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VIEWPOINT

The Disconnect Between the Guidelines, the Appropriate Use Criteria, and Reimbursement Coverage Decisions

The Ultimate Dilemma

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Recently, the American College of Cardiology Foundation in collaboration with the Heart Rhythm Society published appropriate use criteria (AUC) for implantable cardioverter-defibrillators and cardiac resynchronization therapy. These criteria were developed to critically review clinical situations that may warrant implantation of an implantable cardioverter-defibrillator or cardiac resynchronization therapy device, and were based on a synthesis of practice guidelines and practical experience from a diverse group of clinicians. When the AUC was drafted, the writing committee recognized that some of the scenarios that were deemed "appropriate" or "may be appropriate" were discordant with the clinical requirements of many payers, including the Medicare National Coverage Determination (NCD). To charge Medicare for a procedure that is not covered by the NCD may be construed as fraud. Discordance between the guidelines, the AUC, and the NCD places clinicians in the difficult dilemma of trying to do the "right thing" for their patients, while recognizing that the "right thing" may not be covered by the payer or insurer. This commentary addresses these issues. Options for reconciling this disconnect are discussed, and recommendations to help clinicians provide the best care for their patients are offered. (J Am Coll Cardiol 2014;63:12–4) © 2014 by the American College of Cardiology Foundation

Since antiquity, the primary responsibility of the physician has been to serve the best interests of his or her patients. This responsibility is not negotiable and should never change. When we take the Hippocratic Oath, we commit ourselves to doing the "right" thing for our patients. However, "right" is a relative term, and who defines or should define "right" is not always clear.

In recent years, professional medical associations, including the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) have developed clinical practice guidelines to help physicians, patients, and payers address how to best serve our patients (1). Committees of well-respected leaders rigorously review the available data and synthesize guidelines to improve the effectiveness of care and optimize outcomes. When there is a paucity of data, recommendations may be made based on clinical experience and consensus among experts in the field. Although optimal clinical management becomes more challenging when evidence is less substantial, the absence of trial data does not invalidate the clinical decisions that

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conscientious, patient-focused, and well-intended clinicians make nearly every day. This is especially true when making a decision about whether or not to implant an implantable cardioverter-defibrillator (ICD).

The ACC, the AHA, and the HRS first published guidelines for the implantation of cardiac pacemakers and antiarrhythmia devices in 1984. Based on new data, these guidelines were updated in 1991, 1998, 2002, 2008, and last in 2012 (2). Although these guidelines serve as general rules, there are multiple scenarios that have not been specifically assessed in these guidelines. To help clinicians, the ACC and HRS have developed appropriate use criteria (AUC) to adjudicate the appropriateness of ICD implantation in these not uncommon scenarios (3). The rigorous methodology of the AUC process incorporates evidence-based medicine gleaned from our clinical practice guidelines and randomized controlled trials, along with practical experience from a carefully constructed panel consisting of electrophysiologists, heart failure specialists, and general cardiologists (4).

Payers have a similar responsibility to serve the best interests of their beneficiaries. However, whereas physicians have a primary responsibility to serve the best interests of individual patients, payers have the responsibility to assure viability of the entire payment/reimbursement system. Toward this end, Medicare has developed a series of National Coverage Determinations (NCDs) to adjudicate what medical therapies are appropriate for reimbursement. The guiding principle underlying these determinations is the assessment of whether an item or service is "reasonable and necessary" for the treatment of the Medicare beneficiary (5).

The current NCD for primary-prevention ICD implantation (6) is based on seminal trials, including, most importantly, MADIT (Multicenter Automatic Defibrillator Implantation Trial) (7), MADIT II (8), MUSTT (Multicenter Unsustained Tachycardia Trial) (9), and SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) (10). For pragmatic reasons, the entry criteria for randomized controlled trials are often restrictive, and these are used almost verbatim by the NCD. Consequently the NCD, last revised in 2005, does not address many of the scenarios for primary-prevention ICD use that were considered appropriate by the AUC authors. This leaves physicians in the uncomfortable position of knowing that appropriate clinical recommendations may fall outside the scope of the NCD. For patients, physicians, and insurers, these distinctions are critically important because patient-centered care may warrant implantation of a device appropriate for the individual patient's situation that does not fit precisely into a covered NCD. Importantly, this may place practitioners and hospitals at risk for denial of payment or investigation for possible abuse or fraud even when the decision was clinically justified. An example might be a patient with long-standing left ventricular dysfunction who develops complete heart block after revascularization surgery. Implanting a pacemaker during this hospitalization and subsequently upgrading the device to an ICD 3 months later if the left ventricular function does not improve would increase both risks and costs. The current NCD, however, precludes ICD implantation during this waiting period. Another example would be an individual resuscitated from a cardiac arrest who has a small troponin elevation without frank myocardial infarction. If the troponin elevation is improperly coded as a myocardial infarction, then ICD implantation would not be allowed.

Abbreviations and Acronyms

ACC = American College of Cardiology
AHA = American Heart Association
AUC = appropriate use criteria
CRT = cardiac resynchronization therapy
DOJ = Department of Justice
HRS = Heart Rhythm Society
ICD = implantable cardioverter-defibrillator
NCD = National Coverage Determination

Because the denial of reimbursement and potential legal liability of fraud outlined in the well-publicized Department of Justice (DOJ) investigation (11) are of great concern to physicians who prescribe and implant defibrillators, we felt this issue should be addressed. The DOJ investigation, which initially started as a limited complaint into fraudulent and inappropriate ICD implantation, has expanded into an investigation of virtually all ICD implantations performed early post-MI or early post-revascularization in the Medicare program. Although many have been troubled by the nature and scope of this investigation, we congratulate the DOJ in recognizing that this is not a black-and-white issue and that there are circumstances outside the scope of the current NCD in which the decision to implant an ICD is medically appropriate and in the best interest of the patient. In their settlement resolution model, the DOJ identified several "buckets" or categories of ICD implantation that although outside the scope of the current NCD will not be subject to requests for repayment or penalties (12). Unfortunately, these buckets are only applicable retrospectively to ICDs that have already been implanted. Just because an indication falls within the DOJ bucket list does not indemnify the physician from future liability. The resolution model does not replace or update the NCD and should not be utilized to determine whether an ICD is currently payable by Medicare.

So what should cardiologists and electrophysiologists do? First, we believe and will strongly encourage the HRS, AHA, and the ACC to advocate for legislation that protects physicians who follow the clinical guidelines or the AUC. Simply put, a physician who follows the standards of his profession in the best interest of the patient should not be subject to civil or criminal penalties. However, it is important to recognize that physicians and their hospitals have an obligation to understand the current guidelines, be aware of the AUC scenarios, and practice within the scope of the ICD NCD whenever possible. Conversely, we also believe that inappropriate practice outside the guidelines and AUC should not be tolerated. Each one of these positions falls under the rubric of "utilizing the right procedure at the right time for the right patient." It is both

our professional responsibility and also the privilege of self-regulation to be wise stewards of our limited healthcare resources (13).

In the short term, if an ICD is considered medically appropriate for the individual patient, and the implantation falls outside of the NCD, there are several options. When clinically appropriate, the patient may be a candidate to wear an external defibrillator vest until the requisite time period has passed (14). Alternatively, the hospital may choose not to charge for the device or may contact the Medicare fiscal intermediary to prevent any allegation of fraudulent billing or deception. When there is no good alternative, the patient can be asked to sign an Advanced Beneficiary Notice to acknowledge that the ICD implant may not be covered, and he or she may be responsible for the costs of the procedure and the device (15). We recognize these options are imperfect.

In all cases, the line of reasoning should be documented clearly in the medical record. Physicians who believe that a device is indicated in a situation not covered by the NCD must document their thought process and rationale. All factors used in decision making, for example, ejection fraction, functional status, and arrhythmia tracings, should be documented in the medical record. We can also protect ourselves and our health systems from legal action by becoming involved with teaching coders about what we do, what constitutes a myocardial infarction (not all troponin elevations represent an MI), and clearly stating in the chart when events occur, such as the diagnosis of heart failure and the initiation of guideline-directed medical therapy.

Finally, in the longer term, the disconnect between the guidelines, the AUC, and the NCD must be reconciled. Re-assessment of the NCD should be considered on a regular basis to keep up with the latest clinical evidence. In an ideal world, the NCD should be constructed in a flexible format enabling ease for adaptable coverage criteria to be congruent with the evidence-based science and appropriate clinical use. As past and current leaders of our societies, we urge the AHA, ACC, and HRS to work collaboratively with CMS towards this end. ICDs are life-saving therapies. Our patients and their beneficiaries deserve nothing less.

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Key Words: Appropriate Use Criteria ■ guidelines ■ implantable cardioverter-defibrillator ■ National Coverage Determination.