Automated External Defibrillation in the Occupational Setting

Larry M. Starr, PhD

On November 13, 2000, President Clinton signed into law H.R. 2498, the Cardiac Arrest Survival Act, designed to expand the availability of automated external defibrillators (AEDs) in public settings and that required the Secretary of the Department of Health and Human Services to establish guidelines for the placement of AEDs in buildings owned or leased by the federal government. In May 2002, President Bush signed into law the Community Access to Emergency Devices Act within H.R. 3448 (sections 159, 312, and 313) of the Public Health Security and Bioterrorism Response Act, and on June 12, 2002, he finalized this as Public Law 107-188. The provisions authorized the availability of grants to states and localities for the purchase and placement of AEDs in public places where cardiac arrests are likely to occur and encouraged private companies to purchase AEDs and to train employees in cardiopulmonary resuscitation (CPR) and emergency defibrillation.

To support AED federal legislation, to increase awareness and value, and to offer recommendations about AEDs in the occupational setting, the American College of Occupational and Environmental Medicine (ACOEM) has included the *AEDs in the Workplace* Web site, containing survey data, case studies, reference database, and other academic and practice resources, in their Health and Productivity Management Center.[1] ACOEM also issued in 2001, and reaffirmed in 2006, a position statement on AEDs in the workplace.[2] This document updates that statement by addressing the following topics: (1) history and overview of AEDs; (2) epidemiology, morbidity, mortality, and incident locations; (3) sudden cardiac arrest (SCA) and the "chain of survival" paradigm; (4) AED technologies; (5) public-access defibrillation; and (6) guidance for the use of AEDs in occupational settings.

HISTORY AND OVERVIEW OF AEDS

Making its debut in 1979, the term "AED" commonly refers to any device that analyzes cardiac rhythm and enables the delivery of an electric shock when necessary.[3] Utilizing solid-state circuitry and microcomputer technologies, AEDs identify ventricular fibrillation (VF) and ventricular tachycardia (VT) then voice prompts a user to prepare for delivery of a shock. Two modes of AED are available. An "automated" AED analyzes then prompts a user to press a button to deliver a shock. Some AEDs are multifunctional and can be set to operate in "automatic" mode, which analyses and delivers a shock without a user prompt.

Annual sales and the total number of AEDs in the United States are difficult to confirm. One study published in 2006 estimated that more than 200,000 are sold annually for public use in the United States.[4] A 2011 industry report estimated that total US sales in 1996 were approximately 18,645 devices, and by 2006 total sales had reached more than 775,000, an increase of 30% per year over the decade.[5] Annual revenue forecasts for the defibrillator market by 2015 are estimated to be $1.7 billion in the United States,[4] and when implantable cardioverter defibrillators are included, in excess of $11 billion globally.[6]

Submitting key words, "automated external defibrillator," to the National Library of Medicine's pubmed.gov search site produces more than 11,000 scholarly papers written about AEDs including clinical and field reports. Although some devices have had safety alerts and recalls commonly attributed to manufacturer quality control,[4,7] most research has demonstrated that overall, devices are safe, effective, accurate, and increasingly cost-effective.[8–12] As AEDs are easy to transport due to reduced size and weight (less than 7 pounds),[13] and because federal and state legislation enables and provides liability protection to acquirers and users,[14] AEDs are a standard of care device for health and allied health providers and are commonly available within medical institutions and for emergency medical services and fire departments, and police officers.[15,16] More than 30 years of evidence has also shown that little or no training or education is required for proper use,[17–20] because devices have easy-to-follow audio and visual prompt instructions,[21–23] or operate automatically without user decision making after pads are placed on the chest of the patient. For these reasons, AEDs are commonly available for voluntary emergency first aid responders and untrained bystanders who may be present at the scene of a cardiac arrest. This open access is promoted in part because the *2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations* published by the International Liaison Committee on Resuscitation (ILCOR), which represents principal resuscitation organizations worldwide including the American Heart Association (AHA), European Resuscitation Council, and the Heart and Stroke Foundation of Canada has recommended that "AED use should not be restricted to trained personnel. Allowing the use of AEDs by persons without prior formal training can be beneficial and may be lifesaving. Because (however) even brief training improves performance (eg, speed of use, correct pad placement), it is recommended that training in the use of AEDs be provided." [24]

As rapid use saves lives, AEDs are available for lay citizens across a broad spectrum of private and public locations including airports, casinos, community centers, educational institutions, and sports and shopping centers, and in tens of thousands of occupational settings where they are provided for use by health care and nonmedical first aid responders. Indeed, data collected from May 1, 2006, to April 30, 2007, from the Resuscitation Outcomes Consortium, an observational study involving 13,769 out-of-hospital cardiac arrests from 10 North American sites (8 US and 2 Canadian), showed that overall survival to hospital discharge was 7%, survival with bystander CPR but no AED was 9%, and when an AED was used and shock delivered survival was 38%.[25]

EPIDEMIOLOGY, MORBIDITY, MORTALITY, AND INCIDENT LOCATIONS

Cardiovascular diseases (CVD), including coronary heart disease and SCA, remain significant concerns to general public health and the occupational setting in particular. According to the 2011 statistical

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Address correspondence to: Larry M. Starr, PhD, Organizational Dynamics Graduate Studies, University of Pennsylvania, 3440 Market Street, Suite 100, Philadelphia, PA 19104-3335 (lstarr@sas.upenn.edu).

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update provided by the AHA an estimated 82,600,000 American adults have one or more types of CVD.[26] Of these, 40,400,000 are estimated to be younger than 60 years. Total CVD includes 76,400,000 people with high blood pressure, 16,300,000 with coronary heart disease, 7,900,000 who experienced myocardial infarction, 9,000,000 with angina pectoris, 5,700,000 with heart failure, and 7,000,000 who experienced a stroke.

The AHA noted that CVD accounted for 33.6% (813,804) of all 2,243,712 deaths in 2007 (the most recent data available), an average of one death every 39 seconds.[25] Data have also indicated that approximately one of every six or 406,351 deaths in the United States resulted from coronary heart disease. The AHA estimate for 2011 is that 785,000 Americans will have a new coronary attack, approximately 470,000 will have a recurrent attack, and an additional 195,000 silent first myocardial infarctions will be identified.

A significant number of cardiac arrests occur in out-of-hospital locations. Out-of-hospital cardiac arrests data collected by emergency medical service programs in Seattle and King County, Washington, from January 1, 1990, through December 31, 1994,[27] revealed that public sites represented 16% of incidents. The Resuscitation Outcomes Consortium examined the period 2005–2007 for seven US sites (Alabama, Dallas, Iowa, Milwaukee, Pittsburgh, Portland [Oregon], and Seattle and King County) and three Canadian sites (Ottawa, Toronto, and Vancouver) and reported 12,930 out-of-hospital cardiac arrests, of which 15.8% occurred in public locations.[28] In a 2007 report of the Save Hearts in Arizona Registry and Education program, which reviewed emergency medical services (EMS) first-care reports submitted voluntarily by 30 municipal fire departments responsible for approximately 67% of Arizona's population, the total number of out-of-hospital adult arrests of presumed cardiac etiology reported statewide was 1097.[29] Of these, 15% occurred in public locations.

There are several electrical abnormalities that result in SCA, but the majority of deaths begin with an initial rhythm of VF.[30–32] If VF is not treated quickly, nearly all patients degenerate to asystole,[33] which is fatal.[34] In patients known to have ischemic heart disease, the out-of-hospital cardiac arrests incidence of VF and VT is 80% to 90%.[35]

Over the past three decades, the recorded incidence of VF or pulseless VT as the initial rhythm encountered by EMS in out-of-hospital cardiac arrests has decreased significantly,[36,37] from approximately 70% to 23%,[25,38] with an overall incidence of 26%.[27] Ventricular fibrillation or VT is higher for bystander-witnessed events in public and occupational settings, because bystanders arrive sooner than EMS; thus, survival to hospital discharge is nearly three times higher when an AED is applied by a lay responder after a cardiac arrest in a public location than in a private home where the initial assessment and responses are primarily made by EMS (34% vs 12% for arrests at home).[39] The consensus of science to correct VF and pulseless VT is immediate chest compression followed by a single electric shock with a controlled dose and duration of energy followed by resumption of chest compressions. If circulation does not return, this is followed by a sequence of compression and electric shock with the same or with increasing energy levels.[40]

Cardiopulmonary resuscitation without electric therapy may sustain a patient in VF for a short time but only rarely restores an organized rhythm. Indeed, performing CPR in the period of 1.5 to 3 minutes before defibrillation does not necessarily improve survival for patients with out-of-hospital VF or pulseless VT.[41,42] And delaying CPR even for AED rhythm assessment is associated with decreased probability of conversion of VF to another rhythm.[42,43] As return of an adequate perfusing rhythm requires immediate application of the combination of CPR, defibrillation, and pharmacotherapy as soon as possible after arrest, establishing controls to support these enhances the probability of survival.

SUDDEN CARDIAC ARREST AND THE CHAIN-OF-SURVIVAL PARADIGM

Factors contributing to out-of-hospital survival following SCA have been described primarily in terms of a time-related, linear chain-of-survival paradigm.[44,45] The sequential interventions (links) leading to survival are (1) early recognition and call for EMS; (2) early initiation of basic life support CPR; (3) early defibrillation (AED); and (4) early advanced (cardiac) life support (ALS) primarily involving drug intervention protocols. Following the release of the *2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*, a fifth link, integrated post–cardiac arrest care, was added.[46]

Sudden cardiac arrest survival has been described as dependent on the sequential availability of the links although more advanced applications may jump ahead of lesser ones. For example, if workplace allied health personnel or the arriving community EMS responders are not qualified or prepared to deliver ALS, this link may not be available until the patient arrives at a medical center. If CPR-trained first aid responders initiate chest compressions in conjunction with an AED, and this is quickly followed by intervention by ALS-level responses, then timing between these links will likely be shorter.

In a systematic review of literature through 2008, the factors most correlated with survival to hospital discharge following out-of-hospital cardiac arrest were witnessed by a bystander, witnessed by EMS, applying bystander CPR, being found in VF or VT, and achieving return of spontaneous circulation.[47] Without intervention, survival following SCA decreases rapidly to zero. Several studies have reported that for each minute of untreated cardiac arrest, the probability of successful rhythm conversion decreases by up to 10%, producing an equivalent per-minute-death rate.[48,49] Conversely, survival rates as high as 90% have been reported when the collapse-to-defibrillation ("drop-to-shock") time is within 1 minute.[50–52]

To empirically define the contribution of each link in the chain of survival, data from the Seattle experience were examined between 1976 and 1991.[49] A best-fit model demonstrated the following equation:

Survival rate = 67% at collapse − 2.3% per minute to CPR − 1.1% per minute to defibrillation − 2.1% per minute to ACLS

As noted by the authors,

> The regression constant, 67%, represents the probability of survival in the hypothetical situation in which all treatments are delivered immediately after collapse to patients with prehospital cardiac arrest . . . . With delays in CPR, defibrillatory shock, and definitive care, the magnitude of the decline in survival rate per minute is the sum of the three coefficients (−2.2%, −1.1%, −2.1%), or −5.5%.[49]

Although the chain-of-survival paradigm is an established metaphor, some argue that it is too simple because the forces that affect survival are complex.[53] For example, when the four survival categories are examined in more detail, at least 50 "known or speculative" and additional "yet to be identified" factors not included in the chain can be acknowledged as influencing SCA survival.[54] In addition, only approximately 7.9% of victims survive out-of-hospital cardiac arrest in the United States (a number that has not changed significantly in almost 30 years[47]) and there is a fivefold difference in survival rate among US communities.[38] Thus, some commentators have called for a rethinking of the approach to cardiac arrest in terms of relevant links,[55] and the use of a chain metaphor.[56]

AED TECHNOLOGIES

AED Analysis of Rhythms, Waveforms, Energy Levels, and Application

Automated external defibrillators utilize microprocessors to analyze several

characteristics of the surface electrocardiogram signal. Wave frequency, amplitude, and some integrated features such as slope or morphology are identified and compared with preset values. In an unresponsive, nonbreathing, pulseless patient, an AED will advise shocks for monomorphic and polymorphic VT, supraventricular tachycardia, or VF.

Early AED models offered monophasic or biphasic waveforms. Monophasic waveforms provide current flows in a single direction (polarity). When the rate at which the pulse falls to zero is gradual, they are referred to as monophasic damped sinusoidal. When the rate is instantaneous, they are called monophasic truncated exponential. Biphasic waveform defibrillators deliver a sequence of two pulses in which the second is of opposite polarity to the first. Although biphasic damped sinusoidal and biphasic truncated exponential are both technically possible, almost all AEDs currently provided are biphasic truncated exponential devices.

Reviewing all levels of evidence, ILCOR and AHA recommended that for a biphasic truncated exponential waveform for defibrillation of pulseless VT/VF cardiac arrest, it is reasonable to start with an energy level of 150 to 200 J.[40] Although they note that there is insufficient evidence to determine the initial energy level for any other biphasic waveform, initial and subsequent shocks using this waveform should be at 360 J. Although there is lower total shock success for monophasic defibrillation,[57] in the absence of a biphasic defibrillator, a monophasic defibrillator is acceptable and use of a high initial energy (360 J) seems preferable.[40]

Shock success is usually defined as termination of VF 5 seconds after the shock. When defibrillation is required, a single shock should be provided with resumption of chest compressions/CPR immediately after the shock. Chest compressions should not be delayed for rhythm reanalysis or a pulse check immediately after a shock. For second and subsequent biphasic shocks, the same initial energy level is acceptable.

Device "Errors"

With the increase in size and competition of the AED manufacturing and distribution market over the past decade, the defibrillator industry has recalled hundreds of thousands of devices and has notified the US Food and Drug Administration (FDA) about thousands of adverse incident reports including device failure during a rescue attempt that may have contributed to patient harm or death.[58] In response, the FDA's Circulatory System Devices advisory committee has discussed whether additional regulatory controls may be needed to ensure safe and reliable performance and long-term monitoring of devices.[59,60] Despite these reviews, the remarkable lifesaving benefits continue to outweigh the number or nature of reports so federal agencies including FDA and the Occupational Safety and Health Administration continue to advocate use of these important lifesaving devices. Indeed, there is no recommendation from any federal, state, or medical agency to make any change to current AED clinical practice.

PUBLIC ACCESS DEFIBRILLATION

The public access defibrillation (PAD) concept gained momentum in 1992 when the AHA Task Force on the Future of CPR challenged the medical device industry to create AEDs that would make early defibrillation accessible to the public.[61] Public access defibrillation applies to all US organizations including the federal government,[62] and is defined as out-of-hospital cardiac arrest treated with an AED by persons other than the community-designated personnel. For example, the state of Maryland PAD exempts from PAD policy "all healthcare facilities, physician's offices, dentist's offices, federal government agencies, jurisdictional EMS operational programs, and commercial ambulance services."[63]

The rationale for PAD was based on the concern that in many densely populated areas, traditional EMS responders cannot respond in sufficiently short time to perform resuscitation and maximize survival. It was determined that training and equipping lay responders to use AEDs and provide resuscitation until arrival of EMS was a practical and appropriate solution to that problem.

All US states have passed a version of PAD legislation describing the process of acquisition, control, and use of an AED by lay responders. Elements commonly addressed in state legislation include immunity for rescuers, acquirers, and enablers; training requirements for users; medical supervision or involvement; and EMS notification. A summary of the details of state PAD legislation is available in AED-information databases such as the National Conference of State Legislatures,[64] and the National Center for Early Defibrillation.[65]

Although survival from PAD has been shown to be increasing and effective,[66] and although PAD legislation requires AED sales to be state-registered, registry compliance and governance continue to show challenges. For example, a 2004 review of PAD in North Carolina indicated that the state EMS database contained only 18% of PAD locations, suggesting that there are a large number of AEDs placed in communities that are not registered within the community PAD system.[67] Arlington, Texas, with a population of more than 365,000, provides a list and map of only 32 AEDs available for "all businesses."[68] In Philadelphia, researchers from the University of Pennsylvania have designed a contest to find AEDs in the city to "enable us to build a comprehensive map and registry of Philadelphia AEDs that can be used in emergency situations by the 911 center and the public."[69]

GUIDANCE FOR THE USE OF AEDS IN OCCUPATIONAL SETTINGS

Federal and state government agencies and dozens of professional, safety, and medical societies have issued AED position statements over the past decade.[70] Occupational Safety and Health Administration has established partnerships with the American Association of Occupational Health Nurses[71] and ACOEM,[72] in which resources are offered to occupational sites including reference to the ACOEM AED guidance[73] and by citing that "volunteers trained in CPR and the use of AEDs had twice as many victims survive compared to ... volunteers trained only in CPR."[74] The following are updated ACOEM guidance for the use of AEDs in the occupational setting.

Establishment of a Management System for the AED Program

A management system should be established within each organization to have clearly defined lines of responsibility for those who oversee and monitor the program.

Medical Direction and Administrative Control of the AED Program

A qualified medical director should be assigned to manage all medical aspects of the AED program. Medical direction responsibilities include but are not limited to providing the required written authorization to acquire the AED and performing a case-by-case review each time the AED is used in the occupational setting.

An administratively qualified person should be responsible for the program's overall administration and coordination activities. Responsibilities include but are not limited to establishing or integrating the AED program with an ongoing quality assurance system, ensuring compliance with industry-related and other regulatory requirements, ensuring proper interface with local EMS, and ensuring proper education, training, or support for AED users prior to and following use.

Awareness of and Compliance With Federal and State Regulations, and Policies

An occupational AED program must comply with appropriate federal guidelines such as the Cardiac Arrest Survival Act and federal and state PAD legislation. As the details of state PAD legislation vary, a single

corporate policy for a geographically separated organization may be insufficient unless it addresses all elements where the AEDs are placed. An occupational AED program should address and be in compliance with relevant medical practice insurance requirements and insurance programs for the organization, and for occupational physicians and nurses, and any programs affecting lay responders.

Development of a Written AED Program Description for Each Location

A written summary of the AED program should be prepared, distributed, and discussed with all relevant (eg, administrative, safety, security, health care) personnel at an occupational facility. As state PAD legislation requires registration of AEDs and EMS notification, and may require additional communication to ensure smooth application of medical protocols, all information associated with PAD state requirements and compliance should be included in the written program.

Integration With an Overall Occupational Emergency Response Plan and Coordination with Local Emergency Medical Services

The AED program should be a component of the more general plan describing emergency responses at the occupational setting. Topics addressed by the AED component should include but not be limited to the awareness and placement of AEDs to ensure easy and timely access; procedure for notification of suspected cardiac emergency to occupational medical, trained first aid responders, and bystanders; assessment of scene and patient; proper body substance isolation procedures; CPR and AED response protocols; clinically appropriate patient transport to a medical facility including how continuation of care will be ensured; occupational responder and bystander debriefing; equipment review, service, and replacement; and methods to review follow-up care.

Coordination with local EMS should be part of an integrated plan. This includes but is not limited to review and coordination between EMS protocols and occupational response protocols; communication and logistic support to ensure rapid EMS access to the occupational site and to patient location; collaboration between EMS and occupational responders about on-site patient treatment and supervision; transition from the occupational site to the local medical center; and integration of occupational follow-up protocols with those at the medical center.

Selection and Training of Responders

Although an AED should be used by the first available bystander, trained or not, all designated occupational first aid responders and all occupational health care users should receive training that is recognized and standardized. Topics should include adult (and child, if appropriate) CPR and use of the specific AED expected to be available and used at the occupational site. Short video/computer self-instruction (with minimal or no instructor coaching) that includes synchronous hands-on practice ("practice-while-you-watch") in basic life support can be considered as an effective alternative or retention method to instructor-led courses. Occupational medical and administrative leaders are encouraged to identify individuals at the workplace who would be regularly trained in CPR/AED and first aid or ALS procedures, if appropriate to the work environment. Such people would be more likely to recognize, respond, and support the responses of bystanders when SCA or another medical emergency occurs.

Selection of AEDs

All AEDs must meet federal FDA medical device and federal and state PAD legislation criteria. Automated external defibrillator devices should also meet the most current recommendations of ILCOR and AHA. When an older, previously acquired device is available, training of responders should address any aspects of the device that vary from current recommendations.

Selection of and Placement of AED and Ancillary Supplies

Ancillary supplies should be available for use when managing an occupational SCA involving an AED. Examples include but are not limited to bloodborne pathogens responder and cleanup kits to ensure compliance with body substance isolation procedures,[75] CPR barrier masks with one-way valve, AED responder kits to support application of self-adhesive defibrillation pads (razor to shave chest hair and towel to dry the chest after removal of a transdermal patch),[76] and a CPR audio prompting device to guide action and timing sequences of CPR ventilations and compressions.[77,78]

As dyspnea, hypoxemia, or signs of heart failure or shock are indications for oxygen administration and as use of 100% oxygen during adult cardiac arrest continues to be part of the recommended treatment algorithm according to ILCOR and AHA,[24] a CPR resuscitation mask with an oxygen port to permit delivery of supplemental oxygen for the breathing or nonbreathing patient and a portable emergency oxygen device should be available. To support this, the 2011 training guidelines issued by the American Red Cross[79] and the National Safety Council[80] include administration of oxygen as part of AED and CPR responding. Also, FDA medical device and drug policies continue to recognize emergency oxygen as appropriate for use without prescription by properly trained personnel.[81] Precautions to minimize sparking from the paddles/pads and avoidance of use when high-flow oxygen is directed across the chest should be taken.[58]

When practical, AEDs and ancillary supplies should be placed to allow initiation of resuscitation and use of the AED ("drop-to-shock" interval) within as brief a period of time as possible following suspected cardiac arrest. As probability of survival reportedly can decrease by 7% to 10% per minute until defibrillation,[49] a 5-minute response time is a goal. Estimating the time needed for transport and set up of the AED in various work areas can help determine whether a proposed location is appropriate.

Schedules for Training/Retraining

As life support knowledge and skills, both basic and advanced, can deteriorate in as little as 3 to 6 months, frequent assessments and, when needed, refresher training are recommended to maintain knowledge and skills.[79]

Scheduled Equipment Maintenance and Replacement

A preventive and postresponse service procedure should be established. Records should be maintained for the AED and all ancillary supplies.

Establishment of an AED Quality Assurance Program

The AED program should be incorporated into or have its own quality assurance program. Elements should include but are not limited to medical review by a qualified physician after every AED use; record keeping of all AED-related training, locations, servicing; and records of all medical reviews following AED use. In addition, a method to evaluate the efficacy of the program against its objectives (educational and administrative), and a method to improve or sustain critical elements should be provided.

Cost of Start-up and Continued Management

Administrators and health care practitioners should be aware that *acquiring* an AED is one element of a comprehensive and ongoing program. Costs must be identified to initiate (eg, acquisition of the device, training, and materials; administration, coordination) and to sustain the continued operation of a program. These ongoing costs should be monitored.

CONCLUSION

Development of a program to acquire and utilize AEDs is a reasonable, appropriate, and increasingly common aspect of managing SCA in the occupational setting. However, acquiring the AED is but one of the elements necessary for such a program. To comprehensively address the prevention of SCA morbidity and mortality among working age adults, a complete AED program is recommended.

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