Implantable cardioverter-defibrillators (ICDs) have revolutionized the treatment of patients at risk for sudden cardiac death. In the nearly 3 decades since the first human ICD implant, millions of devices have been implanted worldwide and innumerable lives have been saved. Successful resuscitation of a potentially lethal ventricular arrhythmia by an ICD system depends on successful arrhythmia detection and timely delivery of therapy. Both the ICD generator and the ICD lead are critical components of this system. The lead, in particular, is a literal lifeline whose purpose is to convey critical information about the heart’s rhythm to the ICD generator and, in turn, to deliver life-sustaining therapy when needed. Failure of an ICD lead may result in significant clinical events, including failure to pace, failure to defibrillate, inappropriate shocks, and even death.

The definition of ICD lead “survival” or lead “performance” varies from study to study. Most commonly in published studies, lead malfunction is defined as electrical abnormalities on lead testing, a chest roentgenogram consistent with a fracture, or evidence of oversensing unrelated to cardiac signals. Other studies rely on physician clinical judgment and require replacement of the ICD lead in order to consider the lead to have malfunctioned. In most published studies, thresholds for action are poorly defined and ambiguous. The varying definitions make it difficult to compare study to study and lead to lead.

In the current issue of Circulation, Eckstein et al add to our understanding of ICD lead performance. The investigators conducted a retrospective analysis of 1317 consecutive patients who received ICD systems (including 38 different ICD lead models) at 3 centers in Germany between 1993 and 2004. Follow-up after implantation included noninvasive routine lead evaluation every 3 to 6 months. Lead failure was defined as a lead-related problem requiring surgical revision performed at the discretion of the treating physician. Abnormalities were classified as either structural (insulation defects or lead fracture) or functional (far-field sensing; T-wave or physiological oversensing, noise from contact with another lead, unstable impedance measurements, R-wave reduction, or loss of capture).

During a median follow-up of 6.4 years, 38 ICD leads required surgical revision, resulting in a reported cumulative ICD lead survival rate of 97.5% at 5 years. Compared with previous reports on ICD lead performance, this failure rate is low. This low rate could be due to underdetection of lead failures, a high clinical threshold for replacing a failed lead, a strict definition of lead failure, or the great skill of the implanting physicians. Interestingly, patients who underwent ICD lead revision for malfunction had an 8-fold higher incidence of experiencing another lead failure; this higher incidence underscores the important contribution of patient factors to ICD lead performance. Causes of malfunction were similar to those in prior published reports and most often were related to insulation defects and lead fractures. Inappropriate ICD therapies occurred in 76% of those patients who experienced a lead malfunction.

Like the Eckstein study, a number of prior published reports inform us about the reliability and durability of ICD leads4–11 (Figure 1). Reported ICD lead “survival” varies from 91% to 99% at 2 years, 85% to 98% at 5 years, and 60% to 72% at 8 years. Several conclusions may be drawn from review of the data:

1. The definition of ICD lead “survival” or lead “performance” varies from study to study. Most commonly in published studies, lead malfunction is defined as electrical abnormalities on lead testing, a chest roentgenogram consistent with a fracture, or evidence of oversensing unrelated to cardiac signals. Other studies rely on physician clinical judgment and require replacement of the ICD lead in order to consider the lead to have malfunctioned. In most published studies, thresholds for action are poorly defined and ambiguous. The varying definitions make it difficult to compare study to study and lead to lead.

2. ICD lead performance varies by model. Although conceptually simple, ICD leads are complicated devices with lead designs that vary from model to model. These design differences may include variations in insulation, cable/conductor, length, diameter, and fixation mechanism. Pool-

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

From the Medical Device Safety Institute, Department of Medicine, Beth Israel Deaconess Medical Center (W.H.M.), and Department of Medicine, Massachusetts General Hospital (D.B.K.), Boston, Mass.

Dr Maisel is a US Food and Drug Administration consultant, a member of the Medicare Coverage Advisory Committee, and Cochair of the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines. Dr Kramer is a member of the US Food and Drug Administration Medical Device Fellowship Program. The opinions expressed in this article are those of the authors and do not necessarily represent the practices, policies, positions, or opinions of the Food and Drug Administration, Center for Medicare and Medicaid Services, or the Heart Rhythm Society.

Correspondence to William H. Maisel, MD, MPH, Medical Device Safety Institute, Beth Israel Deaconess Medical Center, 185 Pilgrim Rd, Baker 4, Boston, MA 02215. E-mail wmaisel@bidmc.harvard.edu

Circulation is available at http://circ.ahajournals.org
DOI: 10.1161/CIRCULATIONAHA.108.776807

© 2008 American Heart Association, Inc.

Downloaded from http://circ.ahajournals.org by guest on May 30, 2017
lead performance definitions hinders data collection and well defined and understood, the lack of standardized ICD yielded varying results (Figure 1).

Given the aforementioned complexities of monitoring ICD lead performance and the weakness of the published studies, it is not surprising that reports of ICD lead performance have yielded varying results (Figure 1).

Whereas ICD lead malfunction mechanisms are generally well defined and understood, the lack of standardized ICD lead performance definitions hinders data collection and analysis, as well as communication about device performance. In the wake of recent high-profile ICD lead performance questions, such as those affecting the Medtronic Sprint Fidelis and the St. Jude Medical Riata ICD leads, the Heart Rhythm Society announced in March 2008 the formation of the Task Force on Lead Performance Policies and Guidelines. The task force will make recommendations to the US Food and Drug Administration, Congress, industry, physicians, and patients on lead performance, communication of lead performance, surveillance, threshold for activation of lead advisories, communication after abnormal performance is identified, clinical management of lead performance issues, and regulatory considerations.

A number of ongoing efforts will greatly enhance our understanding of ICD lead performance in the coming months and years. The National Cardiovascular Data Registry ICD Registry will incorporate ICD leads. The US Food and Drug Administration is developing HeartNet, a sentinel network of electrophysiology laboratories throughout the United States, specially trained to report adverse events and device malfunctions, including those affecting ICD leads. Independent registries, such as the Multicenter Registry, continue to carefully monitor device performance and to provide early warning signals for devices whose performance expectations are not met. In addition, a number of ICD lead manufacturers have embarked on prospective ICD lead clinical studies and registries to better monitor ICD lead performance. Wireless remote monitoring of ICD lead function also offers enormous potential to identify performance issues early and to provide an automated warning system to improve patient safety (Figure 2).

ICDs are clinically proven to improve survival in select patients at risk for sudden cardiac death. Although ICD leads are a mature technology, monitoring of these devices remains critical to inform physicians and patients about device per-
formance and to identify underperforming products as early as possible. Ongoing efforts to standardize definitions of performance, improve timeliness of data collection, and enhance performance reporting are underway and will benefit the millions of patients who enjoy the benefits of these devices.

Disclosures
None.

References

Keywords: Editorials □ death, sudden □ defibrillation □ registries □ tachyarrhythmias

Figure 2. Information obtained remotely during routine follow-up from an ICD patient is shown. Right ventricular lead impedance, measured in ohms, is displayed. The lead impedance is stable in the 400 to 600 Ω range from January 2006 (*) until a sudden increase in lead impedance is noted (arrow). The high impedance is consistent with a lead fracture, and this patient’s ICD lead was replaced. The patient was asymptomatic, and the early detection afforded by the remote monitoring likely prevented an inappropriate shock or other adverse clinical event.