External Defibrillator Improvement Initiative

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Executive Summary

External defibrillators are medical devices that diagnose life-threatening abnormal heart rhythms, or cardiac arrhythmia, and treat them by delivering electrical energy to the heart to restore its normal rhythm. They are used in emergency situations on patients who have collapsed due to sudden cardiac arrest. When used in the first few minutes following collapse, these devices often save lives.

External defibrillators are used in many settings by medical professionals, emergency responders, and by trained and untrained bystanders. The technology is based on decades of research and evolving knowledge of effective defibrillation therapies and rescue sequences.

There is risk associated with all medical devices, and external defibrillators can malfunction. The defibrillator industry has conducted dozens of recalls for external defibrillators, affecting hundreds of thousands of devices. Additionally, the Food and Drug Administration (FDA) has received thousands of reports of external defibrillator malfunctions, including some where the device failure occurred during a rescue attempt and may have contributed to patient harm or death. While the FDA continues to advocate use of these important life-saving devices and is not recommending any change to current clinical practices, we believe the devices can be improved in ways that materially improve patient safety.

Given the large number of recalls and medical device reports received for all types of external defibrillators and for all manufacturers of such devices, the FDA is beginning an initiative to foster the development of safer and more effective external defibrillators through improved design and manufacturing practices, and urge industry to address current practices for identifying, reporting, and acting on the device complaints. This initiative is part of the FDA’s Center for Devices and Radiological Health’s (CDRH) 2010 Strategic Priorities to proactively facilitate medical device innovation, making available to manufacturers CDRH’s expertise and experience to improve the safety and effectiveness of marketed devices that have demonstrated safety problems and to facilitate the development of new devices to address unmet public health needs. It is representative of the agency’s balanced public health approach to foster innovation for the next generation of medical devices while assuring that devices that enter the market are and remain safe and effective.

FDA’s External Defibrillator Improvement Initiative will:

1. Promote innovation of next-generation external defibrillators to improve safety and effectiveness;
2. Enhance the ability of industry and the FDA to identify and resolve problems with devices currently on the market to address safety risks more quickly and effectively; and
3. Designate an appropriate premarket regulatory pathway for automated external defibrillators (AEDs) that promotes best practices for design and testing.
Background

External defibrillators (including automated external defibrillators, AEDs) are life-saving devices designed to restore normal heart rhythms following sudden cardiac arrest.

Each year, nearly 300,000 Americans collapse from sudden cardiac arrest. In sudden cardiac arrest, the heart unexpectedly stops pumping blood to the body. When normal heart rhythms are not restored quickly, sudden cardiac arrest can cause death.

Sudden cardiac arrest usually happens without warning, and the majority of people have no previously recognized symptoms of heart disease. Patient survival depends on a rapid sequence of rescue events that may include the successful delivery of a high-energy shock from an external defibrillator. Speed is critical -- first responders have only minutes before patients are beyond rescue. Each year, hundreds of patients in all kinds of settings are successfully rescued with the aid of external defibrillators.

1. Types of External Defibrillators

Defibrillators are devices that are designed to deliver electrical energy to the heart for the purposes of stopping a life-threatening cardiac arrhythmia and restoring the heart’s normal rhythm. The term “external defibrillator” is generally used to refer to any device that operates outside the body and delivers energy through paddles or electrode pads for the purposes of restoring normal heart rhythm.

The types of external defibrillators that are the subject of this initiative are as follows:

**Automated external defibrillators (AEDs)** can be semi-automated or fully automated. Semi-automated defibrillators analyze the heart’s rhythm, and if an abnormal rhythm is detected that requires a shock, then the device prompts the rescuer to press a button to deliver a defibrillation shock. Fully automated defibrillators deliver a defibrillation shock if commanded by the device software without user intervention. AEDs are used by trained users, first responders, and by untrained bystanders. They are used in homes and are increasingly found in public places such as airports, hotels, schools, and sports facilities.

**Monitor Defibrillators** are more complex devices that can include the ability to monitor different kinds of bodily functions such as blood oxygen level, pulse, and heart rhythm. These devices deliver external cardiac pacing and external defibrillation either manually or automatically. The monitor/defibrillators are used by medical professionals and are found mostly in hospitals and emergency medical systems.

**Manual external defibrillators** are used with (or have built-in) an electrocardiogram display to diagnose the rhythm of the heart. On the basis of the diagnosis, the clinician determines the energy level to be delivered to the patient. These devices are used predominantly in hospitals and on some ambulances.
2. **Uses of External Defibrillators**

External defibrillators are used in many settings, by people who have different levels of training. These training differences may play a role in external defibrillator performance.

- In the clinical setting, external defibrillators are used in emergency rooms, intensive care units (ICU) and throughout the hospital by trained professionals. Training is usually mandatory and refresher training is provided regularly. There are established systems for maintaining and assuring that the devices are ready to be used.

- Outside of hospitals, external defibrillators are used by emergency medical personnel and first responders such as police. The frequency and type of training required for first responders is set by employers and by state or local regulations.

- AEDs are found in airports, community centers, schools, government buildings, and other public locations. These devices are intended for use by the general public, but most require a prescription from a physician for purchase. Public Access to Defibrillation (PAD) programs make AEDs available in places where large numbers of people gather or where people who are at high risk for heart attacks live. PAD programs include training requirements. Currently, the American Heart Association provides training in basic life support (BLS) and advanced cardiac life support (ACLS) which includes the use of external defibrillators. Recertification in BLS and ACLS is required every two years. PAD programs must have a medical director who oversees the program and a program coordinator who is usually responsible for device maintenance.

- AEDs are also found in homes where they are intended to be used by minimally trained or untrained individuals.

3. **Causes for Concern**

External defibrillators are important, life-saving devices. However, over the past five years we have seen persistent safety problems with all types of external defibrillators, across all manufacturers of these devices. From Jan. 1, 2005 to July, 10, 2010, there were 68 recalls, exhibiting an increase from nine (in 2005) to 17 (in 2009, the last complete year for which data are available). During this period, the FDA received more than 28,000 medical device reports (MDRs), which also exhibited an increase from 4,210 (in 2005) to 7,807 (in 2009, the last complete year for which data are available). The FDA conducted multiple inspections of all external defibrillator manufacturers throughout this time period.

Many of the types of problems we have identified are preventable, correctable, and impact patient safety. As part of a comprehensive review the FDA identified several industry practices that have contributed to these persistent safety risks including industry practices for designing and manufacturing defibrillators, handling user complaints, conducting recalls and communicating with users. In some cases, these practices can contribute to device performance problems, place undue burden on users and put patients at risk.

To date, the FDA has addressed individual device problems on a case-by-case basis. However, our analysis of MDRs, recalls and inspections confirms that common problems persist across all types of external defibrillators and all manufacturers. Therefore, the FDA is taking steps to address these pervasive issues on an industry-wide basis.
The following are examples of industry practices contributing to continued safety concerns that the FDA identified during its review of external defibrillators:

**Engineering Design Practices.** Review of past recalls suggests that manufacturers of external defibrillators sometimes use design practices that lead to inconsistent device performance. In one example, a firm designed its voltage-monitoring circuit to draw power from the same power source it was intended to monitor. Because of this design, a momentary drop in the voltage caused a false signal to shut down the AED and the device was unable to deliver a shock, which may have caused a patient’s death. In another case, a firm used the wrong kind of component in one of the circuits, causing the device to be susceptible to interference from noise coming from the device’s power line. Good engineering design practices also require user interfaces (like dials, monitors, alarms, and connectors) meet users’ needs. Recent surveys suggest that improvements in user interfaces may be warranted.

**Manufacturing Practices.** The FDA’s analysis of recalls and inspections identified problems in how manufacturers test and incorporate components used in the manufacture of external defibrillators, as well as how they evaluate changes to the device before they are implemented to assure that device modifications do not adversely impact the safety and effectiveness of the technology. Between 2005 and 2010, the FDA issued nine warning letters to external defibrillator manufacturers, seven of which cited the firms for failing to appropriately control these aspects of their manufacturing process.

In several cases, manufacturers purchased components from suppliers who did not meet the manufacturers’ required specifications. In some cases, the problem with the component was due to a change in how the component was manufactured by the supplier. However, it is the manufacturer’s responsibility to assure that the components it receives meet its specifications.

**Communicating Systemic Problems to Users.** The FDA has observed cases where external defibrillator manufacturers have used a “fix-on-fail” strategy to deal with the problems they find. “Fix-on-fail” refers to the industry practice of identifying and trending problems on a case-by-case basis and repairing individual devices rather than communicating the problem to all users as part of the recall process.

In one example, a firm tracked hundreds of complaints tied to a known, trended defect. They serviced each device when it failed, but did not systematically notify other users of the problem so that these devices could be proactively evaluated and fixed if warranted. Companies must take appropriate actions when they identify known, trended defects by communicating to customers, conducting recalls when warranted, and reducing further device failures.

The FDA has also observed different industry practices for communicating the risk of device malfunctions to users. Some firms calculate these risks as the number of device failures out of the total number of months of device use, while others calculate the number of failures or deaths out of the number of products in distribution. These differences make it difficult for users to understand how common a problem is.

**Adverse Event Reporting.** From January 2005 through May 2010 the FDA received more than 28,000 adverse event reports for external defibrillators, including
malfunctions, patient injuries and deaths. The FDA found the amount and quality of information in these reports to be highly variable across manufacturers. For some firms, a significant proportion of their malfunction reports failed to contain adequate information about the root cause of the problem, which limits the FDA’s ability to identify, track, and address device safety problems and suggests that these manufacturers may not have conducted appropriate follow up in some cases.

Between 2005 and 2010, the FDA issued nine warning letters to external defibrillator manufacturers, four of which cited the firms for failing to appropriately report events.

**External Defibrillator Improvement Initiative**

The FDA is launching the *External Defibrillator Improvement Initiative* to foster the development of better-performing external defibrillators and to address current industry practices for designing and manufacturing devices and for identifying, reporting, and taking action to address device complaints they receive. The initiative will:

1. **Promote innovation of next generation external defibrillators to improve safety and effectiveness.**

   To promote innovation and better understand patient outcomes, the FDA is collaborating with the University of Colorado’s Department of Emergency Medicine to develop a multi-city AED registry. The registry will provide the infrastructure to foster the development of innovative AED features such as automated integration into local 9-1-1 systems. In July 2010, an initial meeting was held in Washington D.C., bringing together key stakeholder groups in discussions focused on the need for developing a comprehensive AED registry that can be used to track patient outcomes, optimize AED placement in communities and increase AED utilization by bystanders.

   Continuing this effort, the FDA will work with multiple stakeholders to facilitate the development of next-generation defibrillators, enhance surveillance of defibrillators in community settings, and improve the rapid delivery of treatment for sudden cardiac arrest patients. The FDA will host a public workshop on Dec. 15 – 16, 2010, to further these efforts, bringing together government, industry, academia, and users, including clinicians and consumers, to share perspectives.

   To assure that current and future devices are designed and manufactured appropriately, the FDA is also sending a letter to all manufacturers of external defibrillators encouraging them to meet with the agency early in the device development process to discuss ways in which they can avoid common problems in the design and manufacturing of these devices.

2. **Enhance the ability of industry and the FDA to identify and respond to problems with devices currently on the market to address potential safety risks more quickly and effectively.**

   The FDA will be working with device manufacturers to improve current industry practices for handling user complaints, reporting adverse events, failure analysis of device malfunctions, conducting recalls, and communicating with users. The Dec. 15-16, 2010
public workshop will discuss the nature, scope, and impact of the defibrillator problems that have been observed and outline expectations for how industry should improve compliance with FDA regulations. In addition, the multi-city AED registry will enhance surveillance of defibrillators in community settings to more rapidly identify and address potential safety problems.

3. **Designate an appropriate premarket regulatory pathway for AEDs that promotes best practices for design and testing.**

The FDA classifies medical devices into one of three categories based on the level of control necessary to provide reasonable assurance of safety and effectiveness. The classification process is a risk-based process that allows the FDA to apply the appropriate level of regulatory oversight before devices are marketed. Class III devices are those requiring the greatest level of control due to their life-saving impact, their potential for injury, or lack of information about how to control the device's risks.

Automated external defibrillators (AEDs) were given a Class III designation when they were determined to be substantially equivalent to similar Class III devices that were on the market prior to the 1976 Medical Device Amendments. They have always been regulated through the 510(k) process, a premarket pathway that is typically reserved for Class I and Class II devices, but which has also been used for some Class III devices that were allowed to be reviewed under the 510(k) regulations until reclassified or determined to require a PMA.

According to a 1990 amendment to the 1976 legislation, the FDA must either down-classify AEDs to Class II or keep AEDs as Class III and require they go through the more stringent Premarket Approval (PMA) process. The FDA is now proceeding with the formal classification of AEDs. In January 2011, the FDA is convening an advisory panel meeting to discuss which of these regulatory pathways is more appropriate for AEDs to provide reasonable assurances of safety and effectiveness for these devices.

A final decision about the classification and regulatory pathway for AEDs is anticipated to be published in 2011.

**Conclusion**

External defibrillators are used in hospitals, public places, and homes worldwide to save the lives of patients in sudden cardiac arrest. External defibrillators have contributed to significant improvements in patient care. However, they may occasionally malfunction. Through the **External Defibrillator Improvement Initiative**, the FDA seeks to support the benefits of external defibrillators while reducing the associated risks by promoting innovation, enhancing problem identification and response, and designating an appropriate premarket regulatory pathway for these devices. Because of their proven public health benefit, FDA continues to strongly encourage the use of external defibrillators when appropriate during the resuscitation of cardiac arrest victims.