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Ironic Technology: Old Age and the implantable cardioverter defibrillator in US health care

Sharon R. Kaufman[*],
University of California, San Francisco

Paul S. Mueller, MD, MPH,
Mayo Clinic

Abigale L. Ottenberg, MA, and
Mayo Clinic

Barbara A. Koenig, PhD
Mayo Clinic

Abstract

We take the example of cardiac devices, specifically the implantable cardioverter defibrillator, or ICD, to explore the complex cultural role of technology in medicine today. We focus on persons age 80 and above, for whom ICD use is growing in the U.S. We highlight an ironic feature of this device. While it postpones death and 'saves' life by thwarting a lethal heart rhythm, it also prolongs living in a state of dying from heart failure. In that regard the ICD is simultaneously a technology of life extension and dying. We explore that irony among the oldest age group -- those whose considerations of medical interventions are framed by changing societal assumptions of what constitutes premature death, the appropriate time for death and medicine's goals in an aging society. Background to the rapidly growing use of this device among the elderly is the 'technological imperative' in medicine, bolstered today by the value given to evidence-based studies. We show how evidence contributes to standards of care and to the expansion of Medicare reimbursement criteria. Together, those factors shape the ethical necessity of physicians offering and patients accepting the ICD in late life. Two ethnographic examples document the ways in which those factors are *lived* in treatment discussions and in expectations about death and longevity.

Keywords

USA; aging society; US health care; risk prevention; ethics and policy; medical technology; heart failure

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"I have an ICD and a pacemaker. It's prolonged my life a little bit. But the longer it prolongs my life, the more things happen to me that it can't correct. So the question is, do you want to have those effects, or do you want to end it all?"

-----86 year old man.

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[*]Corresponding Author's Contact Details: sharon.kaufman@ucsf.edu.

Introduction

This article takes the example of cardiac devices, specifically the automatic implantable cardioverter defibrillator (ICD or AICD), to explore the complex cultural role of technology in American medicine today. It specifically addresses the use of the ICD for elderly persons age 80 and above and its impacts on the end of life. We pay particular attention to the ironic feature of this device. While it postpones death and 'saves' life by thwarting a lethal heart rhythm, by firing a precise dose of electricity into the right ventricle, it also, then, alters the dying trajectory among the elderly from an unpredictable, but swift death to that of a progressive, symptomatic dying of heart failure. It prevents sudden death from a potentially fatal arrhythmia, the kind of death many claim to want in late life, yet, in doing so, it contributes to prolonged dying (Goldstein and Lynn, 2006). In that regard the ICD is *simultaneously a technology of life extension and dying*. This article explores that irony among the oldest age group – those who must now consider *what they want* in terms of medical intervention in older age, and whose considerations are framed by changing societal assumptions about premature death, the appropriate time for death, and medicine's goals about thwarting death in later life.

As background to our exploration, we draw on the work of Latour and Venn (Latour & Venn, 2002), who point out the ways in which technologies of all kinds are not merely means to specific ends, and that 'ends' are not static and already known. Rather, they describe how we change the ends as new means emerge and develop – and the ICD (as well as other medical technologies) illustrates this phenomenon. Technologies, they argue, are never merely instruments, utensils fulfilling a pre-determined function. Rather, they are active agents and a form of mediation – between intention and the discovery of multiple functions not foreseen, between original plans and their inevitable mutations. Thus while specific tools may in fact fulfill one intended purpose, they also, and perhaps more importantly, incite new ways of thinking about the kinds of ends we may desire.

The mechanical ventilator provides perhaps the most well known example of the way in which the use of a technique modifies the original intention. It was developed over a 50-year period in response to the demands of surgeons who needed to maintain patients' respiratory function while they operated on hearts, lungs and other organs. The mechanical ventilator became standard equipment in American hospital intensive care units by the mid-1970s. Within a few years, it was indicated for a long list of diseases and problems beyond its original intention. Recovery from life-threatening pneumonia or chronic obstructive lung disease became possible. Because that technology keeps the organs of the dead oxygenated, it opened up the realm of organ transplant beyond anything previously imaginable. It quickly came to be used, also, to keep people 'alive' who are in a vegetative state, leading to a new world of dilemmas about familial, medical and legal responsibility, and new questions about personhood, life and death (Kaufman, 2000).

Latour and Venn state, "If we fail to recognize how much the use of a technique, however simple, has displaced, translated, modified, or inflected the initial intention, it is simply because we have *changed the end in changing the means*, and because, through a slipping of the will, we have begun to wish something quite else from what we at first desired" (Latour & Venn, 2002:252).

Today's implantable cardiac devices, which may include pacing, defibrillating and heart chamber coordination functions (the latter is called cardiac resynchronization therapy or CRT), are examples of this constant re-invention (Jeffrey, 2001). Most recently, the ICD function often is included with cardiac resynchronization therapy, which helps the two chambers of the heart beat in a synchronized or balanced way, thus relieving the debilitating

symptoms of heart failure. (Cleveland Clinic, 2010; “Pacemakers: the new generation. Today’s implantable units do far more than previous models,” 2006)

These multi-function devices can improve cardiac function, reduce debilitating symptoms and treat and prevent lethal rhythms. The development of these ‘all in one’ devices makes it easy for physicians to suggest to patients that they should consider adding the ICD function when they are offered or advised to get a pacemaker and a resynchronization device. The important point here is that the ICD, invented and then first used to prevent people from dying prematurely, while still young, is now implanted primarily in older patients, often as part of a multi-function device, mostly with no plans for its impacts on end-of-life care or for its eventual deactivation in the elderly near death. The expanded means of the ICD, coupled with its expanded use, have contributed to an altered end -- a socio-medical emphasis on diminishing the risks of death, regardless of advanced age or disease state. The pursuit of that end precludes or complicates individual physician and patient choice, as we will see below. The goal of avoiding death in ever-older, sicker patients fosters, also, new pathways to death and new qualms for patients and families facing the responsibility of choosing one form of dying over another.

The ironic dual identity of the ICD as a technology of life extension *and* the dying transition, coupled with its contemporary end of managing the risk of nearness to death, present a useful example for exploring the ways in which choices about life extension, the timing of death and forms of dying, the management of risk in late life and the pursuit of technological innovation are shaping health care delivery in an aging society. The trend of averting death among the ever-older and ever-sicker has policy implications for the rising economic and social costs of health care in a society in which there are few economic constraints on technology use and multiple incentives for that use.

We begin with a brief background of the expansion of ICD use among the elderly in the U.S. We then turn to our study and our on-the-ground ethnographic examples of doctor-patient dialogue and patient and family deliberation about use of the device. The two case studies we present highlight the kinds of conversations that occur about ICD use and consequences, especially how the device is presented to patients and how they consider its ramifications. Next, we broaden the frame of our discussion to focus on first, a description of the mediating effects of ICD technology, and second, the structural-cultural context of ICD use in the US. We show how evidence-based studies -- through their reliance on and support of technological innovation and technology use -- contribute to standards of care and to the expansion of Medicare reimbursement criteria. Together all those factors bolster the ethical necessity of offering and accepting the ICD in late life. That structural-cultural framework is essential for understanding the parameters of choice for older persons and the ways in which risk is perceived by professionals and patients. Our ethnographic examples document the ways in which those factors are *lived* in treatment discussions and in expectations about death and longevity. They reveal as well the inadequacy of bioethical discussions focused narrowly on enhancing choice.

The ICD and the Elderly

The implantable cardioverter defibrillator (ICD) is a small electronic device (like a pacemaker) that monitors heart rate and rhythm and recognizes the onset of life-threatening arrhythmias. When it detects an abnormal rhythm, it delivers timed electrical discharges or shocks to the heart muscle, thereby disrupting and ending a life-threatening rhythm. It is commonly referred to as an “emergency room in the chest” and functions like the defibrillator paddles used in emergency room resuscitation (Pollock, 2008). A normal rhythm then can resume, either through the pacing function of the device which corrects the

rhythm or via the heart's own return to a normal beating pattern (Jeffrey, 2001; Kamphuis, Verhoeven, Leeuw, Derksen, Hauer, & Winnubst, 2004). There is no question of the unequivocal 'good' of this device for preventing people from dying young. Yet today, most persons with ICDs are older and sicker with underlying cardiac disease, and shocks from ICDs "might not significantly extend the patient's life or improve quality of life" (Jeffrey, 2001:258).

Initially approved by the US Food and Drug Administration (FDA) in 1985, the device was conceptually framed by Medicare (the US government program that pays for acute medical treatment for persons aged 65 and over) at that time as "a treatment of last resort…" for patients who had documented episodes of life-threatening arrhythmias or cardiac arrest (de Lissovoy, 2007). In the ensuing decades, the device has become smaller and lighter, battery life has increased and implantation has grown simpler. Still, the ICD was used sparingly up to 2002 or 2003 for those at high-risk of life-threatening cardiac events. Following a series of clinical trials between 2002 and 2004, in which results showed survival benefits for increasingly lower risk populations (but not for the elderly specifically), the ICD has come to be considered more broadly as a means of primary prevention of sudden cardiac death (Gillick, 2004; Hlatky, 2004). That is, it has come to be seen as appropriate for a substantially larger population of lower-risk patients who have never suffered a cardiac event. As Latour and Venn (2002) note, its meaning shifted so that, in a very few years, the ICD has become a tool to reduce the risk of death from a *potentially* lethal cardiac event for those with underlying heart disease, even for persons who have never had an arrhythmia. Similar to other technologies, it has been subject to 'indication creep,' the inevitable extension of its use to more and more persons, with varying conditions. This is a new 'end,' created by the same technological means.

As a result of expanding indications for use, Medicare coverage criteria for the device have broadened considerably, and many more persons – approximately 600,000 annually – are considered appropriate candidates for the device (Grant, 2010; McClellan & Tunis, 2005; Tung & Swerdlow, 2009). In 2008, 339,076 Americans received the device, up from 34,000 implantations in 2000 (Hlatky, 2004) and 75,000 in 2001 (Grant, 2010). Seventy-eight percent of those had the device implanted because they were considered at high risk for a potentially lethal arrhythmia (Hammill, Kremers, Stevenson, Heidenreich, Langn, Curtis et al., 2010).

The National ICD Registry annual report for 2008 notes that the average age of patients was 68 years and that Medicare beneficiaries accounted for 68% of patients with the device (Hammill et al., 2010). As the US population ages and Medicare and other insurance reimbursement criteria for ICD use continues to expand, the number of older persons receiving the device will increase – and, importantly, the proportion of devices going to the very elderly will increase as well. Currently, one-fifth of ICD and CRT devices are implanted in persons age 80 and above (Swindle, Rich, McCann, Burroughs, & Hauptman, 2010). No longer rare among the very old, these cardiac devices have become standard of care for patients with moderate to severe heart disease (Goldstein & Lynn, 2006). One study notes that ICDs have become so commonplace that in one clinical trial, patients randomized to the non-ICD group withdrew from the study in order to have the ICD implanted (Bristow, Saxon, Boehmer, Krueger, Kass, De Marco et al., 2004).

Ethnography of ICD deliberation

Through two ethnographic case studies – one of doctor-patient communication, the other of patient and family dialogue – we show how the ICD is shaping an imaginative, technological and newly ethical enterprise in which the limits to the body and limits of

bodily integrity and longevity are under pressure. The case studies -- drawn from a larger study -- provide 'on the ground' findings for the ways in which ICD technology has contributed to new ways for considering future scenarios about health and illness, suffering and dying. Both cases illustrate why the device is compelling and why it is difficult to say 'no' to it. Together they illustrate the range of patient responses to ICD consideration.

The first case reports on conversations in an outpatient clinic; the second reflects a conversation in the hospital – the two contexts in which the device is recommended. We see that in the clinic, Mr. Albert, age 81, is urged to consider survival in the long term. There is no emergency. In the hospital, Mr. Jones, age 84, is urged to implant the device if he wants to live. These two examples illustrate the ways in which the US clinical environment fosters ICD use. The cases also highlight the patient's experience of considering the device in the context of its potential, negative consequences. For Mr. Albert, potential consequences include infection and shocks (both appropriate and unneeded). For Mr. Jones, the consequence is prolonged suffering and dying from heart failure. In addition, the cases highlight the use of the ICD for individuals over the age of 80.

Ethnographic methods

Study and sample

Our case studies are drawn from a larger two-site project investigating older patient and provider decisions about and experience regarding starting and stopping cardiac devices. Using the traditional anthropological techniques of interviews and participant-observation (Hammersley & Atkinson, 1995), the aspect of the project described here explores how older persons, their families and their doctors understand, deliberate and respond to recommendations for implanting a device in the first place. The project also describes the socio-medical and institutional developments that drive the use of these devices among ever-older persons.

Interviews and observations

The case studies reported here represent a sub-sample of 10 older patients who were contemplating ICD implantation in outpatient clinics and hospitals. Observations and interviews about the ICD took place in two US locations between 2007 and 2009. In one of them, the ethnography was conducted in collaboration with BK, PM and AO. Interviews and observations took place with the following groups of patients age 70 and above: 30 individuals who have an ICD (alone or in a combination device); one man who proactively deactivated his ICD; 4 individuals who refused to have an ICD implanted; and 10 interviews/observations of persons being evaluated for an ICD. Additional interviews and observations were conducted with persons between the ages of 60 and 70. In the clinics extensive, nearly verbatim, hand written notes were taken of physician, patient and family remarks and dialogue. The case studies specifically focus on dialogue among physician, patient and family members. Interviews were tape-recorded or documented by extensive notes. We also interviewed and observed patients with pacemakers and VADs (to be reported elsewhere.)

The ethnographic goal of the open-ended interviews was to document in real time the circumstances that patients understood as leading up to device implantation or refusal, and the ways in which individual choice figured in disease treatment. In clinical settings in which we observed doctor-patient conversations, we paid particular attention to the ordinary practices and conversations that occur, including the ways in which physicians, patients and family members held discussions about whether to proceed, and in which they described their rational for their decision. The ICD may be considered a paradigm case for analysis of

ironic technology -- those interventions that, in fulfilling the purpose of 'saving' life by staving off one kind of death, may then, as a result, shape and give rise to other disease patterns, treatments and forms of dying.

Treating aging and the risk of death: The case of Mr. Albert

The conversation between the doctor and patient, below, emphasizes that the ICD can reduce the risk of death. The other feature of the device, its contribution to prolonged dying from heart failure, is not made apparent. Rather, the conversation informs the patient's way of thinking about desired ends -- in this case, an open-ended and non-symptomatic old age. This scenario resonates with the widespread cultural sensibility that medicine can almost miraculously restore health, despite advanced age and heart disease.

The cardiologist at a major medical clinic greeted Mr. and Mrs. Albert and said, "I want to talk to you about a defibrillator and a pacemaker. The question is whether you might benefit from an ICD with or without pacing of the heart all the time. The defibrillator is a special pacemaker that has the ability to shock the heart in a rhythm that would lead to death. It can be thought of as an insurance policy to prevent that kind of arrhythmia. Do we want to insure the cost – for something we may not need? It's a balance that needs to be thought of in that way, because it's hard to predict which individuals will actually benefit from the device."

"Really," he continued, "that's all the defibrillator is. It's not going to make you feel better. In fact, sometimes, it gives inappropriate shocks when it doesn't need to. It's extremely painful. Also, there's risk of infection. So, it's that type of decision."

The physician then offered an additional procedure because there is newer technology that might benefit the patient. The newer, resynchronizer pacer (CRT) could improve the symptoms of Mr. Albert's advancing heart failure. The doctor continued, "If we decide to do the ICD, should we do a more extensive procedure at the same time? Putting in an extra lead in the heart, to better synchronize the two chambers. It is a more complex procedure. We have to inject dye in the heart, go into a small vein. The cardiac resynchronizer is designed to make you feel better. The problem is, we don't know who will feel better. About two-thirds of patients will feel better; but one-third won't. So, you could undergo the surgery, and not feel better." Though he clearly invoked the range of technological options, he did not paint an unduly rosy picture.

The patient and his wife asked: Is it worth it when you're in your 80s? What would you do? And of course it was impossible for the doctor to answer definitively. After more discussion, the doctor summarized the rather complex decision tree the patient now faced. He said, "There are two possibilities. First, the defibrillator—you do *qualify* for it. You are *eligible*." This language is used repeatedly, and it is important. The physician is referring to the fact that the patient's medical condition fits both the clinical trial evidence for a good outcome and the Medicare reimbursement criteria developed from the clinical trials data. To the patient, however, this language sounds as though he has won something in publisher's sweepstakes, in a lottery. That language contributes to the desire and obligation to accept. "Second," the doctor noted, "we could go for the ICD and the resynchronizer, in hopes of making you feel better in terms of symptoms. But this is an unknown."

He concluded, "Considering your risk, it would be appropriate to buy the insurance. It's not black and white. I'm not the one who is paying the premium, having to live with infections, shocks, etc. I do think it might benefit you, that's why we are offering it." Mr. Albert's reply is a common one. It is based on the clinical expectation that the symptoms of heart failure in later life can be reduced, and on the societal expectation that the signs of aging can be

pushed farther away (or even made to disappear) by medical technique. This physician's clear recommendation shapes the patient's desire and influences his choice. Mr. Albert replied, "I'm wearing out. Things are degenerating, deteriorating. That's why I'm here. I think I should have it." Having given his consent, the doctor scheduled the procedure.

The availability of the device organizes the ways in which life planning strategies based on risk awareness and prevention are embodied and lived. As we see in this clinical encounter, conversations between patients and physicians reflect back to patients their own hopes for the regeneration and continued health of the body/self. Those hopes are bolstered by widespread assumptions that one can both 'add time' and reduce or eliminate senescence through biotechniques. This case illustrates how physicians offer and recommend interventions for which patients are considered 'eligible' and 'appropriate,' according to the results of clinical trial data which document survival benefit, but for patients mostly between ages 60 and 70 (Myerburg, 2008) and then according to Medicare reimbursement criteria. Those data and criteria are persuasive reasons for patients and families to want and thus 'choose' the full range of capabilities that a device currently carries. Those criteria set aside the value question about the actual existential worth of these technologies to persons in late life.

Similar to other technologies, the device enables many to assume that "growing older without aging" (Katz & Marshall, 2003) is possible, indeed, normal, via the right medical procedures. Because medicine has contributed so powerfully to cultural assumptions about the malleability of the body and the promise for better health into late life (Rose, 2007) patients expect these technologies to make them 'feel like themselves,' that is, to feel the way they did prior to the worsening of their disease (Shim, Russ, & Kaufman, 2007). There is no natural end point for these aspirations. The fact and inevitability of their eventual failure is not acknowledged.

Importantly, these devices do not 'act' alone (Mol, 2008). Together, the availability and use of more clinical options at ever older ages, their proven efficacy for certain populations in reducing symptoms and pushing back mortality, the subsequent need for physicians to offer what has become routinized as 'best' in terms of mortality reduction, and the expanded clinical goals that result – to treat increasing heart failure and risk of death with the best and usually newest tools available for as long as possible – promote the notion that the corporeal symptoms of aging and decline can be treated *always* (Callahan 2009). That notion is not as pervasive in European countries (although the situation there is changing [see, for example Heath, 2010]), where state-mandated limitations to health care resources are more robust than in the US. (Fairfield, 2010).

The ironic feature of the device is not yet apparent to Mr. Albert because the topic of prolonging advanced heart failure is not mentioned. In addition, Mr. Albert is not (yet) aware of what other research has revealed (Pollock 2008) – that some persons with ICDs become acutely aware of how they will not die, that "terror" is frequently associated with receiving a shock and that there is fear of receiving multiple shocks and then dying. In short, we do not know if Mr. Albert will experience a feeling of the foreshadowing of death and if the fact that he is over 80 matters in that regard. We do not know, also, to what extent the device will extend his time of living with increasing heart failure.

Like Mr. Albert, a growing number of older individuals who receive these devices are enabled to live with progressive heart failure. They then may become candidates for even more complex implantable therapies – such as the left ventricular assist device (LVAD), a mechanical pump that enables a severely weakened heart to pump blood through the body. Increased use of the ICD as ordinary, standard treatment to stave off death paves the way for

more practitioners and patients to consider treating end-stage heart failure later, with even more invasive and powerful devices that have the ability both to extend life and prolong dying.

Imagining and choosing among future scenarios: The case of Mr. Jones

In this case study the ICD as technological actor confronts the patient and family with a demand to imagine and choose between future scenarios in which the risk of imminent death, potentially 'more' (yet debilitated) life, and future suffering all are invoked. In contrast with the above case example, Mr. Jones is starkly confronted with the ironic feature of the device. Its dual possibilities shape patient and family responsibility for considering the worth of a (potentially) extended life *but with worsening heart disease* (Weber et al., 2006). Through the physicians' urging, the device elicits, for Mr. Jones, a confrontation with the necessity of 'choosing' -- between living with increasingly uncomfortable symptoms into a dreaded, open-ended future, because the device may create that kind of future, and assuming full responsibility (it seems to him) for dying soon yet unnecessarily, because the device can prevent death, for a time. The ironic feature of the ICD shapes an unprecedented form of being and knowing. (And, it argues that technological interventions to stave off death should be accompanied by concurrent palliative care.) Mr. Jones takes age into consideration as he decides.

Mr. Jones, 84, has been struggling with congestive heart failure and has had several emergency hospitalizations within a few months. Because his cardiac function was monitored closely during the hospitalizations, the staff observed some episodes of ventricular tachycardia, a potentially life-threatening rhythm. Mr. Jones' daughter, a nurse, tells the following story about what ensued.

"My dad's cardiologist, who had been treating him for a long time, became concerned about the documented runs of ventricular tachycardia and said to him, 'I want you to have an ICD.' And so, my dad said to me, 'What do you think I should do?' And I think he wanted me to make the decision for him. So, I gave him a list of questions to ask the cardiologist: What's the intended outcome? Will it really make a difference to the state of the heart failure? What's it going feel like when it defibrillates? I felt I knew the answers to those questions. But I wanted the cardiologist to address the pros and cons with my father. That it would, very simplistically, prevent a ventricular tachycardia that could possibly cause sudden death. But that it would not cure the heart failure. I phoned my dad after the cardiologist had been in to see him. I asked, 'What did he tell you?' My dad started sobbing on the phone and replied, 'He told me I need to have one right away or I will die.'

"I went to the hospital with an internal struggle. As a daughter I wanted him to have it. I didn't want him to die. On the other hand, I didn't want him to suffer. And how much will he suffer when he's kicked in the chest [by the defibrillator]? How many episodes [of ventricular tachycardia] is he going to have anyway? He may have been having them for five years. We don't know. It just happened that he was monitored in the hospital and they happened to see it. So, if he's been having episodes for years and hasn't died, why put in an expensive device? He already has a pacemaker. The heart failure is the debilitating part, and treating that is the hard part.

"When I got to the bedside he was still sobbing, telling me how frightened he had been, that he thought he might die immediately. I told him that the defibrillator would protect him against the likelihood of sudden death. But it would not cure the heart failure. He asked me a few questions. And it didn't take very long for him to say, 'Well, I'm not going to have it.' He said that the heart failure is bad enough. 'Why would I want to keep from dying from

that? If the heart failure is going to get worse and worse wouldn't it be merciful if I would have a sudden death, instead of a long suffering?'"

Mr. Jones lived another three years, without an ICD, in his own home. Mr. Jones' daughter spoke what the doctor failed to describe -- living with the prolongation of end-stage heart failure. The device does more than was originally expected of it, and it does more than some clinicians anticipate or acknowledge when they advocate its use. For patients, the device can raise thoughts about what constitutes value in living and suffering. Those topics, in turn, guide their responses. For families, the device creates tension between wanting one's loved one to live longer and wanting suffering to end.

The now standard and widely used ICD is difficult to refuse first, because it seems against medical progress and common sense to say 'no' to it, and second, because medical discourse emphasizes that refusing an ICD puts one at risk for death – as though one (and certainly Mr. Jones) were not at risk for death already, simply by having advanced heart failure in old age. The physician's mention of the urgent need for the device insists that the risk of death is more imminent now than it was before the idea of the device was introduced. What Mr. Jones heard from his physician illustrates this, "*He told me I need to have one right away or I will die*." In this example death becomes a symptom to be treated, and not what Dickerson refers to as "a state of nonbeing" (Dickerson, 2002:365), a state that may be accepted at a certain age and stage of life when the alternative is prolonged debility and accompanying suffering.

While Dickerson's project differs from the case studies reported here in that she interviewed younger persons and spoke with them after they experienced a life threatening event and after they had had an ICD implanated, the overall pattern she describes of ICD recipient concerns resonates with our example of Mr. Jones. Patients Dickerson interviewed also were told they needed the device in order to live. Among her interviewees, patient 'choice' was actually pre-empted by the technological imperative. "It was not acceptable not to want the device implanted," she reports (2002:365).

Together, these scenarios add to the qualitative research findings about patient perspectives of ICD experience, choice and lack of choice as evidenced in the work of Dickerson (2002) and Pollock (2008). Yet the case studies reported here depart from those works in at least two ways, and they thus offer a contribution to our understanding of ICD use – especially for persons over age 80. First, these two patients are not living with an ICD – instead, they are shown in the process of considering whether to have one implanted. (In her analysis of the experience of living with an ICD following the event of sudden cardiac death, Dickerson (2002) identifies three themes that became important in patients' lives as time goes on. These are: the sense of losing control over one's life as one became immersed in the health care system, coupled with the feeling that the ICD both saved life and changed life; the need to learn to live with and manage the fear of possible death so that one could get on with life; and the ability, as time passed, to find new value in the "second chance" at life they were given.)

Our ethnographic material focuses not on the existential experience of 'living with,' but rather on the ways in which the structural forces of Medicare reimbursement criteria and clinical trial evidence, along with the cultural press for technological innovation and the widespread expectations that death can always be averted and that good health can be extended into late life, all shape physician and patient consideration of device implantation. Secondly, the oldest patient interviewed in Pollock's study was 72; Dickerson's subjects ranged in age from 40 to 76. No study has yet compared the experience of living with the

device between persons in mid-life and those in later life. And no study describes the process, for older persons, of considering the device in the first place.

The mediating effects of ICD technology

Technological progress is an enduring feature and primary value in modern medicine, and its deep roots in Enlightenment philosophy and science are well known (Gordon, 1988). Its most powerful form in contemporary US clinical practice is the 'technological imperative,' a term coined by health economist Victor Fuchs in 1968 (Fuchs, 1968). It refers to the way in which determinations about appropriate therapy—including for the very old—are driven by the availability and value accorded to technological solutions (especially the newest, most advanced) over other modalities. The technological imperative has been criticized by observers of medicine for four decades for being a means without an end, an activity carried out in the absence of reflective consideration for its implications, especially regarding quality of life and end-of-life care (Cassell, 1991; Rosenberg, 2007). Despite ongoing critique, the technological imperative remains a powerful driver of medical practice in the US (Callahan, 2009; Gillick, 2004, 2007) because the notion of medical progress is tied to technological innovation (especially drugs and devices), because clinical medicine in the US is financed and organized around the delivery of discrete procedures, and because the profit-driven drug and device industries contribute so centrally to rapidly transforming standards of care in US medical practice.

For clinicians, the unavoidable technological imperative becomes, also, a moral imperative. Koenig pointed this out more than two decades ago, showing that the shift in meaning occurs because new technologies almost immediately "feel" routine to practitioners and then quickly become standard care. "Once a new technology is developed, the forces favoring its adoption and continued use as a standard therapy are formidable" (Koenig, 1988:467). "The standard of care becomes a moral, as well as technical, obligation," she noted (p. 486), and it is exceptionally difficult (if not impossible) for clinicians, and then patients and families, to refuse.

Since the 1980s the notion of open-ended technological progress in medicine has been challenged mostly at the site of death – by social movements both within and outside medicine that call for "death with dignity," that is, patient-centered control over the dying process and a rejection of interventions thought to prolong the dying transition and cause pain and suffering at life's end. Most recently, societal awareness of the overuse of technologies has focused both on the problem of the prolongation of suffering and on the unsustainable rising costs of US health care in an environment in which half of the annual increase in total health expenditures is for new and expanding technology use (Callahan, 2009; Emanuel & Fuchs, 2008; Lubitz, 2005). The ICD complicates the quest for control and the dying transition, and it creates quandaries distinct from other therapies in at least five ways. First, many patients are unaware that the ICD can be deactivated at any time (by reprogramming the device so that it does not deliver a 'shock' and abort a lethal rhythm), and reports show that physicians have not generally discussed that option with them (Goldstein, Mehta, Teitelbaum, Bradley, & Morrison 2008b; Meier, 2010; Withell, 2006).

Second, because "ICD therapy transforms sudden death risk to a subsequent heart failure risk" (Goldenberg, Moss, Hall, McNitt, Zareba, Andrews et al., 2006:2810), it may simply prolong living in a state of dying from heart failure (Goldstein & Lynn, 2006; Kirkpatrick & Kim, 2006; Withell, 2006), creating 'downstream' consequences as yet under-explored. Despite the growing strength of the palliative care movement, medicine's hierarchy of values still emphasizes avoiding mortality above all else (Gawande, 2010; Kaufman, 2005). While extending a period of living with end-stage heart failure is impossible to evaluate as

'good' or 'bad' in a normative sense, some note that such life extension may not always "serve the patient's best interest" (Jeffrey, 2001; Kirkpatrick & Kim, 2006:6). Because of expanded Medicare reimbursement criteria and the pathways of care in the US that move patients to sub-specialists who implant devices (Shim, Russ, & Kaufman, 2006), the relatively easy availability and use of the ICD sets up those two kinds of dying as alternatives. The result is that patients and families are placed in a position of having to consider one (potential) sort of death over another – sudden and without warning, or drawn out with distressing symptoms. The device thus contributes to a heightened reflexivity about one's role in the *timing* (amidst uncertainty) of one's own (or a loved one's) death. The case of Mr. Jones illustrates this dilemma. Families, especially, then feel ethically responsible for the kind of death that occurs. The burden they bear in that regard is rarely acknowledged within the medical community.

Third, as both cases show, increased usage of the ICD reinforces the powerful societal assumption that sudden death is *premature* death *regardless of age*. Timmermans (1999) traces the history of the origin of that assumption, both in Europe and the US, to the 1960s, with the normalization of emergency cardiopulmonary resuscitation (CPR) (see also Jeffrey, 2001). Timmermans shows how the technology of emergency CPR moved into the hospital and quickly became the default practice there, enabling sudden death to be framed as "one more road block waiting to be cleared by modern medicine" (Timmermans, 1999:53), regardless of the patient's age, frailty or otherwise terminal condition, and regardless of mounting evidence showing that the vast majority of patients who receive emergency resuscitation in the hospital never leave the hospital alive. The ICD *reinforces* the lack of medico-social acceptability about dying from sudden death and *extends* that lack of acceptability to older persons with advanced heart disease. In that regard the device reveals how end-stage cardiac disease is perceived differently from terminal cancer (Goodman, 1997). Timmermans shows how emergency CPR became a necessary, ordinary act on the way to hospital death. The implantable defibrillator seems to be becoming that kind of a standard tool as well, framing sudden death, *even in advanced age*, as a failure.

Fourth, the shock the ICD produces, while intended to prolong life, may also prognosticate death. One study found that patients with an ICD for primary prevention "who receive shocks for any arrhythmia have a substantially higher risk of death than similar patients who do not receive such shocks" (Poole, Johnson, Hellkamp, Anderson, Callans, Raitt et al., 2008:1009). Thirty percent of patients who received shocks in that study died within 24 hours after the shock. Thus, an arrhythmia that triggers an ICD shock is not necessarily a random event in an otherwise stable condition, but rather marks serious change in the patient's condition that may not be reversible even if abnormal rhythms are diagnosed (Healey & Connolly, 2008).

Finally, the ethics of deactivating cardiac devices looms large in the medical literature (Goldstein, Mehta, Siddiqui, Teitelbaum, Zeidman, Singson et al., 2008a;) Mueller, Jenkins, Bramstedt, & Hayes, 2008) and the popular press (Meier, 2010). For older patients with heart failure and other ailments, and for those already near the end of life, this fact is significant. Toward the end of life, ICD shocks can occur repeatedly while a patient's condition deteriorates (Eckert & Jones, 2002); shocks can occur while the patient is dying. In addition, physicians generally do not discuss deactivation of the device with patients (Goldstein, Mehta, Teitelbaum, Bradley, & Morrison, 2008b), and most patients and families are thus unaware that they may decide to switch off the ICD portion of their device at any time. Although the bioethics literature notes that the deactivation of the device can be classified as the foregoing of extraordinary means of care and thus is acceptable ethically and is a patient's right and choice (Mueller et al, 2008; Sulmasy 2007), Sulmasy (2007:70) states, "…both physicians and patients view the deactivation of the device as something

different from the withdrawing of other life support technologies, and therefore, as problematic." The fact that the device is inside the body, and is pre-programmed to abort a lethal rhythm, makes deactivation confusing and morally troubling for some when considering deactivation near life's end (Goldstein et al., 2008a; Goldstein et al., 2008b; Meier, 2010; Withell, 2006). Importantly, the ethics surrounding ICD deactivation has not been explored specifically for persons age 80 and above, those who now comprise 20% of the patient population for implantable cardiac devices (Swindle et al., 2010). Proposed policy solutions that focus on enhanced choice, such as requiring advance care planning discussions at the time of initial device insertion, are likely inadequate given the complex dynamics revealed in our cases.

Evidence, standards and ethical necessity

In the culture of medicine today, the technological imperative is bolstered by the value given to evidence-based studies, which show, primarily through clinical trial results, the efficacy of new clinical tools for specific populations with particular conditions. Technical ability (via drugs, devices and procedures) to reduce mortality becomes "best treatment" (Armstrong, 2007) and takes priority over the quality of life implications of those treatments (Goldstein & Lynn, 2006). Emphasis on treatments that thwart mortality (even in the short term) become strongly valued and seem, thus, to be ethically necessary. The dominance of clinical trial data in assessing the benefits of expanded ICD use and the outcomes of those trials have enabled the US medical community (as well as others) to think in a new way about cardiac risk and prevention. Yet few clinical trials for the ICD include persons over age 70 (Chan, Nallamothu, Spertus, Masoudi, Bartone, Kereiakes et al., 2009; Redberg, 2007), and few are designed for persons over age 75 (Chan et al., 2009; Swindle et al., 2010).

Lively discussion in the medical literature since 2005 has pondered which patients, and especially, which elderly patients, might benefit the most from ICD implantation (Buxton, 2007; Yarnoz & Curtis, 2007). The device has been shown, in a 2009 study, to be effective in reducing mortality for certain groups of patients over age 75 specifically (Chan et al., 2009). Yet few patients age 80 and above were enrolled in that study, the first to focus on older patients. A 2004 study (Krahn, Connolly, Roberts, & Gent, 2004) found that the value of an ICD in patients age 85 and above – that is, the likelihood of a patient surviving long enough to have an arrhythmic event and receive ICD "shock" therapy – will most often be much smaller than for younger patients (Heidenreich & Tsai, 2009).

In US aging society, the two cultural moves – from new technique to standard treatment, and then, from standard treatment to ethical necessity – are evident in the growing trend to suggest, offer, implant and accept the ICD. Although the risk of unintentional, prolonged suffering at life's end is enhanced by ICD use, and while faulty devices that can cause problems and that need removal are common (Weber et al., 2006), the social and medical sense of risk surrounding the ICD focuses instead on the risk of sudden death – and doing everything possible to reduce that risk (Fleck, 2009). Once the idea of extending even the oldest lives with the device has been conceived and made widely available, it becomes an ordinary, normal part of the medico-socio-ethical landscape. For the oldest patients and their families, this logic is ironic because it carries with it ramifications for 'living with' prolonged dying.

In the US, Medicare is the primary institutional vehicle linking together the technological imperative, clinical trial and other evidence-based data, payment, and standard practice. Committees working through the Centers for Medicare and Medicaid Services, which administers the Medicare program, constantly review and assess clinical studies and new

evidence about what constitutes the therapeutic. Their reviews are the basis for reimbursement and coverage decisions. Those coverage decisions strongly influence the 'need' for certain treatments, the organization of specific options that physicians employ, which therapies become standard, and the effects of those options on patients' and families' lives (Gillick, 2007; Hlatky, 2004; Tunis, 2004). Physicians are bound by canons of professional practice and ethics to offer standard therapies, and patients and families do not often or easily say 'no' to them (Kaufman, Shim, & Russ, 2004, 2006). Given the promise of "comparative effectiveness research" as a policy fix for controlling health care costs, it is particularly important to understand how evidence in and of itself cannot resolve questions like appropriate ICD use.

The ICD is an example of a therapy that has shifted from "unthinkable" a couple of decades ago, to routine and standard treatment for older persons today (Jeffrey, 2001). Expanding Medicare coverage has enabled that conceptual, clinical and ethical shift to be embodied in a growing older population. The widely discussed individual *ethical decision making* that takes place downstream – by patients, families, and doctors, and that has been the focus of the bioethics enterprise – is thus already prefigured by changing notions of standards of care and ethical necessity. Bioethicists' call for more patient choice does not address the larger structural framework within which that choice is circumscribed (Drought & Koenig, 2002).

As the use of the ICD becomes routine and normalized, the "extravaganza of cardiology," that physicians describe (Shim et al., 2006) -- as they reflect on the convergence of the technological imperative, shifting standards of care and the rising age of patients --becomes an increasingly accepted and, indeed, ordinary part of old age in the US (Shim et al., 2006). The source of the "extravaganza" is the confluence of mounting clinical trial evidence for efficacy (although what efficacy actually means in the oldest age groups is not clear), expanding Medicare coverage for lower-risk populations and the reduced risk of device implantation itself (although at least one study notes that the complication rate for ICDs is over 10% [Weber et al., 2006]).

Conclusion

The ICD has complicated the experience of living, the management of heart failure, end-of-life care and the dying process. Thus advising a patient in the eighth or even ninth decade to implant an ICD as a preventive strategy carries with it ramifications that patients and families do not necessarily foresee. Postponing death from a sudden cardiac event allows one to live with and suffer longer from the symptoms of heart failure and, potentially, from a host of other degenerative conditions. While opinions diverge about whether the use of the ICD in very old individuals is appropriate therapy (Redberg, 2007; Weber et al., 2006), physicians agree that use of this device is on the rise because it prevents death, because clinical trial evidence has paved the way for its expanded use as standard of care; because specialist and subspecialist referrals organize their use, and because the treatment of the *risk* of dying in late life has become so important in medicine. Because the sub-specialty fields that implant the devices are technical, and because it is unusual for practitioners to see the structures of evidence, payment and necessity that drive the use of these devices *among ever-older individuals*, the bigger picture of ICD use among a growing elderly population (with multiple frailties and co-morbidities), is simply not seen, or is not acknowledged in practice trends.

Using the implantable cardiac defibrillator as an example, we have shown how medical technologies move beyond their original intention as specific means, reshaping responsibilities and the ends of medicine in an aging society. There is no question that implantable cardiac devices have already reshaped the horizon of our expectations, and will

continue to do so, by urging us, guiding us to reduce the risk of our own deaths, even though success in averting sudden death now often leads to prolonged dying with the worsening symptoms of heart disease and may cause a death traumatic for both patients and families due to repeated shocks during the dying transition.

Four powerful socio-cultural engines drive a great deal of the open-ended technology use for the elderly in the US. Clinicians are aware that treatments for the very old can be a double-edged endeavor, yet they want and feel obligated to provide life-extending options, sometimes regardless of a patient's age or extreme frailty. Older persons, some of whom are ambivalent about living on and on with deteriorating health, do not easily want to authorize their own deaths by proactively stopping or rejecting a (potentially) life-saving therapy, for that is what saying 'no' to technology has come to imply (Dickerson, 2002; Kaufman, 2005). Families do not want the responsibility of saying 'no' to life-extending interventions for their loved ones and, of course, they are hopeful that treatments can extend meaningful life. Importantly, bioethics discourse often excludes the effects of life-prolonging/death-prolonging technologies on families and the fact that clinical practice today tends to ethically 'offload' decision-making about 'life' and 'death' to patients and families. Finally, procedure-driven health care finance arrangements guide everyone in the U.S. toward more and more technology use. Innovative technologies that prolong some lives will continue to emerge, to be approved for insurance coverage and to be, thus, ethically necessary. As both the means and the ends of cardiac and other technologies evolve, societal ambivalence – about value, cost effectiveness, the idea of a 'natural' life span, and how much intervention is appropriate at ever-older ages – will remain.

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