COMMENTARY

Mandates for Shared Decisions: Means to which Ends?

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Carefully aligning invasive cardiovascular therapies to patients' health care goals appeals to every stakeholder involved in treatment decisions.[1] Patients should only pursue procedures intended to promote outcomes they value balanced against risks they consider acceptable. Physicians performing procedures and payers providing reimbursement similarly ought to favor matching expensive devices with patients most likely to benefit according to patient-centered preferences for extended survival, improved quality of life, or both. Cardiac electrophysiology therapies including implantable cardioverter-defibrillator (ICD) insertion highlight these shared goals in stark terms: Treatment is designed only to extend survival, without improving quality of life; includes small but important risks for implantation and long-term therapy; and only provides clinically significant benefits to a subset of device recipients.[2] ICD implantation would thus seem an ideal environment for formally implementing shared decision-making (SDM) to ensure that patients are well-informed not just on acute procedural considerations, but the overall place of ICD implantation within their health care.[3]

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In this issue of *JLME*, Rao and colleagues explore implications of the controversial 2018 Centers for Medicare and Medicaid Services (CMS) final memo updating national coverage determination conditions for ICD implantation.[4] CMS issued its first national coverage determination for ICDs in 1986 and has updated it periodically as new evidence and technology emerged, most recently in 2005 with expansion of primary prevention implantation to include most patients with systolic heart failure. The 2018 updated memo (which CMS curiously called "relatively minimal") included a controversial requirement for a SDM encounter using an "evidence-based decision aid" prior to primary prevention ICD implantation for heart failure patients.[5] As Rao et al observe, formally mandating SDM in a legally-binding, nationwide requirement adding logistical and practical complexity to a common, costly procedure demands a clear understanding of what CMS hoped to accomplish in doing so. It is critical to note that CMS coverage determinations have real teeth: In 2015, nearly 500 hospitals paid >$250 million over False Claims Act allegations brought by the Department of Justice related to ICD implantation outside of coverage requirements.[6]

Rao et al suggest 3 potential overlapping goals of SDM requirements, briefly summarized here as improving knowledge and engagement; improving alignment of values with actual treatment choices; and improved utilization, understood either as reduced variability in care, reduced overall use, or improved clinical outcomes in the eligible population. Disambiguating these goals is essential, they correctly argue, because the metrics for assessing the impact of SDM on each varies widely and potentially conflict with each other. For example, if selected groups of older ICD-eligible patients decline ICD implantation based

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on their values, this may improve value-choice concordance while potentially worsening overall survival for that same group of patients. Their case study in SDM use and careful dissection of potential CMS objectives also illustrates that apparently simple changes in implementation may impact selected outcomes (such as knowledge) differentially, whereas other potential goals seem poorly advanced by any known approach to SDM for ICDs. Their summary question — is this mandate worthwhile? — thus lingers uncomfortably.

What *did* CMS intend with this requirement, and does the SDM mandate actually meet its own goals in a measurable way? Defending the SDM requirement explicitly in response to submitted public comments, CMS observes: "We believe that an SDM encounter … is a critical step in empowering patient choice in their treatment plan. While ICDs have remained a common treatment option for many years, the strength of evidence for an ICD benefit is different for different patient populations … We want to ensure that the patient receives more information than the risks and benefits of the procedure."[7] Rao et al suggest, though, that the SDM requirement at best only addresses the last observation — improving patients' understanding — while leaving the treatment heterogeneity and overall survival benefits among eligible patients completely unexplored.

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The CMS memo summarizes primary data calling into question the clinical benefits of ICDs under conditions that are currently within covered circumstances. For example, the added benefits of ICD back-up to cardiac resynchronization therapy,[8] or in patients with non-infarct cardiomyopathy,[9] appears increasingly narrow based on accumulated observational studies and randomized trials. Routine ICD replacement at the end of expected battery life also provides uncertain benefits to many patients, particularly those whose left ventricular systolic function has recovered and those who have not previously received an ICD shock.[10] Secondary prevention ICD implantation — device insertion following a cardiac arrest for non-reversible causes — also has not been evaluated in a randomized trial for 25 years despite advances in diagnostics, medical therapy, and resuscitation. As the memo notes, even within the boundaries of the Class IA recommendations for primary prevention ICDs, substantial treatment heterogeneity exists that might improve device utilization and patient selection with better prospective data to guide decisions.[11]

Yet CMS ultimately dodges responsibility for developing these data: "While we encourage such research on risk stratification to continue, we acknowledge that other agencies are better equipped and have clearer authority to take the lead in vetting and supporting such a large and varied research portfolio, some of which is in earlier discovery and testing phases."[12]

In taking this stance, CMS undersells its potential influence with an overly narrow reading of its regulatory mandate. CMS retains substantial discretion in characterizing services as reasonable and necessary for its beneficiaries, particularly in regards to extrapolating data from randomized trials to real-world cohorts that tend to be older and sicker than those in pivotal studies.[13] Every *month*, it is likely that more CMS beneficiaries receive ICDs than in all of the randomized trials evaluating their effectiveness combined. (The 2 pivotal trials on which most primary prevention ICD implantations are based randomized only 3753 patients combined, only 1571 of whom received an ICD.[14]) CMS has ample authority and discretion to require the exact evidence generation it deems currently lacking to clearly demonstrate meaningful benefits to its own beneficiaries. For example, the coverage with evidence development pathway allows CMS to require all device recipients to participate in a study approved by CMS as a condition of reimbursement.[15] A previously required study focused more narrowly on procedural complications and straightforward descriptive outcomes was included in the 2005 coverage memo; the ICD registry enrolled over 1 million patients over its nearly 15 year history.[16] In other contexts, including selected cardiac devices, CMS has engaged with manufacturers as well as the Food and Drug Administration to ensure that clinical trials performed for marketing authority also meet evidentiary standards for CMS coverage.[17]

As the largest payer for ICDs in the United States, CMS could take the stance — entirely defensible based on accrued evidence — that a new randomized trial was required for even a subset of its beneficiaries prior to ICD implantation either for initial primary prevention placement, routine replacement, or even secondary prevention. Indeed, European regulators

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are supporting design and implementation of 2 prospective clinical trials of ICD explicitly targeting treatment heterogeneity among patients to identify those at greatest likelihood of benefit.[18] CMS might have declared restrictions on coverage, with or without a specific requirement to enroll in a prospective study, around patients with plausible equipoise around the benefits of ICDs, prompting immediate scientific engagement from researchers, industry, and potential payers (including CMS itself). If CMS' goal is to "empower patients" and provide data beyond simple procedural risks, requiring SDM even with the best available tools will necessarily fall short without better evidence on which to base shared decisions.

Note

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