Medical Policy
Automated External Defibrillator

Effective Date: October, 2009;
Revised [10/11; 10/13; 10/15]

Subject: Automated External Defibrillator

Overview: An automated external defibrillator (AED) is a portable machine that is designed to use an algorithm to distinguish ventricular fibrillation (VF) from other cardiac rhythms, advise the rescuer that a shockable rhythm is present, and then allow for the delivery of the appropriate amplitude shock to "restart" the individual's heart.

Policy and Coverage Criteria:

Automated external defibrillators for home use are **NOT** covered by Harvard Pilgrim. Their use in the home is considered investigation/experimental and unproven.

An international trial showed access to a home AED did not significantly improve overall survival compared to reliance on conventional resuscitation methods.

Exclusions: N/A

Supporting Information:

1. Technology Assessment: An automated external defibrillator (AED) is a computerized medical device. It can check a person's heart rhythm and can recognize a rhythm that requires a shock. The AED uses voice prompts, lights and text messages to tell the rescuer the steps to take.

2. Literature Review:
There is little published information on the efficacy of AED use in the home. The Public Access Defibrillation (PAD) Trial, a community-based prospective multicenter trial, was designed to determine whether the rate of survival would increase if laypersons are trained to attempt defibrillation with the use of AEDs. A diverse group of community facilities (e.g., shopping malls, recreation centers, hotels and apartment complexes) was recruited to participate. Each facility had to have a pool of potential volunteer responders and the ability to deliver an AED within three minutes to a person in cardiac arrest. The number of patients who survived to discharge after out-of-hospital cardiac arrest where volunteers recognized the event, telephoned EMS, and performed cardiopulmonary resuscitation (CPR) was compared to the number who survived to discharge when volunteers could also provide early defibrillation with an on-site AED. There were more survivors to hospital discharge in units assigned to have responders trained in CPR plus the use of AEDs (30 survivors/128 arrests) than in the group assigned to have volunteers trained only in CPR (15 survivors/107 arrests). When the data for arrests that occurred in residential units and public units are examined separately, however, there is no demonstrated survival benefit of CPR plus AED in residential patients. There were 37 arrests/one survivor in residential units and 95 arrests/29 survivors in public units in the group treated by CPR only, compared to 33 arrests/one survivor in the residential units and 70 arrests/14 survivors in public units in the group treated by CPR and AED. The authors concluded that training and equipping volunteers to attempt early defibrillation within a structured response system can increase the number of survivors to hospital discharge after out-of-hospital cardiac arrest. This study, however, does not provide evidence that AEDs in residences improve survival beyond what is achieved with standard EMS response.

The Home Automatic External Defibrillator Trial (HAT), an international, multicenter trial sponsored by the
National Heart, Lung, and Blood Institute (NHLBI), was designed to test whether an AED in the home of patients with intermediate risk of sudden cardiac arrest could improve survival (Bardy et al., for the HAT Investigators, 2008). A total of 7001 patients at 178 clinical sites in seven countries were randomized between 2003 and 2005. Patients in stable medical condition who had a previous anterior-wall Q-wave or non-Q-wave MI were randomized to receive one of two responses after a cardiac arrest occurring at home: either the control response that included calling emergency medical services (EMS) and performing cardiopulmonary resuscitation (CPR) \((n=3506)\), or the use of an AED, followed by calling EMS and performing CPR \((n=3495)\).

The primary outcome was death from any cause. Patients who were candidates for an ICD were excluded from the study. Evidence-based drug therapy was encouraged for all patients. Participants were required to have a spouse or companion willing and able to call for assistance from emergency medical services (EMS), perform CPR, and use an AED. The median follow-up was 37.3 months. A total of 450 patients died; 228 of 3506 (6.5%) in the control group and 222 of 3495 patients (6.4%) in the AED group \(p=0.77\). Only 160 deaths (35.6%) were considered to be from sudden cardiac arrest from tachyarrhythmia. Of these deaths, 117 of occurred at home and 58 events were witnessed. AEDs were used in 32 patients; 14 received an appropriate shock, and four survived to hospital discharge. No inappropriate shocks were documented. Access to a home AED did not significantly improve overall survival this intermediate risk population, compared to reliance on conventional resuscitation methods. The authors stated that the high proportion of unwitnessed events, the underuse of the AEDs in emergencies, rather than a lack of device efficacy, appear to explain these results.

On January 28, 2015, the FDA issued a final order to require the filing of premarket approval (PMA) application for automated external defibrillator (AED) systems. Prior to the FDA order, AEDs were eligible for FDA market clearance via a less rigorous 510(k) process. The FDA order comes as a result of concerns regarding AED failure. The agency received approximately 72,000 reports of device failure from January 2005 to September 2014. More than 2 million AEDs have been recalled by manufacturers since 2005 due to design and manufacturing issues, including inadequate control of components purchased from other suppliers.

There is not enough evidence in medical literature to demonstrate the safety, efficacy, and improved outcomes of use of an AED in the home. An AED in the home is primarily considered a safety device kept in the home as a precautionary measure to address a possible acute event, rather than a device for active treatment.

**Codes:**

E0617 - External defibrillator with integrated electrocardiogram analysis

**References:**


**Summary of Changes**

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<tr>
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