

Pacemaker and ICD Generator Malfunctions

Analysis of Food and Drug Administration Annual Reports

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PACEMAKERS AND IMPLANTABLE cardioverter-defibrillators (ICDs) are 2 of the most clinically significant and complex medical innovations of the past century. Yet, despite millions of implants worldwide and their increasingly frequent use, surprisingly little is known about device reliability.¹⁻³

Pacemakers and ICDs occasionally malfunction.^{1,4,5} Several database registries have monitored pacemaker and ICD safety performance but have been limited by their relatively small size or voluntary nature.^{1,4,5} In total, hundreds of device malfunctions affecting dozens of pacemaker and ICD models have been reported.¹ A study of pacemaker and ICD advisories, a surrogate marker of device reliability, demonstrated that the number and rate of pacemakers and ICDs affected by advisories has increased since 1995.^{1,6}

Pacemakers and ICDs have become increasingly sophisticated. For example, devices in the early 1990s typically had less than 1 kB of random access memory, compared with more than 512 mB today.⁶ Meanwhile, ICDs have decreased in size by more than 80% during the past 15 years, while maintaining their high energy output and

Context Pacemakers and implantable cardioverter-defibrillators (ICDs) are complex medical devices proven to reduce mortality in specific high-risk patient populations. It is not known if increasing device complexity is associated with decreased reliability.

Objectives To analyze postapproval annual reports submitted to the US Food and Drug Administration (FDA) by manufacturers of pacemakers and ICDs to determine the reported number and rate of pacemaker and ICD malfunctions and to assess trends in device performance.

Design and Setting Pacemaker and ICD annual reports submitted to the FDA for the years 1990-2002 were reviewed. A pacemaker or ICD generator was defined as having malfunctioned if it was explanted due to an observed malfunction, returned to the manufacturer, and confirmed by the manufacturer to be functioning inappropriately. Leads and biventricular devices were not included in the study. Deaths were attributed to device malfunction only if they were witnessed, the malfunction immediately led to the death, and the malfunction was confirmed by the manufacturer.

Main Outcome Measures Number of implanted pacemaker and ICD generators; number of reported malfunctions; and annual malfunction replacement rates. Generator malfunction replacement rates were defined as the annual number of replacements due to confirmed malfunction divided by the annual number of implants.

Results During the study period, 2.25 million pacemakers and 415 780 ICDs were implanted in the United States. Overall, 17 323 devices (8834 pacemakers and 8489 ICDs) were explanted due to confirmed malfunction. Battery/capacitor abnormalities (4085 malfunctions [23.6%]) and electrical issues (4708 malfunctions [27.1%]) accounted for half of the total device failures. The annual pacemaker malfunction replacement rate per 1000 implants decreased significantly during the study, from a peak of 9.0 in 1993 to a low of 1.4 in 2002 ($P=.006$ for trend). In contrast, the ICD malfunction replacement rate per 1000 implants, after decreasing from 38.6 in 1993 to 7.9 in 1996, increased markedly during the latter half of the study, peaking in 2001 at 36.4 ($P=.04$ for trend). More than half of the reported ICD malfunctions occurred in the last 3 years of the study. Overall, the annual ICD malfunction replacement rate was significantly higher than the pacemaker malfunction replacement rate (mean [SD], 20.7 [11.6] vs 4.6 [2.2] replacements per 1000 implants; $P<.001$; rate ratio, 5.9 [95% confidence interval, 2.7-9.1]). Sixty-one deaths (30 pacemaker patients, 31 ICD patients) were attributable to device malfunction.

Conclusions This study demonstrates that thousands of patients have been affected by pacemaker and ICD malfunctions, the pacemaker malfunction replacement rate has decreased, the ICD malfunction replacement rate increased during the latter half of the study, and the ICD malfunction replacement rate is significantly higher than that for pacemakers. Although pacemakers and ICDs are important life-sustaining devices that have saved many lives, careful monitoring of device performance is still required.

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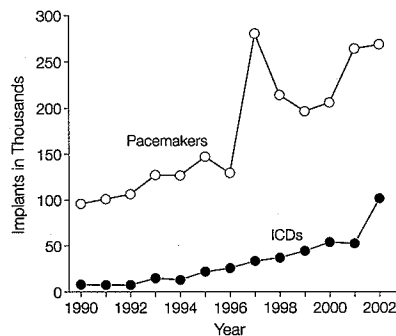
See also pp 1907, 1929, 1944, and Patient Page.

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Figure 1. Annual Pacemaker and Implantable Cardioverter-Defibrillator (ICD) Implants in the United States



The annual number of pacemakers implanted increased almost 3-fold and the annual number of ICD implants increased more than 10-fold during the study period. Implantable cardioverter-defibrillators represented an increasingly larger proportion of implanted devices throughout the study period, increasing from 6.4% of implants in 1990 to 27.2% of implants in 2002 ($P = .002$ for trend).

physiologic pacing.⁷ Whether these reported malfunctions and the increasing advisory rate reflect an actual change in device reliability in the setting of increasing device sophistication is not known.

The US Food and Drug Administration (FDA) is responsible for assessing both the premarket and postmarket safety and effectiveness of medical devices marketed in the United States.⁸ Additional postmarket monitoring of performance is required for selected devices. Because pacemakers and ICDs represent "life-sustaining" therapies for many patients, the FDA requires manufacturers to submit annual reports detailing the number of device implants and malfunctions that have occurred. This study analyzed pacemaker and ICD annual reports to determine the reported number, rate, and reasons for pacemaker and ICD malfunctions and to assess trends in device performance.

METHODS

All pacemaker and ICD generator annual reports submitted to the FDA for the years 1990-2002 were included. Each report contains the number of implanted

devices by model number and information concerning device malfunctions. When a submitted report covered more or less than 1 year, the implant and malfunction data were assumed to have occurred evenly throughout the report period. Of note, there is an approximately 2-year delay in obtaining complete annual report data from manufacturers (ie, data for 2003 is submitted by manufacturers in 2004 and 2005). Biventricular pacemakers and ICDs were excluded because relatively few of these devices were implanted during the study period. Pacemaker and ICD leads were also not included because leads that malfunction are not usually returned to the manufacturer for analysis.

A pacemaker or ICD generator malfunction was defined as a situation in which a device was (1) explanted due to malfunction, (2) returned to the manufacturer, and (3) confirmed by the manufacturer to be functioning inappropriately. Devices that were not explanted, not returned to the manufacturer, or found by the manufacturer to be working normally were not counted as malfunctioning devices. Devices that had not yet been implanted were also not included. Lead malfunctions or issues unrelated to true generator malfunction (such as oversensing, undersensing, or normal battery depletion) were not included as malfunctions. Only true, verifiable, confirmed generator malfunctions were counted. Malfunction classification was based on the manufacturer-determined cause of device failure. It was assumed that malfunctioning devices that were explanted from living patients were replaced with new devices.

A death was attributed to device malfunction only if it satisfied all of the following criteria: (1) the death was witnessed, (2) the device was observed to malfunction and immediately lead to the patient's death, (3) the device was explanted, and (4) the device was confirmed by the manufacturer to have malfunctioned. Death reports due to unconfirmed device malfunction were not considered to be due to device failure.

To calculate the annual device malfunction replacement rates, the annual number of devices explanted from living patients due to confirmed malfunction was divided by the annual number of device implants. Continuous outcomes were compared using t tests; discrete outcomes were compared using χ^2 and Fisher exact tests. Mantel-Haenszel χ^2 tests were used to assess for trends during 3 periods that were selected a priori: 1990-1996, 1996-2002, and 1990-2002.

Several potential sources of uncertainty in the device replacement rates were explored, including (1) variation in malfunction reporting rates, (2) variation in physician practice with regard to device replacement when a malfunction did occur, and (3) variation in physician reporting rate or clinical practice in the management of ICD patients compared with pacemaker patients.

Of 390 annual reports, 366 (94%) were available for review. The remaining 6% were not reviewed either because they were missing, they were not submitted, or the manufacturer was out of business. No specific year or manufacturer was more or less likely to have a missing annual report.

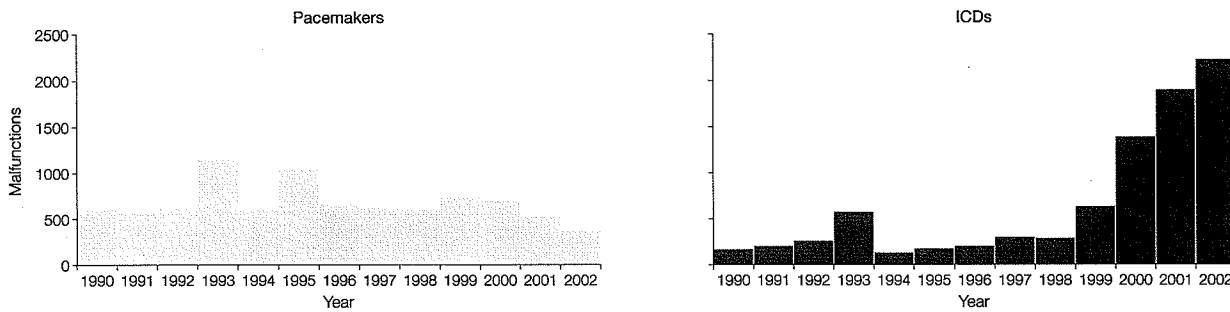
Statistical analyses were performed using SAS version 9.1 (SAS Institute Inc, Cary, NC). A 2-sided P value of .05 or less was interpreted as being statistically significant.

RESULTS

Number of Pacemaker and ICD Implants in the United States

From 1990 to 2002, there were 2.25 million pacemakers and 415 780 ICDs implanted in the United States. The annual number of pacemakers implanted increased almost 3-fold, from 94 755 in 1990 to 267 278 in 2002. During the same period, the annual number of ICD implants increased more than 10-fold, from fewer than 10 000 implants in 1990 to close to 100 000 in 2002 (FIGURE 1). Implantable cardioverter-defibrillators represented an increasingly larger proportion of implanted devices throughout the study period, increasing from 6.51% im-

Figure 2. Annual Pacemaker and Implantable Cardioverter-Defibrillator (ICD) Malfunctions



During the study, 17 323 devices (8834 pacemakers and 8489 ICDs) were explanted due to confirmed malfunction. The annual number of ICD malfunctions increased during the study period, with more than 50% of the ICD malfunctions occurring in the last 3 years of the study and close to one quarter occurring in the last year alone.

plants (6.4%) in 1990 to 99 684 (27.2%) in 2002 ($P = .002$ for trend).

Number and Replacement Rate of Device Malfunctions

During the study period, there were 17 323 devices (8834 pacemakers and 8489 ICDs) explanted due to confirmed malfunction (FIGURE 2 and TABLE). The annual number of malfunctions ranged from 366 to 1152 for pacemakers and from 134 to 2228 for ICDs. The final year of the study demonstrated the single lowest annual number of pacemaker malfunctions. In contrast, the annual number of ICD malfunctions increased over time, with more than half of the ICD malfunctions occurring in the last 3 years of the study and close to one quarter occurring in the last year alone (Figure 2).

The annual device malfunction replacement rate ranged from 1.4 to 9.0 replacements per 1000 implants for pacemakers and 7.9 to 38.6 per 1000 implants for ICDs (FIGURE 3). The mean [SD] annual total device malfunction replacement rate for 1990-2002 was 6.8 [2.3] per 1000 device implants. Overall, the annual mean (SD) ICD malfunction replacement rate was significantly higher than the pacemaker malfunction replacement rate (20.7 [11.6] vs 4.6 [2.2] replacements per 1000 implants; $P < .001$). The ICD malfunction replacement rate was higher than the pacemaker malfunction replacement rate in all 3 pre-

Table. Type and Frequency of Pacemaker and Implantable Cardioverter-Defibrillator (ICD) Malfunctions

Type of Malfunction	No. (%)		
	Pacemaker (n=8834)	ICD (n=8489)	Total (N=17 323)
Hardware	6610 (74.8)	7217 (85.0)	13 827 (79.8)
Battery/capacitor	1392 (15.8)	2693 (31.7)	4085 (23.6)
Charge circuit	0	1477 (17.4)	1477 (8.5)
Connector/header	1188 (13.4)	790 (9.3)	1978 (11.4)
Miscellaneous electrical	2596 (29.4)	2112 (24.9)	4708 (27.1)
Hermetic seal	1082 (12.2)	1 (0.01)	1083 (6.3)
Other hardware	352 (4.0)	144 (1.7)	496 (2.9)
Firmware*	504 (5.7)	127 (1.5)	631 (3.6)
Miscellaneous†	1337 (15.1)	712 (8.4)	2049 (11.8)
Inconclusive‡	383 (4.3)	433 (5.1)	816 (4.7)

*Integral device software.

†Including physical damage, foreign material contamination, "miscellaneous" manufacturing errors, etc.

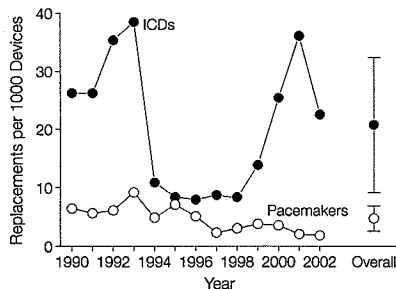
‡Manufacturer confirmed malfunction but could not determine the etiology.

lected periods (1990-1996: rate ratio, 3.4 [95% confidence interval {CI}, 1.8-5.0]; 1996-2002: rate ratio, 7.8 [95% CI, 1.5-14.0]; and 1990-2002: rate ratio, 5.9 [95% CI, 2.7-9.1]).

The annual mean (SD) pacemaker malfunction replacement rate was lower in the second half of the study period than in the first (3.0 [1.3] vs 6.3 [1.4], $P < .001$). Overall, there was a significant decrease in the pacemaker malfunction replacement rate during the study ($P = .006$ for trend) (Figure 3). In fact, in the final year of the study, the pacemaker malfunction replacement rate was only 1.4 per 1000 devices—the lowest rate of any year in the study and far below the mean annual rate of 4.6 replacements per 1000 pacemaker implants. In con-

trast, the ICD replacement rate for malfunction trended down during the first half of the study ($P = .09$ for trend) and reached its nadir in 1994-1998 (Figure 3). The annual ICD malfunction replacement rate for 1994-1998 was less than half the overall ICD malfunction replacement rate. From 1996 to 2002, the ICD replacement rate for malfunction increased markedly ($P = .04$ for trend) (Figure 3). The ICD malfunction replacement rate for the final 3 years of the study, 2000-2002, was 26.8 per 1000 ICD implants, more than 10 times the pacemaker malfunction replacement rate for the same period and more than 3 times the ICD malfunction replacement rate for the mid 1990s.

Figure 3. Pacemaker and Implantable Cardioverter-Defibrillator (ICD) Generator Replacement Rates for Malfunction



The annual mean (SD) ICD malfunction replacement rate was significantly higher than the pacemaker malfunction replacement rate (20.7 [11.6] vs 4.6 [2.2] replacements per 1000 implants; $P < .001$). The pacemaker malfunction replacement rate decreased significantly during the study ($P = .006$ for trend). In contrast, the ICD replacement rate for malfunction increased markedly during the latter portion of the study ($P = .04$ for trend).

Types of Device Malfunctions

Of the 17 323 total device malfunctions during the study period, hardware abnormalities were by far the most common type, affecting 13 827 devices (79.8%) (Table). Hardware abnormalities were the most common type of defect for both pacemakers and ICDs. Of these hardware problems, battery/capacitor abnormalities (4085 malfunctions [23.6%]) and electrical issues (4708 malfunctions [27.1%]) accounted for half of the total device failures. Firmware (integral device software) abnormalities and miscellaneous problems (such as physical damage, foreign material contamination, and various manufacturing errors) were much less frequent causes of device malfunctions. Only occasionally (816 malfunctions [4.7%]) could the manufacturer confirm device malfunction but not determine the cause.

Battery/capacitor abnormalities accounted for a higher percentage of device malfunctions in ICDs than in pacemakers (2693 malfunctions [31.7%] vs 1392 [15.8%], respectively; $P < .001$), as did charge-circuit abnormalities (1477 malfunctions [17.4%] vs 0, respectively; $P < .001$). Hermetic-seal abnormalities affected a much more significant percentage of pacemakers than

of ICDs (1082 malfunctions [12.2%] vs 1 [0.01%], $P < .001$), primarily because a single manufacturer had repeated problems in multiple pacemaker models in the early 1990s. Miscellaneous electrical problems, such as broken wires, current leakage, and electrical short circuits represented similar percentages of malfunctions, both in pacemakers and in ICDs.

Timing of Malfunctions in Product Life Cycle

Among the models implanted, 1.73 million pacemakers (76.7%) and 356 442 ICDs (85.7%) had received FDA approval within 3 years of implantation. In contrast, the majority of pacemaker and ICD malfunctions (6194 [70.1%] and 5539 [65.2%], respectively) occurred more than 3 years after marketing approval.

Deaths

Device malfunction was directly responsible for 61 confirmed deaths during the study period (30 pacemaker patients, 31 ICD patients). Reported pacemaker and ICD malfunctions were equally likely to have resulted in death (0.34% vs 0.37%; risk ratio, 0.93; 95% CI, 0.56-1.5; $P = .78$). Patients with ICDs, however, were more likely to die of device malfunction than were patients with pacemakers because of the smaller number of ICD patients (risk ratio, 5.6; 95% CI, 3.4-9.2; $P < .001$).

Sensitivity Analysis

Sensitivity analysis was performed to assess the impact of potential changes in malfunction reporting frequency, physician practice regarding replacement of a malfunctioning device, and variable physician practice in the management of pacemaker vs ICD patients. The observed trends in ICD and pacemaker malfunction replacement rates were insensitive to changes in the malfunction reporting rates of even 50% during the latter half of the study. Similarly, they were insensitive to changes in physician practice (ie, ICD and pacemaker trends were still

significant, even if physicians were twice as likely or half as likely to replace a device in later study years as compared with early study years). Finally, the finding that the malfunction replacement rate for ICDs was significantly higher than that for pacemakers was insensitive to even significant variable physician practice regarding management of patients receiving ICDs compared with pacemakers.

COMMENT

Pacemakers and ICDs are complex medical devices, clinically proven to effectively reduce mortality in specific high-risk populations.⁹⁻¹³ These devices have saved countless lives and remain an important therapy for patients with life-threatening arrhythmias. As a result, pacemaker and ICD implants are becoming increasingly common. Yet, despite millions of pacemaker and ICD implants worldwide and the perception that the devices are generally safe, surprisingly little is known about actual device reliability.¹ This study demonstrates that, while the pacemaker malfunction replacement rate has decreased since 1990, ICD replacements due to malfunction increased in number and rate between 1996 and 2002. Pacemaker and ICD malfunctions have affected thousands of patients since 1990 and have resulted in thousands of procedures to replace defective devices. The malfunction replacement rate for ICDs was more than 5 times that for pacemakers.

That pacemakers and ICDs may occasionally malfunction has been recognized for many years.^{1,4,5} Several database registries have monitored the performance of these devices and have noted failures involving dozens of different models affecting hundreds of devices.^{4,5} These registries, however, have been limited primarily by their relatively small size or voluntary nature. In addition, because the number of at-risk patients is difficult to determine, failure rates or trends have not been previously reported.^{1,4,5} Individual manufacturers do publish prod-

uct performance reports, which contain information regarding device performance by model number.¹⁴⁻¹⁶ While these reports provide valuable information, historically they have not contained comprehensive information about the number of device malfunctions or the rate or reasons for malfunction.

Manufacturers are required to report to the FDA any medical device-related event or malfunction that caused or could have caused a serious injury or death.⁸ Hospitals, nursing homes, and other medical facilities are required to report serious device-related injuries to the manufacturer and device-related deaths to both the manufacturer and the FDA.⁸ Patients and clinicians may voluntarily report observed device malfunctions or adverse events via the FDA MedWatch program (<http://www.fda.gov/med-watch>). The FDA annually receives more than 160 000 device-related adverse-event reports, some of which involve pacemakers or ICDs.¹⁷ Calculation of device failure rates is hampered by the absence of data regarding the number of patients implanted with a given device.¹⁸ The FDA, therefore, requires more thorough monitoring of postmarket performance by manufacturers for selected devices, including pacemakers and ICDs.⁸ These pacemaker and ICD annual reports offer the unique opportunity not only to count malfunctions but also to determine trends in device reliability as reported in this investigation.

Because ICDs are substantially more sophisticated than pacemakers, it is not surprising that they have a higher device malfunction replacement rate. The specific types of malfunctions observed most often in ICDs (battery, capacitor, charge-circuit, and electrical abnormalities) are unique, critical features of the device. After an improving ICD malfunction replacement rate during the first half of the 1990s, the number and rate of ICD replacements due to device malfunction increased. During this latter period, ICDs shrank in size, maintained their high energy

output, and provided more therapeutic features (such as the addition of dual-chamber pacing). The decrease in size, in particular, has necessitated modifications to battery, capacitor, and circuitry design that appear to account for some of the observed malfunctions.¹ In contrast to ICDs, the pacemaker malfunction replacement rate declined during the study period. While pacemakers also have evolved and become increasingly sophisticated, they are a "mature" technology.¹⁹ As such, they did not undergo the same degree of integral component modification during the study period that ICDs underwent.

After initial marketing approval, data supporting proposed pacemaker or ICD design changes must be submitted by the manufacturer to the FDA Office of Device Evaluation prior to marketing the modified device. Applications for a battery change, for example, may be accompanied by "bench testing" describing the behavior of the battery under "rapid depletion" conditions to model anticipated battery behavior over the lifetime of the device. Firmware or software changes may be accompanied by testing that simulates conditions of clinical use. These testing scenarios have their limitations, particularly as they cannot possibly duplicate every combination of conditions that may be encountered clinically. Manufacturer bench testing may need to be improved to better identify design flaws in the premarket phase of device evaluation and to better predict actual device clinical behavior. In addition, the quality system procedures implemented by ICD manufacturers, such as purchasing controls for suppliers, production and processing controls, or corrective and preventive action procedures, may need to be strengthened.

The clinical implications of pacemaker and ICD malfunctions are substantial. The malfunctions reported in this study resulted in thousands of device explantations and replacements, although the risks of generator replacement are relatively low (small risk of

bleeding, infection, etc).²⁰ Additionally, 61 deaths were observed during the study to be directly due to device malfunction, although it is likely that additional unwitnessed deaths were also due to device failure.¹ Because this study only counted actual device malfunctions, explantations due to device advisory (ie, the potential for malfunction) were not included and may account for a substantial number of additional explants.¹

Routine device checks at regular intervals remain the best way for physicians to monitor ongoing device performance in individual patients.⁶ Technological advances that allow for remote wireless monitoring or monitoring via the Internet may become increasingly important. Despite this newly recognized increase in ICD malfunction replacement rate, ICDs effectively reduce mortality in specific high-risk populations.⁹⁻¹³ These devices have prevented innumerable sudden deaths, and they remain an important therapy for patients at high risk for sudden cardiac death.

Limitations

There are several limitations to this study. Calculation of device malfunction replacement rates assumed that living patients undergoing device removal due to malfunction would receive a new device. The duration of implant of the failed device (ie, the time to failure) was not known, although only implanted devices were counted (because devices that failed prior to implantation were not counted). The observed increase in ICD malfunction replacement rate during the latter half of the study could be due to an increased rate of reporting of ICD malfunctions, a lower threshold to replace a malfunctioning ICD, or a true increase in the ICD malfunction rate.

Device malfunction reporting to the FDA may be subject to underreporting. This investigation studied only malfunctions significant enough to warrant device replacement. Because these replacements typically occur under a manufacturer's warranty, because the

defective device must be returned to the manufacturer to receive warranty consideration, and because the manufacturer must report these abnormalities to the FDA, ICD and pacemaker generators replaced due to malfunction may be less susceptible to underreporting. Similarly, a lower threshold to replace and/or report a defective ICD compared with that for a defective pacemaker could account for the higher observed ICD malfunction replacement rate. Sensitivity analysis, however, demonstrated that the observed trends in pacemaker and ICD performance were relatively insensitive to changes in malfunction reporting rates and changes in physician practice. Indeed, a meta-analysis of pacemaker and ICD registries (not subject to underreporting) demonstrated trends in device performance similar to those reported here.²¹ Finally, because fewer than 12 000 cardiac resynchronization therapy de-

vices were implanted during this study period, reliable estimates of malfunction replacement rates for such devices could not be performed.

CONCLUSIONS

While pacemakers and ICDs are generally safe and effective devices that have saved many lives, this study demonstrates several important findings: (1) thousands of patients have been affected by pacemaker and ICD malfunctions, (2) the pacemaker malfunction replacement rate has decreased, (3) the ICD malfunction replacement rate increased during the latter half of the study period, and (4) the ICD malfunction replacement rate is significantly higher than that for pacemakers. Careful monitoring of device performance is still required. The clinical community must continue to report adverse events in a timely manner, and strategies should be devel-

oped to increase the proportion of defective devices that are returned for manufacturer analysis.

Author Contributions: Dr Maisel had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Maisel.

Acquisition of data: Maisel.

Analysis and interpretation of data: Maisel, Moynahan, Zuckerman, Gross, Tovar, Tillman, Schultz.

Drafting of the manuscript: Maisel.

Critical revision of the manuscript for important intellectual content: Maisel, Moynahan, Zuckerman, Gross, Tovar, Tillman, Schultz.

Statistical analysis: Maisel.

Obtained funding: Maisel.

Administrative, technical, or material support: Maisel, Moynahan, Zuckerman, Gross, Tovar, Tillman, Schultz.

Study supervision: Maisel.

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Disclaimer: Dr Maisel is the Chair of the FDA Circulatory System Medical Devices Advisory Panel and was a special government employee while conducting the study.

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