Automated External Defibrillators: Technical Considerations and Clinical Promise

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Early defibrillation is the most important determinant of survival for victims of cardiac arrest due to ventricular fibrillation. The automated external defibrillator (AED) was developed as the result of the American Heart Association's Public Access Defibrillation initiative. The goal of this initiative is to place AEDs in strategic locations so that laypersons with minimal training could promptly defibrillate victims of cardiac arrest. Because of changes in design and the use of alternative waveforms for defibrillation, the modern AED is compact and portable, simple to use, and highly efficacious; in addition, it requires little maintenance. Automated external defibrillators have been used successfully by traditional and nontraditional responders as well as laypersons. In special environments, such as casinos and commercial aircraft, AEDs have performed particularly well. State and federal legislation has eased concerns about AED use by extending legal protection to AED users under Good Samaritan laws. Since the experience continues to be positive, AEDs are being used in increasingly diverse community locations, and public awareness is growing. The American Heart Association's initiative is progressing rapidly.

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Cardiac arrest due to ventricular fibrillation remains a leading cause of death in the United States. Although early defibrillation has been identified as the single most important intervention to improve survival, fewer than 5% of the 250 000 persons who experience out-of-hospital cardiac arrest each year survive to hospital discharge (1). It has been estimated that chances for survival decrease approximately 7% to 10% with each passing minute and that survival rates after 12 minutes are only 2% to 5% (2). These findings contrast with the high survival rates observed when defibrillation is immediately available. For example, in rehabilitation facilities with immediate access to defibrillators, survival rates of over 80% have been reported (3, 4). The American Heart Association (AHA) recognized the importance of early defibrillation and, in the early 1990s, challenged the medical industry to develop defibrillators that could be deployed in public places, making early defibrillation widespread and increasing chances of survival after cardiac arrest. The medical industry answered this challenge, which is known as the Public Access Defibrillation initiative, by developing the modern automated external defibrillator (AED).

The recent AHA guidelines for emergency cardiac care place increased emphasis on the importance of early defibrillation and recommend AED training (5). The guidelines state that "public access defibrillation, which places AEDs in the hands of trained laypersons, has the potential to be the single greatest advance in the treatment of ventricular fibrillation cardiac arrest since the development of CPR [cardiopulmonary resuscitation]." Working knowledge about AEDs will become crucial for all physicians. On a local level, physicians will be asked to help determine and oversee placement of AEDs in existing emergency medical services, as well as in strategic locations, such as local businesses, schools, and nursing homes. Also, physicians' individual patients may become more interested in obtaining their own personal AEDs (6). Finally, as AEDs become more widely available, physicians can expect to use them directly to aid persons who have had cardiac arrests. One study that monitored domestic airlines over a 2-year period found that volunteer physicians provided onboard emergency medical care when needed in more than 85% of cases (7).

In this review, we provide general information on AED technology and operation, summarize the experience of AED trials (in emergency medical systems and in special environments), and discuss legislative and legal concerns.

Methods

We searched MEDLINE for relevant studies by using the term *electric countershock* in conjunction with the terms *emergency medical services*, *biphasic waveform*, *heart arrest*, and *cardiopulmonary resuscitation*. Only English-language articles were considered for inclusion. Case reports and series, clinical trials, letters to the editor, and review articles in peer-reviewed journals were selected. Conference proceedings and bibliographies of reviews were searched for appropriate articles. Articles were screened for relevance on the basis of the title and abstract. Product information for AEDs was obtained from official specification documents provided by the manufacturers (**Table**).

ATTRIBUTES AND TECHNOLOGY

The AHA Task Force (8) listed qualities that an ideal AED should possess in order to be compatible with the goal of public access defibrillation. An ideal AED should be easy to use, small, light, rugged, low maintenance, inexpensive, and self-testing; should be able to deter misuse; and should be able to provide data archiving and retrieval. Most modern AEDs meet these criteria.

Defibrillation Waveforms and Energy Levels

An important advance over the past decade has been the development of alternate waveforms for defibrillation (**Figure 1**). Traditional defibrillators used monophasic waveforms, in which electrical energy is delivered in a single polarity—the current travels in a single direction. In contrast, the newer biphasic waveforms involve a reversal of current at a specific time in the energy shock. Biphasic waveforms require less energy for successful defibrillation, which translates into smaller batteries and components and leads to an overall reduction in size and weight. Additional advantages are lower manufacturing costs, easier maintenance, and longer battery storage life.

For monophasic shocks, the established protocol is to deliver a progressive escalating sequence, usually 200, 300, and 360 J. This strategy attempts to minimize the amount of energy required to defibrillate and theoretically diminish the potential for myocardial injury caused by the energy shock. By contrast, biphasic waveform devices can be equally successful or even superior at lower energy levels. Human studies conducted under controlled circumstances in electrophysiology laboratories have shown that 115-J and 130-J biphasic truncated shocks and 200-J damped monophasic shock have equivalent defibrillation efficacy (9–11).

More important is the efficacy of AEDs during real cardiac arrests. Observational prospective studies have consistently demonstrated that biphasic devices using nonescalating sequences have high efficacy rates for termination of ventricular fibrillation (12, 13). In a recent multicenter prospective study, 115 persons with cardiac arrest were randomly assigned to the traditional monophasic sequence of 200, 300, and 360 J or the nonescalating impedance-compensating biphasic sequence of 150, 150, and 150 J (14). Although survival did not differ between groups, the 150-J biphasic sequence defibrillated at higher rates than the traditional shocks and the patients assigned to this group were more likely to have good cerebral function. This study supplemented earlier data showing that nonescalating biphasic shocks were at least as effective as, and possibly superior to, the traditional higher-energy monophasic shocks.

Because biphasic defibrillators require less energy, lithium batteries can be used. Lithium batteries have a predictable life expectancy, do not require recharging or maintenance, are energy dense, and in some cases do not require special disposal. For example, one of the most popular AED models on the market uses a consumer-grade 13-oz battery pack that allows 5 years of standby, 300 shocks, or 12 hours of continuous monitoring.

On the basis of evidence from animal studies, data from controlled inpatient trials with transthoracic biphasic defibrillators, and limited data from out-of-hospital experiences, the AHA has upgraded the use of biphasic waveform in AEDs to a class IIa recommendation (5). This indicates that a majority of experts consider biphasic waveform to be the standard of care and the intervention of choice.

Automated Rhythm Analysis

Automated external defibrillators have high sensitivity and specificity for identifying ventricular fibrillation. With the use of sophisticated microprocessors, findings are interpreted through analysis of surface electrocardiography. Various components are measured, such as amplitude, frequency, slope, and wave morphology integration. The devices also filter for extraneous signals that could interfere with proper interpretation, such as motion artifact, loose electrodes, and nearby radio transmission.

In many field trials, AEDs have proven extremely accurate in the interpretation of cardiac arrhythmias (15–20). The sensitivity for detection of ventricular fibrillation ranges from 96% to 100% (18, 20–22). The accurate withholding of defibrillation (specificity) in appropriate rhythms (sinus tachycardia, asystole) approaches

Table. **Commercially Available Devices Approved by the U.S. Food and Drug Administration***

AED Model	Manufacturer (City, State)	Wave Form	Energy Levels, *J*	Weight, *kg*
FirstSave	Survivalink Corp. (Minnetonka, MN)	Biphasic truncated, monophasic truncated	Biphasic, variable escalating, 140–360; monophasic, 200–360	3.4
Heartstream ForeRunner II†	Agilent Technologies (Seattle, WA)	Impedance-compensating biphasic	Nonescalating 150, 150, 150	2.1
LIFEPAK 500	Medtronic Physio-Control (Redmond, WA)	Impedance- and voltage-compensating biphasic, monophasic	Biphasic, adjustable, 200–360; monophasic, 200–360	Biphasic, 2.9; monophasic, 3.2
LifeQuest	Medical Research Laboratories, Inc. (Buffalo Grove, IL)	Biphasic, monophasic	Biphasic, 2–360; monophasic, 200–360	2.1
ZOLL M Series	ZOLL Medical Corp., Inc. (Burlington, MA)	Rectilinear biphasic, monophasic	Biphasic, 120, 150, 200; monophasic, 1–360	Biphasic, 5.2; monophasic: 6.3

* AED = automated external defibrillator; ECG = electrocardiography; IL = Illinois; MA = Massachusetts; MN = Minnesota; PC = personal computer; WA = Washington.
† The Heartstart FR2, made by Laerdal Medical Corp. (Wappingers Falls, New York), is also approved by the U.S. Food and Drug Administration and has the same price and specifications as the Heartstream ForeRunner II.

100% (18, 20–22). The rare errors in electrocardiographic analysis have been those of omission, where the device recommends no shock in response to fine ventricular fibrillation. Additional misinterpretations result when operators do not adhere to AED instructions (23, 24).

Ease of Use

The name *automated external defibrillator* is to be distinguished from automatic external defibrillator. Unlike the automatic device, which delivers the shock without operator intervention after being turned on, the automated device only "advises" a shock by a voice and text prompt; it requires the operator to take the final step of pressing the "shock" button. Manufacturers have made AEDs as simple to use as possible by incorporating four universal steps (**Figure 2**).

1. Power on. This is accomplished by flipping a power switch or by lifting the monitor cover. Turning on the device initiates a series of voice prompts that guides the user through the operation sequence.

2. Attach electrode pads. Voice prompts and diagrammatic instruction prompt the operator to place electrode pads in an anterolateral position. Transdermal medication patches must be removed. For some patients, chest hair will need to be shaved. If the victim is wet or diaphoretic, drying the chest wall will help prevent arcing between the electrode pads. The pads and cables are preconnected in some models but not in others.

3. Analyze the rhythm. In some models, analysis occurs automatically after electrode pads are placed and connected; others require that the rescuer press an "analyze" button. Instructions are given to stop cardiopulmonary resuscitation and to reduce the possibility of any other motion artifact.

4. Advise shock. If the interpreted rhythm is ventricular fibrillation, the device will advise shock. For the shock to be delivered, the operator must manually depress the "shock" button. After defibrillation, some AEDs require the operator to again press the "analyze" button. Other models automatically reanalyze and continue to advise shocks until a maximum of three shocks has been delivered. At that time, the AEDs are programmed to pause for 1 minute to allow continuation of cardiopulmonary resuscitation. After 1 minute, if ventricular fibrillation is still present, an additional round of three shocks is delivered until the AED advises "no shock indicated" or until help is available.

To investigate the ease with which an AED could be used by laypersons, Gundry and colleagues (25) compared time to defibrillation during a mock cardiac arrest when AEDs were used by 15 sixth-grade children with no previous training and 22 trained emergency medical technicians. The children were able to operate AEDs in an accurate, timely fashion and defibrillated the mock victims just 23 seconds later than the trained paramedics (90 seconds vs. 67 seconds), a clinically insignificant difference. The authors concluded that only modest training would be required for widespread use of AEDs and suggested that "even a child could do it."

Table—**Continued**

Archival Capacity	Battery	Display	Cost, $
Internal memory for 20-minute ECG; optional rescue data (5-hour data card or 26-minute voice recording)	Lithium disposable (5-year standby)	Optional text display	Biphasic, 3495; monophasic, 3495
Elapsed time and number of shocks; optional PC data card	Lithium disposable (5-year standby)	Optional ECG monitoring	3125, or 3490 with ECG
20-minute audio recording optional; ECG and event log of operator and device actions	Sealed lead acid; sealed lithium (5-year standby)	Text display	Biphasic, 3500; monophasic, 3167
Optional PC data card	Sealed lithium or rechargeable nickel metal hydride	ECG monitoring	Biphasic, 3260; monophasic, 3260
Optional PC card with continuous ECG and device data	Rechargeable, sealed lead acid	ECG monitoring	Biphasic, 5490; monophasic, 4195

USE OF AEDs IN CHILDREN

Currently available AEDs are designed and intended for use on adults. Therefore, their use on small children raises concerns about accuracy of rhythm analysis, appropriateness of electrode paddle size, and safety of delivered energy. Researchers are concerned about rhythm analysis algorithms in children because in many children, sinus tachycardia could overlap with the cutoff rate for recognition of ventricular fibrillation. The amplitude of the signal could differ in children as well. Field studies of cardiac arrest in infants and children demonstrated that AEDs had good sensitivity and specificity for ventricular fibrillation, but only modest sensitivity for fast ventricular tachycardia in infants (19, 26). These studies are encouraging and suggest that a single algorithm for both adults and children could be developed.

The use of adult electrode pads (83 cm^2) rather than pediatric electrode pads (21 cm^2) has been shown to reduce transthoracic impedance and to increase peak current flow, further facilitating defibrillation (27, 28). Therefore, large pads might be adequate for almost all children and small pads might be required only for infants.

While the recommended energy for monophasic defibrillation in children is 2 to 4 J/kg, animal models suggest that 10 J/kg can be delivered without myocardial toxicity (29). Therefore, the use of biphasic AEDs with adult electrode pads seems to be safe for children weighing more than 25 kg (usually those $>$8 years of age). In children younger than 8 years of age, the energies available in most AEDs might exceed the recommended safe dose. For these reasons, the AHA states that AEDs are safe, acceptable, and within the standard of care (class IIb recommendation) for children older than 8 years of age who weigh more than 25 kg. For children younger than 8 years of age, AEDs are not recommended.

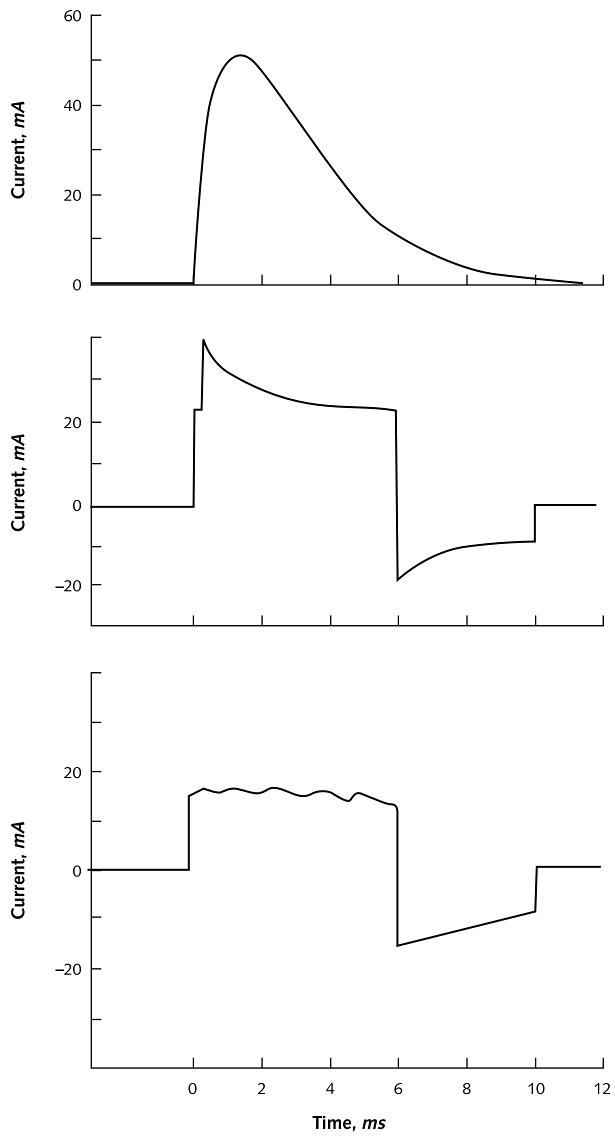
FIELD EXPERIENCES WITH THE AED

Over the past decade and a half, extensive experience has been gained with the AED. Initially, AEDs were made available to "nontraditional" first responders, such as firefighters and police officers in emergency medical systems. More recent experience has been obtained in special environments, such as commercial airplanes and casinos.

Nontraditional First Responders

In traditional emergency systems, an emergency medical technician or paramedic performs cardiac defibrillation. Since police officers and firefighters in many communities arrive at the scene of a cardiac arrest before paramedics, programs have been developed to improve survival by equipping these nontraditional responders with AEDs. In a landmark trial, investigators in Seattle, Washington, studied survival outcomes after equipping firefighters with AEDs (20). Fire stations were selected from districts that had experienced a delay in paramedic response time (average arrival, 3 minutes after firefighters). Survival rates for patients with ventricular fibrillation were significantly better when firefighters used an AED than when they provided only basic life support until paramedic arrival (30% vs. 19%; $P < 0.01$). After multivariate analysis, patients with ventricular fibrillation treated by AED-equipped firefighters had an improved odds ratio of survival of 1.8 (95% CI, 1.1 to 2.9). When firefighters were equipped with AEDs, mean time to defibrillation ($\pm$SD) decreased by 5.1 $\pm$ 3.2 minutes. Additional field studies in which nontradi-

Figure 1. **Different defibrillation waveforms available in automated external defibrillators.**



Top. Damped sinusoidal monophasic waveform. **Middle.** Truncated exponential biphasic waveform. **Bottom.** Rectilinear biphasic waveform.

tional first responders, such as police officers (who often arrive earlier to medical emergencies in rural communities), used AEDs have also found that survival improves with early defibrillation (30–33). A meta-analysis of studies of nontraditional responders reinforced the fact that survival is not improved unless time to defibrillation is reduced (34).

AEDs Aboard Commercial Aircraft

Passengers on commercial aircraft are exposed to a special environment that may exacerbate medical conditions and precipitate sudden cardiac death. Adverse factors include the stress of flying, exertion required to reach the gate, disruption of circadian rhythms, and reduced oxygen level in the cabin (equivalent to up to 2400 m [8000 ft] above sea level). Furthermore, if a medical emergency occurred during a flight, it would take an airplane under perfect circumstances at least 20 minutes to reach ground-based assistance (which would result in a dismally low chance of survival for a person in cardiac arrest). Placing AEDs onboard aircrafts and training the cabin crew in their use allow the opportunity for rapid treatment that would otherwise be unavailable.

After installing AEDs on its fleet, Qantas Airways reported a series of 27 onboard cardiac arrests over a 5-year period (21). Of these, 6 patients were in ventricular fibrillation and 5 had an initial successful defibrillation. After 2 years, 2 of the 5 patients were alive and had no residual cerebral deficits. In 1997, American Airlines became the first U.S. airline to place AEDs aboard its aircraft. The experience with the first 200 uses of the AEDs was recently reported (22). Ventricular fibrillation was documented in 14 cases, with appropriate recommendation for shock in all 14. Therapy was withheld in 1 patient with a terminal illness at the request of the family. In 2 other cases, ventricular fibrillation was presumed but electrocardiographic data were not available for analysis; both patients received AED shocks but did not survive. Thus, a total of 15 patients had presumed or documented ventricular fibrillation and received shocks. Survival to hospital discharge after shock was 40% (6 of 15 patients); it is important to note that all discharged patients had intact neurologic function.

In addition to demonstrating efficacy of AEDs in treating ventricular fibrillation, the study showed that the devices were safe in the isolated aircraft environment. Automated external defibrillators were frequently used for medical emergencies that did not involve loss of consciousness, typically at the request of a volunteer passenger physician (present 69.5% of the time). In these situations, most of the recorded rhythms were not appropriate for shock. The AED correctly interpreted these rhythms and did not recommend a shock, nor was a shock delivered.

AEDs in Casinos

In casinos, patrons are exposed to many stresses, including lack of sleep, long travel, alcohol ingestion, and the anxiety and excitement associated with gaming. This type of environment could predispose persons to cardiac arrest, especially older and more sedentary visitors (35). Ubiquitous videotape and security officer surveillance allows prompt intervention that is not possible in most other sites.

In 1997, selected casinos in Nevada and Mississippi began placing AEDs on their premises and training security personnel in their use. The data from 10 casinos were recently published, describing cardiac arrest in 148 persons between 1 March 1997 and 12 October 1999 (36). Of these persons, ventricular fibrillation was found in 105. When cardiac arrest was witnessed (90 persons [86%]), mean time to defibrillation (±SD) was 4.4 ± 2.9 minutes. Arrival of paramedics was recorded at 9.8 ± 4.3 minutes. Survival with prompt defibrillation was 59% (74% for those defibrillated in <3 minutes). A historically based model would have predicted a survival rate of 10% for patients defibrillated when paramedics arrived (37).

LEGISLATIVE ISSUES

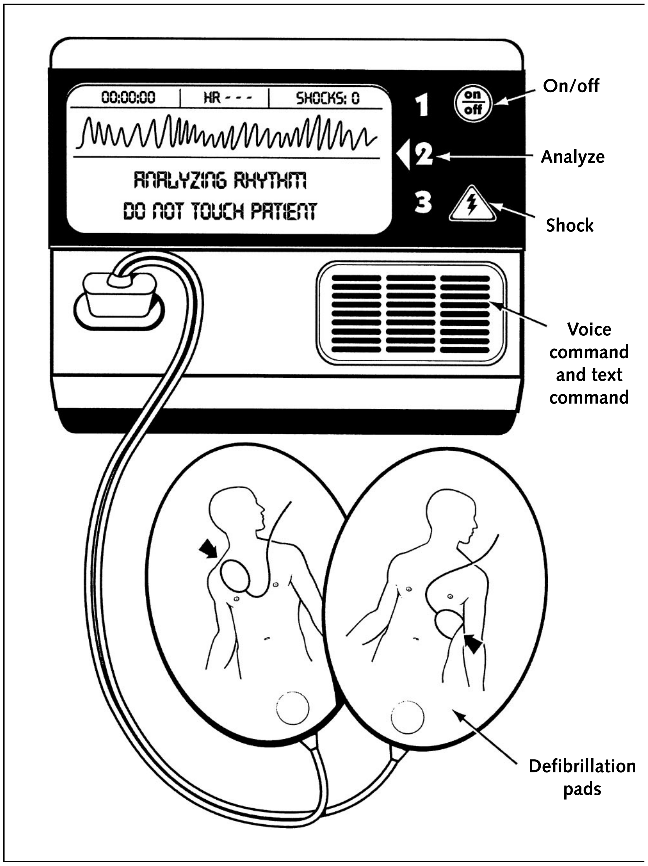
In the past, community use of AEDs was limited in part by concerns of liability (8, 38–42). Historically, the use of a defibrillator has been considered a medical act that requires certification and licensing. Since Good Samaritan laws did not clearly apply when "medical devices" were used to aid victims, the concern for malpractice liability was a deterrent to the widespread deployment of AEDs.

The initial fear of injury from AEDs in clinical practice has proven unfounded, as has the fear that the use of AEDs in the workplace would result in malpractice lawsuits. Indeed, the evolving legal trend may ultimately lead to higher risks for businesses that fail to purchase and train their employees in the use of AEDs. In June 1996, a Florida jury found Busch Gardens negligent for not properly training its employees to provide emergency care and failing to have the proper medical equipment, including an AED, on the premises (43). In a federal case, the German airline Lufthansa was found negligent for failing to provide timely treatment to a passenger and was ordered to pay $2.7 million in damages.

The AHA and other interested groups have actively pursued changes in legislation at both the federal and state levels. Several states have adopted legislation that allows a layperson to use an AED and provides legal immunity for proper use (44). This bill, based on model legislation crafted by the AHA, confers legal immunity on the layperson operator, anyone instructing him or her, and the physician or medical authority under whose supervision the AED has been placed. Essentially, any person who in good faith and without compensation used the AED to care for a victim of cardiac arrest would be protected as long as he or she acted prudently (44).

The Airline Medical Assistance Act of 1998 indemnified both airlines and volunteers in use of the AED aboard aircraft (45). On 23 May 2000, Congress passed the Cardiac Arrest Survival Act (later signed into law by President Clinton). This amendment to the Public Health Service Act extends Good Samaritan protection to AED users in states that do not currently have pro-

Figure 2. **The automated external defibrillator.**



tective legislation. It also instructs the U.S. Department of Health and Human Services to develop guidelines for placement of AEDs in all federal buildings. This legislation removes an important legal hurdle for the general use and deployment of AEDs.

Public Access Defibrillation

For public access defibrillation, AEDs should be distributed within the community to enable bystanders to become potential first responders in the event of a cardiac arrest. Several important questions must be answered before widespread distribution occurs. Where should AEDs be placed? What is the cost? What is the efficiency?

In its revised guidelines for emergency cardiac care, the AHA recommends that AEDs be placed at public locations in which one cardiac arrest occurs every 5 years (5). Community surveys have shown that several public venues fulfill this criterion, including international airports, county jails, large shopping malls, public sports arenas, and large industry sites (35). The experience with a public access defibrillation program implemented at Chicago's O'Hare and Midway airports (the Chicago Heart Save Program) was recently reported (46). Fifty-one AEDs were deployed in strategic locations to allow 1-minute access. The units were alarmed and well marked. A total of 14 cardiac arrests were reported during the first 10 months. Twelve patients had documented ventricular fibrillation, and 9 were resuscitated with intact neurologic function (overall survival, 64%; survival in patients with ventricular fibrillation, 75%). It is important to note that airport travelers without previous AED training attended 9 of the 14 victims.

The cost per quality-adjusted life-year of public access defibrillation varies enormously with any changes in key variables, including the proportion of patients surviving cardiac arrests, the cost of implementing and maintaining AEDs, and the survival benefit of public access defibrillation. According to one estimate, implementation of a public access defibrillation program in urban centers in the United States would cost $44 000 per quality-adjusted life-year for lay responders and $27 000 per quality-adjusted life-year for police officers (47). The cost of airline AEDs was recently estimated to be less than $50 000 per year of life saved (48). These cost estimates, which compare favorably with the cost of other medical interventions (49), suggest that implementation of public access defibrillation programs is economically attractive, especially in communities where time to defibrillation can be decreased.

The effectiveness of public access defibrillation in improving survival depends on careful planning and integration within existing emergency medical systems. As field trials have demonstrated, use of AEDs by nontraditional first responders has not always decreased time to defibrillation and improved survival (50, 51). Although AEDs have now been shown to be extremely effective in such environments as airplanes and casinos, no data are available for effectiveness of AEDs in the general community. A study sponsored by the National Heart, Lung, and Blood Institute, the Public Access Defibrillation Community Trial, will help provide some information on this issue.

An alternative approach to public access defibrillation is consumer distribution of AEDs (52). Since approximately 75% of out-of-hospital cardiac arrests occur in the home, over-the-counter availability of AEDs would allow consumers to place AEDs in the home much like a fire extinguisher. For this to occur on a major scale, AEDs would need to dramatically decrease in price and continue to demonstrate a low potential for misuse.

The availability of AEDs is increasing. As more positive experiences continue to be reported, such commercial locations as hotels, amusement parks, and casinos will come under increasing public and legal pressure to provide AEDs and appropriately trained support staff. Outpatient medical clinics, dental offices, and other nonemergent medical facilities will also be expected to have these devices (53). Influenced by major organizations, such as the AHA, and grassroots programs, such as the Public Access Defibrillation League, Congress has passed federal legislation authorizing AED funding. The Rural Access to Emergency Devices Act authorizes $25 million in funds to assist rural communities in purchasing AEDs and training lay rescuers. We expect future improvements in AED design, along with lower cost, to further accelerate widespread AED deployment.

Conclusion

Newly developed AEDs allow people with modest training to safely deliver effective cardiac defibrillation.

The modern device incorporates advanced technology, including biphasic waveform, sophisticated rhythm analysis, and improved battery technology. The devices are simple to use and have a long shelf life. Recent experience, especially in casinos and aboard commercial airplanes, has confirmed that early defibrillation can improve survival. State and federal legislation has addressed many of the legal obstacles that have prevented widespread distribution of AEDs by recognizing that trained laypersons can operate the device safely and by providing legal protection under Good Samaritan laws. As AEDs become more widely distributed, public access defibrillation is likely to become a reality. What must still be determined are the results of marketing efforts for home defibrillation and perhaps even over-the-counter AEDs.

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