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## Implantable Cardioverter-Defibrillator Use in Older Adults: Proceedings of a Hartford Change AGENTS Symposium

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### Background

Since their initial clinical demonstration in 1980, implantable cardioverter-defibrillators (ICDs) have prolonged countless lives with successful treatment of sudden cardiac arrest.<sup>1</sup> No other therapy has proved as effective in preventing death from ventricular arrhythmias,

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and important advances in ICD technology continue to improve outcomes for well-selected patients.<sup>2</sup> While indicated for a wide range of inherited and acquired conditions,<sup>3</sup> ICDs are predominantly placed in older patients with left ventricular systolic dysfunction and either prior myocardial infarction or congestive heart failure.<sup>4</sup> In the United States alone, over 50,000 ICDs are placed annually in patients aged  $\geq 65$ , and nearly 500,000 more may meet current guidelines for device implantation.<sup>5</sup>

However, decision-making for older patients considering ICD implantation is particularly challenging. Subjects in the landmark trials had average ages in the 60s, and thus the survival benefits of ICDs in older age groups is less well-established.<sup>6</sup> In addition, compared to the younger participants in most clinical trials, older adults have a lower ratio of arrhythmic death to non-arrhythmic death due to competing risks for mortality, resulting in a potentially lower absolute risk reduction. At the same time, living and eventually dying with an ICD introduces potential risks including a lower quality of life, hospitalizations, and potential suffering at the end of life.<sup>7</sup> A rigorous consideration of the benefits, risks, and ongoing care surrounding ICD use in older patients is long overdue.

On April 22, 2014, we convened a conference of multidisciplinary experts in cardiac electrophysiology, heart failure, geriatrics, ethics, and palliative care in Boston, supported by the Hartford Change AGENTS and Paul B. Beeson Career Development Award programs, and the Hebrew SeniorLife Institute for Aging Research. The objectives of the conference were: (1) to review what is currently known regarding ICD use in older patients: epidemiology, clinical outcomes, cardiac resynchronization therapy (CRT), health status evaluation, decision support, palliative care, and ethics; (2) identify research priorities for the field; and (3) define opportunities for immediate practice improvement. Participants presented lectures summarizing the current evidence and proposing key research gaps needed to better select and support older patients for ICD treatment. Summary conclusions were discussed and debated collectively. This article summarizes the discussion and conclusions of this symposium. Though not intended as a complete review of the literature, this proceedings summary may serve to orient the clinical community towards the most pressing clinical and research problems while suggesting a roadmap for improvement.

## Current Knowledge

### Epidemiology

ICD use remained relatively limited until the early 2000s. Estimates in the U.S. derived from the National Inpatient Sample described annual implantation rates of 25,000-50,000 in the years 1997 – 2001, with few CRT-D implants prior to 2002.<sup>8</sup> However, advances in transvenous ICD lead design, publication of pivotal studies in primary prevention populations,<sup>9-11</sup> and the advent of CRT<sup>12, 13</sup> supported dramatic increases in ICD use.<sup>14</sup> Data from the National Cardiovascular Data Registry (NCDR) – ICD Registry provides the most comprehensive recent assessment of ICD utilization in the United States. In 2011, there were 175,000 implantations entered in the ICD Registry, of which 75% were aged  $\geq 60$  years, approximately 50% aged  $\geq 70$  years, and nearly 20% were aged  $\geq 80$  years.<sup>5</sup> Importantly, nearly 40% of all procedures were ICD generator replacements. A separate

U.S. registry similarly demonstrated > 40% of new implantations in patients aged 70, and more than 12% aged 80<sup>15</sup>

Data from registries outside the U.S. clearly illustrate that the use of ICDs in older patients is an international challenge. For example, over 40% of ICDs in an Ontario study were in patients aged 70,<sup>16</sup> and 25% in an Italian registry were aged 75.<sup>17</sup>

Among recipients of ICDs aged > 60 years, approximately 80% receive the ICD as primary prevention, i.e, they have not previously experienced sudden cardiac arrest or sustained ventricular tachycardia.<sup>5, 15</sup> Of these, an estimated 75% meet indications for ICD implantation as defined by the inclusion criteria of the SCD-HeFT study, which enrolled patients with a left ventricular ejection fraction of 35% and clinical heart failure.

Though, in theory, ICD implantation primarily serves to prevent sudden cardiac arrest, for which only a single-chamber device is necessary, a large proportion of implants involve either dual-chamber or CRT systems.<sup>18</sup> Data from the ICD Registry demonstrate that a large percentage of patients without a clear indication for pacing nonetheless receive dual-chamber ICDs. There is considerable regional and hospital-level variation in this practice.<sup>19, 20</sup> Furthermore, approximately 30-40% of ICD implants are CRT-D devices, implanted for improvement in heart failure symptoms as well as mortality benefit. The highest proportion of such implants occurs in patients aged 80 years. The use of CRT systems without an ICD is less well-established, but appears to be less common than CRT-D implantation.<sup>8</sup>

### Clinical Outcomes

Clinical trials and observational studies inform estimates of ICD effects on survival and quality of life alongside procedural complications. Most clinical trials of ICD therapy enrolled patients with median ages in the 60s, and extrapolating data even from the few older patients represented in these studies to the real-world elderly is fraught with difficulty.<sup>21</sup> Meta-analyses of pivotal trials in both primary prevention<sup>6</sup> and secondary prevention<sup>22</sup> populations, stratified according to age did not show a significant survival advantage for older patients (aged >65 or >75 years, respectively), although some of this difference may have been due to the smaller numbers of elderly patients enrolled. A separate pooled analysis of clinical trial data demonstrated a persistent survival advantage in older ICD recipients (with a hazard ratio for those aged 65-74 of 0.67, 95% posterior credible interval 0.53-0.85).<sup>23</sup> Several non-randomized studies have proposed that the survival advantage in older patients remains statistically and clinically significant. For example, propensity-matched evaluation of Medicare beneficiaries with heart failure and left ventricular systolic dysfunction demonstrated a significant survival advantage among those who received ICDs (hazard ratio 0.71, 95% confidence interval 0.56-0.91).<sup>24</sup> This was similar to findings from a separate cohort study of US patients in which age alone was not a predictor of survival benefits.<sup>25</sup> However, there remains substantial confounding in practice due to selection of healthier patients for ICD, who among the Medicare population had fewer subsequent hip fractures (HR 0.77) and nursing home admissions (HR=0.53) than patients not receiving ICDs.<sup>26</sup> Other studies have indicated similar rates of appropriate shock among older and younger patients,<sup>27</sup> despite the consistent finding of higher overall

mortality with older age – with a higher proportion of deaths from causes other than sudden arrhythmic causes—and accumulated comorbidity in patients receiving both new and replacement ICDs.<sup>28-30</sup>

Acute complications appear to be slightly more common in older recipients of ICDs, although still relatively unusual: <2% overall, with each decade of age increasing this absolute risk by only about 0.2% according to one estimate.<sup>31</sup> Other analyses have similarly showed a gradient of risk with increasing age, largely driven by the accumulated comorbidities.<sup>32</sup> However, these estimates are based largely on index admissions, and analyses exploring longer term complications may be as high as 10%.<sup>33</sup>

Given the frequent utilization of ICD therapy in older patients alongside concerns regarding survival and complication rates, several investigators have developed risk models for mortality following ICD implantation.<sup>34-39</sup> Though the methods vary by study, in general these models illustrate the feasibility of risk-stratifying patients at the time of implant along a spectrum of 1-year mortality risk from as low as 3% to 40% or more depending on accumulated risk factors. Though age emerges as an independent risk factor for early mortality in these models, the consistent message across these studies is the important contribution of associated conditions such as renal dysfunction and atrial fibrillation as modifiers of the impact of age alone.

Fewer data inform outcomes and the benefits for older patients following ICD generator replacement, though ICD Registry data has shown a higher rate of death following replacement compared with initial implantation,<sup>28</sup> with age independently increasing the hazard for death.<sup>29</sup> Similarly, a small registry study illustrated that half of octogenarians receiving elective generator replacements died within 1 year post-procedure.<sup>40</sup>

### Cardiac Resynchronization Therapy

Registry data described above clearly shows that CRT systems are commonly implanted in older patients, and account for a greater share of all ICD implants in older patient than in younger groups, including as much as 40% in those aged > 80 years.<sup>15, 41, 42</sup> As with ICDs, the clinical trials in severe heart failure<sup>12, 13</sup> and more mild heart failure<sup>43-45</sup> did not exclude patients based on older age alone. Though the median age in the COMPANION and CARE-HF studies was 67 and 66 years respectively, the proportion of patients in either trial aged 80 years was not reported. Both studies provided only limited subgroup analyses of its older patients. In the 3 largest studies of mild heart failure, the mean age was approximately 65 years and generally suggested trends towards benefits in the older subjects, though only MADIT-CRT had sufficient power to demonstrate a statistically significant improvement in its composite endpoint (death or heart failure).<sup>46</sup> Meta-analyses of CRT trials have not reported outcomes specifically in subjects > 65 years.<sup>47, 48</sup>

Observational studies have suggested benefits in older patients in other important clinical endpoints, including quality of life, as well as physiologic and echocardiographic parameters.<sup>49-51</sup> In sum, though definitive clinical trials just in older patients have not been performed, both ICD therapy alone and in concert with CRT appear to be effective in older patients according to prevention of arrhythmic death and (for CRT) improvement in quality

of life – but with important limitations posed by slightly increased risks of complications, substantial competing risks for non-sudden deaths, and attenuation of physiologic benefits from cumulative comorbid conditions.<sup>21</sup>

### Measuring Health Status

ICDs and, particularly CRT-D devices may impact quality of life, functional status, hospitalizations, and other outcomes apart from survival. Yet, to date, there is limited insight into the patient characteristics associated with greater or worse health status after device implantation. This creates a compelling need to understand the patient and treatment characteristics associated with patients' self-reported health status after device-based therapy. Health status evaluation in cardiovascular patients aims to characterize several domains of patients' experience and can leverage either generic or disease-specific tools. Though instruments vary, most include measures of symptoms, activity restrictions, psychological factors, and an assessment of patients' overall self-perceived quality of life. Several existing instruments can measure and track health status in patients eligible for ICD implantation, particularly those with heart failure. For example, the Kansas City Cardiomyopathy Questionnaire (KCCQ) has been well-validated in a variety of contexts,<sup>52-54</sup> and predicts clinical outcomes,<sup>55</sup> including in study cohorts with relatively old patients.<sup>56</sup> Similarly, disease-specific instruments for patients with coronary artery disease have been developed and validated.<sup>57, 58</sup> In older ICD recipients, it has been suggested that general health considerations play a role in decision-making.<sup>26</sup> However, more formal integration of health status measurement into pre-implant considerations, idiographic recommendations for courses of treatment, and outcomes assessment has not been performed and is a critical gap in existing knowledge.

Quality of life alone has been assessed to a limited extent in several clinical trials of ICD recipients. Compared to control patients receiving medical therapy, ICDs patients overall had a similar quality of life in SCD-HeFT<sup>59</sup>, MADIT-II<sup>60</sup> and AVID,<sup>61</sup> worse quality of life in CABG-Patch,<sup>62</sup> and improved quality of life in CIDS.<sup>63</sup> However, predictors of quality of life remain poorly understood,<sup>64, 65</sup> and older data are further limited by earlier generations of ICD technology, which included larger generators and less sophisticated measures for avoiding inappropriate shocks.

### Decision Support

The epidemiology and outcomes data make it clear that ICD use in older patients is common, and yet deciding whether or not to get an ICD can be a difficult decision for anyone, and integrating options for CRT (with or without an ICD) markedly complicates this process. These decisions are even more difficult for older patients and demand an understanding of the relative importance of survival and quality of life for each patient. Given that everyone ultimately dies, the decision for a patient with heart failure considering an ICD is not between life and death but rather between accepting an ICD and having a potentially longer life with advancing heart failure or declining an ICD and having a potentially shorter life but retaining the opportunity to die quickly, and indeed even with an ICD a small risk of sudden death untreatable by the device remains. Recently, the ACC/AHA guidelines for heart failure were modified to specifically include language stating that this

trade-off should be discussed.<sup>66</sup> This is particularly urgent given the many studies now available providing opportunities to provide quantitative estimates for individual patients. As noted previously, several models describe the risks of 1-year mortality in ICD recipients,<sup>34, 37, 39</sup> and a smaller group of studies include non-ICD control arms for comparison.<sup>35, 36</sup> These models have not, however, been prospectively validated and their role in clinical practice remains uncertain, even alongside pooled clinical trial data demonstrating a persistent, if attenuated, benefit of ICDs in older patients.<sup>23</sup> As noted earlier, though less well-studied, there are data available to provide prognostic information around ICD generator replacement as well.<sup>21</sup>

Unfortunately, evidence on how decisions are actually being made suggests that patients are not appropriately involved or informed. A recent integrative review of 24 articles related to patients' perceptions of ICD decision-making identified a significant degree of misunderstanding about the risks, benefits, and trade-offs in ICD treatment.<sup>67</sup> Patients often overestimate the benefits and underestimate the risks. One survey of patients demonstrated that they overestimate the benefits of ICD by over 400%.<sup>68</sup> Another study demonstrated that patients reported learning of many of the risks after implantation.<sup>69</sup> Importantly, a consistent theme of many of the studies in the integrative review was that many patients were unaware of the option to deactivate their ICD<sup>67</sup>, a particularly critical point of knowledge for older patients who may have multiple comorbidities.

These misunderstandings may be a function of the way that decisions about defibrillators are presented to patients. One study used standardized patients to explore 11 different cardiologists' discussions with patients related to ICD decision-making.<sup>70</sup> The authors found a strongly paternalistic tone focused on the patient "needing" the device. Another study identified that physicians were frightened to tell the patients too many of the risks because they didn't want them to make a "bad decision."<sup>69</sup> A survey of over 1200 members of the American College of Cardiology noted that physicians rated guidelines and mortality data much higher than patient preferences or patient knowledge in their recommendations for ICDs.<sup>71</sup>

This limited literature on ICD decision-making suggests marked room for improvement on purely clinical grounds – that is, to improve patient selection and participation in the process of receiving and managing an ICD over time. One approach leveraging both paper and video tools is under investigation currently.<sup>72</sup> In addition, however, there is an ethical imperative to improve informed consent, and existing survey data suggests unacceptable deficiencies in patients' understanding regarding the purpose, functions, and options regarding ICD therapy.<sup>73</sup>

### **Advance Care Planning and End-of-Life Care Involving ICDs**

Even with an ideal decision-making process prior to implantation, the vast majority of patients who receive ICDs will have a functioning device in place at the end of their life, and thus decisions about device deactivation are inevitable. Similarly, even with the sudden death prevention provided by ICDs, mortality among older ICD recipients remains high, placing great importance on careful advance care planning. However, patients unaware of



ICD deactivation as an option<sup>67</sup> may leave patients and families unprepared at the end of life. ICD shocks at end of life are painful for patients and distressing for families.<sup>74</sup>

Unfortunately, failure of ICD patients to complete advance directives, and lack of inclusion of the ICD specifically even when completed, has been a consistent finding in surveys.<sup>75, 76</sup> As such, ICD deactivation remains needlessly complex for many clinicians and surrogate decision-makers. This is in stark contrast to other life-sustaining therapies, as shown in one survey in which physicians were overall (~ 90%) self-rated as comfortable discussing treatment withdrawal in general, though less than half were comfortable discussing ICD deactivation.<sup>77</sup> A recent detailed case series of 150 patients who had their ICD or pacemaker deactivated demonstrated that most deactivations occurred within 2 days of death.<sup>78</sup> In only one of these patients was the device addressed in an advance directive. This lack of preparation meant that surrogates were responsible for over half of the deactivation decisions. Among a group of family members of deceased patients, only 27% reported actually having had a discussion about ICD deactivation prior to death.<sup>79</sup>

One important barrier to more effective advance care planning is physician knowledge and experience. Qualitative studies suggest that clinicians are uncomfortable with these discussions: As one physician stated, “that’s an end-of-life conversation, when you put them in, you’re having a life-prolonging conversation.”<sup>80-83</sup> While the majority feel it is important to disable the ICD in terminally ill patients,<sup>82, 84-87</sup> there was no consensus on who should have these discussions.<sup>81, 85, 86</sup>

### **Ethics of ICD Deactivation**

Ideally, evolving health care goals in the face of advancing illness become integrated into advance directives or other vehicles for advance care planning. However, even under optimal circumstances hard questions may remain, leading to decision-making dilemmas. These dilemmas principally include conflicts over the ethical and legal status of ICD deactivation in isolation and in comparison to other therapies, circumstances and outcomes of ICD deactivation, and improvements to the informed consent process for ICDs and CRT.

A 2010 Heart Rhythm Society consensus statement on managing ICDs in patients nearing end of the life or requesting withdrawal of therapy included an extended discussion of the ethical principles supporting ICD deactivation.<sup>88</sup> This statement anchored the management of ICDs in longstanding moral and legal precedents establishing the right of patients to decline medical interventions or request their cessation.<sup>89, 90</sup> This right is grounded in the moral principle of autonomy, which in this context reflects the right of individuals to define and determine their own treatment goals and interventions. There is general consensus among ethicists that refusing or withdrawing medical therapy (including ICDs) are equivalent, and doing so is not euthanasia or physician-assisted suicide. However, multiple survey and focus group studies including patients, physicians, and nurses have demonstrated that many individuals view ICDs as morally different from, for example, CPR or mechanical ventilation.<sup>75, 77, 91</sup> The underlying justification for these beliefs, however, despite the lack of a clear moral or legal foundation, remains unclear.<sup>92, 93</sup>

## Key Research Questions

Several of the most pressing areas of inquiry around ICD use in older patients involve implantation patterns, particularly the marked variability in dual-chamber use and the apparently high utilization of CRT-D in older patients. Specifically, defining the association between more detailed patient- and provider-level characteristics with ICD implants may provide insights towards how and why specific devices are selected, particularly when selecting patients for CRTP versus CRT-D. In addition, ICD replacement patterns remain very poorly understood,<sup>94</sup> and almost nothing is known in particular about how frequently, why, and with what outcomes older patients choose to decline ICD replacement. Lastly, though some commentary on ICD utilization in older patients suggests suspected overuse<sup>95</sup>, understanding whether there are populations of otherwise healthy older patients who may benefit significantly from ICD implantation but are not offered ICDs – and what drives these decisions – may provide an important opportunity for usefully expanding the thoughtful application of ICDs.<sup>96-99</sup>

Similarly, while professional society guidelines assert that age alone should not be a contraindication to ICD implantation or replacement, refinement of patient selection towards those most likely to benefit remains an urgent public health priority.<sup>36</sup> This may be particularly valuable for ICD replacement, around which no prospective clinical trial evidence yet exists.<sup>94</sup> Strategies of ICD non-replacement in patients who arrived at the end of ICD battery life having recovered left ventricular function, or those who have not previously received ICD shocks, have not been explored in detail. In addition, given the comparatively short battery life of CRT systems compared with other ICDs,<sup>28</sup> understanding how decisions regarding replacement for older CRT patients are made would benefit from further study.<sup>94, 100</sup>

Importantly, many older individuals value quality of life as much or more than survival, and the interaction between CRT and ICDs on each of these outcomes is complex. The limited data suggest an urgent need to better inform patients regarding the risks and actual expected benefits of ICD therapy. Older ICD patients also combine disease-specific health status concerns arising from their underlying cardiovascular problems with complexities introduced by the device itself. Thus, whether any of the existing quality of life and health status measurements adequately capture all of the relevant clinical, psychological, and psychosocial domains of importance for these patients remains uncertain.

Few studies have targeted seemingly simple questions: Which patients want to share decisions? Given that there is likely a spectrum of patient preferences regarding involvement in decisions, how should decision support be structured to capture this variability? How should families, other surrogates, or other professionals (other medical specialists, clergy, social workers, nurses, etc.) be involved? What information would be most valuable to them in considering ICD treatment (survival, QoL outcomes, peri-procedural risks), with a goal of helping patients identify their goals and values and make a concordance decision? How should decision support be different between initial ICDs, replacement ICDs, and CRT-P vs. CRT-D? How well do older patients understand the decisions they make? What are the patient, physician, and system barriers to promoting shared decision-making? In short, while



the legal and ethical frameworks supporting decision support are clear, the optimal strategies to actually improve decision making remains unknown.

Similarly, overcoming barriers to conversations about ICD management as patients reach the end of life is the central question challenging the ethics and palliative care considerations for older ICD patients. Patients and surrogates face predictable decisions, but the optimal way the care of the ICD and its complications should be incorporated into ongoing palliative and supportive care discussions for these patients requires further study. Indeed, palliative care is already a CMS requirement for destination left ventricular device therapy – and the same principles apply to ICDs. In particular, approaches to making patients aware of ICD deactivation *prior to or at the time of implantation* need exploration. This may in part depend on a clearer understanding of exactly why patients and providers persist in their perception of ICDs as morally distinct from other life-sustaining therapies. Whether these beliefs rest on legal or technical confusion, lack of familiarity with ICD deactivation compared with other treatments, or reflect other concerns, will have important implications for improving the informed consent, decision-making, advance care planning, and – one hopes – outcomes for older patients with ICDs.

## Opportunities for Immediate Practice Improvement

Despite these research gaps, the existing knowledge base in ICD therapy supports several immediate changes to current practice. Indeed, while developed with a focus on older patients, the suggestions described here readily apply to any patient considering ICD therapy whose clinical context (whether elderly or not) supports a holistic assessment of prognosis, treatment goals, and preferences. These suggestions include the following changes to *processes of care* and support for *individualization of care* (**Table**).

1. Public reporting of heart failure outcomes should focus not only on rates of ICD implantation in “eligible” patients but rather on quantifying the frequency of a high-quality discussion of ICD risks and benefits with patients meeting initial clinical criteria.

Efforts to define “quality of care” for patients receiving ICDs to date have focused on the use of optimal medical therapy<sup>101</sup> and in-hospital complications,<sup>31</sup> and future work may well generate both process and outcome-based quality standards for public reporting and pay-for-performance incentives. Trends in heart failure management and public reporting may thus inadvertently bias ICD implantation recommendations to achieve a more uniform outcome (e.g. implant an ICD in all eligible subjects) that may not capture the reality for many older patients. By contrast, a more patient-centered approach integrating quality of life and health status assessment may support a more uniform *process*, but with more variable *results*. An initial step in this direction would be to ensure that detailed discussions occur prior to implantation, but how the quality of these can be quantified warrants further research.<sup>102</sup> The National Quality Forum's recent report on priority setting for person-centered care and outcomes notes that that care should be respectful of, and responsive to an individual's priorities, goals, needs, and values and that measures need to be developed in kind.<sup>103, 104</sup> In other contexts, measures of “decision quality” have been developed to assure that decisions are informed and concordant with a person's values.<sup>105</sup> The cardiovascular

community would be wise to take the lead in developing measures of decision quality and person-centered care. Fully capturing these data may require a prospective registry of older patients apparently meeting indications for ICD implantation in order to characterize referral patterns, decision-making processes, and outcomes both with and without ICD implantation and from which the collected data can be used to create an assessment tool for the quality of medical decision-making in the consideration of device-based therapies.

2. Include health status measures in the National Cardiovascular Data Registry – Implantable Cardioverter-Defibrillator registry case report form.

The ICD Registry form captures information on the overwhelming majority of ICD implants in the US. Though significant information on comorbidities is collected, no validated health status measurement is included in the form – a missed opportunity for large-scale, real-world measurement of a critical clinical variable. Integration of a relatively simple, but robust, metric such as the newly-introduced, 12-item Kansas City Cardiomyopathy Questionnaire, which takes ~2 minutes for patients to complete and has recently been included in both the INTERMACS registry of left ventricular assist devices and the Trans-Valvular Therapeutics Registry. Collecting the health status of ICD recipients at the time of implantation and over time could be used to assess the appropriateness of CRT therapies, document changes in health status over time that could be used to generate estimates of health status benefits as a foundation for future shared medical decision-making tools, and as a means of comparing patient-level benefits across centers for quality assessment and improvement purposes.

3. Society guidelines and practice standards should emphasize the need for individualization of ICD implantation decision-making based on context, clinical status, and patient preferences.

ICD implantation is an exquisitely preference-sensitive decision. This is particularly true for older adults given that the trade-offs become even more pronounced in the context of increased peri-procedural risks, the decreased timeline for benefit, and evolving preferences regarding aggressiveness of care and mode of dying. Individualization by use of risk models<sup>29, 34, 35</sup>, decision-aids, and collaboration among specialists involved in each patients' care may support a more tailored approach to ICD use.

4. Documentation of appropriate advance care planning for older patients with ICDs should become routine practice.

Current practice patterns and reimbursement standards for ICD implantation focus on indications and device selection, carefully reflected in peri-procedure documentation. Expanding this to include advance care planning may also be the swiftest way to improve the frequency of advance care planning discussions prior to ICD implantation, as has been done with CMS requirements for left ventricular assist devices. ICDs are resuscitative devices, implanted in patients for whom prognostic models illustrate predictable decisions regarding ICD deactivation, generator replacement, and overall goals of care. This argues for higher clinical standards for advance care planning in these patients prior to implantation.<sup>106</sup> Documentation of, for example, designation of a health care proxy, completion of an advance directive, other state-specific vehicles and description of patients'

preferences for ICD management, as standard practice has the potential to improve the end-of-life care of these patients in particular. Making this practice a condition for reimbursement would serve as a powerful incentive for providers, but even without this external requirement (which would face many practical obstacles), the field of electrophysiology can take a firm position on making advance care planning as routine as measuring left ventricular systolic function in patients “eligible” for ICDs.

Several potential barriers to these four proposed recommendations merit comment. Public reporting and primary data collection such as the ICD registry efforts already struggle with limited resources. Changes to professional society guidelines tend to be gradual and largely focus on emerging clinical trial evidence. Providers may also balk at additional documentation layered onto an already ornate process for illustrating clinical necessity and conformation with reimbursement guidelines. However, there is a clear ethical imperative to improve the care of older patients considering ICD implantation and living with these devices. ICDs are clearly life-saving in well-selected older patients, yet necessarily engage patients in providers – recognized or not – in a therapeutic process that directly asks hard questions about quality and duration of life, goals of care, preferences, and priorities. Thoughtfully reorienting the application of device-based therapy away from mere alignment with clinical trials towards the patient-centered approach advocated for here has never been more urgent.

## Conclusion

ICD use in older patients is certain to grow in the coming years. Aggressive pursuit of the research goals and practice changes identified here will help support utilization that is thoughtful, patient-centered and compassionate.

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**Table**

## Opportunities for Immediate Practice Improvement

1. **Public reporting of heart failure outcomes should focus not only on rates of ICD implantation in “eligible” patients but rather on quantifying the frequency of a high-quality discussion of ICD risks and benefits with patients meeting initial clinical criteria.**
2. **Include health status measures in the National Cardiovascular Data Registry – Implantable Cardioverter-Defibrillator registry case report form.**
3. **Society guidelines and practice standards should emphasize the need for individualization of ICD implantation decision-making based on context, clinical status, and patient preferences.**
4. **Documentation of appropriate advance care planning related to future ICD deactivation for older patients with ICDs should become routine practice.**

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