Recalls and Safety Alerts Affecting Automated External Defibrillators

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SUDDEN CARDIAC DEATH IS A leading cause of mortality in the United States, accounting for nearly 330,000 deaths annually.1 Successful resuscitation of persons with cardiac arrest depends on prompt emergency care, with early defibrillation a key component to improved survival.2 The advent of automated external defibrillators (AEDs) and their increasingly widespread distribution in public places has been an important development that has resulted in improved survival of persons with cardiac arrest.3-10 Indeed, widespread installation of AEDs has occurred in a number of public places, including many airports, casinos, sports arenas, and shopping centers, and has resulted in the saving of innumerable lives.3,7 Because of the important lifesaving potential of AEDs and their ease of use, the US Food and Drug Administration (FDA) has approved some models for home use without a prescription.11

Automated external defibrillators provide automated rhythm analysis, voice commands, and shock delivery.7 Several clinical trials have demonstrated that AEDs are safe and clinically effective and that they may be used appropriately by individuals with as little as a sixth-grade education.3-10 Indeed, widespread installation of AEDs has occurred in a number of public places, including many airports, casinos, sports arenas, and shopping centers, and has resulted in the saving of innumerable lives.3,7 Because of the important lifesaving potential of AEDs and their ease of use, the US Food and Drug Administration (FDA) has approved some models for home use without a prescription.11

While easy to use, AEDs are technologically complex devices that occasionally malfunction.12 The FDA is responsible for the safety and oversight of all medical devices in the United States. Weekly FDA Enforcement Reports are issued that include recalls and safety alerts (collectively referred to as “advisories”), a number of which have involved AEDs.13 Advisories are usually issued to notify the public about potentially defective devices that may not function as intended. Implantable cardioverter-defibrillators (ICDs), devices similar to AEDs, have been subject to frequent recall by the FDA because of observed malfunctions affecting device performance and reliability.14,15 Whether AEDs are likewise prone to FDA recall is not known. Because AEDs have become more sophisticated and increasingly prev-

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Methods
Safety Alerts and Recalls
All FDA safety alerts and recalls (collectively referred to as “advisories”) affecting AEDs or AED accessories were identified by reviewing weekly FDA Enforcement Reports between January 1996 and December 2005. Each advisory is classified by the FDA into 1 of 4 categories: class I (reasonable probability that use of the product will cause serious adverse health consequences); class II (use of the product may cause temporary or medically reversible adverse health consequences or the probability of adverse health consequences is remote); class III (use of the product is not likely to cause adverse health consequences); or safety alerts (a communication issued to inform of the potential risk of substantial harm from a medical device—may be of same importance as class I, class II, or class III recall). Only advisories affecting AEDs (FDA product codes MKJ, NPN, and NSA) or critical AED accessories (ie, batteries, capacitors, cables, resistors, electrode pads, and the like) were included. Advisories affecting external defibrillators without automated functions and advisories affecting noncritical accessories (ie, where accessory malfunction would not affect life-sustaining device performance) were excluded from the study.

The number of AEDs affected by advisories was determined from FDA Enforcement Reports. The number of “at risk” AEDs in the United States was estimated by identifying all US AED manufacturers and reviewing all available relevant US Securities and Exchange Commission annual reports for the study period. In addition, independent financial market research reports were reviewed to verify the findings. The annual AED advisory rate was then calculated by dividing the annual number of AEDs affected by FDA advisories by the estimated total number of AEDs at risk in a given year. It was assumed that once an AED was distributed, it remained in service.

Device Malfunctions
Because advisories represent the potential for device malfunction, additional analysis was performed to assess actual AED advisories. All AED and AED accessory adverse event reports involving a patient death and submitted to the FDA between July 1996 and December 2005 were analyzed. Manufacturers are required to report to the FDA any medical device–related event or malfunction that caused or could have caused serious injury or death to a patient. These reports are entered into the publicly searchable Manufacturer and User Facility Device Experience (MAUDE) database. Each MAUDE AED report was independently reviewed in detail by 2 physicians and was classified into 1 of the following categories: (1) device malfunction; (2) no device malfunction; or (3) indeterminate (insufficient data to classify event). The AED or AED accessory was considered to have malfunctioned only if: (1) manufacturer analysis confirmed the malfunction or (2) the device was not returned to the manufacturer for analysis but the malfunction was witnessed and confirmed by trained health care personnel on the scene. Only malfunctions that occurred during sustained ventricular arrhythmias were counted. When available, manufacturer analysis of stored electrograms was used for arrhythmia classification. When stored electrograms were not available for analysis, the device’s automated analysis was used. If AED rhythm analysis and on-site health care personnel analysis did not agree, the event was classified as indeterminate. Unsubstantiated claims of device malfunction or reports containing insufficient information were not counted as device malfunction. Only true, definite device malfunctions were counted. Malfunction classification disagreements were resolved by consensus of the 2 physician adjudicators.

Statistical Methods
Statistical comparisons were performed using SAS statistical software (version 9.1, SAS Institute, Cary, NC). A 2-sided P value of .05 or less was interpreted as being statistically significant. Student t and chi-square tests were used to compare continuous and discrete outcomes, respectively. Mantel-Haenszel chi-square tests were used to assess for trends during 3 time periods that were selected a priori: 1996–2000, 2001–2005, and 1996–2005. Although the precise number of annual AED units distributed was determined, sensitivity analysis was performed to account for potential inaccuracies in manufacturer reporting of AED sales.

Results
Number of AEDs
The annual number of AEDs marketed is shown in Figure 1. The mean (SD) annual number of AEDs marketed was 77,539 (57,362). In total, 775,387 AEDs were marketed during the study, with the annual number of...
units sold increasing approximately 10-fold during the study (approximately 30% per year), from 18,645 in 1996 to 192,400 in 2005. A total of 2.78 million device-years of observation occurred during the study period.

Number, Type, and Rate of Advisories

There were 52 advisories during the study period affecting 385,922 AEDs and AED accessories (FIGURE 2). Between January 1996 and December 2005, 37 AED advisories (range, 0-8; median [25th and 75th percentiles], 3.5 [2.0 and 5.0] advisories per year) affecting 164,102 AEDs (mean [SE], 16,410 [5409] AEDs per year) and 15 AED accessory advisories (range, 0-4; median [25th and 75th percentiles], 2 [0 and 2] advisories per year) affecting 221,820 AED accessories (mean [SE], 22,182 [8,725] AED accessories per year) occurred. Automated external defibrillators were recalled in 9 of the 10 study years, and AED accessories were recalled in 7 of the 10 years studied. No year was advisory free. The annual number of AEDs affected by advisories varied from a low of 0 in 1998 to a high of 53,323 in 2005. The annual number of AED accessory advisories and AED accessory units affected by advisories is shown (right panel). Between 1996 and 2005, 15 AED accessory advisories affecting 221,820 AED accessories were issued.

![Figure 2. Annual Automated External Defibrillator (AED) and AED Accessory Advisories and Units Affected](image)

The annual number of AED advisories and AED units affected by advisories is shown (left panel). Between 1996 and 2005, 37 AED advisories affecting 164,102 AEDs were issued. The annual number of AED accessory advisories and AED accessory units affected by advisories is shown (right panel). Between 1996 and 2005, 15 AED accessory advisories affecting 221,820 AED accessories were issued.

**Table 1. Type and Frequency of Automated External Defibrillator (AED) and AED Accessory Advisories**

<table>
<thead>
<tr>
<th>Reason for Advisory</th>
<th>AED Advisories</th>
<th>AED Units Affected</th>
<th>AED Accessory Advisories</th>
<th>AED Accessory Units Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery</td>
<td>3 (8.1)</td>
<td>20,651 (12.6)</td>
<td>3 (20)</td>
<td>5,916 (2.7)</td>
</tr>
<tr>
<td>Capacitor</td>
<td>3 (8.1)</td>
<td>6,840 (4.2)</td>
<td>1 (6.7)</td>
<td>16,736 (7.5)</td>
</tr>
<tr>
<td>Electrical</td>
<td>8 (21.6)</td>
<td>31,906 (19.4)</td>
<td>4 (26.7)</td>
<td>50,925 (23.0)</td>
</tr>
<tr>
<td>Failure to detect*</td>
<td>4 (10.8)</td>
<td>31,963 (19.5)</td>
<td>5 (13.5)</td>
<td>51,545 (31.4)</td>
</tr>
<tr>
<td>Failure to shock*</td>
<td>5 (13.5)</td>
<td>64,393 (3.9)</td>
<td>4 (10.8)</td>
<td>64,393 (3.9)</td>
</tr>
<tr>
<td>Miscellaneous hardware</td>
<td>4 (10.8)</td>
<td>12,311 (7.5)</td>
<td>6 (16.2)</td>
<td>22,182 (100)</td>
</tr>
<tr>
<td>Software</td>
<td>6 (16.2)</td>
<td>51,545 (31.4)</td>
<td>4 (26.7)</td>
<td>22,182 (100)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (10.8)</td>
<td>2,447 (1.4)</td>
<td>1 (6.7)</td>
<td>16,736 (7.5)</td>
</tr>
<tr>
<td>AED Total</td>
<td>37 (100)</td>
<td>164,102 (100)</td>
<td>AED Accessory Total</td>
<td>15 (100)</td>
</tr>
<tr>
<td>AED Accessory Total</td>
<td>15 (100)</td>
<td>221,820 (100)</td>
<td>AED and AED Accessory Total</td>
<td>52 (100)</td>
</tr>
</tbody>
</table>

*More specific mechanism of potential failure not reported. These advisories may be due to hardware or software abnormalities.

Of the 37 AED advisories, most were classified by the FDA as either class I (4 advisories [10.8%]) or class II (31 advisories [83.7%]). In contrast, all but 1 (14 advisories [90.3%]) of the AED accessory advisories were judged to be class II recalls. Advisories affecting AEDs were most often issued because of electrical (8 advisories affecting 31,906 devices) or software-related issues (6 advisories affecting 12,311 devices) (TABLE 1). Failure of the device to detect the arrhythmia.
Table 2. Examples of Automated External Defibrillator (AED) and AED Accessory Advisories

<table>
<thead>
<tr>
<th>FDA Advisory Classification</th>
<th>Description</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Affected AED may shut itself off before delivering shock</td>
<td>AED</td>
</tr>
<tr>
<td></td>
<td>AED may display error message, fail to analyze the patient’s ECG, and fail to deliver appropriate therapy</td>
<td>AED</td>
</tr>
<tr>
<td>Class II</td>
<td>AED may fail to operate because of faulty component in circuit board</td>
<td>AED</td>
</tr>
<tr>
<td></td>
<td>Pads may fail because of excessive corrosion of the electrode</td>
<td>AED Accessory</td>
</tr>
<tr>
<td>Class III</td>
<td>AED does not display the alarm off indicator</td>
<td>AED</td>
</tr>
<tr>
<td></td>
<td>External case of the AC power charger may exhibit localized melting</td>
<td>AED Accessory</td>
</tr>
</tbody>
</table>

Abbreviations: ECG, electrocardiogram; FDA, Food and Drug Administration.

Figure 3. Automated External Defibrillator (AED) Advisory Rates for 1996 to 2005

The annual AED advisory rate ranged from 0 to 13.6 advisory devices per 100 AED device-years at risk. Overall, the mean (SE) annual rate of AED advisory device-years was 5.1 (1.5) per 100 AED device-years.

2000 (P for trend=.11); 2001-2005 (P for trend=.19); 1996-2005 (P for trend=.33). However, between 1996 and 2005 there was a significant increase in the annual number of AED advisories (P for trend=.02) and in the annual number of AED advisory devices (P for trend=.01).

Recent Advisories and Alerts

During the first half of 2006 (January through June), there were an additional 6 advisories affecting 28,795 devices. Five advisories affecting 27,530 AEDs and 1 advisory affecting 1,265 AED accessories were reported.

Analysis of Malfunction Reports

A total of 801 AED or AED accessory adverse event reports involving a death were reported to the FDA during the study period. Fewer than half of the reported device failures were classified as confirmed device malfunctions (370 reports [46.1%]). The remaining reports (431 reports [53.9%]) were adjudicated as either no malfunction or indeterminate. Specific examples of reported adverse events are described in the BOX.

Sensitivity Analysis

Sensitivity analysis was performed to assess the impact of potential inaccuracies in manufacturer reporting of AED sales and to account for potential changes in AED longevity. The observed increasing trends in number of AED advisories and number of AED advisory devices were unaffected by even 50% increases or decreases in annual AED sales or device longevity.

COMMENT

Automated external defibrillators are complex medical devices designed to function during life-threatening emergencies. These devices have saved numerous lives over the past decade but do occasionally malfunction. Despite exponential growth in the AED industry and increasing evidence that early defibrillation is a critical component to the survival of persons with cardiac arrest, little is known about AED performance. This study reassuringly demonstrates that despite increasing AED complexity, the AED advisory rate did not significantly increase during the study period.

However, AED and AED accessory advisories do occur frequently. The annual number of AED advisories and the annual number of AEDs affected by advisories increased, and numerous confirmed AED malfunctions occurred during the past decade. Still, the total number of device malfunctions is small compared with the number of lives saved. Indeed, hundreds of thousands of patients underwent attempted resuscitation of ventricular arrhythmias by an AED during the study period accounting for thousands of lives saved.

Sudden cardiac death is a leading cause of cardiovascular mortality in the community. Increasing evidence suggests that time to defibrillation for out-of-hospital patients with a shockable rhythm is the most important determinant of survival. Numerous studies have demonstrated clinical benefit of AEDs in public gathering places such as airports, casinos, schools, and public arenas. These clinical trials have demonstrated that approximately 40% to 70% of the patients in shockable rhythms treated in a timely fashion by an AED will survive. However, because AED clinical trials have been designed to evaluate the device’s clinical efficacy and not its technical performance, studies have been underpowered to evaluate the incidence of rare but important device malfunctions. In contrast, the current...
study involved 2.78 million device-years of observation.

Advisories from the FDA indicate the potential for a device to malfunction, not an actual device malfunction. As such, they are a surrogate marker of device reliability. In general, advisories are issued by the FDA when a product may not function as intended and the potential malfunction could result in patient harm. Importantly, some advisories are issued even when the risk of device failure is less than 1%. Timely communication of advisory information to device end users is of critical importance, as some units may require repair or replacement. Manufacturer response after issuing an advisory is variable. While some offer repair or replacement at no cost, others have simply recommended discontinuing device use without offering a remedy. However, it is often impossible to predict who the actual end user of the device will be in any given emergency. While a patient's ICD is routinely "registered" with the manufacturer at the time of implantation, no such process reliably occurs with AEDs. This creates a challenge for the FDA and industry to develop a reliable system that will permit timely, accurate communication to potential users and identification of affected advisory devices. Current advisory notification schemes arguably do not adequately inform the public. The inability to track devices and end users makes it impossible to know how many AED units were actually fixed or taken out of service during the study period because of these advisories.

The actual clinical implications of the AED and AED accessory advisories are difficult to estimate because some advisory devices may never be used, and others may be used repeatedly. While the weekly FDA Enforcement Reports and manufacturer Securities and Exchange Commission filings used for the advisory analysis are robust and allow for accurate determination of advisory numbers and rates, no such benefit exists for analysis of actual device malfunctions presented in the FDA MAUDE database. The MAUDE database is widely recognized to be subject to potential underreporting of device failures. In addition, many reports of device "failures" are cryptic and contain insufficient information to determine whether a true device malfunction has occurred. By counting only confirmed device malfunctions, this study demonstrates that numerous actual AED malfunctions have occurred. Because AEDs, by their very nature, are used in critically ill patients, it is not possible to predict whether a given device malfunction directly led to a patient's death.

Hardware malfunctions were the most common type of failure observed for AEDs. Often, these failures result in the inability of the device to deliver life-sustaining therapy because of failure of the device to power on, failure of the device to charge, or failure of the device to deliver a shock. Similar hardware failures have been observed in ICDs. Although ICDs and AEDs share many similarities, the majority of AED manufacturers do not make ICDs. Therefore, the AED safety issues described in this study are distinct from those recently described for ICDs. Every major AED manufacturer recalled products during the study period, suggesting that this is an industry-wide issue and not specific to a single device or manufacturer.

A possible limitation to our study was that advisory classification was based on the FDA- and manufacturer-reported cause of device malfunction. While the precise number of recalled units with the potential to malfunction is known, the actual number of device failures is not. However, it is evident that AED malfunctions do occasionally occur and may contribute to adverse patient outcomes. It was assumed that all AEDs remained in service once distributed. If devices were actually removed from service, the true advisory rate may be underestimated by this study. Sensitivity analysis, however, demonstrated that the reported trends of an increasing number of AED advisories and an increasing number of AED advisory devices were insensitive to even moderate changes in annual AED sales and AED longevity. A changing threshold by manufacturers or the FDA to issue an advisory could account for some of the observed increase in the number of advisories.
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visors and advisory devices, but would not diminish the public health consequences of these recalls.

CONCLUSIONS

Automated external defibrillator and AED accessory advisories occur frequently and affect many devices. Actual AED malfunctions do occur occasionally, although the number of observed malfunctions is small compared with the number of lives saved. As the prevalence of AEDs continues to increase, the number of devices affected by advisories can also be expected to increase. Efforts should be directed at developing a reliable system to locate and repair potentially defective devices in a timely fashion.

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.

REFERENCES


Study concept and design: Shah, Maisel. Acquisition of data: Shah, Maisel. Analysis and interpretation of data: Shah, Maisel. Drafting of the manuscript: Shah, Maisel. Critical revision of the manuscript for important intellectual content: Shah, Maisel. Statistical analysis: Maisel. Administrative, technical, or material support: Maisel. Study supervision: Maisel.

Disclaimer: Dr Maisel is a US Food and Drug Administration (FDA) consultant and chair of the FDA Circulatory System Medical Device Advisory Panel. The opinions expressed herein are the personal views of the authors and do not necessarily represent the policies, practices, positions, or opinions of the FDA.

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