



# GROUNDING THEORY REVIEW

## An international journal

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Surrounding Primary Prevention Implantable Cardioverter Defibrillator Therapy

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2015

*Grounded Theory Review, Vol 14 (Issue #2), 55-73*

The online version of this article can be found at:

<https://groundedtheoryreview.org>

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Originally published by Sociology Press

<https://sociologypress.com/>

Archived by the Institute for Research and Theory Methodologies

<https://www.mentoringresearchers.org/>

## **Embodied Revelation: A Classic Grounded Theory of Heart Failure Patient Decision Making Surrounding Primary Prevention Implantable Cardioverter Defibrillator Therapy**

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### **Abstract**

The purpose of this classic grounded theory study was to explain the complex decision making process of heart failure (HF) patients considering primary prevention implantable cardioverter defibrillator (ICD) therapy. Sudden cardiac death (SCD) is the leading cause of death for people with HF as well as the primary cause of death in the United States (US). ICDs represent the standard of care as the only effective therapy for primary prevention of SCD. However, a significant proportion of qualifying HF patients declines this invasive, yet life-saving device. The grounded theory is of Embodied revelation. The threat of SCD for ICD candidates consists of four stages: living in conscious denial, heightening of awareness, sanctioning ICD therapy, and living in new assurance. The first stage ends abruptly with the critical juncture of grasping the threat of SCD. This grounded theory has implications for research, nursing and medical practice, as well as bioethical considerations.

**Keywords:** Heart failure, implantable cardioverter defibrillators, patient decision making.

### **Introduction**

Heart failure (HF) is a severe, chronic condition characterized by high mortality and high morbidity (American Heart Association, 2010). Unlike many other cardiovascular conditions, the incidence of HF is increasing; approximately 5.8 million people in the United States (US) have HF (Mozaffarian et al., 2015). Sudden cardiac death (SCD), the result of a lethal arrhythmia, is the leading cause of death for people with HF as well as the primary cause of death in the US (Mozaffarian et al., 2015). *The number of people who die each year from SCD approximates the deaths from Alzheimer's, firearm assaults, breast cancer, cervical cancer, colorectal cancer, diabetes, HIV, house fires, motor vehicle accidents, prostate cancer and suicides combined (Sudden Cardiac Arrest Foundation, 2015).*

Primary prevention ICDs represents the standard of care as the only effective therapy to prevent SCD in people with HF (Bardy et al., 2005; Echt et al., 1991; Moss et al., 2002; Yancy et al., 2013). Contemporary ICDs, metallic devices similar to pacemakers, are surgically implanted underneath the skin usually in the chest area. These devices aim to detect lethal arrhythmias and emit an electrical shock that aborts the arrhythmia. Primary

prevention therapies are aimed at preventing a first occurrence. Secondary prevention refers to therapies that prevent a disease or event from recurring or exacerbating (van Welsenes et al., 2011). In the case of ICDs, secondary prevention devices are implanted in patients who have already demonstrated potentially lethal ventricular arrhythmias by surviving such an event or having had an inducible ventricular arrhythmia demonstrated by an electrophysiologic study. Those patients offered a secondary prevention ICD have already survived SCD. Prior to 2002, ICDs were implanted only for secondary prevention.

Based on landmark trials demonstrating significantly improved survival from SCD, ICDs now represent a class IA recommendation as primary prevention for all patients with systolic HF deemed high risk for lethal tachyarrhythmias defined as a left ventricular ejection fraction (LVEF) of 35% or less on optimal pharmacologic therapy (Bardy et al.; Duray, Israel, & Hohnloser, 2006; Moss et al., 2002). Factors influencing patient decision making about primary prevention ICDs could be significantly different than issues involving secondary devices. These patients are asked to consider a potentially burdensome, yet life-saving therapy.

The problem that this investigation addresses is a significant proportion of qualifying HF patients who are at risk for life-threatening arrhythmias decline ICD therapy (Gravelin et al., 2011; Hernandez et al., 2007; Lakshmanadoss et al., 2011; LaPointe et al., 2011; Ruskin, Camm, Zipes, Hallstrom, & McCrory-Ussert, 2002; Thomas et al., 2007). Understanding patient decision making surrounding ICDs and other burdensome life-sustaining treatments could hold social significance as policies and standards of care are adopted. Health care providers are obligated to promote evidence-based, life-saving therapies, but also respect and facilitate autonomous patient decisions. Patients must understand and be able to weigh the potential risk and benefit issues in order to make well-informed decisions. This new grounded theory explains patient decision making surrounding primary prevention devices that can avert the most common cause of death in the US. An understanding of the patient's perspective in such health care decisions could help clinicians and facilitate development of pre-implant assessment and patient education tools.

### **Method, Data Collection, Analysis**

Classic grounded theory methodology is most useful when the phenomenon of inquiry is a complex social process thus holding great meaning to the subjects. The decision to accept or decline an ICD, a life-saving yet potentially burdensome, permanent therapy, emerges after a decision making process. Heart failure patients face a dilemma when considering prophylactic implantation of an ICD. They must weigh the potential risks and benefits. This dilemma is particularly suited to classic grounded theory because of the importance of meaning and context in the decision making process.

To ensure protection of human rights, this research was approved by the Institutional Review Board for the Protection of Human Subjects at West Virginia University. Sampling, data collection, data analysis and interpretation occurred iteratively. Sampling

for this study was purposive in that participants were referred to the investigator when identified as meeting study criteria. The sample came from four separate cardiology practices. Inclusion criteria consisted of English-speaking adults (age eighteen or older) who had systolic HF for whom a primary prevention ICD was indicated and had been offered. Cardiology providers identified potential participants who met the inclusion criteria and were given ample opportunity to review the study information. So as not to influence the decision, patients were interviewed after the decision to accept or decline ICD therapy had already been made. Sampling continued until saturation of the data had been reached and no new concepts were emerging. This investigation ended with a sample of 12 HF patients. Three of the 12 participants had declined ICD implantation. Females made up 25% of the sample. The challenge of recruiting females and ICD decliners was consistent with prior research. The youngest participant was 33 years old, and the oldest was 82 years of age. As a part of the demographic data, participants were asked what type of provider first recommended primary prevention ICD therapy. Half of the participants were first approached by a physician. The other 50% of the participants first received an ICD recommendation from an advanced practice or registered nurse.

The HF patients in this study who faced the decision to accept or decline primary prevention ICD therapy lived a unique experience. Initially, a single, loosely structured, in-depth interview was completed. All device recipients were interviewed at least nine months after implant. Those who declined ICD therapy were interviewed at least one year after refusal.

Data were recorded in the form of field notes immediately following each interview. As advised by Glaser (1998), interviews were not tape-recorded. This practice allowed for more openness by the participant and more attentiveness by the researcher (Glaser). This method also followed Glaser's (1998) basic principle of delimiting data through constant comparison and subsequent theoretical sampling. Follow-up questions were based on what data had been discovered already, what appeared to hold importance to the participants, and what ideas required further description. Using constant comparison, data were analyzed, coded, and organized into concepts and categories. This researcher trusted the emerging theory and strove to formulate concepts that best described the main concerns of the participants. The concept of embodied revelation encompassed the core concept for both acceptors and decliners of primary prevention ICD therapy.

### **The Theory of Embodied Revelation**

Four stages, conditions, properties, sub-properties, and a critical juncture emerged as a new substantive theory. Methods to assure rigor were ensured in terms of credibility, transferability, dependability, and confirmability. Those participants who ultimately accepted primary prevention ICD therapy moved through all stages of the theory. Those participants who ultimately declined ICD implantation did not experience the critical juncture and remained in the first stage of this grounded theory. The experience of these declining participants will be discussed separately.

### **Stage One: Living in Conscious Denial**

The first stage of living in conscious denial describes patients as being aware on some level that they have HF and that they could die from the condition. This stage embodies a continuum of patient comprehension of what it means to have HF. Participants maintain a low level of realizing threat. This first stage includes three properties of repressing risk awareness, reciprocating nonchalance, and imposing normality.

#### Risk awareness

Participants enjoy a relative ease during this stage as they are repressing risk awareness with regard to SCD. Participants have some general knowledge of the risk for SCD while not completely appreciating or validating their own personal risk. The ICD is viewed by the participants as an option. They do not recall being given any compelling reason to proceed with the implantation procedure. Agreeing to an ICD requires awareness of personal risk of SCD AND the life-saving capability of an ICD. While repressing awareness, the patient does not believe he or she needs an ICD. One participant explained that he wanted to deny that there was a real problem. An elderly gentleman admitted that he did not want to believe how serious his condition was. In most cases the idea of an ICD had been broached by a health care provider more than once, but was perceived by the participant as a casual reference.

#### Reciprocating nonchalance

Conscious denial is partially maintained by the property of reciprocating nonchalance. Participants and their providers converse regarding serious issues such as SCD using a casual tone that perpetuates nonchalance. This casual attitude perpetuates the patient's conscious denial, which, in turn, facilitates further nonchalance on the part of the clinician. Participants implied during interviews that clinicians might have delivered the message casually in an effort not to alarm them and engender hope. Such casual discussions with health care providers actually reinforce the conscious denial for the patient by affirming the perception that the patient is not seriously ill and the ICD is not really needed; such verbal tone provides comfort for participants and providers. Participants seem to equate time and care taken with explanations with the amount of importance a provider attaches to a topic. One patient remarked, "they never took the time to really explain things". Participants said of physicians: "He said that we should probably do this at some point", "It didn't sound like a big deal", "They just sort of mentioned it in passing". In turn, the casual response by the patient appears to affirm the casual nature taken by the provider as if to say that the patient is not ready for such discussions.

#### Imposing normality

While in the stage of conscious denial, participants convince themselves and others that they are not the victims of a serious condition, as they concentrate on mundane issues and try to live like healthy people through imposing normality. Participants demonstrated the need to prove to themselves that their risk is not only low, but also that they were "normal" or "okay". This investigator would be remiss if she did not acknowledge that a nearly

identical concept was defined by Charmaz (1991) as supernormalizing. In her description of people attempting to return to routines following heart attacks, Charmaz described how a person, despite having a serious medical condition, attempted to withhold, recapture or achieve his or her identity as “normal.”

One high school music teacher explained that he was commonly up all night worrying about music, but admitted to giving little thought to his serious medical condition. A few participants talked about how they kept from worrying about themselves by thinking about others with “worse EFs (ejection fractions)”. In some cases imposing normality was manifested as participants felt the need to prove how well they were by testing their hearts with extreme physical activities. Upon being discharged after a silent myocardial infarction, one male participant decided to immediately walk five miles: “I just wanted to see if I could do it”.

The stage of living in conscious denial may last days to years. Participants who declined a primary prevention ICD appear to share the first stage in common with those who accepted an ICD. The two groups diverge following the first stage. For those who ultimately accepted primary prevention ICD therapy, the first stage ends with the critical juncture of grasping the real threat of sudden cardiac death, which sends the participant into the second stage of heightening of awareness.

#### Critical juncture: Grasping the real threat of sudden cardiac death

Those who accepted ICD therapy experienced a revelation about their personal risk of SCD. This revelation was embodied in two ways. The revelation came from the body in that the realization was contextually rich, based on feelings, beliefs, and values. Secondly, the revelation was embodied in that the decision to accept or decline a life-sustaining device represented a tangible expression of the revelation of personal risk.

### **Stage Two: Heightening Awareness**

For those people who ultimately accept primary prevention ICD therapy, the heightening awareness of mortality risk is dependent on the condition of valuing longevity. Properties of heightening awareness include experiencing a significant medical event, perceiving new candor, which contains the sub-property of engendering trust, and strongly recommending an ICD, with the condition of delivering the message.

#### Valuing longevity

The stage of heightening awareness crescendos with the critical juncture of grasping the threat of sudden cardiac death only if the condition of valuing longevity is present. Those patients who agree to a primary prevention ICD place a high value on living longer. Participants discussed the importance of sustaining life to them: “They told me it (ICD) saves lives, and I was interested in living”, “I wanted to live longer”, “I wanted to be around for my grandbabies”.

### Experiencing a significant medical event

As a property of heightening awareness, the HF patient experiences a significant medical event that serves as a trigger. The medical event frightens the patient and uncovers the reality of the severity of his or her condition as well as elicits sudden candor by the provider. The medical events that participants experienced were not arrhythmic in nature. In other words, they had not experienced a life-threatening arrhythmia that would have deemed ICD therapy a secondary prevention. Examples of significant medical events that triggered heightening awareness included hospitalizations for acute congestive HF and cardiac testing that reconfirmed the weak condition of their heart muscle. One participant described a hospitalization as a "wake-up call from God". Two patients talked about new and bothersome symptoms that confirmed their condition. "After being in the hospital, I could no longer make my bed without getting tired. I knew I wasn't getting any better".

### Perceiving new candor

In all cases, heightening of awareness is precipitated by newly perceived candor displayed by the health care provider following a significant medical event. To the participants, discussions surrounding SCD and ICDs take on a much more serious tone. Participants described the property of perceiving new candor as "they were straight up with me", "I could die". This new candor served to engender trust in the HF patient.

### Engendering trust

Engendering trust represented a sub-property of perceiving new candor. In some cases, the patient is experiencing a first encounter with this specific clinician. In other cases, their known health care provider displays a new frankness regarding SCD and an ICD engendering a heightened trust on the part of the HF patient. Almost all the participants discussed how much they trusted the provider who successfully recommended the ICD. Quality time spent between patient and provider took on a new significance. Patients described the clinician in the following ways: "He makes you feel like you're his only patient", "I trust the doctor and his staff to know what they're doing", "They were straight up with me so I trusted them". The enhanced trust in the candid provider further strengthened the grasp of SCD risk. The participants can no longer deny an understanding of the real chance of death as the risk has been carefully and clearly explained. The provider, in turn, continues to engender trust from the patient by strongly recommending an ICD.

### Strongly recommending an ICD

As the HF patient gains heightening awareness grasping the threat of SCD, the clinician, who in many cases, formerly presented the device as an option, now strongly recommends an ICD. Participants explained the recommendation as "He just told me I needed to have this done", "Would I rather be working or be dead"? The stronger the awareness of SCD risk, the stronger the recommendation for an ICD is perceived. How the message recommending the ICD is delivered determines how strongly the recommendation is

perceived. The strong recommendation for an ICD is vital to the critical juncture of grasping the threat of sudden cardiac death.

#### Delivering the message

The HF patient perceives new candor as the clinician uses simple language in delivering the message. The provider is now frank with the HF patient about the significant risk of SCD and the life-saving capabilities of an ICD. One participant recalled being told that he would have an episode and either he would have the device that would likely save his life or he would not have the device and would die.

### **Stage Three: Sanctioning ICD Therapy**

The third stage of sanctioning ICD therapy occurs quickly after heightening awareness and includes two properties of feeling unsettled and passive decision making; a sub-property of desiring implant as soon as possible exists. The HF patient experiences some degree of anxiety related to the unearthed understanding regarding the risk of SCD and the life-saving capabilities of an ICD. The patient takes a passive role and acquiesces to the provider's recommendation. Although numerous interviewees express their desire to be active participants in their health care decisions, they exhibit relative ease in agreeing to the device their trusted provider recommended. Participants described the decision to accept an ICD as "I didn't want it to be my decision", "The doctors know a lot more than I do", "When they tell me I need something for my heart, I listen". The participants not only promptly agreed to a primary prevention ICD, but they also requested the device to be implanted as soon as possible.

#### Feeling unsettled

This is a stage of increasing anxiety for the patient as he or she is feeling unsettled until the device is finally implanted. Participants feel vulnerable to SCD without the benefit of an ICD. The comfort of conscious denial is gone. The feeling of urgency remains until the device is implanted and a sense of reassurance ensues.

#### Desiring implant as soon as possible

A sub-property of feeling unsettled is the HF patient's desire to have the implant as soon as possible. Fueled by anxiety surrounding SCD, the life-saving capabilities of an ICD, the value of longevity, and the provider's strong recommendation for the device, the patient requests the ICD be implanted now. Participants described this property as "My only question was when", "It was now or never", "I just wanted to get it done". One patient explains how agonizing the eight-week waiting period of optimizing medical therapy prior to implant was for him.

#### Passive decision making

Participants who accept primary prevention ICD therapy were generally found to be passive decision makers. Those who accepted the device appeared to agree gladly to the device their provider had strongly recommended. Participants explained how they preferred not to be expected to make such an important decision. They preferred to leave the decision up to the provider and or family members: "They know what's best for me", "I liked when my family stepped in. I didn't want to be the one to make that decision". Accepting patients talk about their lack of qualifications to make such a big health care decision: "I'm not smart enough. They (the doctors) know a lot more than me". In fact, clinicians who promoted autonomous patient decision making regarding an ICD were not trusted as much. In describing one such provider an ICD-accepting patient remarked, "How could he expect me to make that decision? He's supposed to know a lot more than me. I want him to tell me what to do".

#### **Stage Four: Living in New Assurance**

The investigator includes a final theory stage of living in new assurance for acceptors of ICD therapy. The decision making process surrounding the ICD continues in that the HF patient considers, verbalizes, and supports the decision made. The fourth stage occurs after the condition of ICD implant. The HF patient continues to consider and support the decision made often displaying the property of downplaying the process. The patient enjoys a more blissful state of assurance fueled by a new sense of security with having an ICD. Living in new assurance continues indefinitely.

##### Downplaying the process

Now relaxing into a new reassurance, participants, downplay the implant procedure and, in some cases, the entire decision making process. The participants uniformly described the ICD procedure and recovery period including the present as something on the lines of "no big deal". This stage is embodied by a renewed sense of nonchalance and ease similar to what was expressed in the first stage of conscious denial. However, the new ease is fueled by a sense of reassurance that the patient is no longer vulnerable to SCD. One participant remarked that "I'd rather have this done than go to the dentist". Another gentleman downplayed the procedure by saying "I don't even remember the surgery. It was no big deal. They just put it in". Another participant diminished the decision by saying "I know I'll probably never even need it (the ICD)". As in the first stage, participants often "test" themselves in an attempt to return to normality. One female participant explained that she still had many things on her bucket list. Participants expressed no regret concerning their decision to accept a device; they were at peace with their decision. They often spoke of counseling others regarding the inconsequential ICD procedure.

During this final stage, acceptors have the need to reiterate their trust in the provider who recommended the ICD by detailing the provider's professional attributes. Heart failure patients, who almost unanimously made the abrupt decision to accept the ICD solely on the recommendation of their provider, now express the importance of considering loved ones when deciding to have the ICD implanted. They often speak of wanting to live

for specific family members and view the decision to have the ICD implanted as relatively selfless.

### **Declining Primary Prevention Implantable Cardioverter Defibrillator Therapy**

The HF patients who declined a primary prevention ICD were forthcoming about their reasons for not accepting device therapy. The decliner participants share the first stage of living in conscious denial with those who accepted ICD therapy. There was no apparent epiphany as to personal risk of SCD, or validation that the risk was critical enough to accept an invasive prophylactic device implant. Therefore, decliners did not move on to the second stage of heightening awareness. They expressed no regrets about their decision to decline ICD therapy.

### **Repressing Risk Awareness**

The decliner participants, remaining in conscious denial, maintain various degrees of understanding as to their personal risk of SCD. People in this group do not appear to grasp the fact that symptom level or how well one feels with HF has little or nothing to do with the risk of SCD. Declining participants downplayed their condition and the ICD issue. One patient preferred to talk about other people he knows with "much worse" medical problems as compared to his medical issues. He described his HF as a "silly problem" that "no one wanted to hear about." He also remarked "ICDs are for very sick people". Another decliner expressed pride in his decision to decline an ICD. He explained that he never felt his condition "warranted" such an invasive procedure.

### Reciprocating nonchalance

The property of reciprocating nonchalance also emerged from the decliner data. One participant was approached only once about an ICD. The situation was presented to him as "a little heart problem". He was told that he "probably needs a defibrillator". Another participant explained that his doctor told him about SCD and the ICD, but when the patient was not interested, the subject was dropped so the participant did not perceive the issue as a vital one. Declining participants discussed ICDs and SCD in casual terms similar to how they described discussions with health care providers.

### Imposing normality

There was evidence of the property of imposing normality among the declining group. These participants talk about treasuring their good quality of life. One gentleman explained how he made sure he was very physically active and remained able to "everything" he wanted to do. Another participant actually described ICD therapy as "stepping out of normality," something he never wished to do.

### Missing the critical juncture and heightening awareness

Participants in the declining group did not experience the critical juncture of grasping the threat of sudden cardiac death. They never entered into the second stage of heightening awareness and the condition of valuing longevity; properties of that stage were not observed in the decliner group.

#### Not valuing longevity

Not valuing longevity describes the decliners' somewhat deterministic view of life and death. They do not describe a high personal value for sustaining life. Rather, they speak in terms of the course of one's life and timing of death being predetermined. In speaking of his heart attack 10 years ago, one gentleman said, "Maybe I should have died back then". In talking about death, another declining patient explained, "I'm not big on insurance policies. What happens happens. You can't fight it". Another decliner described living "day by day" and "not worrying about tomorrow". What is not clear is whether the decliners who lacked high esteem for longevity would have considered primary prevention ICD therapy if they were to have experienced a significant medical event, perceived new candor, and/or perceived a strong ICD recommendation. One participant appeared to try and answer that question with the remark "I don't think anyone could have ever talked me into it (the ICD)."

#### Not experiencing a significant medical event

None of the three patients who declined primary prevention ICD therapy had experienced what they considered to be a significant medical event. One participant explained that he "felt fine", "It (HF) doesn't affect me". He was not "convinced" that his condition warrants such an invasive procedure. Another patient explained that he has not had any hospitalizations in years. He commented "If it ain't broke . . .". The third decliner remarked that he felt "the same as when my EF was 45%".

#### Not perceiving new candor

These participants did not feel they were ever given a good enough reason to accept the device. None of the decliners described any kind of candor expressed by providers regarding the risk of SCD or ICD therapy. Those in the decliner group did not express engendered trust in their health care providers. On the contrary, the decliners recounted stories expressing lack of trust in providers. One decliner, in reference to the clinician who presented the ICD, remarked, "I just don't trust people. I question everything". The two other decliners recounted stories about how they had been wrongly advised by a medical professional in the past and were relieved they had not followed the advice. One decliner described how he felt providers are "too eager" to recommend procedures "without looking at all the aspects". That participant felt that patients should better educate themselves to be prepared for difficult medical decisions. No one in the decliner group perceives new candor or received a strong recommendation for an ICD from a provider.

#### Active decision making

An unexpected divergent finding between the two groups of participants was that acceptors and decliners of ICD therapy exhibited differing decision making styles. As the acceptors of

primary prevention ICDs displayed a preference for passive decision making, the decliners all expressed qualities of active decision making. To clarify, acceptors of ICDs generally desired not to make the decision alone. But, they actively expressed a preference to have the decision made for them by their trusted provider. On the other hand, decliners of ICDs preferred more autonomy in their resolution. One decliner explained medical decision making: "It's a very personal decision. Everyone needs to make his or her own". Another decliner spoke about a friend of his who received an ICD saying: "They talked him into it". Another decliner remarked that he "would never blindly follow orders".

### **Discussion**

The new theory, embodied revelation: the threat of sudden cardiac death for ICD candidates, grounded in participant interview data, explains the decision making process HF patients face when presented with ICD therapy. Stages, conditions, properties, sub-properties, and a critical juncture emerged and were detailed. The same theory was discussed in terms of those participants who declined ICD therapy. Although the first stage of the theory was shared between the accepting and declining groups, the divergence of the declining group was described.

The threat of SCD was realized on some level by all participants. For some, the risk was always understood to varying degrees. For others, the enlightenment regarding personal risk was exposed suddenly following a significant medical event and/or a strong recommendation from a provider. Embodied, as used in the title of this study, is defined as made concrete or perceptible (Merriam-Webster, 2015). The decision to accept or decline a life-sustaining device is an embodiment or a tangible expression of what SCD, the ICD, and desire for longevity mean to a particular HF patient. In this way, meaning is a revelation that comes as a result of the individual's interpretation of thoughts and feelings about issues surrounding ICD therapy.

### **Critique of the Theory**

The new grounded theory embodied revelation: the threat of sudden cardiac death for ICD candidates will be evaluated in terms of Lincoln and Guba's (1985) criteria to assure qualitative research rigor followed by a discussion of the limitations of the study. Validity, reliability, and objectivity will be addressed as credibility, transferability, dependability, and confirmability.

Credibility was achieved by the constant comparative method as new data were compared to previously discovered data. This theory emerged directly from participant data. The study began without hypotheses or any preconceived ideas that the researcher hoped to support. The investigator began with one open-ended question similar to "Tell me about what was going on as you came to the decision to accept (or decline) an implantable defibrillator." The participants started talking from that point. Any follow-up questions from the investigator were derived from data already shared for purposes of clarification or

expansion of concepts. The categories, properties and stages resulted from analyzing and conceptualizing the stories patients told about the decision to accept or decline a primary prevention ICD. All concepts included in the theory can be traced back to participant data. Therefore, the theory meets the criteria for credibility.

This theory fits the criteria of transferability in that it can be modified beyond the scope of the present study. Grounded theory studies do not rely on description of participant experiences, but rather conceptualization by the researcher (Glaser, 2002). This conceptualization transcends specific experiences. Concepts were constantly modified as new data emerged. The findings of this study are viewed as groundwork for future investigations that will add to the data and knowledge. The stages of this theory should be able to be transferred to explain other decision making processes involving complex and/or troubling issues.

The theory was found to be dependable based on auditing of the data, findings, interpretations, and concepts. Audit techniques are advised to examine all processes of the study (Lincoln & Guba, 1985) and ensure that the concepts represent appropriate and accurate labels for the data (Martin & Gynnild, 2011). Although interviews were not audio recorded as per classic grounded theory methodology, direct quotes from participants were jotted down throughout the interviews to enrich the data. Field notes were transcribed immediately following each interview, and numbered and dated according to participant. All concepts, properties, and stages can be traced back to the data.

Once again, an audit trail confirmed the findings of this theory. As new data and concepts emerged, findings were constantly crosschecked with recorded data and memos. After constantly comparing new with existing data and analyzing and reanalyzing, this theory truly does explain what was going on during the decision making process to accept or decline a primary prevention ICD.

The findings of this study provide the framework for further research. A goal of a classic grounded theory study is to present a set of tentative theoretical hypothesis that invites *limitations of the theory*. This investigator recognizes several limitations to this study. The sample size was small at 12 participants. Data saturation was met rather early in data collection despite including only three ICD decliners. Consistent with extant data, patients who declined primary prevention ICDs were difficult to recruit. This researcher cannot say with certainty that decliner data were saturated. The three decliners interviewed were volunteer participants. Unheard data from ICD decliners who are unwilling to be interviewed could modify the theory.

Many participants discussed the first and subsequent times primary prevention ICDs were recommended to them. Participants did not offer specific knowledge nor did they likely know exactly how long they had qualified for a primary prevention device. The knowledge of how long a patient had a very low ejection fraction and thus was at significant risk for SCD could have framed the provider's recommendation message.

Finally, the classic grounded theory demand for the researcher to collect, analyze, and conceptualize the data can pose challenges with regards to subjectivity. Glaser (2002)

described grounded theory as a “perspective-based” methodology. Despite the investigator’s best efforts to remain objective, what stood out in the data to the researcher could have reflected, partially, the researcher’s own understandings and perceptions. This researcher is also a clinician and in a few cases, participants were former patients of the researcher. Participants were given clear explanations as to the unique role of the researcher as opposed to that of a clinician. However, the possibility of bias must be acknowledged. Separating research and clinical ethical standards was, in some cases, challenging when participants clearly expressed misinformation or misunderstanding of issues surrounding SCD and ICDs. This researcher did her best not to intercede with corrective explanations. Additionally, for the participants who had been former patients of the researcher, the potential for a Hawthorne-like effect bias existed (Gillespie, 1991). These participants had enjoyed a positive and trusting relationship with a clinician who was now interviewing them about a health care decision. The participants could have downplayed any negative aspects regarding specific providers and information received.

### **Implications for Research, Nursing Science, Clinical Practice, and Bioethical Considerations**

The new grounded theory of embodied revelation: the threat of sudden cardiac death for ICD candidates has potential implications for nursing research, nursing and medical clinical practice, and bioethical considerations. The preponderance of data surrounding ICD decision making remains on secondary devices. Studies including more participants who declined primary prevention devices are needed. Decliners are more difficult to recruit, but data from decliner volunteers may not represent decliners who are not willing to be interviewed. Additionally, further study on provider perspectives surrounding primary prevention devices would be helpful. This data show that providers who are in a position to discuss and recommend ICDs hold enormous power with regard to the decision making process of the patient. How the primary prevention ICD issue is discussed and how the message and/or recommendation are delivered to the patient has significant ramifications as to whether the patient accepts or declines the device. How this discussion is framed could be at least partially dependent on the provider’s personal views and values surrounding device therapy. A better understanding of the provider perspective could facilitate tools to help providers evaluate themselves and facilitate informed patient decisions.

This new grounded theory contributes to the discipline of nursing. Margaret Newman and colleagues (1991) submitted caring in the human health experience as a focus for the study of nursing. Embodied revelation is a human health experience. In this unitary-transformative paradigm, objects of inquiry are recognized as contextually dynamic involving high levels of mutuality. The knowledge gained from this theory resulted from high levels of trust between the nurse researcher and participant. The interviews changed and grew in response to gathered data. The theory that emerged was grounded in patient orientation and highly contextual in its embrace of values, meanings, roles of others, choices, and purpose as they applied to the patient’s decision.

Similarly, Reed (1995) suggested that new nursing knowledge be patient oriented, context sensitive, pattern focused and participatory. A meta-narrative of human developmental potential and transcendent capacity for health and healing was proposed as a framework for nursing research. The merit of nursing research is examined in terms of its relevance to nursing practice. The research problem of HF patient decision making surrounding primary prevention ICDs was born from a caring nurse's practice story. The theory that emerged explains a contextually dynamic decision making process that, for acceptors of ICD therapy, involves stages involving powerful circumstances. The knowledge gained from this theory will help nurses foster and respect well-informed patient decisions at various levels of autonomy as prescribed by the patient. A classic grounded theory demands a level of transcendence as data are conceptualized rather than reported as experiences. This new theory has potential nursing science implications beyond the scope of HF patients and ICDs. The findings should be studied as they relate to other complex decision making processes involving burdensome therapeutic options.

#### Nursing and medical practice

This grounded theory holds implications for clinical practice. For half of the participants in this study, nurses or advanced practice nurses first discussed the ICD topic with patients. Even if not in a position to recommend life-sustaining therapies, nurses have an inherent obligation to facilitate well-informed patient decisions. Understanding the issues involved in the decision making process of patients considering primary prevention ICD therapy is important to all nurses caring for people with HF.

Clinicians need to examine their own perceptions surrounding primary prevention ICD therapy prior to discussing or recommending the device to patients. Care needs to be taken in how the message is delivered in order for the true intent of the clinician to be perceived by the patient. This study revealed that patients respond best to providers who have engendered trust. Frank discussions containing expert information are expected and admired by patients. Clinicians need to ensure that they are imparting accurate information and check that the patient has received the intended message.

The study implies the potential for decision making instruments throughout the process. Decision aides could be helpful during all stages of the theory. Ensuring accurate and frank information is vital during the first stage of conscious denial. In their attempts to define "good" decisions, Elwyn and Miron-Shatz (2009) emphasize that information does not equate to understanding. This study highlighted the need for improved discourse between patients and providers. Patients must be made aware that options exist, and all aspects of these options need to be discussed, understood, and considered.

Participants described the anxiety they experienced during the second stage of heightening awareness. Patients, at this stage, had experienced an epiphany with regard to their personal risk of SCD. They were troubled and impatient until they had the ICD implanted. Clinician measures to ease the anxiety of patients during this stage would be beneficial.

Clinician interventions could be helpful after ICD implantation. Participants expressed a willingness to talk about their decision to accept an ICD and their experiences with the device during the last stage of new assurance. They did not discuss feelings of depression or anxiety. However, all these patients were interviewed at least one year after device implant. There are many support group options for patients with ICDs. Many hospitals, health plans, and heart failure clinics offer such programs. Online support groups and chat rooms are also available for patients that clinicians feel could benefit.

#### Bioethical implications

The new grounded theory harbors bioethical implications surrounding the decision making process of HF patients considering primary prevention ICD therapy. Ethical obligations are inherent to nursing. Decision making involving ICDs is a good example of how complex health care decisions have become for patients. The choices are not always clear. Beauchamp and Childress (2012) provided ethical principles to serve as a moral compass in helping health care providers advocate for patient rights. Respect for patient autonomy is one of those principles that guides nursing analysis and resolution of health care decision dilemmas. Respect for autonomy recognizes the right of the individual to decide for him or herself based on personal values, beliefs, and projected lifespan stemming from the person's life experience (Ridley, 1998). The obligation to facilitate active patient participation in health care decisions presumes that autonomy is what the patient desires.

This researcher proposes that an implication of this study is the need for an expanded view of patient autonomy and further investigation regarding the measure of good decision making processes. Participants who accepted ICDs in this study generally preferred a more passive role in decision making. In fact, they preferred to be told what was best for them by their trusted provider. This decision presents a dilemma for providers. Patients count on their provider to share their expertise and knowledge to help the patient make a decision. Providers may be reluctant to engage in too much discussion surrounding proposed therapies for fear of unduly influencing the patient's decision. Patients in the first stage of the theory describe their providers as avoiding much serious discussion regarding risk of SCD and ICDs. Perhaps fear of perpetuating paternalistic attitudes in favor of facilitating patient autonomy contributed to lack of meaningful information provided. Facilitating autonomous patient choices must include respect for the option to include healthcare providers, family, and loved ones in the decision making process, and the realization that patient preferences may not always be clear, may fluctuate over time, and may include refusal of care or participation in healthcare decisions.

Nurses and all providers who are in a position to present major therapeutic decisions to patients ought to be mainly concerned with an informed, "good" decision by the patient rather than any "right" decision. Elwyn and Miron-Shatz (2009) proposed that decisions should not be evaluated by reference to their outcomes, but rather, they emphasized focus on the pre-decisional deliberation process, the act of determination, and post-decisional outcomes. These periods mirror the stages of embodied revelation. Bioethicists and clinicians often refer to patient preferences as a criterion for good decisions. Clinicians

ought to embrace the fact that the information imparted to and understood by the patient partially creates the patient preference for which respect for autonomy strives.

Facilitating informed, good decisions involves more than the informed consent procedure. Unfortunately, supporting patient autonomy for many providers basically consists of "you have the right to refuse." A patient who shows lack of enthusiasm for a therapeutic option is often described as refusing therapy. The assumption is that the decision has already been made and that there is little need for further explanation or discussion. Respect for patient autonomy in the course of decisions regarding life-sustaining therapies can be challenging. As such, clinicians need to give the time and effort required to fully explain options and promote useful dialogue with the patient regarding their main concerns. Contrary to the traditional interpretation of respect for patient autonomy, providers need to become more comfortable assuming a more active role in the actual health care decision if this is what the patient chooses.

### **Conclusion**

Embodied revelation: the threat of sudden cardiac death for ICD candidates represents a new substantive theory that explains the decision making process of HF patients considering primary prevention ICD therapy. The decision is a result of the revelation of his or her personal risk of SCD and embodies what that risk means to him or her. This theory helps fill the existing gap in knowledge surrounding a patient's decision to accept or decline the only effective therapy to prevent the leading cause of mortality in the US. The theory holds implications for research, nursing science, practice, and bioethical considerations.

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