### Don't Mess With a Good Thing

All patients in our study agreed: If you felt well, why would you need treatment? A focus on current health status, as opposed to future health trajectory, was the single most cited reason that patients declined CIED implantation. Patients described their health as "going good" and mentioned being able to "outpace" family members. Asymptomatic health status, along with a general satisfaction with quality of life, made patients hesitant to undergo an invasive procedure such as CIED implantation:

"When you feel good, there's not a lot of pressure on you to make a change." (P8, male, 61)

Not all patients believed that CIED implantation was out of the question permanently. Several patients agreed that if their health status was to change, they would reconsider. For patients who expressed openness to the prospect of receiving a CIED in the future, their response to clinicians was "not right now":

"I guess I never ruled out the idea of doing it. It was more a ruling out of doing it at that time. I guess I don't see any reason for jumping the gun....just because they say you qualify for it, doesn't mean you should run in and go do it..." (P5, male, 44)

Patients underscored the importance of timing when making a medical decision. Putting off CIED implantation until the patient had time to recover from the implant procedure, had reached retirement, or was willing to give up a device-prohibitive hobby all factored into one's decision to wait:

"I can't have one of those defibrillators 'cause I'll lose my job [as a driver, my chauffer's license]...I suppose I could retire now, but I'm not quite ready yet." (P7, male, 86)

Other considerations included patients' perceptions of their quality of life. Overall, patients who declined CIED implantation spoke of the importance of living life in the now, as opposed to living longer in the future. A focus on what gave patients joy and fulfillment right now dominated their thoughts, beliefs, and decision making:

“...my reasons for that was my hobbies, which include some welding...my theory was quality of life was equally or maybe more important to me than quantity.”  
(P13, male, 70)

Belief in a higher power and acceptance of the eventuality of death were also mentioned. Multiple patients trusted that their health was part of a divine plan, which would be carried out regardless of CIED implantation. The idea of “not being afraid of dying” and accepting “God's way to tell [you] when it's time to go” appeared to make patients feel at ease with their decision to decline implantation:

“I just told my wife, at some point you're going have to trust the Lord and forget about the science or You're have so many wires and tubes and monitors you won't be able to do anything...I chose not to have it, not that I think I'm invincible or anything, but I just don't feel that it's going to enhance my quality of life.” (P8, male, 61)

Patients were hesitant to take on the risks of CIED implantation if they felt healthy and happy and were at peace. Some referenced the negative experiences of friends and families with CIEDs while others mentioned CIED device advisories they heard about as evidence for their beliefs in the potential for CIEDs to hurt more than help:

“Well, most of the people that I know that have had [defibrillators] either liked them or they disliked them. I mean, they objected to when these things go off...every once in a while. Some people had situations where their heart would stop quite frequently, and these defibrillators go off right away. ... they had problems.” (P6, male, 60)

Patients resisted taking on the risk of inappropriate ICD shocks, the exhaustion of recovery from the implantation procedure, and the possibility that the procedure could go wrong:

“...They tell you, well, you know, just to make sure the thing is working, we stop your heart on the table, but don't worry about it, there is a whole table full of doctors. Uh, no, I'm sorry, my poor heart has been through too much already...”  
(P5, male, 44)

Patients who felt well, enjoyed life, and felt at peace with their future were confident in their decision to decline CIED implantation. None of the patients believed risk of CIED implantation was worth threatening their current quality of life.

### **My Health Is Good Enough**

Patients elected to follow their intuitions when it came to matters of health. How they viewed their bodies and considered risks affected their decisions to decline device implantation:

“I had a gut feeling I didn't need this defibrillator. Plus, I wasn't ready to have something implanted on my insides. I know they work for some people, but there's a chance they [won't] work, too.” (P12, male, 80)

According to the patients, clinicians gave them clinical indications for why they qualified for their CIED implantation. Nevertheless, some patients perceived their weak hearts not as

failing but “just working harder than others.” The concept of disease was also perplexing for patients. Even if they chose to proceed with CIED implantation, would it mean they were instantly cured? One patient explained why the utility of a CIED was unconvincing:

“I have a problem with 1 word: disease, heart disease. Is there such a thing? I have had 5 bypasses and a new valve put in, and they say I got heart disease? I feel that I'm all fixed up. If you have a broken leg and you get it fixed, do you have a broken leg for the rest of your life?” (P10, male, 78)

Many patients wanted to try to “heal themselves” before considering treatment. Patients were inspired by stories of friends and families who turned their health around through diet and exercise. Many embraced the idea of making small, natural adjustments—such as “try[ing] to get some exercise and try not to eat sweets”:

“My heart was always trying to catch up to make up for [the] bad valve. I knew that but thought maybe it would get better. I like to be able to heal myself. It bothers me to this day that I wasn't able to.” (P3, female, 65)

Past experiences and the outcomes of family and friends who underwent similar procedures affected the way patients thought about CIED implantation. Some patients appeared skeptical of the risks associated with pursuing device implantation. For example, a patient “blamed” his heart condition on his kidney transplant. From experience, patients knew that the burdens and benefits of any treatment should be weighed carefully:

“In 2001, my mom had heart surgery and they talked her into getting a defibrillator, and she got it and that night she passed away. That has kind of turned me off because I'm going, well, if she had problems with it, why do I want to do the same?” (P11, male, 54)

Patients viewed their current health as sufficient to sustain a satisfying life and accepted the risks of not proceeding with CIED implantation. All patients hoped they could control their risk by taking small steps in enhancing their diet and exercise. Negative experiences with health outcomes after treatment made patients cautious about embracing the idea of CIED implantation.

### **Making Independent Decisions**

An independent spirit and willingness to assume responsibility for their choices were key characteristics of the study patients. Although they appeared open to hearing the opinions of clinicians and welcomed the involvement of their loved ones, they rarely felt pressured by clinicians to proceed with implantation. One patient actually mentioned, in reference to clinicians, “they don't push it.” Rather, the patients appreciated receiving more information that could be used to make an informed choice:

“[The nurse practitioner] didn't tell me I should have it...it was more of a discussion...she said, ‘it's something you might want to think about because there is a good chance your heart will just stop for no good reason’...I would say it was more of a suggestion.” (P8, male, 61)

Collecting information was important, but so was the decision to make a choice based on one's individual situation. A desire to avoid CIED implantation in favor of a favorite hobby (eg, working on car engines) or the chance to heal naturally trumped clinical indications. Patients believed in their ability to assess the information at their disposal and make a decision without feeling regret:

“I have always been a believer in mind over matter, positive thinking. I've talked myself out of a lot of problems.” (P10, male, 78)

Patients who decline CIED implantation make decisions independently but not without considering the opinions of others. Furthermore, their “independence” appears to be rooted in a sense of personal responsibility for assuming the outcome of their choice:

“With me, I'm always open to ideas, but I really won't let myself be influenced by a physician or family member because ultimately, I'm the one who is going to have to live with it, whether it is good or bad.” (P5, male, 44)

Patients who decline CIED implantation exhibit a willingness to review clinical data and listen to the opinions of others. Patients filter the information they collect through a lens of personal preferences, to determine whether treatment is the best choice. Specifically, patients who decline CIEDs agree that choice of treatment is ultimately the patient's responsibility.

### **It's Your Job, But It's My Choice**

Clinicians who presented the option of CIED implantation were viewed by patients as “just doing their job.” Patients held no animosity toward their clinicians. Nevertheless, some patients described the device consultation process as a sales pitch:

“I didn't hold it against them—they tried to sell me [an ICD] and I said, I expect it...it is all part of the game.” (P3, female, 65)

Most patients reported discussing the option of CIED implantation more than once. Patients reported clinicians varied in their approach to introducing the CIED. Some were direct in their advice, using language such as, “You need a pacemaker whether you want it or not,” and others appeared more participatory. All patients remarked that their health care teams were accessible and supportive:

“My doctor is very supportive of me and is very upfront with me, and I couldn't ask for better people to ask questions. They are always willing to talk to me and answer my questions...” (P13, male, 70)

Few patients felt overtly pushed by clinicians. However, the pressure to move quickly in a fast-changing health care environment sometimes caused stress for patients. For example, a patient in our study spoke of his interaction with a health care professional who encouraged the patient to act quickly with CIED implantation:

“He said, ‘You need a defib and I can get you in either this afternoon or in the morning. Otherwise, it is going to be at least 30 days. And if you go through the same episode again, you might not make it 30 days.’ So I felt like they were pushing it a bit, that, ‘hey, we got an opening today, we could slide you in right

there, but if you can't do it today, we can't do it until...' If it is so important that I need it today, how come I can go 30 or 40 days?" (P13, male, 70)

All patients in our study felt they benefitted from taking time to process information and examine their motivation for declining CIED implantation:

"They presented me with the idea of putting a defibrillator in, and I'm just not real gung ho on quickly putting things into the body." (P5, male, 44)

Overall, patients appreciated why their health care professional introduced the option of CIED implantation. Nevertheless, the idea that a patient could live longer with a CIED was less convincing for these study patients, who ultimately declined CIED implantation. In fact, the patients in our study often took a step back to examine the larger consequences of their choices. Commentary about the current health care environment was common:

"That's why health care is so expensive. 'Cause people are living so long." (P7, male, 86)

Patients saw CIED implantation as preventive: "It's like they are trying to save you from something they don't know is going to happen." The idea of CIEDs acting as insurance against poor health was viewed as simultaneously optional for the patient and required for the health professional to suggest. Offering all available treatments was viewed as a necessary part of clinicians' obligation to protect patients from harm. Nevertheless, the fast-paced, outcome-driven environment of health care appeared to impose stress on patients who needed time to assess information and make an individually appropriate decision about CIED implantation.

### Gaps in Learning

During focus group sessions, patients identified gaps in their learning about the purposes and functions of a CIED. Patients regularly asked medical questions, suggesting education about the usefulness of CIEDs should be enhanced. Facilitators frequently had to redirect the conversation away from the technical aspects of CIEDs in order to explore why patients declined treatment. Unexpectedly and unintentionally, patients found the focus group discussions educational:

"I've learned more about the devices sitting here in the few minutes we've been talking than I knew about them before." (P8, male, 61)

The value of learning as much as possible about CIED implantation was reinforced through focus group discussion. Patients remarked again and again on the value of collecting as much information as possible in order to make an informed decision:

"You need to be as well educated as you possibly can [be]." (P5, male, 44)

Questions about the purpose and function of a CIED were numerous. Relating to the purpose of a CIED, 1 patient stated, "I don't remember [clinicians saying why I needed the CIED]." Patients expressed deep curiosity about the function of a CIED. How big is the CIED? What does the CIED do? How many more years will you live if you have a CIED? How do you know if the battery is dead? Do microwaves affect CIEDs? If you are not feeling well and you get a CIED implanted, will you feel well? Does insurance pay for the CIED? Despite



patients' insistence on the value of self-education, most admitted having only limited knowledge surrounding CIEDs:

“I don't know much about a defibrillator. Just what I've learned today. That it works and that it's got a battery.” (P7, male, 86)

Regarding how to decrease gaps in knowledge, the patients in our focus groups emphasized the value of speaking with patients who were living with a CIED. The opportunity to ask questions of someone who could relate to their experience was seen as invaluable. Such conversations would allow patients contemplating implantation the chance to ask questions of someone with the time and empathy for their concerns:

“I think it would've been nice to have someone come in, and maybe some sort of counselor or something who came in and said ‘we need to talk about why you should have it. Here are your options.’ Rather than saying ‘we got a slot open.’” (P13, male, 70)

Overall, patients recommended that gaps in knowledge be addressed in 2 ways. First, patients themselves should be empowered to ask questions of clinicians and other patients already living with CIEDs. Second, clinicians should examine how device consultations are being conducted to find ways in which education can be enhanced before implantation, to improve patient knowledge. The patients in the study believed that patients who are confronted with device implantation should trust their intuition and ask questions of others:

“I would tell them to ask as many questions as they have and make sure that they're comfortable with the information. And I would say—this is the one thing I've been telling my kids lately—close your eyes and think about what your gut or what your heart is telling you. Don't listen to me or you, or you, or you, because...it's all [about] you!” (P9, female, 57)

Having a clear vision for what constitutes health and happiness helped patients to identify what information was important to them in making a decision about CIED implantation.

### **Clinician's perspectives**

Patients' comments from focus group discussions about why they declined devices (eg, hobbies, jobs) correspond with notes in their medical record. Clinicians made notes such as “This is a topic for ongoing discussion, and [the patient] agrees with that position” or “[The patient is] not ready to make that decision at this point in time,” confirming our finding that patients are often willing to revisit the subject. The medical record indicates that health care providers respect patients' decisions and motivations for declining. Providers also make such notes as, “[The patient] seems to have a good understanding of the risks vs benefits. I concur with his decision” and “[The patient] understands the rationale for [CIED] consideration, but currently does not wish to pursue any further evaluation.”

However, clinicians seemed unaware that patients lacked knowledge of the purpose and function of the device itself. Many notes included comments such as “These overall [cardiac] issues reviewed and discussed with the patient in detail and recommendations and guidelines provided.”

## Discussion

Little research has explained the perspective of patients who have declined CIED implantation. Experience suggests that in most cases, patients elect to follow the treatment recommendations of their clinicians. [12] [13] Therefore, a patient's decision to say “no” to treatment may be considered a bold choice. Kaufman et al states, “It seems against medical progress and common sense to say ‘no’ to [an ICD]...because medical discourse emphasizes that refusing an ICD puts one at risk for death.” Likewise, Mueller and Cook [14] suggest, “The technological and treatment imperatives compel healers to use them and patients and loved ones to accept them.”

Patients in our study indicated that they chose not to have a CIED because the “need” for one, as expressed by their providers, was not as influential to them as the way they felt. The perspective of patients who decline CIEDs extends beyond a desire to decline unnecessary treatment. [15] If a patient was asymptomatic and generally happy with life, the patient hesitated to make a change. The patients in our study saw no reason to interfere with what they saw as already working, simply because a negative cardiac event might happen. Instead, the patients who declined treatment appeared more focused on the present and accepting of what might happen in the future. Consistent with our findings, a prior study showed that patients who decline CIEDs tend to elect for improved quality of life over prolonged survival time. [16] Nevertheless, several of the patients in our study indicated decision making is a process, not a 1-time-only undertaking, underscoring the importance for clinicians to revisit the option of CIED implantation at intervals they think are appropriate.

Decision-making styles—whether active or passive—also appear to have a role in how patients select treatment. [4] Active decision makers are defined as analytical, reflective, and assertive, whereas passive decision makers are characterized as trusting, apt to generalization, and sometimes disengaged. Our study found that patients who decline CIEDs prefer to collect as much information as possible from clinicians, family members, and friends in order to make an informed decision. Furthermore, these patients need time to analyze data and reflect on how the information fits with their life goals. They push back against the therapeutic imperative or what has been called the “inexorable momentum towards treatment.” [17]

In line with the description of an active decision maker, the patients in our study exhibited an assertive attitude when making their final decisions. All patients had a strong sense about the need to make final decisions about CIED implantations independently in order to be responsible for the consequences of their choice. Regardless, a patient's informed choice can depend on the skill of clinicians to recognize and respond to patient decision-making styles. Assessing how patients process information and weigh choices assists clinicians in guiding patients to arrive at a decision in line with the patient's priorities.

Patients may have difficulty articulating their questions or may not know what questions to ask. However, clinicians should ensure that patients receive sufficient education during a

consultation, as well as effective follow-up resources that are suited to the patient's learning preference, especially if patients intend to revisit the possibility of implantation.

Kramer et al [18] explored the idea of decision making and the treatment imperative in a study focusing on the view of nurses. Patients in that study were encouraged to discuss the perceived utility of ICDs and pacemakers, particularly the utility at the end of life. The statement of a focus group participant formed the short title of the article by Kramer et al: "Just because we can doesn't mean we should." [18] The perspectives of the nurses in the Kramer study deviate from research suggesting that clinicians tend to emphasize the benefits of ICD therapy, but differ in how they explain the risks. [15] Clinicians' desire to adhere to clinical guidelines may in fact impede shared decision making with the patient. [15] Patients must be given information in comprehensible terms about the pros and cons of CIED therapy. Clinicians have an obligation to ask probing questions, request "teach back" explanation, rely on their clinical experience, and use patient-appropriate communication methods to ensure that patients understand the consequences of their choices. Patients should be made aware of alternatives to CIED to make an informed decision, and clinicians also must recognize the patient's right to decline treatment. [2, 19]

Clinicians can take steps to enhance discussions surrounding CIED implantation. Specifically, clinicians should focus on the quality of their conversations with patients and offer multiple ways for patients to make sense of information, including text, visuals, and audio. Asking patients to speak back what they understand about CIED implantation may help to address gaps in learning. Patients and their families should also be encouraged to speak with a friend or family member who is living with a CIED or to attend a local focus group. Lastly, clinicians should reintroduce the option of CIED implantation to patients who initially decline. It also is important for clinicians to impart the message to patients that it is okay if they change their mind.

Our study has limitations including our small sample size. No patients of nonwhite descent were included in our study, which likely is reflective of the demographics within Olmsted County. Thus, our findings may not be transferable to patients with other cultural considerations. Because only 2 women participated in the study, our ability to explore women's unique health concerns was limited. In addition, no patients self-identified with religions outside of Christianity, which prevented us from exploring the impact of religious views on decision making. Additionally, our requirement for patients to attend an in-person focus group session meant we spoke only with patients who were mobile and in relatively good health. Finally, as with any research study, selection bias based on willingness to participate should be considered.

## Conclusion

Focus group findings revealed patients decline implantation of CIEDs for various reasons. Including the 5 themes discussed in this manuscript revealed: 1) don't mess with a good thing, 2) my health is good enough, 3) making independent decisions, 4) it's your job, but it's my choice, 5) gaps in learning; and 6) clinicians' perspectives. Most patients who decline CIED therapy are asymptomatic at the time of their device consult, which suggests that current—as opposed to projected—health status has a major role in decision making. Most patients in

our study elected to “wait it out” or make changes with diet and exercise to improve health. Clinicians can support patients in making individual, culturally appropriate decisions about treatment by addressing gaps in learning, confirming knowledge transfer, and frequently revisiting treatment options.

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## Appendix

### Interview Guide for Patients Who Declined a Cardiovascular Implantable Electronic Device

1. [Opening Question/Demographic Information] Please tell me a little bit about yourself. Where are you from? What is your relationship/marital status (eg, single, committed relationship, married, divorced, widowed, etc.)? What is your family structure? How would you describe your faith? (Probes: Are you a member of a particular faith community? What role has faith played in your daily living?) What is your work background? What is your level of education?
2. [Current Health Status] How would you describe your current health (eg, very poor, poor, average, good, very good, etc.)? Besides the cardiac issues that have been identified, are you living with any other life-altering diseases or conditions? What are they?
3. [Implantation Discussion] In your own words, what heart-related problem/s caused you to be considered for a device? Who told you that you needed a device (eg, primary physician, cardiologist, nurse, etc.)? How were you told? What devices, if any, were offered to you? Do you feel that you had all the time you needed to ask questions? Was the person you spoke with receptive to those questions? Was “not implanting” presented to you as an option?
4. Can you tell us why you declined a device? Can you identify 1 person that was instrumental in helping you to arrive at your decision?
5. Did you discuss device implantation with your family? How did they respond? What were some of their concerns? How much did your family members’ concerns weigh on your decision to not proceed with implantation?
6. What role did your values or religious beliefs play in your decision-making process?
7. What have you done in terms of advance care planning? Do you have an advanced directive? Is your family aware of your wishes?
8. What advice would you give to patients and families contemplating device implantation? What advice would you give clinicians or others who are having these discussions with patients? Is there anything you would change about your experience?

9. [Closing/Wrap-Up] Is there anything I forgot to ask that you would like to add?

## Abbreviations

<b>CIED</b>	cardiovascular implantable electronic device
<b>ICD</b>	implantable cardioverter-defibrillator
<b>P</b>	Patient

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**Table**

Patient demographics and key clinical characteristics

Pt No.	Sex	Age at Interview (device offer), y	Indication for device; device offered	Rationale for refusal	Religion	Marital Status	Outcome
1	M	88 (87)	nICMP, 1 <sup>0</sup> prev; standard ICD	Asx; not sure needed	C	Mar	No ICD; no arrhythmia noted; Died 25 mo after interview
2	M	70 (70)	ICMP, 1 <sup>0</sup> prev; CRT-D or LVAD	Initially not sure needed	C	Mar	CRT-D 14 mo later; Died 37 mo after interview
3	F	65 (63)	ICMP, 1 <sup>0</sup> prev; standard ICD	Asx, Hoped for improvement; not sure needed	NP	Div	No ICD to date, no arrhythmia
4	M	61 (60)	nICMP, 1 <sup>0</sup> prev standard ICD	Asx; not sure needed	C	Mar	EF improved; No ICD to date, no arrhythmia
5	M	44 (39)	ICMP, 1 <sup>0</sup> prev; standard ICD	Multimorbidity, didn't want	Jeh	Mar	Died 37 mo after interview, V-fib arrest
6	M	60 (56)	nICMP, 1 <sup>0</sup> prev; standard ICD	Asx; not sure needed/didn't want	C	Mar	No ICD to date, no arrhythmia
7	M	86 (85)	ICMP, 1 <sup>0</sup> prev; standard ICD	Asx, had concurrent infection so turned down ICD	C	Mar	No ICD to date, no arrhythmia
8	M	61 (58)	ICMP, 1 <sup>0</sup> prev; standard ICD	Asx, not sure needed; job concerns	C	Mar	No ICD to date, no arrhythmia
9	F	57 (55)	nICMP, 1 <sup>0</sup> prev; standard ICD	Asx, Hoped for improvement; not sure needed	C	Div	No ICD to date, no arrhythmia
10	M	78 (77)	ICMP, 1 <sup>0</sup> prev; standard ICD	Asx, job concerns, EF borderline	C	Mar	Developed wide complex tachy, ICD placed 15 mo later
11	M	54 (52)	ICMP, 1 <sup>0</sup> prev; standard ICD	Asx, survived other complications	NP	Mar	EF improved, no ICD or arrhythmia to date
12	M	80 (77)	ICMP, 1 <sup>0</sup> prev; standard ICD	Not sure needed	C	S	No ICD to date, no arrhythmia
13	M	70 (68)	ICMP; 1 <sup>0</sup> prev; had PPM, offered ICD concurrent	Avid welder, felt rushed into slot	C	Mar	HF worsened, upgraded to CRT-D, 9 mo later

Abbreviations: Asx, asymptomatic; C, Christian (eg, Protestant, Catholic); Div, divorced; F, female; ICMP, ischemic cardiomyopathy; Jeh, Jehovah's Witness; LVAD, left ventricular assist device; M, male; Mar, married; nICMP, nonischemic cardiomyopathy; NP, no preference stated; S, single; 1<sup>0</sup> prev, primary prevention; HF, heart failure; EF, ejection fraction

<sup>a</sup> All patients were white.