Management of Recalled Pacemakers and Implantable Cardioverter-Defibrillators
A Decision Analysis Model

Mitesh S. Amin, MD
David B. Matchar, MD
Mark A. Wood, MD
Kenneth A. Ellenbogen, MD

Currently, there are approximately 2 million patients with implantable cardioverter-defibrillators (ICDs) and pacemakers worldwide. These devices are unique because they are often implanted for life-threatening conditions—pacemakers for patients with high-grade heart block and ICDs to provide therapy for patients at risk of sudden cardiac death.

An increasing number of device recalls and advisories has led to heightened awareness of potential device failure. During 2005, US Food and Drug Administration advisories affected more than 200,000 devices. Advisories typically arise from unanticipated device failures that are identified after product release and widespread clinical use.

Despite the increased awareness of device malfunctions, there is a lack of consensus about optimal clinical management in situations involving recalled devices. Formal recommendations are few, with decisions mainly left to physician judgment. A recent survey reported that physicians were replacing more than 30% of the devices under advisory, although the percentage varied widely from 0% to 100% among individual physicians. Device replacement, however, carries risks of complications, including death.

In the face of multiple competing issues and uncertainty, decision modeling can provide useful guidance. Modeling offers quantitative estimates of net benefit and permits examination of the impact of assumptions on preferred outcomes.
RECALLED PACEMAKERS AND IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS

Table 1. Scenarios of Device Failure Characteristics and Risk of Events

<table>
<thead>
<tr>
<th>Device Failure Characteristics</th>
<th>Scenarios (Device; Indication)</th>
<th>1 (Pacemaker; Pacemaker Dependence)</th>
<th>2 (ICD; Pacemaker Dependence, Prior SCD)</th>
<th>3 (ICD; Primary Prevention)</th>
<th>4 (ICD; Secondary Prevention)</th>
<th>5 (Pacemaker; First- or Second-Degree AVB)</th>
<th>6 (Pacemaker; Sick Sinus Syndrome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate death with failure—typically high in situations where continuous device therapy is essential to avoid death</td>
<td>High</td>
<td>High</td>
<td>Negligible</td>
<td>Negligible</td>
<td>Negligible</td>
<td>Negligible</td>
<td></td>
</tr>
<tr>
<td>Event-based delayed death with failure requiring an event trigger (eg, ventricular tachycardia) that would rely on device therapy to stabilize and pose mortality risk with failure</td>
<td>Low</td>
<td>Intermediate</td>
<td>Low</td>
<td>Intermediate</td>
<td>Negligible</td>
<td>Negligible</td>
<td></td>
</tr>
<tr>
<td>Symptoms with failure—key in situations where symptoms are likely to develop with device failure to provide alert and early detection of failure</td>
<td>High</td>
<td>High</td>
<td>Negligible</td>
<td>Negligible</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: AVB, atrioventricular block; ICD, implantable cardioverter-defibrillator; high, high risk, greater than 25% likelihood (lifetime risk with device); intermediate, intermediate risk, between 8% and 25% likelihood (lifetime risk with device); low, low risk, between 1% and 8% likelihood (lifetime risk with device); negligible, negligible risk, less than 1% likelihood (lifetime risk with device); SCD, sudden cardiac death.

We developed a decision model using a Markov structure to examine the implications of immediate device replacement vs continued monitoring of devices under advisory, considering factors relevant to clinical decision making.

METHODS

Our approach directly addresses the competing issues of recalled devices: the risk of death due to device replacement vs the risk of death due to device malfunction. To examine whether to replace a device after an advisory, we focus on the indications for device implantation and the associated potential outcomes of device failure. Table 1 shows 6 scenarios grouped into 3 different categories, which are used throughout this article.

Decision Model

The question of whether to immediately replace a recalled device or to follow the patient until scheduled replacement (continued monitoring) is represented as a Markov model (Figure 1). The primary outcome measure of the model is life expectancy for each strategy (immediate replacement vs continued monitoring).

The Markov model represents a simulation of a 2-armed clinical trial: in one arm, the device is immediately replaced and in the other arm, replacement is delayed until the otherwise scheduled replacement date, based on the remaining generator life. In the immediate replacement arm, the patient enters a health state denoted as device replacement, indicating that the device will be replaced. The patient is at risk of procedure-related death, including death due to complications such as systemic infection or lead extraction, as well as risks unrelated to the implanted device. With successful device replacement, the patient enters the state of device functioning. The patient remains in this state until he/she either experiences a random device malfunction unrelated to the advisory or requires another device replacement procedure (based on the estimated generator longevity). In the former situation, the patient may immediately die, may develop symptoms prompting diagnosis of device failure and resulting in device replacement, or may continue follow-up with an undetected device failure (transitioning to the state of undetected device failure). In the undetected device failure state, the patient is faced with a risk of an event-triggered death (eg, such as ventricular fibrillation) due to device failure. Otherwise, the patient continues until generator battery depletion or failure detection, both of which lead to device replacement. For the initial and any subsequent transitions to the device replacement state, the patient undergoes a device replacement procedure with its associated risks; if surviving the procedure, the patient returns to the device functioning state.

In the continued monitoring arm, the patient first enters the device under advisory state, wherein he/she is at risk of the aforementioned events in the immediate replacement arm, with the exception of the risk from initial device replacement procedure. For the remaining duration of the recalled generator’s life, the patient faces an additional risk of death due to device failure related to the advisory. This risk is in addition to the underlying random device malfunction risk (ie, risk unrelated to the advisory). We assumed that a patient with a device failure would undergo the same transitions as with a randomly occurring device failure and have identical risks as in the immediate replacement arm. In the event of a non-
Squares indicate decision nodes, choices facing the decision maker. Circles indicate chance nodes, events that have multiple possible outcomes and are not in the decision maker’s control. The square at the left indicates 2 initial management options, immediate device replacement and continued monitoring. After the initial decision, each option enters a Markov process, which leads to 1 of many health states. The initial path within the Markov process is forced (bold), device replacement state for the immediate replacement decision and device under advisory state for the continued monitoring decision. The Markov cycle represents a single 1-month cycle of the model (ie, 1 month of a patient’s life), and the end points of each branch indicate the health state in which the patient will begin the next 1-month cycle. For each cycle, an evaluation is made whether the patient is due to have a device replacement based on an elective replacement indicator (ERI). Estimated probabilities drive chance events that may occur in each cycle (eg, remain well, device failure that may lead to immediate death or remain undetected, death due to other causes, and death due to device replacement procedure when incurred).
life-threatening asymptomatic device failure, the patient transitions to the undetected device failure state. This state also considers variations in follow-up frequency in an effort to detect device malfunction prior to symptomatic presentation. Conversely, without device failure, the patient continues in the same state (device under advisory) as long as the generator life of the recalled device is not depleted. When the generator reaches end of life, the patient undergoes device replacement (transitioning to the device functioning state), then moves on to the device functioning state. The latter state is identical to the same state in the immediate replacement arm. In all states, the patient is subject to an age-specific probability of death.

**Model Inputs**

We obtained estimates and plausible ranges of event probabilities from published articles and expert opinion (Table 2). The baseline monthly probability of death was taken from published life tables for the 2002 US population and adjusted for excess cardiovascular mortality associated with being an individual with an implanted cardiovascular device. Monthly mortality transition probabilities were calculated using the declining exponential approximation of life expectancy.

<table>
<thead>
<tr>
<th>Model Variables and Event Parameters</th>
<th>Scenario 1: Pacemaker; Dependence</th>
<th>Scenario 2: ICD; Pacemaker Dependence, Prior SCD</th>
<th>Scenario 3: ICD; Primary Prevention</th>
<th>Scenario 4: ICD; Secondary Prevention</th>
<th>Scenario 5: Pacemaker; First- or Second-Degree AVB</th>
<th>Scenario 6: Pacemaker; Sick Sinus Syndrome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient age, y*</td>
<td>65 (40-80)</td>
<td>65 (40-80)</td>
<td>65 (40-80)</td>
<td>65 (40-80)</td>
<td>65 (40-80)</td>
<td>65 (40-80)</td>
</tr>
<tr>
<td>Remaining generator life, y*</td>
<td>4.5 (0-9)</td>
<td>3 (0-6)</td>
<td>3 (0-6)</td>
<td>3 (0-6)</td>
<td>4.5 (0-9)</td>
<td>4.5 (0-9)</td>
</tr>
<tr>
<td>Total generator life, y*</td>
<td>9 (6-10)</td>
<td>6 (5-7)</td>
<td>6 (5-7)</td>
<td>6 (5-7)</td>
<td>9 (6-10)</td>
<td>9 (6-10)</td>
</tr>
<tr>
<td>Procedural mortality, deaths/procedure</td>
<td>0.003 (0.001-0.01)</td>
<td>0.005 (0.001-0.01)</td>
<td>0.006 (0.001-0.01)</td>
<td>0.006 (0.001-0.01)</td>
<td>0.006 (0.001-0.01)</td>
<td>0.006 (0.001-0.01)</td>
</tr>
<tr>
<td>Advisory device failure, % failures/y</td>
<td>1.0 (0.001-1.0)</td>
<td>1.0 (0.001-1.0)</td>
<td>1.0 (0.001-1.0)</td>
<td>1.0 (0.001-1.0)</td>
<td>1.0 (0.001-1.0)</td>
<td>1.0 (0.001-1.0)</td>
</tr>
<tr>
<td>Underlying random failure, % failures/y</td>
<td>0.1 (0.01-4.0)</td>
<td>2.0 (0.01-4.0)</td>
<td>2.0 (0.01-4.0)</td>
<td>2.0 (0.01-4.0)</td>
<td>0.1 (0.01-4.0)</td>
<td>0.1 (0.01-4.0)</td>
</tr>
<tr>
<td>Immediate death with failure, deaths/failure, %</td>
<td>0.50 (0.40-0.60)</td>
<td>0.50 (0.40-0.60)</td>
<td>0.001 (0.0001-0.01)</td>
<td>0.001 (0.0001-0.01)</td>
<td>0.001 (0.0001-0.01)</td>
<td>0.001 (0.0001-0.01)</td>
</tr>
<tr>
<td>Event-based delayed death with failure, deaths/failure, % per failure</td>
<td>0.05 (0.01-0.25)</td>
<td>0.15 (0.01-0.25)</td>
<td>0.06 (0.01-0.25)</td>
<td>0.12 (0.01-0.25)</td>
<td>0.06 (0.01-0.25)</td>
<td>0.02 (0.01-0.25)</td>
</tr>
<tr>
<td>Follow-up schedule while under advisory, mo*</td>
<td>3 (1-6)</td>
<td>3 (1-6)</td>
<td>3 (1-6)</td>
<td>3 (1-6)</td>
<td>3 (1-6)</td>
<td>3 (1-6)</td>
</tr>
</tbody>
</table>

**Analysis and Assumptions**

For each management option, life expectancy was calculated by tracking a large number of hypothetical individuals whose life history was described by the Markov diagram, summing the outcomes for each hypothetical history, and averaging over the number of modeled individuals. Effectively, patients traverse the model tree cycle by cycle until they die. The average life span is the life expectancy for the cohort. The strategy with the highest value for life expectancy is designated the preferred strategy.

The cycle length for the Markov models is 1 month. The decision analysis is based on this decision being made when presented with a patient with a device under advisory. We assumed that event rates were constant over time. We also assumed that the issue of an active recall or advisory does not affect the underlying random failure rates and that the patient would not be faced with another recalled device beyond the initial device but could experience device failure based on the random device failure rates.

Given the uncertainty in the estimates and to examine a range of possible scenarios, we performed sensitivity analyses by varying each input parameter over its plausible range (Table 2) while keeping all other parameters constant (1-way sensitivity analysis). Potentially key variables were identified by the existence of a threshold value, a value within the plausible range at which the preferred strategy switches from one to the other. We further evaluated combinations of these variables as well as variables that were of particular clinical interest (multi-way sensitivity analysis). In addition, we performed probabilistic sensitivity analyses.
analysis by examining a large number of runs of the model, for each run assigning a random value to the model inputs based on a beta distribution with the baseline value as the mean and the plausible range as the 95% confidence range. The result is an estimate of the confidence — given the inherent uncertainty in the model inputs — that one strategy is preferred over the other.

All modeling and analyses were carried out on a personal computer using a software package designed for medical decision making applications (TreeAge Pro, version 2005, release 1.3, TreeAge Software Inc, Williamstown, Mass). An external decision analysis expert reviewed the decision model and programming. To further validate the model, we set model inputs at extreme values (beyond the plausible ranges) and compared the output with logical predictions. Examples of the tests and logical predications included the following: (1) in all instances with zero risk of immediate and event-based death due to device failure, regardless of advisory failure rates, continued monitoring is preferred; (2) in all instances with zero risk of advisory device failure, regardless of a risk of death due to device failure, continued monitoring is preferred; and (3) in all instances with zero procedural mortality, with any (even minimal) risk of advisory device failure and a risk of death due to device failure, immediate replacement is preferred.

RESULTS

Results are presented by the 3 classes corresponding to the principle concern should failure occur: (1) immediate death, (2) delayed (event-dependent) death, and (3) symptoms without risk of death.

Failure Associated With Immediate Death

Scenarios 1 and 2 typify patients characterized by a high probability of immediate death with device failure due to pacemaker dependence. For both scenarios, the decision to replace the device is strongly influenced by the advisory failure rate and, to a lesser extent, probability of immediate death given failure and remaining generator life (Figure 2A). As indicated by the upper shaded territory for each scenario, advisory failure rates of less than 3 in 10 000 favor continued monitoring rather than immediate replacement. For these scenarios, replacement becomes the preferred strategy when advisory failure rates are in the range of 3 in 1000 to 3 in 10 000, depending on the procedural mortality rate. For example, at the highest procedural mortality, device replacement is preferred with advisory failure rate estimates greater than 3 in 1000.

Beyond the risk of immediate death, scenario 2 also has a higher risk of delayed death due to the need for episodic therapy for ventricular tachycardia or ventricular fibrillation. The analysis shows that this additional risk does not have a significant effect on the final decision to replace the ICD. For both scenarios 1 and 2, higher procedural mortality rates increase the advisory failure rate that would be required for device replacement to be preferred. When the risk of immediate death with device failure varies from 40% to 60%, there is only a slight increase in the preference for replacement.

Given the high risk of early death or symptoms with device failure, the decision in this group of patients is insensitive to the follow-up schedule and the underlying random failure rates. Remaining battery life is significant only when this residual is small (<10% of the total generator life), when continued monitoring of devices is preferred until time for elective replacement.

In a probabilistic sensitivity analysis evaluating these scenarios with hypothetical device advisories, similar results were observed (Table 3; scenarios 1 and 2). At higher advisory failure rates (2.5% for ICDs and 0.5% for pacemakers), 100% of the simulations favored device replacement in situations of pacemaker dependence, regardless of variability in the procedure mortality, underlying random failure rates, or probability of immediate death. With lower failure rates (reflecting the scenario approaching the threshold lines in Figure 2), the preference for immediate replacement strategy becomes less certain. Device replacement is preferred in more instances, with a lower advisory rate in pacemakers compared with ICDs (advisory rate of 0.075% in pacemakers and 0.23% in ICDs, yielding decisions to replace the device in 76% and 58% of simulations, respectively). This is attributed to the lower procedure mortality risks with pacemaker generator replacement. The mean prolongation in survival with the preferred strategy ranges from 1 week to 46 weeks.

Failure Associated With Delayed (Event-Dependent) Death

Scenarios 3 and 4 typify patients who are dependent on their device to provide therapy for ventricular tachyarrhythmias (ie, risk of delayed death due to device failure). Both scenarios are characterized by a relatively low probability of immediate death with device failure and a low likelihood of symptoms developing with device failure. As such, these scenarios also have the potential for undetected failure because device therapy is not required continuously.

Results of our analysis (Figure 2B) reveal that advisory failure rates and risk of delayed death with device failure directly affect the decision. Because of the relatively low risk of death with device failure due to advisory, failure rates greater than 3 in 100 are required for elective device replacement to be preferred. As procedure mortality rates decrease to 0.1% or risk of fatal arrhythmias increase to near 20% per year, there is a decrease in the estimated advisory rate to greater than 1 in 100 needed for replacement to be preferred. Similar to the first group, lower underlying random failure rates and higher generator life decrease the advisory failure rate favoring replacement. A more frequent follow-up schedule appears to provide a slight relative advantage to continue monitoring de-
Figure 2. Three-Way Threshold Analyses Identifying Combinations of Values for Which Device Replacement or Continued Observation Is the Preferred Strategy

Procedural Mortality Risk Thresholds
- 1.0% Deaths/Procedure
- 0.5% Deaths/Procedure in Panels A and B and 0.3% in Panel C
- 0.1% Deaths/Procedure

Immediate Replacement
Continued Monitoring

**Variables include estimated advisory device failure rates (shown on the y-axis in logarithmic scale), remaining pulse generator life, device dependency (x-axis), and procedural mortality, with various threshold lines for differing procedural mortality rates. Shaded regions apply to procedural mortality risk of 0.5% (panels A and B) and 0.3% (panel C); for higher and lower procedure mortality, the regions favoring immediate replacement will contract (shift to the higher threshold line) or expand (shift to the lower threshold line), respectively. Panel A evaluates scenarios 1 and 2, failures associated primarily with concern for immediate death, for either pacemakers or implantable cardioverter-defibrillators with pacemaker dependence. Panel B evaluates scenarios 3 and 4, where failure is associated primarily with concern for delayed (event-dependent) death, for patients with implantable cardioverter-defibrillator for primary or secondary prevention. Panel C evaluates scenarios 5 and 6, failures associated primarily with concern for symptoms without a significant risk of death, typically for patients with pacemakers for various stable bradyarrhythmias.**

©2006 American Medical Association. All rights reserved.
Table 3. Optimal Management Decisions and Probabilistic Outcomes

<table>
<thead>
<tr>
<th>Scenarios (Device; Indication)†</th>
<th>1 (Pacemaker; Pacemaker Dependence)</th>
<th>2 (ICD; Pacemaker Dependence, Prior SCD)</th>
<th>3 (ICD; Primary Prevention)</th>
<th>4 (ICD; Secondary Prevention)</th>
<th>5 (Pacemaker; First- or Second-Degree AVB)</th>
<th>6 (Pacemaker; Sick Sinus Syndrome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypothetical Device Advisory and Advisory Failure Rate*</td>
<td>Immediate replacement (58)</td>
<td>Continued monitoring (100)</td>
<td>Continued monitoring (95)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>ICD advisory; 0.25% risk of failure/y</td>
<td>NA</td>
<td>Immediate replacement (100)</td>
<td>Immediate replacement (55)</td>
<td>Immediate replacement (97)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>ICD advisory; 2.5% risk of failure/y</td>
<td>NA</td>
<td>Immediate replacement (78)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Pacemaker advisory; 0.075% risk of failure/y</td>
<td>Immediate replacement (100)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Continued monitoring (92)</td>
<td>Continued monitoring (99)</td>
</tr>
<tr>
<td>Pacemaker advisory; 0.5% risk of failure/y</td>
<td>Immediate replacement (100)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Continued monitoring (100)</td>
<td>Continued monitoring (100)</td>
</tr>
</tbody>
</table>

Abbreviations: AVB, atrioventricular block; ICD, implantable cardioverter-defibrillator; NA, not applicable; SCD, sudden cardiac death.

*Hypothetical advisory failure rates were used for the analysis.
†Percentages of simulations in which the stated strategy was the preferred decision (associated with a higher life expectancy) are shown in parentheses.

Failure Associated With Symptoms Without Significant Risk of Death

Scenarios 5 and 6 typify patients whose pacemakers have been implanted primarily because of a transient bradycardia leading to cardiac symptoms. Typically, these patients have low risks of immediate and delayed death due to device failure. In general, device failure in these patients will result in a large proportion of patients developing symptoms that alert them and their physicians to possible device malfunction. It is important to note that there are limited data available for this group in terms of risk of death due to device failure, so model inputs were based on expert estimates.

Analysis of model results (Figure 2C) showed that in a wide range of conditions, devices in this group do not require replacement except at advisory failure rates of 1 in 25 or higher. Only at high failure rates are other factors, such as procedural mortality and probability of delayed death, important considerations. Of note, a remaining generator life of less than 2 years strongly influences the decision to continue monitoring most devices.

For this last group, the probabilistic analysis consistently supports continued monitoring for both scenarios (Table 3; scenarios 5 and 6). The simulations show that this preference is relatively certain, with more than 90% of simulations favoring continued monitoring. The mean prolongation in survival with the preferred strategy ranges from 1 week to 2 weeks.

Additional Sensitivity Analyses

A total of fifty-six 1-way sensitivity analyses were performed for all combinations of input variables among the 6 scenarios (available at http://www.clinpol.mc.duke.edu). In the sensitivity analysis, 2 variables exhibited a differential effect on the life expectancy associated with the strategies. These variables were the remaining generator life and the advisory failure rates. In particular, the analysis for advisory failure rates revealed threshold values that increased among scenarios as the unidirectional effects of failure becomes less serious (failures per year of 0.08%, 0.16%, 0.79%, 4.0%, 4.0%, and 7.9% for scenarios 1-6, respectively). Continued monitoring is the preferred strategy with advisory failure rates less than the threshold value, whereas immediate replacement is preferred for rates higher than the threshold values.

Additional sensitivity analyses were used to further evaluate the impact of advisory failure rates, specifically in situations of increasing rates over time. An extreme analysis with rates doubling on a yearly basis found that there was nearly a 10-fold decrease in threshold values compared with the constant base case (data available at http://www.clinpol.mc.duke.edu). However, given limited clinical data on variable or increasing advisory failure rates, subsequent analyses used constant rates. Also, several variables of clinical importance did not exhibit a major impact on the relative strategy preference in the 1-way analysis but were included in the multiway analysis because of their clinical relevance.
COMMENT

The major conclusions of our analysis are that (1) the decision to replace or follow up on a device under advisory is most influenced by the likely impact of device failure, the estimated advisory failure rate, and, to a lesser degree, the procedural mortality rate; (2) the remaining generator life and the patient's age and sex have minimal influence on the decision to replace a device; (3) device replacement appears to be preferred at lower advisory failure rates (approximately 3/10,000) in pacemaker-dependent situations; and (4) in all other instances, higher advisory failure rates are needed to warrant replacement.

Device recalls and advisories confront clinicians with competing risks without a clear management approach described in the medical literature. The notion that replacement or removal of devices may result in a higher mortality than careful follow-up was realized in the management of Accufix pacemaker leads (Telelectronics Pac- ing, Englewood, Colo) as well as in a recently reported Canadian experience. In the case of the Accufix pacemaker leads, a conservative management strategy was associated with lower mortality than lead extraction in most patients. More recently, Gould et al reported a high incidence of serious complications, including death, associated with elective device replacements prompted by advisories.

Our analysis shows that device replacement in the setting of an advisory is not inconsequential and frequently has a greater risk than continued device follow-up. The decision to replace a recalled device should be based primarily on the device failure rate, the degree of patient dependency, and the anticipated procedural mortality from device replacement. Recognizing that the decision to replace a device will be made on a case-by-case basis, this analysis provides a framework for rational discussions with and risk stratification for individual patients.

In this analysis, we considered the potential factors in deciding whether to immediately replace a device under advisory or to continue without replacement. An important issue that we considered is that once the advisory device is replaced, there continues to be a risk of future random failure with the new device. If random failure rates are relatively high, then the impetus to replace a device under advisory is decreased. As random failure rates decrease, the decision to replace a device is altered.

Our analysis has several notable clinical implications. First, the clinical situations favoring device replacement are likely more limited than most physicians estimate, and indiscriminate device replacement may result in more deaths than lives saved. Second, physician reporting is paramount to providing accurate estimates of device failure rates. This assumes that the US Food and Drug Administration, physicians, and manufacturers provide better patient ascertainment data, timely reporting, and more accurate estimates of device failure rates. A stringent, mandatory, simplified reporting system may be needed to accomplish this important goal. Third, individual centers must obtain and report accurate procedural complication rates to determine the real risk of device replacement. Finally, our analysis shows that decisions about removing pacemakers and defibrillators are based on similar factors, the difference being the numbers used in the analysis for degree of device dependency, risk of infection, and risk of lead removal.

Another factor accounted for in our model is the impact of increased patient follow-up. Although our data do not show a clear impact, increased follow-up does alter the failure rate needed for device replacement if there is a high incidence of device failure without immediate death or with delayed death. It is likely that future new technologies of remote follow-up will have an even larger impact favoring device monitoring when device failure is unlikely to result in immediate death.

There are several limitations to our analysis. The model is derived from published data not specifically related to device recalls. The ranges of event rates may not cover all possibilities, and there will be some centers that may have higher or lower risks of infection and death due to lead extraction. Additionally, there is no data on mortality from device failure in patients with different types of electrical heart disease. Our model did not estimate the psychological burden resulting from the knowledge that a device may fail. This is likely to be a factor in many cases, and more studies are needed to appropriately quantify this impact. Additionally, we assumed a constant device malfunction rate over time, acknowledging that for certain devices the probability of device malfunction may increase with the age of the device and that this could significantly affect the decision.

Life expectancy was based on life-table data adjusted for excess mortality associated with cardiovascular disease. We examined a broad range of estimates of excess mortality and found that this did not substantially alter our results. Notably, one benefit of modeling is that a model provides an opportunity to improve estimates of the likely benefit of replacement vs continued observation as estimates of the various risks improve.

In conclusion, as the number of implantable devices increase, device failures and advisories will remain a part of routine practice. Having a rational mechanism to approach these patients is critical to patient care. The risks of replacing devices are not insignificant and outweigh all but very high risks of death due to device malfunction. Ultimately, this decision should be informed by the estimated device malfunction rate, anticipated consequences of device failure, and an individual center’s procedural risk of complications from generator change, in conjunction with patient preferences and tolerance of risk.

Author Contributions: Drs Amin and Matchar had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Amin, Matchar, Wood, Ellenbogen. Acquisition of data: Amin, Ellenbogen. Analysis and interpretation of data: Amin, Matchar, Ellenbogen.
Drafting of the manuscript: Amin, Matchar, Wood, Ellenbogen.
Critical revision of the manuscript for important intellectual content: Matchar, Ellenbogen.
Statistical analysis: Amin, Matchar.
Administrative, technical, or material support: Matchar, Ellenbogen.
Study supervision: Matchar, Wood.
Financial Disclosures: Dr Matchar is the director of the Duke Evidence-based Practice Center, commissioned to work with Center for Medicare and Medicaid Services for purposes of technology assessment. Drs Wood and Ellenbogen participate in device-related clinical research supported by grants from Medtronic, Guidant, St Jude, and Cameron Health. Dr Ellenbogen reports having received honoraria from Medtronic, Guidant, St Jude, and Sorin Biomedica. No other disclosures were reported. None of the outside companies that are mentioned were in any way involved with this work.

Acknowledgment: We thank Shalani Kulasingam, PhD, MPH, from the Center for Clinical Health Policy Research, Duke University, for reviewing the decision analysis model, and Emily Matchar for assistance with copy editing of an early version of the manuscript.

REFERENCES