

Analysis of Automated External Defibrillator Device Failures Reported to the Food and Drug Administration

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Study objective: Automated external defibrillators are essential for treatment of cardiac arrest by lay rescuers and must determine when to shock and if they are functioning correctly. We seek to characterize automated external defibrillator failures reported to the Food and Drug Administration (FDA) and whether battery failures are properly detected by automated external defibrillators.

Methods: FDA adverse event reports are catalogued in the Manufacturer and User Device Experience (MAUDE) database. We developed and internally validated an instrument for analyzing MAUDE data, reviewing all reports in which a fatality occurred. Two trained reviewers independently analyzed each report, and a third resolved discrepancies or passed them to a committee for resolution.

Results: One thousand two hundred eighty-four adverse events were reported between June 1993 and October 2008, of which 1,150 were failed defibrillation attempts. Thirty-seven automated external defibrillators never powered on, 252 failed to complete rhythm analysis, and 524 failed to deliver a recommended shock. In 149 cases, the operator disagreed with the device's rhythm analysis. In 54 cases, the defibrillator stated the batteries were low and in 110 other instances powered off unexpectedly. Interrater agreement between reviewers 1 and 2 ranged by question from 69.0% to 98.6% and for most likely cause was 55.9%. Agreement was obtained for 93.7% to 99.6% of questions by the third reviewer. Remaining discrepancies were resolved by the arbitration committee.

Conclusion: MAUDE information is often incomplete and frequently no corroborating data are available. Some conditions not detected by automated external defibrillators during self-test cause units to power off unexpectedly, causing defibrillation delays. Backup units frequently provide shocks to patients. [Ann Emerg Med. 2011;xx:xxx.]

Please see page XX for the Editor's Capsule Summary of this article.

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INTRODUCTION

Background

Automated external defibrillators are central to the American Heart Association "chain of survival" for the treatment of cardiac arrest.^{1,2} Numerous studies have demonstrated the effectiveness of public access defibrillation programs in casinos, airports, and other public venues. Automated external defibrillators exhibit high sensitivity and specificity for detecting shockable rhythms.³⁻¹⁵ A recent study examined automated external defibrillator device advisories during a 10-year period and concluded that, although automated external defibrillators are frequently affected by such advisories, actual malfunctions were rare and the number of lives saved outweighed the risks of occasional device failures.¹⁶

The Food and Drug Administration (FDA) regulates medical devices in the United States and collects postapproval data on device malfunctions.⁹ Adverse event reports can be filed by patients, health care facilities, health care providers, or device manufacturers and are kept in the Manufacturer and User Device Experience (MAUDE) database.¹¹

Importance

Survival from cardiac arrest depends on the reliable operation of automated external defibrillators. Timely and informative reports of device malfunctions are critical to addressing device failures that may adversely affect outcomes.

Goals of This Investigation

We sought to characterize and analyze the types of automated external defibrillator failures reported to the FDA in

Editor's Capsule Summary

What is already known on this topic

Proper use of an automated external defibrillator can improve survival for cardiac arrest patients.

What question this study addressed

This review of the Food and Drug Administration device adverse event database (Manufacturer and User Device Experience) examined automated external defibrillator adverse event reports in which patients died.

What this study adds to our knowledge

Nearly half of all reported device failures occurred during the attempt to deliver a recommended shock, and a significant portion of these failures are unanticipated device shutdowns.

How this is relevant to clinical practice

Because we do not know the frequency of this occurrence, it is hard to recommend changes to practice, but having a backup available would be the most cautious approach.

which a fatality occurred. Our specific aims were to (1) describe the number and types of automated external defibrillator failures reported; (2) identify where failures occurred in the automated external defibrillator power on—analyze—shock sequence; (3) determine the frequency of unexpected device shutdowns reported; and (4) determine the action of any backup device used.

MATERIALS AND METHODS

Study Design and Setting

A retrospective analysis of automated external defibrillator adverse event reports received by the FDA between January 1993 (when MAUDE was first created) and October 2008 was performed. A deidentified MAUDE data set is available to the public through the Freedom of Information Act and was downloaded from the FDA Web site.¹⁷ The study was reviewed by the University of Arizona Human Subjects Protection Program and was determined to be exempt from institutional review board review.

Selection of Participants

All automated external defibrillator adverse event reports in which a fatality occurred were included in the analysis. An SQL query used MAUDE database fields to select automated external defibrillator reports in which the patient outcome was death.

Methods of Measurement

The MAUDE database contains many fields (manufacturer, serial number, etc) to identify the device and

the setting in which the adverse event occurred. The description of the event itself is an unstructured narrative. A data abstraction instrument was developed and internally validated through pilot testing and focus group analysis before formal data abstraction.¹⁸

The instrument comprises 2 parts (Figure 1). “Descriptive” questions were used to clarify the sequence of events leading to the device failure. “Analytic” questions asked reviewers to identify both likely contributors and the single most likely cause of the failure. Reviewers (L.A.D., A.S., D.B., L.S., U.S., A.P.) were also asked to rate the clarity of the report.

Each adverse event report was analyzed independently by 2 reviewers who were blinded to each other's responses. For any question(s) in which the first 2 reviewers disagreed, a third reviewer attempted to resolve the discrepancy. If the third reviewer could not resolve the dispute in favor of reviewer 1 or 2, the question was forwarded to a committee for arbitration (D.S., K.G., K.D.).

Because some automated external defibrillators are multifunction devices, adverse events might be related to other functions (eg, pacing, monitoring) rather than defibrillation. If 2 primary reviewers classified the event as “not a defibrillation attempt,” the third reviewer could agree to exclude the report or pass the entire report to the arbitration committee for final determination.

The variables used in our analysis are defined below. Reference is made to the survey instrument (Figure 1). We defined “device failure” as failure to complete any step in the “power on—analyze—shock” sequence, even if an error condition (such as “battery low”) was detected and an appropriate error message was displayed.

Descriptive questions were as follows:

- 1: IS_DEFIB—Answered yes if the narrative described a defibrillation attempt. Event reports not describing a defibrillation attempt were excluded from further analysis.
- 2: MAINT—Answered yes if any reference was made to device maintenance.
- 3: WHEN_HOW_FAILED—The values for this categorical value are the possible failure points along the device power on—analyze—shock sequence. If the reviewer believed the device had functioned properly, the “other” option was specified and a note was made in the comment field.
- 4: BACKUP_DID—If a backup defibrillator was mentioned, the action(s) of that device was noted.
- 5: BATTERY_LOW_MSG—Yes if the unit generated a low-battery message, no otherwise.
- 6: POWERED_OFF—Yes if the unit shut down unexpectedly.

For analytic questions, the major components identified were as follows:

- Battery/power problems, including low battery messages, unexpected shutdowns (in the absence of other information to suggest a different cause), and capacitor failures.

1. Does this report describe a <i>failed defibrillation attempt</i> ? If not, please click here to skip this record.	
Please identify the nature of the error that was reported.	
2. Was any sort of maintenance or testing of the device documented in the report <i>prior to the device failure</i> ?	Yes No
3. Where in the POWER ON-ANALYZE-SHOCK sequence did the reported error occur?	Never powered on Failed to analyze rhythm 'SHOCK ADVISED' for NON-shockable rhythm 'NO SHOCK ADVISED' for shockable rhythm Failed to charge or deliver recommended shock Other error / message (specify)
4. What did the backup unit do (if a backup unit is mentioned)?	NO BACKUP UNIT MENTIONED in report Backup unit advised no shock Backup unit advised shock but did not deliver Backup unit advised shock and delivered Backup unit NOT USED FOR DEFIBRILLATION Other action (specify)
5. Did the unit state the batteries were low?	Yes No
6. Did the unit unexpectedly power off?	Yes No
Did the following likely contribute to the reported device failure?	
7. Battery or power problems?	Yes No
8. Pads or connector problems?	Yes No
9. Voice prompts or user interface problems?	Yes No
10. Incorrect rhythm analysis (by device <i>or</i> by operator)?	Yes No
11. Operator errors other than rhythm analysis problems?	Yes No
12. Which of the following was the <i>single most likely cause</i> of the reported device failure?	Battery or power problems Pads or connector problems Voice prompts or user interface problems Rhythm analysis discrepancy Operator errors not related to rhythm analysis Cannot be determined Other cause (specify)
Overall Quality of Report	
13. Please rate the overall clarity of this report:	Completely clear - unambiguous report Somewhat clear - most key info present Somewhat vague - most key info missing Completely vague - No useful information

Figure 1. MAUDE data abstraction instrument

- Pads/connector problems, including difficulties applying pads, problems with attaching pads to the machine, and arcing of electricity.
- Voice prompts or user interface problems, including unintelligible or confusing prompts, inability to actuate the device despite instructions such as “push the button to defibrillate,” and inability to locate controls.
- Rhythm analysis discrepancies, including whether the automated external defibrillator and the user disagreed about whether the rhythm was shockable. Insufficient information was available in MAUDE to reliably determine whether the user or the device was correct.
- Other operator errors, including any event in which the device appeared to function correctly but the fault was due to user interaction with the device.

For questions 7 to 11, reviewers were asked to provide yes/no answers to whether each of the above modes of failure could

have contributed to the device malfunction described in the adverse event report.

- For question 12 (MOST_LIKELY_CAUSE), reviewers were asked to identify the single most likely cause of the device failure (from the choices above or “cannot be determined”).
- For question 13 (CLARITY), reviewers were asked to rate the overall clarity of the report.

The development of the instrument followed an iterative process. Probes for questions of interest (battery failure and unexpected shutdown), operational sequence, and major device components that may have contributed to the failure were compiled into a draft instrument. This instrument was used by 2 of the researchers to independently analyze a small number of reports, after which they met and compared responses. The instrument was modified and reassessed with a different random subgroup of reports. This process continued until the instrument stabilized.

A focus group was convened to fine-tune the survey, comprising 2 attending emergency physicians, 1 PhD biostatistician, and 1 medical student research assistant. Several data reviewers were recruited to test the instrument. All reviewers completed a PowerPoint-based tutorial that provided didactic instruction, sample reports and analyses, and test cases with an annotated answer key. When a predetermined agreement threshold was reached (90% for descriptive questions and 80% for analytic questions), the instrument was considered ready for use.

Fourteen reviewers volunteered (4 attending physicians, 3 emergency medicine residents, 2 fourth-year medical students, 2 nurses, and 3 non-health care providers) who were not blinded to the outcomes of the study. Each reviewer completed the aforementioned tutorial and 20 practice reviews. Their responses were compared with those of a trained reviewer, with a goal of 90% for descriptive questions and 80% for analytic questions. Areas of nonagreement were reviewed by the principal investigator and the trainee was remediated if necessary. After completing training, reviewers were randomly assigned adverse event reports for which they might be first, second, or third reviewer. The arbitration committee was composed of board-certified emergency physicians who had not participated in primary data abstraction.

Data Collection and Processing

MAUDE data files were downloaded from the FDA Web site and uploaded into a Microsoft SQL Server Express 2005 database (Microsoft, Redmond, WA). The database schema provided on the Web site was used to re-create linkages between tables. We implemented data redundancy and an audit trail to allow recovery in the event of software failures. Microsoft Visual Web Developer Express 2005 was used to create a data entry interface, eliminating transcription errors. Data analysis was performed with SQL and Excel 2007 (Microsoft).

Outcome Measures

Our primary outcome measures were the major causes of automated external defibrillator-related failure and where in the power on-analyze-shock sequence the failure occurred.

We inquired about unexpected shutdowns and “battery low” messages because we hypothesized that some battery failures are not detected by the device’s self-test algorithms.

Primary Data Analysis

Individual failures were categorized and tabulated. A time trend was plotted for automated external defibrillator power failures to determine whether time-based events (such as introduction of new automated external defibrillators or changes in battery technology) might influence the rate of battery-related failures. Interrater agreement was assessed between reviewers using percentage agreement. This analysis was also validated by comparing the results with those of a preliminary analysis performed by 2 of the reviewers on a subset of the MAUDE data.¹⁹

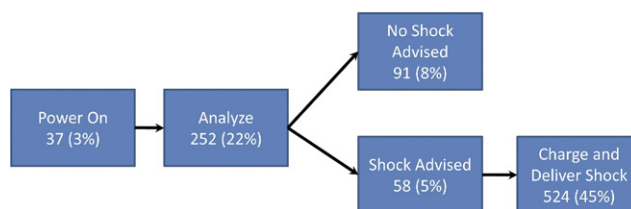


Figure 2. Responses to question 3: “Where in the power on-analyze-shock sequence did the reported error occur?” (n=1,150 defibrillation events analyzed, 188 [16%] of events classified as “other”).

RESULTS

MAUDE data was uploaded from the FDA Web site in October 2008. All reports that were available in the MAUDE database from June 1993 until October 2008 were included. A total of 40,787 automated external defibrillator-related events were reported during this period, including 1,284 events in which a fatality occurred. Of these 1,284 reports, 134 were excluded after they were classified as “not a failed defibrillation attempt,” leaving 1,150 adverse events in the final analysis.

Reviewers were asked to identify where in the power on-analyze-shock sequence the failure occurred (Figure 2). The bulk of failures (45%) occurred during the attempt to charge and deliver a recommended shock. Rhythm analysis discrepancies were frequently reported (13%). In 22% of cases, the automated external defibrillator powered on but failed to complete rhythm analysis. Nearly 1 in 6 reports was classified as “other” because either the reviewers could not identify where in the device operation sequence the error occurred or the automated external defibrillator provided an error message that was not meaningful to the user (eg, “bridge test failed” or “pacemaker fault 117”).

Table 1 lists the actions taken by backup devices that were described in the adverse event reports. Backup devices were mentioned in nearly half of the reports (41%). Backup units delivered shocks to the patient in approximately one third of those cases (13% of total reports), though most of these reports failed to say what, if anything, the unit did.

Fifty-four (4.7%) of the malfunctioning defibrillators provided some sort of “battery low” indication, but an additional 110 (9.6%) units powered off unexpectedly (Figure 3). Only 17 (1.5%) of the adverse event reports included documentation of any sort of device maintenance program or schedule.

When reviewers identified a cause of device failure, pads/connectors (23.7%) and battery/power (23.2%) were the most frequently cited components (Table 2). In 20.6% of reports, reviewers were unable to determine the cause. Most cases attributed to “other” (79%) were because an error message was provided that was not meaningful to the user.

Only 133 (12%) reports were deemed unambiguous, though a much smaller number, 48 (4%), were thought to contain no useful information. The remainder were deemed “somewhat

Table 1. Answers to question 4 (“What did the backup unit do [if a backup unit is mentioned]?”).

Reviewer Response (N=1,150)	Number of Responses (%)
Backup unit advised no shock	29 (2.5)
Backup unit advised shock and delivered	150 (13.0)
Backup unit advised shock but did not deliver	3 (0.3)
Backup unit not used for defibrillation	5 (0.4)
No backup unit mentioned in report	675 (58.7)
Other action (specify)	288 (25.0)*

*In 94% of these reports, a backup unit was mentioned but there was no documentation of what the backup unit may have done (advised and shocked, advised no shock, etc).

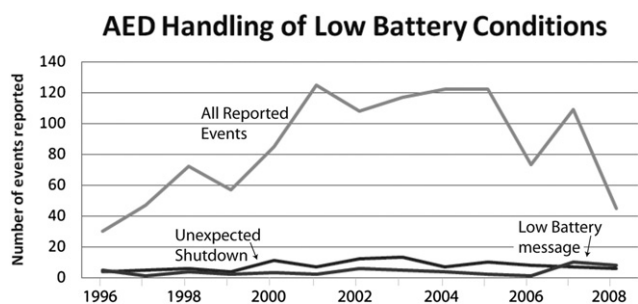


Figure 3. Number of adverse event reports in which the automated external defibrillator unexpectedly powered off and total number of reported broken down by year. The first unexpected shutdown report occurred in 1996 (event date is unavailable in MAUDE for 186 events, 10 of which are unexpected shutdowns). AED, automated external defibrillator.

clear—most key information present” (588 [51%]) or “somewhat vague—most key information missing” (381 [33%]).

Interrater agreement for each question is reported in Table 3. Percentage agreement is reported for reviewers 1 and 2, and the percentage of reports resolved by reviewer 3 is listed. The remainder was resolved by the arbitration committee.

LIMITATIONS

This is a retrospective study using an existing data set of deidentified adverse event reports. A prospective analysis would eliminate much of the ambiguity inherent in analyzing and abstracting the narratives.

Despite the steps taken to ensure highly trained reviewers and a robust instrument, our final interrater agreement between reviewers 1 and 2 was lower than anticipated. Most disputes were resolved by the third reviewer and, in the small number of cases that remained, the arbitration committee. Comparison of our final analysis with our preliminary analysis of a subset of the MAUDE data suggests that this represents noise inherent in quantifying the narrative reports because our major findings were fundamentally unchanged from those of the preliminary analysis.¹⁹

The most significant limitation to our study is MAUDE itself. In MAUDE, the FDA has provided what is arguably the largest publicly available database of device malfunctions. Because there is no central automated external defibrillator device registry maintained, MAUDE provides the closest surrogate, at least for the subset of devices in which a failure has been reported.

The FDA cautions investigators and the public not to use MAUDE to estimate incidence of device failure, and we have taken care to avoid extrapolating these data to produce any sort of generalized device failure rate. This is of particular concern for nonfatal events, for which reporting is voluntary, and the percentage of device failures reported to the FDA likely underrepresents device failures in the field.

FDA adverse event reporting is required by law if a device failure involves a patient fatality. In an attempt to minimize bias from underreporting, our study is limited to the events reported to the FDA in which the reported patient outcome was death. Underreporting is still possible; for example, if the treatment team decides that, although a device may have failed, it was not the cause of the patient’s death. The situation is further complicated for public access defibrillation programs, in which lay rescuers may lack the knowledge or confidence to determine that it was a device failure (and not their own) that led to the patient’s death. Lay rescuers may not even be aware of the mandatory reporting requirement.

Our analysis is significantly limited by the lack of corroborating information. This is most obvious in the case of rhythm analysis discrepancies, in which the category itself is so named because we lack the rhythm data to determine whether the user or the automated external defibrillator was correct in the initial analysis. Even when corroborating information might have been available to the rescuers, it is frequently not reported (eg, what a backup device did).

We did not perform subgroup analysis based on the source of the report. Although the FDA notes whether or not a health care provider filed the report, this cannot be taken to mean that the health care provider was present at the event. FDA reports might be filed by the medical director of a public access defibrillation program, according to a report from a lay rescuer. Similarly, manufacturers’ reports may summarize information relayed to them by the personnel who were present at the event and who may have no technical training.

Nonfatal events may be different in kind or frequency from fatal events related to automated external defibrillators. This issue is not explored in the present study because the optional nature of adverse event reporting in these circumstances makes any analysis of the data difficult to interpret.

DISCUSSION

Automated external defibrillators are an integral part of the American Heart Association’s chain of survival. Cardiac arrest provides a narrow window for therapeutic intervention and patient survival. We demonstrated that devices can fail

Table 2. Answers to questions in the analytic section.*

Reviewer Response (N=1,150)	No. (%) of "Most Likely Cause"	No. (%) of "Possible Contributors" [†]
Battery or power problems	267 (23.2)	612 (53.3)
Pads or connector problems	273 (23.7)	523 (45.6)
Rhythm analysis discrepancy	165 (14.3)	197 (17.2)
Voice prompts or user interface problems	7 (0.6)	33 (2.9)
Operator errors not related to rhythm analysis	23 (2.0)	186 (16.2)
Cannot be determined	237 (20.6)	N/A
Other cause (specify)	178 (15.5)*	N/A

*The first column contains responses for the single most likely cause (question 12). The second column contains the affirmative responses to whether a particular component could have contributed to the device failure (questions 7 to 11).

*In 79% of the cases classified as "other," the device produced an error message that was not meaningful to the end user (eg, "Bridge test failed" or "Pacer fault 117.").

[†]Because it was possible for reviewers to attribute a device failure to multiple possible contributors, the responses in this column total greater than 100%.

Table 3. Interrater agreement for data abstraction instrument.

Question	Reports	R1R2 Agree	R1R2 %	R3 Resolved	R3%
1. Defib event or not	1,284	1,144	89.1	1,279	99.6
2. Maintenance documented	1,069	1,054	98.6	1,277	99.5
3. When/how failed	1,069	738	69	1,208	94.1
4. What did backup unit do	1,069	820	76.7	1,256	97.8
5. Low battery message	1,069	1,059	99.1	1,278	99.5
6. Unexpected shutdown	1,069	1,032	96.5	1,277	99.5
7. Battery problems	1,069	812	76	1,236	96.3
8. Pads/connector problems	1,069	789	73.8	1,245	97
9. User interface problems	1,069	990	92.6	1,262	98.3
10. Rhythm analysis problems	1,069	963	90.1	1,267	98.7
11. Operator error	1,069	765	71.6	1,233	96
12. Most likely cause	1,069	598	55.9	1,204	93.8
13. Report clarity	1,069	478	44.7	1,219	94.9

R1R2%, Interrater agreement between reviewers 1 and 2; R3%, the percentage of questions disputed by R1 and R2 that were successfully resolved by R3.

anywhere in the power on–analyze–shock sequence and that 23% of reported failures could be attributed to battery and power problems. Unexpected shutdowns were classified as battery/power problems in the absence of "other" to suggest an alternative cause and occurred in 10% of reported cases. Regardless of cause, these errors went unrecognized during the automated external defibrillator self-test sequence.

Despite that automated external defibrillator failures are regularly reported to FDA, determining incidence rate remains problematic. MAUDE is frequently used for estimating incidence despite the FDA's warning not to do so.²⁰ Some argue this effect is mitigated because MAUDE contains a larger number of reports than other databases.²¹ It is tempting to calculate a failure rate based on the number of reports and manufacturer reports of units sold. However, failures are underreported for many types of devices. For example, one study estimated that as few as 1% of total adverse events were reported for automated implantable cardioverter defibrillators.^{22–24} A device registry has been proposed, but it is not clear how this would solve the underreporting problem.²⁵

When the data presented here were analyzed, individuals had the option of downloading a portable document format from the FDA Web site and filling it out or speaking by telephone with a representative. The FDA now provides a Web-based

reporting mechanism for MAUDE. The effect of Web-based reporting on rate or quality of adverse event reporting should be evaluated in a future study.

Most medical devices are used under close physician supervision. Public access defibrillation programs, although ostensibly having medical direction, may have little actual oversight. Some online companies selling automated external defibrillators offer "free prescription and medical oversight" as part of their service for all customers.^{26,27} It is uncertain how or even whether these entities would be informed of a device failure or whether they notify users of statutory reporting requirements. Underreporting can occur if consumers do not recognize the significance of the event or conclude that they were responsible for the device failure in some way and choose not to report the incident (eg, by not recognizing that an apparent battery failure identified a serious deficiency in a device's self-test algorithm).

Shah and Maisel¹⁶ examined automated external defibrillator service advisories, as well as adverse event reports, and concluded that failures are rare events. They identified 52 advisories affecting 385,922 automated external defibrillators during the period 1996 to 2005. They also analyzed data from the MAUDE database to determine actual device failures. They included "[a]ll automated external defibrillator and automated

external defibrillator accessory adverse event reports involving a patient death and submitted to the FDA between July 1996 and December 2005." Reports were analyzed by 2 reviewers and classified as "device malfunction," "no device malfunction," or indeterminate. Discrepancies were resolved by the 2 primary reviewers. Device failures were reported to have occurred in 370 reports (46.1%). The remainder were either "no device failure" or indeterminate.

We found a higher proportion of device failures in our analysis of MAUDE, but this was due to differences in our definitions of device failure. For example, Shah and Maisel¹⁶ classified a device displaying a "Red X" after power on and refusing to analyze the device rhythm and shock a patient as "not a device failure." We categorized any inability to complete the power-on-analyze-shock sequence as a device failure; in this instance, as "failed to analyze rhythm" (WHEN_HOW_FAILED). The root cause of the failure (MOST_LIKELY_CAUSE) would be "cannot be determined" because the "Red X" alone is not sufficiently descriptive to draw further conclusions.

The FDA provides a mechanism on their Web site to perform free-text searches of MAUDE, which been used by some researchers.^{28,29} It is attractive because it is easy to type in search terms and rapidly find records of interest. We were able to easily locate an adverse event report we had submitted to the FDA. However, different key words returned different record sets that were not subsets of one another. We used MAUDE device codes to improve the accuracy and consistency of searches. Even if a device is miscategorized, using the MAUDE device types guarantees that a consistent list of records can be obtained for a given timeframe.

Most other researchers have used MAUDE in a relatively unstructured fashion. One study built an instrument to assess tanning bed failures, but most other groups' descriptions of their analytic process are vague,³⁰ perhaps because of the difficulty in abstracting such free-form data, but it makes replicating their findings difficult. We have taken great pains to make our analytic process transparent and reproducible.

Despite the limitations of free-text searches, we acknowledge the difficulty of using the database in a more sophisticated manner. Our attempts to load MAUDE into Microsoft Access met with frustration because the data set exceeded the 2-GB limit. The data dictionary provided was adequate for determining linkages among tables, but building queries and views to filter the records of interest took considerable time. It was also necessary to construct an interface to work with the records. Improperly written software may corrupt the data set, but a robust system is expensive and difficult to implement.

Many MAUDE reports contain raw and incomplete data, and most reports come from manufacturers,²² which complicates analysis in the case of devices in which medical or surgical technique may play a role.²⁵ In most cases, we identified a single most likely cause of the device failure, but our analysis identified multiple possible culprits. Reports from lay

users may not be as complete or detailed as those of medical personnel.

Analyzing reports is challenging because corroborating data are frequently unavailable. Although users frequently reported that the automated external defibrillator incorrectly analyzed the rhythm, it is impossible to verify this without ECG data from the device. When automated external defibrillators first arrived on scene, Internet technology was still in its infancy, and the cost of ancillary data storage was high. Automated external defibrillator data collection and storage modules are offered, at least by some manufacturers, as options at additional cost.³¹ Today, consumers can receive regular software updates through the Internet for laptops, and portable music players allow us to carry gigabytes of information in our pockets. If all automated external defibrillators provided audio recording, ECG capture, and data collection on available parameters (such as cardiopulmonary resuscitation quality or battery level) and users were instructed to upload data after every event, a substantial improvement in the quality and completeness of the data available on automated external defibrillator usage and failure would be realized, without significant oversight burdens to existing public access defibrillation programs.

We conclude that, although not a specific aim of our research, a device-specific instrument could improve the quality of data collected. Despite our rigorous analytic process, we were unable to determine the cause of the device failure in 20.6% of reports. We found that a minority of reports lacked most key information required to determine the cause of the device failure (33%), and some had so little information that they were uncharacterizable (4%). Data on device maintenance and specific actions of backup devices were frequently absent. If a device-specific instrument was used during initial error reporting (whether in person or Web based), the chances of capturing valuable data would be increased.

This confluence of factors—underreporting, inadequate tools for analysis, and lack of structured data collection—poses significant challenges to manufacturers. In March 2009, one manufacturer recalled 180,000 defibrillators to fix a problem in the devices' self-testing algorithm for detecting battery-low conditions. The manufacturer's recall notice stated that they were aware of "one clinical report" despite that 50% of the unexpected shutdowns we identified occurred in units from this manufacturer and had been regularly reported to FDA for many years.^{32,33} Structured reporting instruments, automated upload of automated external defibrillator data, and better tools for analyzing MAUDE data might have helped the manufacturer identify this problem years earlier.

MAUDE contains useful data, but analysis is cumbersome. MAUDE meets a statutory requirement for collecting adverse event data, but problems of underreporting and the generic nature of the reports hinder timely detection of serious device problems, as illustrated by our example of unexpected device shutdowns.

Pads/connector and battery/power problems are the ones most frequently reported to the FDA. However, given that 20% of reports were sufficiently vague that no clear cause for the failure could be identified, improvements in reporting or analysis may reveal that other causes are more important than previously thought.

Nearly half of all reported device failures occurred during the attempt to deliver a recommended shock, and a significant portion of these failures are unanticipated device shutdowns. Because this is the last step in the sequence, earlier and better detection of problems with device charging or discharging has the potential to significantly reduce delays in the time to shock delivery.

Backup devices frequently delivered shocks when deployed. It may be desirable for public access defibrillation programs to maintain a backup unit if it is feasible to do so. Improved reporting would better help characterize the cost-effectiveness of backup automated external defibrillators.

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Author contributions: LAD and KRD were responsible for the development of the study as a whole. LAD, AS, LS, US, DS, and AP participated in successive phases of the development and refinement of the data abstraction instrument. LAD drafted the original article and all authors contributed substantially to its revision. LAD and US performed statistical analysis. LAD 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. LAD takes responsibility for the paper as a whole.

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