ciaries in 2002 and overshot its estimated per capita SGR target by 80%. In contrast, Alaska overshot its target by 110%, but since it has a small population, it contributed less to the SGR deficit. Several states most likely undershot their targets and therefore appear to the left of the vertical dotted line. Despite this varying spending growth, all states would face the same fee reductions if the SGR formula or broad fee cuts were enforced.

In addition to the wide variation by state, there is also considerable variation by specialty. Using a similar analysis, we computed estimated SGR targets for physician specialties to see which ones had probably contributed most to the SGR hole. Panel B of the figure shows the estimated variation in undershooting and overshooting of the SGR target by specialties (x axis), as well as each specialty's share of the total 2002 expenditures on physician services (y axis). Specialties with the highest excess growth and the largest share of total expenditures contributed to the SGR deficit the most; these include internal medicine, cardiology, diagnostic radiology, and family practice. Cardiology, for example, accounted for about 10% of total expenditures on physician services in 2002 and overshot its SGR target between 2003 and 2009 by a total of 79% of 2002 expenditures. Meanwhile, general surgery undershot its estimated SGR target by 106% during the same period, but general surgeons would still face large fee cuts if the SGR were ever enforced.

We do not mean to suggest that the SGR physician-payment system should be restructured according to either state or specialty. For example, the arrival of new technologies in one area of medicine may justify faster growth in some specialties relative to others. Rather, our analysis illustrates that across-the-board cuts in fees are too blunt an instrument to restrain the growth of spending on physician services. In fact, any form of target expenditures for physicians who are not part of a coherent risk-bearing organization that is responsible for patient care will produce pathologies similar to those revealed in the graphs. Indeed, setting expenditure targets by state or specialty would fail to provide incentives for more efficient use of services, because the units are too large for physicians to feel individual responsibility to control volume. The state or specialty is not the correct unit of analysis for payment policy. Similarly, setting targets for groups of physicians who are linked artificially through retrospective claims analysis but are unrelated through an explicit organizational form such as an accountable care organization will probably be ineffective.

We believe it is imperative that a post-SGR payment system encourage the creation of organizational structures that can accept global payments or payments bundled by episode of care. These alternative forms of reimbursement give provider organizations and physicians the incentives to capture gains from eliminating lower-value therapies and delivering higher-value health care. This approach is far superior to cost-containment strategies in which physician fees decrease in an arbitrary and across-the-board manner.

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From the Department of Health Care Policy, Harvard Medical School, Boston (A.A., M.E.C.); and the John F. Kennedy School of Government, Harvard University, Cambridge, MA (A.C.).

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Time for a Change — A New Approach to ICD Replacement

Daniel B. Kramer, M.D., Alfred E. Buxton, M.D., and Peter J. Zimetbaum, M.D.

Clinical trials of implantable cardioverter–defibrillators (ICDs) continue to drive expanding indications for these devices.[1] More than 100,000 ICDs are implanted in the United States annually. Of these procedures, at least 25% are generator replacements required as a result of depleted battery life.[2] Because of the high cost and concern about patient selection, the appropriateness of initial device placement has been closely scrutinized. But there has been little consideration as to what happens in the years after implantation, when ICD batteries drain sufficiently to require replacement, device leads become defective, or systems become infected. Should

all these patients receive replacement ICDs?

Though ICDs are lifesaving for some patients, evaluation of the clinical and ethical aspects of ICD replacement is long overdue. As clinicians, we frequently encounter cases such as that of an 80-year-old patient with mild but progressive dementia who has a primary-prevention ICD with a depleted generator that has never fired appropriately. Such patients are often referred for ICD replacement with scant evidence of a well-informed discussion of the risks, expected benefits, and overall goals of care. We believe that patients and clinicians must move beyond the view of ICD therapy as a lifelong treatment committing patients to obtaining replacement devices for years or decades after implantation. There are several important opportunities for and obstacles to making ICD replacement a more deliberative process.

First, the clinical data for patients presenting for ICD replacement must be thoroughly reevaluated. During an average of 5 years with an ICD, patients' health may have evolved in ways that should influence decisions about replacement. Information regarding progression of underlying cardiovascular and noncardiovascular problems should be considered, including crucial coexisting conditions known to attenuate the benefits of ICD therapy, such as renal disease. Guidelines for initial ICD implantation state that patients should be expected to survive for at least 1 year with a reasonable quality of life,[1] and the same assessment should be critical for making recommendations regarding replacement. Conversely, in some cases, ventricular systolic function may improve so dramatically that a patient may no longer be at identifiably heightened risk for sudden death. In these cases, replacement of a primary-prevention ICD may not be necessary, particularly if the patient's ICD has not delivered therapy appropriately for ventricular tachyarrhythmia.

Second, patients' experiences living with their devices may influence their views on replacement. Patients approach initial ICD implantation with highly variable understanding and expectations about living with a device. Yet many patients will have complications of device therapy, including inappropriate shocks, and ICD replacement itself exposes patients to a 5% risk of major complications.[3] After several years of living with an ICD, patients might reasonably be expected to take these experiences into account when evaluating future therapy.

Third, for many patients, changes in values and preferences since initial implantation may shift the balance of risks and benefits of device therapy. For example, progressive heart failure or end-stage renal disease with multiple hospitalizations may change a patient's perspective on sudden death in relation to other possible outcomes, such as death from end-stage systolic dysfunction. A more concrete expression of a patient's wishes might emerge through an advance directive. Although such documents often do not include ICDs specifically, patients' expressed wishes about life-sustaining therapies generally may inform a more nuanced discussion regarding ICD replacement.[4]

There are several barriers to integrating these clinical and personal aspects of patient care into decision making. Patients often receive care from primary care physicians, geriatricians, general cardiologists, heart-failure specialists, and cardiac electrophysiologists — and in many cases, other specialists such as pulmonologists, nephrologists, and oncologists as well. Such fragmentation may mean that no one physician holds responsibility for identifying reasons to avoid a potentially unnecessary and costly procedure. Arguably, the implanting physician should lead this assessment. But that physician may not actually be in the best position to understand a patient's prognosis, quality of life, and health care goals. A referring physician who is more closely engaged with a patient's day-to-day course may have crucial information — yet may defer device-related questions to the proceduralist.

The misaligned incentives in our health care system create another obstacle to rational replacement of ICDs. Whereas third-party scrutiny of initial implantations has led providers to pay close attention to indications, there is no similar assessment of generator changes. In a fee-for-service system, there is little incentive for physicians to decline ICD replacement or to suggest replacing an ICD with a pacemaker for patients who still have an indication for pacing. Fear of losing referrals may further obstruct attempts to move away from a default plan of replacing the ICD.

A third challenge arises when physicians do not know how to raise the possibility of electively stopping a potentially lifesaving therapy. Refraining from replacing an ICD may be viewed in the same light as deactivating a currently functioning one, and physicians or patients may object to doing so on moral grounds or out of uncertainty about legality, or they may never broach the subject at all. Indeed, some patients

Recommendations for Improving Decisions Surrounding ICD Replacement.

1. A comprehensive medical evaluation should occur before ICD replacement, with direct communication between the implanting physician and primary care physician, as well as other specialists involved in each patient's care.
2. Patient preferences, past experiences, and advance care planning should be explicitly included in decision making.
3. Advance care planning should be revisited and patients should be educated about the possibility of device deactivation at the time of potential ICD replacement.
4. A multidisciplinary task force should be created to establish guidelines regarding the clinical, ethical, and logistic aspects of ICD replacement.
5. Prospective studies should be conducted of patients at high or low risk for sudden death who are eligible for ICD replacement to identify populations that are unlikely to benefit from therapy.

or physicians might consider nonreplacement equivalent to either physician-assisted suicide or euthanasia, despite consensus statements that clearly reject this view.[4,5]

Finally, the lack of empirical data on outcomes after ICD replacement has prevented the development of firm recommendations to guide clinicians. To our knowledge, no clinical trials have compared outcomes in specific populations of patients who are eligible for ICD replacement. In the absence of such guidance, clinicians may not feel confident in identifying patients who might not benefit from replacement and may even feel vulnerable to litigation for not replacing an ICD if a patient subsequently dies from arrhythmia.

ICD replacement has not received enough attention, and untold numbers of patients will continue to receive devices whose implantation they might reasonably elect to defer if the system were more rationally designed to support decision making. Despite the challenges outlined here, we can begin to improve the care of these patients immediately (see box).

We propose that physicians who implant ICDs take the lead in engaging and educating primary care physicians, general cardiologists, and other specialists regarding the appropriateness of ICD replacement for individual patients. At the very least, cases should be identified early — well before the need for replacement — in which significant coexisting conditions (e.g., new cancers or progressive dementia) raise commonsense questions about procedures. Direct communication among specialists is common and expected, for example, when chemotherapy is started in patients with important cardiovascular problems; the same should be standard for replacement of ICDs in patients with accumulated medical conditions. Patients and their families should be made aware that device replacement is not obligatory. This conversation should begin at the time of initial device implantation and occur again before potential replacement. Patients should not find themselves committed to a lifelong therapy or trapped by misconceptions about the clinical, ethical, and legal aspects of choosing not to replace a device.

At the same time, professional societies and patient groups must push for studies of outcomes after ICD replacement, including cost-effectiveness, to inform the development of more evidence-based guidelines. Closer examination of generator replacement does not necessarily imply rationing. If the default pathway is to replace all generators, a change to a more patient-centered approach will inevitably prove to be cost-saving, even as it promotes individualization of a highly personal process and thereby improves patient care. From both patient and societal perspectives, the expense and uncertainty of ICD therapy argue for a more considered and nuanced approach to generator replacement. It is time for a change in our approach to this common, costly, and complex clinical decision.

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From Beth Israel Deaconess Medical Center and Harvard Medical School — both in Boston.

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