

The Automated External Defibrillator Clinical Benefits and Legal Liability

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SUDDEN CARDIAC ARREST IS THE MOST COMMON CAUSE of death in the United States, accounting for an estimated 350 000 deaths annually, and it is a leading cause of disability and health care costs.¹⁻⁵ Life-threatening cardiac arrhythmias such as ventricular tachycardia or ventricular fibrillation usually cause sudden cardiac arrest.⁶⁻¹⁴ Early defibrillation of ventricular tachycardia or ventricular fibrillation is necessary to resuscitate individuals with cardiac arrest, and survival depends directly on the time to defibrillation. Automated external defibrillators (AEDs) reduce the time to defibrillation and have improved survival rates.⁶⁻¹⁴ Although clinical benefits of AEDs are established, individuals, institutions, and organizations implementing AED programs have faced a seemingly complex and evolving legal and regulatory landscape. However, compliance with relevant regulations minimizes legal risks of AED ownership, use, or medical oversight.^{15,16} Healthcare professionals should be aware of the clinical benefits of AED programs and strategies for risk management.

Evidence Supporting AED Use

In an effort to improve survival from cardiac arrest, the American Heart Association has promoted the Chain of Survival concept, describing a sequence of prehospital steps that result in improved survival after sudden cardiac arrest.^{1,17} These interventions include rapid access to emergency medical services by calling 911, prompt cardiopulmonary resuscitation, early defibrillation when indicated, and early initiation of advanced medical care. Early defibrillation has emerged as the most important intervention with survival decreasing by 10% with each minute of delay in defibrillation.⁶

Multiple studies and meta-analyses⁸⁻¹⁴ have demonstrated that early defibrillation improves survival for individuals with sudden cardiac arrest. Despite this evidence, many communities continue to have poor survival rates because of long response times of emergency personnel and delays in delivering definitive therapy with defibrillation.⁵ To address these limitations in the chain of survival, the concept of public access to defibrillation has been promoted to

expand the use of an immediately available defibrillator for minimally trained first-responders such as police officers, firefighters, security guards, flight attendants, and trained laypersons.^{1,6,17} In one small study, AEDs were safely and successfully operated by sixth graders who performed defibrillation in 90 seconds in a simulated resuscitation; in the same study, trained paramedics performed defibrillation in 67 seconds.¹⁸ In another small study of AED use in airports, 11 of 18 individuals with cardiac arrest due to ventricular fibrillation were alive and neurologically intact at 1 year¹⁹ and 6 of the 11 successful rescuers were travelers who did not have formal AED training.¹⁹

The Public Access to Defibrillation Trial demonstrated that trained laypeople can use AEDs safely and effectively to provide early defibrillation.⁵ In this prospective randomized trial, 993 communities were randomized to cardiopulmonary resuscitation training with response by emergency personnel or a trained layperson with an AED. Survival in the AED groups was nearly 2-fold greater.⁵ Of 129 cardiac arrests in the cardiopulmonary resuscitation plus AED communities, 29 patients survived. Of the 103 cardiac arrests in the communities trained only in cardiopulmonary resuscitation, 15 survived. In 21.5 months of follow-up, there were no adverse events related to AED use. No patient received an inappropriate shock or failed to receive a needed shock. The Public Access to Defibrillation Trial demonstrated that training and equipping volunteers within a structured response system increases the number of survivors after out-of-hospital sudden cardiac arrest in public locations, and that trained laypersons can use the AED safely and effectively.⁵ Based on their proven benefit, AEDs are increasingly being used in public and private locations.²⁰

Federal Policies and Legal Considerations

Federal laws provide the basic framework for limiting liability for AED ownership, oversight, and use.^{15,16} Until recently, expansion of AED programs has been hampered by largely unfounded concerns regarding legal liability.^{15,16,21} To address liability concerns, state and federal Good Samaritan legislation has been developed specifically to protect responders using AEDs.^{22,23} Good Samaritan legislation refers to statutes that provide immunity from claims

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of negligence for a volunteer aiding others. Such laws are intended to reduce hesitation to aid others because of liability concerns.

The federal Cardiac Arrest Survival Act (CASA)²² was enacted in 2000 with provisions to encourage AED use in federal buildings and create immunity for qualified individuals who use AEDs.^{22,23} CASA provides conditional immunity from legal liability for harm resulting from use or attempted use of an AED by lay responders, but does not provide protection from liability for licensed or certified health care professionals acting within the scope of their license and within the scope of their employment. Paid educators or medical oversight physicians are probably not protected by CASA.^{22,23} If those who acquire the AED provide appropriate training, properly maintain the AED, and notify local emergency medical authorities, they also qualify for immunity.^{22,23} Each state has its own Good Samaritan protections and the levels and scope of protection provided vary by state. However, CASA provides a basic level of protection to a broad class of persons using or acquiring AEDs in out-of-hospital settings. If CASA provides protection to a particular class of persons and their state does not, CASA supersedes the state law to the extent necessary to protect the users or acquirers.²²⁻²⁴

AEDs are regulated by the US Food and Drug Administration, which has the responsibility of overseeing medical device manufacturing, sales, and postmarketing surveillance.²⁵ In September 2004, the Food and Drug Administration authorized sales of AEDs without a prescription.^{26,27} One potential benefit of this approach is that public perception may change from viewing AEDs as complex medical devices to viewing them as consumer safety products, like smoke detectors or fire extinguishers. The Food and Drug Administration's clearance language generally specifies that AEDs be used by trained individuals, but allows local authorities to determine specific training requirements.²⁸ All AED models have similar features and the slight differences allow them to meet a variety of needs. Potential buyers including those purchasing for individual, institutional, or business use should consider all models and consult with their local emergency medical services.

The Medical Aviation Assistance Act of 1998 (CFR 121.803 [b]⁴), the first federal AED mandate in any setting, led to a study that resulted in mandating AEDs and training of flight attendants in most commercial aircraft effective in 2004. Other perhaps lesser known federal legislation pertaining to public access defibrillation programs and AED use also has passed. For instance, the Rural Access to Emergency Devices Act of 2000 or Rural AED Act authorized appropriation of \$25 million to equip rural areas with AEDs (Public Law 106-505). The Community AED Act of 2002 allocated \$30 million in funding to cover all expenses associated with instituting public access to defibrillation programs (Public Law 107-188). Similarly, AED use in workplaces and businesses is strongly encouraged by the Occupational Safety

and Health Administration.^{29,30} These federal programs and policies reflect increased recognition regarding the public health benefits of AEDs by legislators and policymakers.

State Policy and Legal Considerations

All 50 states have Good Samaritan laws that vary in scope and conditions but that match, supplement, or even supersede the basic protections from liability afforded by federal regulations.²⁴ The state AED program requirements generally include the provisions of Good Samaritan immunity, medical oversight, agency notification, policies, quality assurance measures, training, AED maintenance, and postevent reporting. Those considering starting an AED program should consult and adhere to state regulations to minimize potential risks associated with AED ownership, oversight, or use.²⁴ The application of federal and state provisions for liability protection in specific situations is complex, such that answers to contested liability issues may be provided by the courts in the future

Some states have gone beyond Good Samaritan legislation to mandate AED placement. Current legislative mandates that have either passed or are pending include AED use in public schools in Pennsylvania (Pennsylvania SB 459; 568; HR 996; and Act 4 of 2001, section 1423), New York (New York Education Law § 917), Nevada (Nevada Revised Statutes § 450B.600 1.a), California (California AB 760), Delaware (Delaware H 332, 430; Title 16 Health and Safety, Part II, Chapter 30c), Florida (Florida H411), Georgia (Georgia S566), Illinois (Illinois SB1559, 1560, 2038, 2046), Maine (Maine LD1432), Massachusetts (Massachusetts HB 971), New Jersey (New Jersey SB 2170, 446, 141 AB 901), Rhode Island (Rhode Island SB 2239, H 7336, SB 2276, 2277), and Virginia (Virginia HB 2097, HB 1049).

The American Heart Association supports AED placement in selected schools.³¹ Preliminary outcomes data related to AED placement in schools have been published.³² Several states including Illinois (Illinois Public Act 93-0910), New York (New York General Business Law § 627-a), Rhode Island (Rhode Island General Laws Chapter 5-50, Public Law No 440), California (California AB1507), Louisiana (Louisiana Act No 885), and Arkansas (Arkansas HB1970) have followed the American Heart Association's recommendation for AED placement in selected health clubs.³³ AEDs are mandated in public buildings in several states, including Arizona (Arizona Revised Statutes § 34-401), California (California Government Code § 8455), Nevada (Nevada Revised Statutes § 450B.600 1 e and f), New Jersey (New Jersey Statutes Annotated § 2A:62A-29), and New York (New York Public Buildings Law § 140), with specific mandates in large occupancy buildings and sporting arenas in Nevada (Nevada Revised Statutes § 450B.600 1 day).

Legal Protection for Medical Directors

Specific concerns exist over immunity and legal responsibility for physicians serving as medical directors of AED pro-

grams. To date, there has been no legal determination whether medical directors qualify as acquirers under CASA.²² For physicians who volunteer their services as medical directors of AED programs, the Federal Volunteer Protection Act of 1997 (Volunteer Protection Act of 1997, Public Law 105-19) affords broad immunity nationwide to persons providing services to nonprofit organizations and governmental agencies. Most states also provide similar immunity, even where reasonable reimbursement is allowed to the volunteer for travel or out-of-pocket expenses.^{15-17,25,26} At present AEDs designated for use other than in homes can only be obtained with a prescription. Therefore, all programs must be under the direction of a physician.^{15-17,24} The exact responsibilities of the medical director vary between programs but generally include coordination with local emergency centers, developing emergency response protocols, ensuring proper training for users, and assuming overall responsibility for any patient care-related activities.²⁴ To protect medical directors who are essential for establishing an AED program, some states such as Massachusetts have passed laws securing immunity for medical directors (Massachusetts General Laws, Chapter 112, Section 12 VI/2).

Recent Court Opinions

In addition to these federal and state legislative initiatives, court opinions also influence AED deployment. Legally, the issue presented to a jury is whether the defendant's conduct was unreasonable. In most instances the duty of care is a requirement to take reasonable measures to protect patrons, customers, and clients from reasonably foreseeable risks of harm. Generally, the higher the risk, the higher the duty of care that must be met. Numerous lawsuits have been filed or are pending against airlines, health clubs, hotels, and businesses arising from their failure to have AEDs deployed. Several suits have resulted in large verdicts or settlements for failure to have an AED.³⁴⁻³⁷ Other cases tried for incidents occurring in the 1990s or early in this decade have resulted in verdicts for the defendants.

Several factors combine to create a legal duty including legislation, judicial decisions, and evolving industry or professional standards. With the passage of time, these factors have been evolving toward broader acceptance of public access defibrillation and the creation of a legal duty in certain settings. The use of defibrillators is widely viewed as no longer the exclusive province of health care professionals. Accordingly, an increasing number of companies, offices, and institutions are using AEDs. In addition, standards to define the important components of an AED program will likely evolve.

Cost

The cost of AEDs for consumers has decreased over the last several years, and prices range from \$1000 to \$2500 depending on the model, manufacturer, and service warranty.³⁸ Although based on multiple assumptions on cost

of the device, frequency of cardiac arrest, and improvements in survival, cost-effectiveness analyses have suggested that public access to defibrillation programs using the AED are economical compared with other common treatments for life-threatening conditions. Cost-effectiveness studies estimated that AED deployment costs less than \$50 000 per quality-adjusted life-year provided that the annual probability of device use is 12% or more.³⁹⁻⁴² Accordingly, the AED becomes more cost-effective as the frequency of sudden death increases in any location.³⁹⁻⁴²

Conclusions

As evidence-based medicine has defined the clinical benefits of AED use, public policy, laws, funding programs, and court decisions have served the societal interest of promoting use of AEDs by minimizing legal liability. Adding to the widespread perception that AEDs are prudent safety measures, insurance companies now are supporting the AED programs⁴³ and some have entered into alliances with manufacturers to offer purchase discounts.⁴³ Healthcare professionals should be aware of the clinical benefits of AEDs and the limited liability associated with their use and should also consider the potential liability that could arise from failure to use AEDs.⁴⁴⁻⁴⁷

Although some concerns remain over legal responsibility, these appear largely unfounded because there has never been, to our knowledge, a successful lawsuit against an individual who has purchased, used, or provided medical oversight for an AED. It is evident that clinical benefits of the AED outweigh the minimal legal risks. Adherence with all regulations for an AED program serves to minimize any legal risks. With growing recognition of the survival benefit provided by AEDs, it is likely that, like airbags, smoke detectors, and fire extinguishers, AEDs will be firmly established in the realm of public safety in the near future.

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