placed under the coordinated care of a Veterans Administration (VA) facility near their home. More than 50 VA managers have been assigned to Army hospitals to facilitate such transfers and to help with planning for long-term care and with the adjudication of benefits when a soldier leaves active duty.

The goal is more than just the physical healing of the soldiers. The emotional effects of war and wounds must be tended to as well, so the behavioral health component of care is key. In addition to the patients themselves, the families of patients receive help from the military medical center. They, too, come from long distances, often the same night as their soldier arrives, and require support as they begin to participate in rehabilitation. Ultimately, the goal of all the coordination, from the forward surgical team to the VA and beyond, is to enable these young men and women to reenter society and lead full lives. In many cases, new life skills and new vocational skills must be taught. In addition to the integration with the VA system to facilitate follow-up care, a Disabled Soldier Support System has been put into place as a clearinghouse for financial, administrative, medical, vocational, and other services.

Although the continuum of care has never been stronger, we have learned and will continue to learn from this war, as we have from previous wars. In the end, the success of rehabilitation will boil down to the people involved — the medical personnel of the military whose competence and compassion make all the difference.

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**Medicare Coverage of ICDs**

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The results of the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), reported in this issue of the Journal (pages 225–237), show that there are likely to be expanded clinical indications for the use of an implantable cardioverter-defibrillator (ICD) in the prevention of sudden death from cardiac causes. Medicare beneficiaries currently account for 80 percent of such deaths in the United States, and the Center for Medicare and Medicaid Services (CMS) is poised to expand its ICD coverage substantially to reflect the results of this trial. Through this policy decision, CMS will also support the development of further evidence to help patients and doctors use this technology as effectively as possible.

Previous expansions of Medicare coverage for ICDs have been incremental. Coverage began in 1986 but was limited to patients with a documented history of cardiac arrest due to ventricular fibrillation. In 1999, coverage was expanded to include patients with documented spontaneous or induced sustained ventricular tachycardia. In June 2003, in response to the results of the second Multicenter Automatic Defibrillator Implantation Trial (MADIT-II), Medicare expanded coverage again, to include prophylactic use in many patients at high risk of sudden death due to ischemic cardiomyopathy.

On the basis of the initial public presentation of the SCD-HeFT results in March 2004, CMS proposed in September a further expansion of coverage for ICDs. This decision affects patients whose characteristics are similar to those of participants in SCD-HeFT, including most patients with ischemic or nonischemic cardiomyopathy who have a left ventricular ejection fraction of 35 percent or less. Aggregated data from several ICD trials now suggest that patients with a normal QRS complex receive a smaller but still significant survival benefit, so such patients will now have coverage as well. We expect to finalize this decision within days, after synthesizing public comments and the final published evidence. This policy change may increase the number of Medicare beneficiaries who are eligible for an ICD to more than 500,000 — two to three times the number who are currently eligible.
As Kadish notes in his editorial (pages 285–287), SCD-HeFT is one of several recent multicenter trials of ICD therapy that have helped to refine our understanding of the appropriate clinical use of this device. However, important questions remain about how ICDs can be used most effectively and efficiently. In order to gather further data that may guide clinical decision making, Medicare proposes to use its expansion of coverage to support the development of additional practical evidence through one or more large-scale prospective, observational studies or registries.

Data from registries are intended to help clinicians and patients weigh the risks and benefits of ICD use. For example, there is limited published evidence regarding the subgroup of patients with a low left ventricular ejection fraction who will probably benefit most from an ICD — or the subgroup of patients who are likely to have procedure-related complications and little or no benefit. Observational data may help to characterize the patients — representing the majority of ICD recipients — whose ICD will never be triggered. After four years of follow-up in the SCD-HeFT trial, slightly more than 20 percent of implanted ICDs had fired appropriately — a firing rate similar to that found in MADIT-II.3

Better evidence regarding the clinical outcomes in defined subgroups of patients receiving ICDs may also help clinicians to provide the devices more reliably to the patients who will benefit the most. Only 20 to 25 percent of patients who are currently eligible for an ICD benefit under Medicare now receive one of these devices, and because many high-risk patients do not appear to receive them, many deaths could be avoided if they were provided more consistently to patients with clinical characteristics known to place them at very high risk for sudden death.

Other important questions about use of ICDs might also be answered through further study. What are the real-world clinical outcomes in patients with a left ventricular ejection fraction of 31 to 35 percent or class IV heart failure, and do these outcomes confirm that ICD use offers a meaningful benefit in this group? What is the optimal timing for the insertion of an ICD in patients after acute myocardial infarction? Recent data indicate that there is no benefit for patients who have had acute myocardial infarction within the previous 40 days, and subgroup analysis of MADIT-II data suggest that there is minimal benefit within 18 months after such an event.4,5

It is also possible that the firing rates and population outcomes may prove different outside the context of controlled clinical trials. The devices have been improved since the single-lead ICDs used in SCD-HeFT became available. Many implantations today involve more sophisticated dual-lead devices that may have different risk profiles. Moreover, the technical skills of the clinicians who implant these devices will also vary. In addition, data from registries can help to identify important hypotheses to be studied in traditional and practical clinical trials designed to aid in medical decision making, and CMS intends to cover clinical and treatment costs in more of these studies in the future.

Through this coverage decision, CMS aims to support the development of additional evidence that can help doctors and patients make more informed decisions. We can do this by making sure that we have mechanisms in place for collecting additional data on the benefits and risks of new technologies after regulatory approval has been obtained and they have become eligible for reimbursement. Linking payments for new technologies with opportunities to learn more about them enables us to move toward more timely access to new products while simultaneously providing a stronger foundation for doctors and patients to use them effectively.

The potential for more effective, targeted therapies is greater than ever, but such treatments are likely to be developed only if clinicians understand how the benefits and risks associated with a treatment differ for different types of patients. New information technology is increasingly allowing this kind of routine data to be collected at much lower cost and burden than was the case with the abstraction of paper-based records and spontaneous reports from overworked health care professionals.

The opportunity to improve evidence aligns well with Medicare’s fiduciary responsibility to taxpayers, since it enables CMS to assure Americans that their money is spent as effectively as possible and to assure beneficiaries and health care providers that we will avoid crude cost-containment strategies that impede access to effective care. This approach is particularly critical for valuable but costly forms of technology such as ICDs, for which Medicare pays about $30,000 per case.

For all these reasons, developing better evidence through data registries and practical clinical trials is an increasingly important feature of Medicare’s coverage decisions. Our experience with ICDs as
well as other recent coverage decisions, including expanded coverage for certain drugs to treat cancer, positron-emission tomography, and carotid stents, indicates that faster progress toward better care with continuously improving evidence is possible through the collaboration of medical professionals, patient advocates, payers, and product developers.


