

HB

4

<TARGET><BILL>HB 4</BILL><SUBJECT>HB
4</SUBJECT><COMM>SHSS29</COMM></TARGET>

Alaska State Legislature
House of Representatives
Representative Tammie Wilson

Interim
301 Santa Claus Lane 3B
North Pole, Alaska 99705
Phone - (907) 451-2723



Rep.Tammie.Wilson@akleg.gov

Session
State Capitol Rm 412
Juneau, AK 99801
Phone - (907) 465-4797

SPONSOR STATEMENT

HB 4

“An Act Relating to Automated External Defibrillators.”

On behalf of the Alaska Fire Chiefs Association I am pleased to introduce HB 4. The purpose of this bill is to reduce impediments in state law to allow for more public access to Automated External Defibrillators (AEDs).

AEDs are automated medical devices that can be safely used by an untrained bystander to restore a normal cardiac rhythm in a person experiencing sudden cardiac arrest. The device provides both verbal and written instructions to the user.

The use of AEDs are currently covered by Alaska’s Good Samaritan Law (AS 09.65.090), which is designed to encourage would-be rescuers to take action without fear of litigation. However, Alaska’s Good Samaritan attaches conditions to building owners and institutions that provide AEDs (AS 09.65.087). These conditions include requirements to provide training, maintenance, a means to notify 911, and registering the device(s) with emergency medical services (EMS).

Large companies and institutions cannot confidently assure that each of the conditions can be reliably met; therefore, exposing them to liability and discouraging access to AEDs. Removing these conditions would encourage the increased availability of AEDs in our communities.

Thank you for your support.

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SECTIONAL ANALYSIS

HB 4

“An Act relating to automated external defibrillators.”

Section 1: AS 09.65.087 (b) is amended to add “...gross negligence.”
AS 09.65.087 (b) subsections 1 through 4 are repealed:

Section 2: AS 09.65.087 (d) is repealed

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HB 4 Presenters

1. Doug Schrage / Alaska Fire Chiefs Association/in-person or Fairbanks LIO
2. Michael Levy, MD / Anchorage Fire Department/Anchorage LIO
3. James Foster / Loren Marshal Foundation/Anchorage LIO
4. Janet Bartels or Jamie Macnaughton / American Heart Association-Fairbanks/Fairbanks LIO
5. Ron Templeton / University of Alaska Fire Department/?
6. Sherry Modrow / Heart Association and UAF advocate/Fairbanks LIO

HB 4

An act relating to automated external defibrillators

Sudden cardiac arrest (SCA)

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- ▶ Sudden Cardiac Arrest is a leading cause of death in the United States, resulting in approximately 350,000 deaths per year.
 - ▶ Most common cause is a disorder of the heart rhythm called ventricular fibrillation (VF).
 - ▶ Ventricular fibrillation is an "electrical problem" in the heart.
- ▶ For each minute Sudden Cardiac Arrest is untreated by defibrillation
 - ▶ Survival chances decrease 7 % per minute in the first 3 minutes and 10 % per minute after the first 3 minutes.

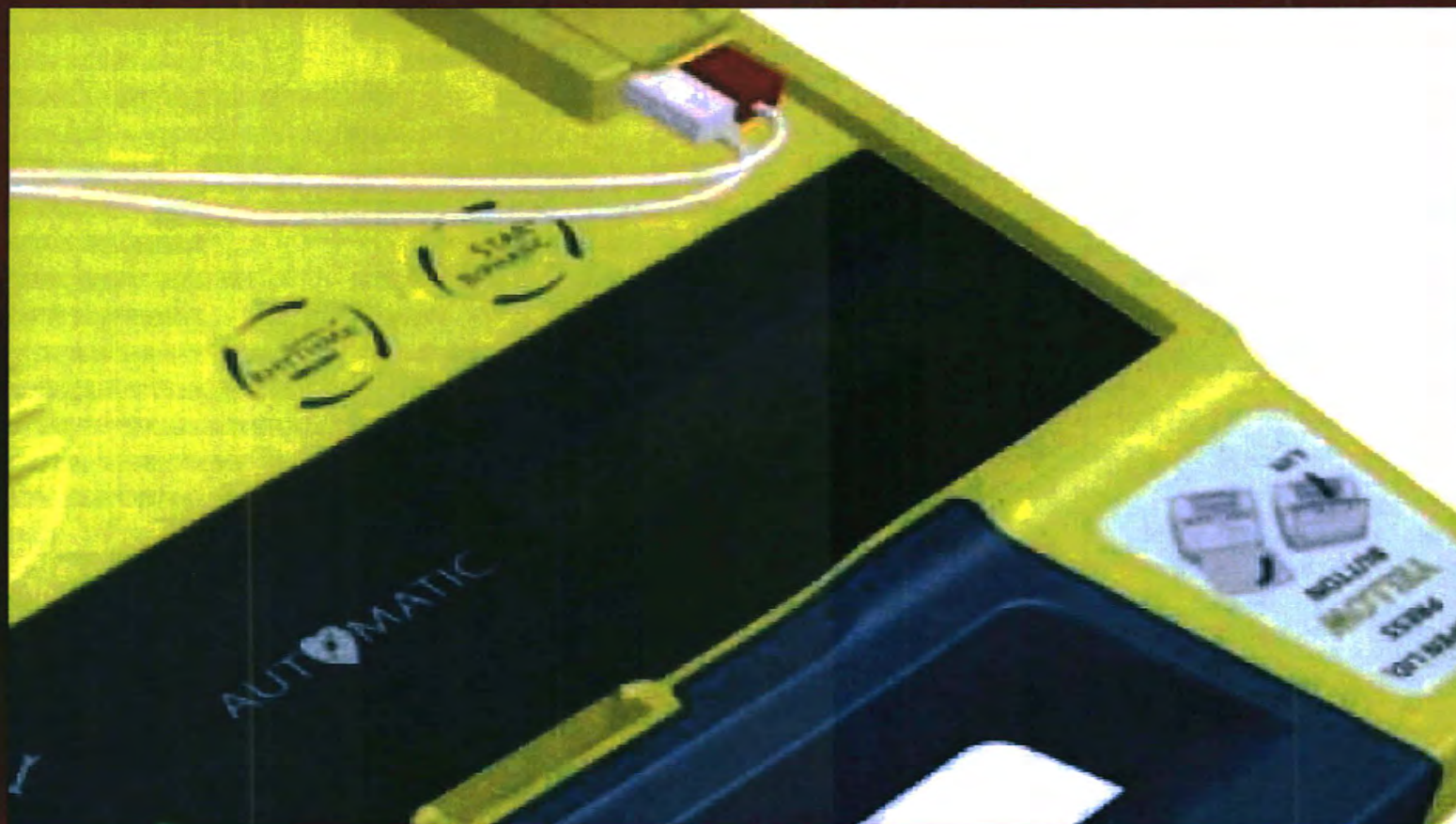
Simplicity of AED Operation

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- ▶ Automatic external defibrillators, (AEDs), are automated medical devices that can be safely used by an untrained bystander to restore a normal cardiac rhythm in someone who is in sudden cardiac arrest.
- ▶ When it is turned on, the device provides step-by-step verbal and written instructions.
- ▶ These devices have an impressive success rate.

Video of AED Operation

4



Purpose of HB

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- ▶ Individuals who use an AED are protected under the Good Samaritan law; however, building owners and institutions are not.
- ▶ Removing certain conditions and requirements will increase the number of AEDs in our communities.

The Future of AEDs

6



Thank You
For Your Support

Video Links on YouTube

- ▶ **AED Automated Defibrillator voice prompts**
 - ▶ <https://www.youtube.com/watch?v=0jaqSFCNrX0>
- ▶ **TU Delft - Ambulance Drone**
 - ▶ <https://www.youtube.com/watch?v=y-rEI4bezWc>

Fiscal Note

State of Alaska
2015 Legislative Session

Bill Version: HB 4
Fiscal Note Number: _____
() Publish Date: _____

Identifier: HB004-LAW-CIV-02-04-15
Title: AUTOMATED EXTERNAL DEFIBRILLATOR
Sponsor: WILSON
Requester: (H) JUDICIARY

Department: Department of Law
Appropriation: Civil Division
Allocation: Torts & Workers' Compensation
OMB Component Number: 2719

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2016 Appropriation Requested	Included in Governor's FY2016 Request	Out-Year Cost Estimates				
			FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
OPERATING EXPENDITURES	FY 2016	FY 2016					
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Fund Source (Operating Only)

None							
Total	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Positions

Full-time							
Part-time							
Temporary							

Change in Revenues							
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Estimated SUPPLEMENTAL (FY2015) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2016) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? No
If yes, by what date are the regulations to be adopted, amended or repealed?

Why this fiscal note differs from previous version:

Prepared By: <u>Valerie Rose, Budget Analyst</u>	Phone: <u>(907)465-3674</u>
Division: <u>Administrative Services Division</u>	Date: <u>02/04/2015 08:13 AM</u>
Approved By: <u>Craig W. Richards, Attorney General</u>	Date: <u>02/04/15</u>
Agency: <u>Department of Law</u>	

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2015 LEGISLATIVE SESSION

BILL NO. HB04

Analysis

Alaska Statute 09.65.087(b) grants immunity to a person who acquires or provides an automated external defibrillator device (AED) for use on a victim of a medical emergency when that device is used on a victim of a medical emergency, except for civil damages that result from four enumerated activities: notifying local emergency responders of the placement of an AED, maintaining and testing the device, providing a means to notify local responders that is located within reasonable proximity to the AED, and providing appropriate training. This bill deletes the four enumerated activities and replaces it with "gross negligence." The result is that a person who acquires or provides an AED has immunity when that AED is used on a victim of a medical emergency, unless civil damages result from gross negligence.

In addition, the bill repeals the definition of "appropriate training" in AS 09.65.087(d), presumably because of the deletion of the term in the proposed changes to subsection (b), described above.

The Department of Law does not foresee a fiscal impact as a result of this bill passage.



**American
Red Cross**

Richard Bradley, MD, CPR Sub-Council Chair
American Red Cross National Headquarters
2025 E Street, NW
Washington, DC 20006

January 30, 2015

Douglas Schrage, Fire Chief
Alaska Fire Chiefs Association
217 2nd St - Suite 200
Juneau, AK 99801

Dear Chief Schrage:

The American Red Cross and its Scientific Advisory Council are longstanding advocates for widespread access to automated external defibrillators (AEDs).

My colleagues on the American Red Cross Scientific Advisory Council and I are charged with advising the Red Cross in areas related to the development and dissemination of audience-appropriate information for CPR/AED, first aid, aquatics, emergency preparedness and safety education. Our guidance is based on the latest evidence-based scientific and medical knowledge.

Based on this research, knowing how to activate the emergency medical services system, how to perform CPR and how to use an AED saves lives. Every year, more than 300,000 deaths are the result of Sudden Cardiac Arrest. We believe that the closer a victim is to an AED and a trained responder who will take action the better his or her chances are for survival.

The Red Cross has trained individuals to save or sustain a life, prepare and cope with disasters and help others for more than one hundred and thirty years. Since access to AEDs could save 50,000 lives each year, the vision of the American Red Cross AED Program is for "all Americans to be within four minutes of an AED and someone trained to use it."

Please contact me via email at richard.n.bradley@uth.tmc.edu if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Bradley".

Richard Bradley, MD
CPR Sub-Council Chair
American Red Cross Scientific Advisory Council
Professor of Emergency Medicine
The University of Texas Health Science Center at Houston



ALASKA FIRE CHIEF'S ASSOCIATION

217 2nd Street, Suite 200 Juneau, AK 99801
Phone: (907) 586-1325 FAX: (907) 463-5480

20 November 2014

The Honorable Tammie Wilson
Alaska State Legislature
State Capitol Room 412
Juneau, AK 99801-1185

Dear Representative Wilson,

The Alaska Fire Chiefs Association stands in support of your proposal to remove impediments in state law to the provision of automatic external defibrillators, or AEDs, in public places. The Alaska Fire Chiefs Association's members are career and volunteer chief executive officers of fire and emergency medical services organizations throughout Alaska. We believe that by removing conditions for immunity for building owners and institutions, more AEDs will be made accessible to the public and that our constituents will be better served.

AEDs are modern, automated medical devices that can be safely used by an untrained bystander to restore a normal cardiac rhythm in someone in sudden cardiac arrest. When it is turned on, the device provides step-by-step aural and textual instructions on how to attach and use the device. These devices have an impressive success rate for people in certain cardiac rhythms in a witnessed cardiac arrest.

The use of AEDs are currently covered by Alaska's Good Samaritan law (AS 09.65.090), which is designed to encourage would-be rescuers to take action without fear of litigation. However, Alaska's Good Samaritan law attaches conditions to building owners and institutions that provide AEDs (AS 09.65.087). These conditions include requirements to provide training, maintenance, a means to notify 9-1-1, and registering the device(s) with emergency medical services.

We agree that providing training and maintaining AEDs, as well as other measures, are good and necessary. However, we're finding that large institutions can't confidently assure that each of the conditions can be reliably met, therefore exposing them to liability and discouraging the provision of AEDs. Removing these conditions would increase the number of AEDs available in public places. As is currently true under the Good Samaritan law, building owners and institutions would still be liable for gross negligence.

Thank you for bringing this bill forward for the safety and welfare of Alaskans.

Best Regards,

James C. Baisden

James Baisden, President

The Honorable Tammie Wilson
Alaska State Legislature
State Capitol Room 412
Juneau, AK 99801-1185

Dear Representative Wilson,

I represent three entities that fully endorse your proposal to remove impediments in state law to the provision of automatic external defibrillators, or AEDs, in public places. The Loren Marshall Foundation through the "Big Wild Heart of Alaska" provides advocacy, education and support for reducing death from out of hospital cardiac arrest (OOHCA) in Alaska. The Heart Rescue Project of Washington-Oregon-Alaska has received a five-year grant from the Medtronic Philanthropy to improve outcomes from OOHCA in our respective states by 50%. Our methods target improved bystander CPR and enhanced availability and use of public access defibrillators. The Anchorage Fire Department and Anchorage Area wide EMS have strived for years to identify AEDs in the community and to enhance community use of the devices. We believe that by removing conditions for immunity for building owners and institutions, more AEDs will be made accessible to the public and that our constituents will be better served.

AEDs are modern, automated medical devices that can be safely used by an untrained bystander to restore a normal cardiac rhythm in someone in sudden cardiac arrest. When it is turned on, the device provides step-by-step aural and textual instructions on how to attach and use the device. These devices have an impressive success rate for people in certain cardiac rhythms in a witnessed cardiac arrest.

The use of AEDs is currently covered by Alaska's Good Samaritan law (AS 09.65.090), which is designed to encourage would-be rescuers to take action without fear of litigation. However, Alaska's Good Samaritan law attaches conditions to building owners and institutions that provide AEDs (AS 09.65.087). These conditions include requirements to provide training, maintenance, a means to notify 9-1-1, and registering the device(s) with emergency medical services.

Providing training and maintaining AEDs, as well as other measures, are good and necessary. However, we're finding that large institutions can't confidently assure that each of the conditions can be reliably met, therefore exposing them to liability and discouraging the provision of AEDs. Removing these conditions would increase the number of AEDs available in public places. As is currently true under the Good Samaritan law, building owners and institutions would still be liable for gross negligence.

Thank you for bringing this bill forward for the safety and welfare of Alaskans.

Best Regards,



Michael Levy MD, FACEP, FACP
President Loren Marshall Foundation 501(c)(3)
Principal Investigator Alaska, Heart Rescue Project
Medical Director Anchorage Fire Department

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Western States Affiliate
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www.heart.org

February 3, 2015

The Honorable Tammie Wilson
Alaska State Legislature
State Capitol Room 412
Juneau, AK 99801-1185

Dear Representative Wilson,

On behalf of the American Heart/American Stroke Association, we are pleased to support HB 4. This bill will make Automated External Defibrillators (AEDs) more accessible to the public by removing barriers to the use of AEDs, resulting in more opportunities for Good Samaritan acts and saved lives.

Each year, nearly 424,000 people have sudden cardiac arrest outside of a hospital in the United States, and only 10.4% of these victims survive. The key to survival is administration of bystander CPR and the use of an AED. AEDs are extremely accurate, user-friendly, computerized devices with audio prompts that guide the user through the steps to safely deliver life-saving shocks.

Unfortunately, businesses and institutions are not voluntarily installing AEDs because current law contains numerous conditions related to training, reporting, and maintenance for immunity, resulting in the fear of liability.

HB 4 removes these conditions for businesses and institutions that voluntarily install AEDs. It is important to note that the bill does not provide Good Samaritan liability protections for cases resulting from gross negligence.

While the American Heart/American Stroke Association believes that the requirements in current law are important, we know that sudden cardiac arrest is 100 percent fatal if not treated quickly. For every minute without a shock to the heart, the chance of survival decreases by 7 to 10 percent.

The American Heart/American Stroke Association believes that passage of this bill will result in increased access to AEDs and more opportunities for Good Samaritan acts and more lives saved.

Sincerely,

Jamie Morgan
Senior Director of Advocacy and Policy Campaigns

Sudden Cardiac Arrest Fact Sheet

- Sudden Cardiac Arrest (SCA) is a leading cause of death in the United States, claiming more than 350,000 lives each year. ^{1,2}
- An estimated 382,800 people experience sudden cardiac arrest in the United States each year. ¹
- Approximately 92% of those who experience sudden cardiac arrest do not survive. ²
- SCA kills more than 1,000 people a day, or one person every 90 seconds ^{1,2} — a number great than the number of deaths each year from breast cancer, lung cancer, stroke or AIDS.
- Cardiovascular disease³ is the leading cause of death in the U.S. and most deaths from it are attributable to SCA, where the heart abruptly and unexpectedly ceases to beat so that no blood can be pumped to the rest of the body.
- The most common cause of SCA is a heart rhythm disorder (arrhythmia) called ventricular fibrillation (VF). VF is an "electrical problem" in the heart. Without immediate emergency help, death follows within minutes of an episode of ventricular fibrillation.
- SCA most often occurs in patients with heart disease, especially those who have congestive heart failure and have had a heart attack. ²
- It is estimated that 95 percent of victims who experience SCA die before they reach a hospital or some other source of emergency help. ⁷
- As many as 75 percent of people who die of SCA show signs of a previous heart attack. Eighty percent have signs of coronary artery disease. ⁴
- SCA is *not* a random event. Although it may occur in outwardly healthy people, most victims *do* have heart disease or other health problems, often without being aware of it. ⁵
- SCA is *not* a heart attack, or myocardial infarction (MI), which is when a blockage in a blood vessel interrupts the flow of oxygen-rich blood to the heart, causing the heart muscle to die. If you think of your heart as a house, SCA would be a problem with the electricity; a heart attack would be a problem with the plumbing.
- African Americans are more likely to die from SCA than Caucasians. ⁶

-
- 1 Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics—2012 update: a report from the American Heart Association. *Circulation*. 2012;125:e2–e220.
 - 2 MMWR Weekly July 29, 2011. Surveillance Summaries Vol. 60/No.8. Out-of-Hospital Cardiac Arrest Surveillance – Cardiac Arrest Registry to Enhance Survival (CARES), United States, October 1, 2005 – December 31, 2010.
 - 3 Murphy SL, Xu JQ, Kochanek KD. Deaths: Preliminary data for 2010. National vital statistics reports; vol 60 no 4. Hyattsville, MD: National Center for Health Statistics. 2012.
 - 4 Cleveland Clinic Heart Hub. Accessed September 26,2012.
<http://my.clevelandclinic.org/heart/disorders/electric/scd.aspx>
 - 5 Fishman GI, Chugh SS, Dimarco JP, et al. Sudden Cardiac Death Prediction and Prevention. Report From a National Heart, Lung, and Blood Institute and Heart Rhythm Society Workshop. *Circulation*. 2010 Nov 30;122(22):2335-48.
 - 6 Galea S, Blaney S, Nandi A, Silverman R, Vlahov D, Foltin G, Kusick M, Tunik M, Richmond N. Explaining racial disparities in incidence of and survival from out-of-hospital cardiac arrest. *Am J Epidemiol*. 2007; 166:534 –543.
 - 7 Pell JP, Sirel JM, Marsden AK, et al. Presentation, management, and outcome of out-of-hospital cardiopulmonary arrest: comparison by underlying etiology. *Heart*. 2003; 89:839-42.

What Is an Automated External Defibrillator?

An automated external defibrillator (AED) is a portable device that checks the heart rhythm and can send an electric shock to the heart to try to restore a normal rhythm. AEDs are used to treat [sudden cardiac arrest](#) (SCA).

SCA is a condition in which the heart suddenly and unexpectedly stops beating. When this happens, blood stops flowing to the brain and other vital organs.

SCA usually causes death if it's not treated within minutes. In fact, each minute of SCA leads to a 10 percent reduction in survival. Using an AED on a person who is having SCA may save the person's life.

Overview

To understand how AEDs work, it helps to understand [how the heart works](#).

The heart has an internal electrical system that controls the rate and rhythm of the heartbeat. With each heartbeat, an electrical signal spreads from the top of the heart to the bottom. As the signal travels, it causes the heart to contract and pump blood. The process repeats with each new heartbeat.

Problems with the electrical system can cause abnormal heart rhythms called arrhythmias (ah-RITH-me-ahs). During an arrhythmia, the heart can beat too fast, too slow, or with an irregular rhythm. Some arrhythmias can cause the heart to stop pumping blood to the body. These arrhythmias cause SCA.

The most common cause of SCA is an arrhythmia called ventricular fibrillation (v-fib). In v-fib, the ventricles (the heart's lower chambers) don't beat normally. Instead, they quiver very rapidly and irregularly.

Another arrhythmia that can lead to SCA is ventricular tachycardia (TAK-ih-KAR-de-ah). This is a fast, regular beating of the ventricles that may last for only a few seconds or for much longer.

In people who have either of these arrhythmias, an electric shock from an AED can restore the heart's normal rhythm. Doing CPR (cardiopulmonary resuscitation) on someone having SCA also can improve his or her chance of survival.

AEDs are lightweight, battery-operated, portable devices that are easy to use. Each unit comes with instructions, and the device will even give you voice prompts to let you know if and when you should send a shock to the heart.

Learning how to use an AED and taking a CPR course are helpful. However, if trained personnel aren't available, untrained people also can use an AED to help save someone's life.

You often find AEDs in places with large numbers of people, such as shopping malls, golf courses, businesses, airports, airplanes, casinos, convention centers, hotels, sports venues, and schools. You also can purchase a home-use AED.

Outlook

Ninety-five percent of people who have SCA die from it—most within minutes. Rapid treatment of SCA with an AED can be lifesaving.

When Should an Automated External Defibrillator Be Used?

Using an automated external defibrillator (AED) on a person who is having [sudden cardiac arrest](#) (SCA) may save the person's life.

The most common cause of SCA is an [arrhythmia](#) called ventricular fibrillation (v-fib). In v-fib, the ventricles (the heart's lower chambers) don't beat normally. Instead, they quiver very rapidly and irregularly.

Another arrhythmia that can lead to SCA is ventricular tachycardia. This is a fast, regular beating of the ventricles that may last for a few seconds or much longer.

In people who have either of these arrhythmias, an electric shock from an AED can restore the heart's normal rhythm (if done within minutes of the onset of SCA).

What Are the Signs of Sudden Cardiac Arrest?

If someone is having SCA, you may see him or her suddenly collapse and lose consciousness. Or, you may find the person unconscious and unable to respond when you call or shake him or her.

The person may not be breathing, or he or she may have an abnormal breathing pattern. If you check, you usually can't find a pulse. The person's skin also may become dark or blue from lack of oxygen. Also, the person may not move, or his or her movements may look like a seizure (spasms).

An AED can check the person's heart rhythm and determine whether an electric shock is needed to try to restore a normal rhythm.

How Does an Automated External Defibrillator Work?

Automated external defibrillators (AEDs) are lightweight, battery-operated, portable devices that are easy to use. Sticky pads with sensors (called electrodes) are attached to the chest of the person who is having sudden cardiac arrest (SCA).

The electrodes send information about the person's heart rhythm to a computer in the AED. The computer analyzes the heart rhythm to find out whether an electric shock is needed. If a shock is needed, the AED uses voice prompts to tell you when to give the shock, and the electrodes deliver it.

Using an AED to shock the heart within minutes of the start of SCA may restore a normal heart rhythm. Every minute counts. Each minute of SCA leads to a 10 percent reduction in survival.

Training To Use an Automated External Defibrillator

Learning how to use an AED and taking a CPR (cardiopulmonary resuscitation) course are helpful. However, if trained personnel aren't available, untrained people also can use an AED to help save someone's life.

Some people are afraid to use an AED to help save someone's life. They're worried that something might go wrong and that they might be sued. However, Good Samaritan laws in each State and the Federal Cardiac Arrest Survival Act (CASA) provide some protection for untrained bystanders who respond to emergencies.

Facility owners who are thinking about buying an AED should provide initial and ongoing training to likely rescuers (usually people who work in the facility). Also, it's important to properly maintain an AED and notify local emergency officials of its location.



Simulation and education

Effects of AED device features on performance by untrained laypersons^{☆,☆☆}

Vincent N. Mosesso Jr.^{a,*}, Alan H. Shapiro^a, Karen Stein^b, Kelly Burkett^c, Henry Wang^a

^a Department of Emergency Medicine, University of Pittsburgh School of Medicine, Pittsburgh, PA, United States

^b Magee-Womens Hospital of UPMC, Pittsburgh, PA, United States

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ABSTRACT

Objective: Our study evaluates the impact of features of automated external defibrillators (AEDs) on the performance and speed of untrained laypersons to deliver a shock and initiate CPR after a shock.

Methods: This was a randomized trial of volunteer laypersons without AED or advanced medical training. Subjects were assigned to use one of six different models of AEDs on a manikin in simulated cardiac arrest. No instructions on AED operation were provided. Primary endpoints were shock delivery and elapsed time from start to shock. Secondary endpoints included time to power-on, initiation of CPR, adequacy of pad placement and subjects' ratings of ease of use (1 = very easy, 5 = very difficult).

Results: Most subjects (109/120; 91%) were able to deliver a shock. Median time from start of scenario to shock delivery was 79 s (IQR: 67–99). Of the 11 participants who did not deliver shock, eight never powered on the device. Time to power-on was shorter in devices with open lid (median 12 s, IQR 8–27 s) and pull handle (17 s, IQR 9–20 s) mechanisms than with a push button (37 s, IQR 18–69 s; $p = 0.000$). Pad position on the manikin was judged adequate for 86 (77%) of the 111 subjects who placed pads. Devices which gave more detailed voice instruction for pad placement had higher rates of adequate pad position [38/39 (97%) versus 50/73 (68%), $p = 0.001$]. With AEDs that provided step-by-step CPR instruction, 49/58 (84%) subjects began CPR compared to 26/51 (51%) with AEDs that only prompted to start CPR ($p = 0.01$). Participants rated all the models easy to use (overall mean 1.48; individual device means 1.28–1.71).

Conclusions: Most untrained laypersons were successful in delivering a shock. Device features had the most impact on these functions: ability and time to power-on device, adequacy of pad position and initiation of CPR.

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1. Introduction

Sudden cardiac arrest (SCA) is the leading cause of death among adults in the United States, striking as many as 325,000 individuals per year.¹ A common cardiac rhythm disturbance associated with sudden cardiac arrest is ventricular fibrillation (VF), for which the only effective treatment is rapid defibrillation.

New simplified automated external defibrillators (AEDs) enable untrained laypersons to deliver shocks to victims of cardiac arrest. A simulation study showed that sixth graders can deliver a rescue shock only 30 s slower than an experienced emergency medical technician or paramedic.² Another study showed that a 30 min

course in CPR and AED use was equivalent to the traditional full length course even after 6 months had passed, and that the AED was applied 93% of the time.³ Additionally, a recent study using three distinct methods of instruction to teach AED application and CPR, showed that all three methods were highly effective at instructing participants on AED use.⁴

There are many AED models available and these models have been shown to have varying success rates when used by laypersons. These models have similar functions, but features that affect the ease and speed of use vary among the devices. Simulation studies have shown marked variation in layperson operation.^{5–9} Since rapid defibrillation is of paramount importance in the treatment of SCA, it is important to identify what makes a device easy to use.

The majority of studies involving layperson AED use focus on the operation of the overall device and how quickly a shock can be delivered.^{5–10} One study looked at pad placement and successful shock delivery,⁴ and another study looked at the time from first shock to the initiation of CPR.⁸

This study focuses on specific ergonomic features of AEDs and how they affect the ease and speed with which a shock can be delivered, and how quickly after a shock CPR is initiated. We

[☆] A Spanish translated version of the abstract of this article appears as Appendix in the final online version at doi:10.1016/j.resuscitation.2009.07.016.

^{☆☆} Presented at National Association of EMS Physicians Annual Meeting, Naples, FL, 11 January 2007.

* Corresponding author at: Department of Emergency Medicine, University of Pittsburgh School of Medicine, 3600 Forbes Avenue, Forbes Tower, Suite 10028, Pittsburgh, PA 15213, United States. Tel.: +1 412 647 1103; fax: +1 412 647 1111.

E-mail address: mosesso@upmc.edu (V.N. Mosesso Jr.).

hypothesized that successful device operation is based on the ability to rapidly perform these main steps: turning the device on, placing the pads, delivering a shock, and starting CPR.

2. Methods

This was a prospective, randomized, observational evaluation of features of selected trainer AEDs in a controlled simulation environment. Volunteer subjects were assigned to one of the devices using a computer generated randomization table (Microsoft Excel). Cross-over design was not used due to concern for learning effect. The study was conducted at a university-affiliated sports medicine clinic and at a university event center.

A "trainer AED" was defined for this study as a training device designed to not deliver an electrical current while simulating shock or a clinical device with the shock function modified to prevent actual shock delivery. The devices were otherwise similar to the actual clinical devices.

The model of AED for each manufacturer was selected and provided by the manufacturer as the model that would be easiest for use by untrained lay persons. Device features were categorized a priori by the authors as shown in Table 1. Voice instruction for pad placement was categorized as simple or detailed. Simple instruction was voice prompt stating only to place pads on chest; detailed included more step-by-step instruction such as to remove backing from pads and more specific location description. All AEDs were programmed according to The American Heart Association 2000 Guidelines.

Volunteer subjects were recruited by flyers and direct contact with the investigators. The only exclusion criteria were prior training or experience in the use of an AED. Subjects received a five dollar gift card for use at the on-site coffee shop.

The study protocol was as follows: after agreeing to participate, subjects were screened for prior AED training and/or use and informed consent was obtained. The subject was given an instruction card that read, "In the adjacent area you will find a manikin and an Automated External Defibrillator. The manikin represents a person who is unconscious and not breathing. When instructed, enter the room and attempt to use the device as quickly as you can." No instructions on AED operation were given. The subject entered the room and attempted to use the device. The scenario was designed such that the first analysis made by the AED recommended a shock

and, if a shock was delivered, the next analysis advised shock not indicated. The scenario was stopped when CPR was initiated, 5 min of time had elapsed, or the subject expressed the desire to stop. The subject then completed a questionnaire. Questions addressed device operation, ability to locate and place pads, and voice, text and graphic prompts.

Time and event data were collected using simulation training software (SimMan, Laerdal Corporation) and transferred to Microsoft Excel. Times for the following actions were documented: start of scenario, AED power-on, pads placed, shock delivered, and start of CPR. The manikin's chest was photographed at the end of the scenario. Using the photos, a paramedic and a nurse not associated with the study independently evaluated the adequacy of pad placement for every scenario. They were instructed to judge each case as "adequate" or "not adequate" based on pad location and placement on bare skin to deliver successful shock. In the event they were unable to agree, an EMS physician not involved in the study was consulted to make the final determination.

Primary endpoints were shock delivery and elapsed time from start of scenario to shock. Sample size determination was calculated based on power of 0.8 to detect 25% absolute difference from 90% of subjects performing shock delivery with alpha at 0.05; this yielded need for 102 subjects. Secondary endpoints included time to power-on, time from second rhythm analysis to initiation of CPR, adequacy of pad placement and subject survey responses. Dichotomous data were compared with Chi-square or Fisher's exact test and continuous data with ANOVA. We compared performance differences among ergonomic features using survival analysis. Subjects rated the ease of use on a 5-point Likert scale (1 = very easy, 5 = very difficult). Data were analyzed using Microsoft Excel and STATA. We compared elapsed time differences using the Kaplan–Meier log-rank and Kruskal–Wallis tests. Only subjects who completed the specific task were included in time analyses.

This study was approved by the university Institutional Review Board.

3. Results

One hundred and twenty persons participated in the study. All but one completed high school and 45% had obtained a bachelor

Table 1
Comparisons of individual characteristics of AEDs by model.

Device name	Power on mechanism	Pad location	Pad placement voice instruction ^a	Shock instruction	CPR instruction	Extras
Cardiac Science PowerHeart AED G3	Open lid button	In lid upon opening	Detailed	Flashing light, voice and audio prompt	Step by step	Backlit screen to reinforce audio prompts, CPR countdown
HeartSine Samaritan PAD	On/off button	Pre-connected, underneath machine	Simple	Flashing lights, voice prompt	Prompt to start	Voice instruction for rescuer, audible manikin clicking noise every time a chest compression is to be delivered
Medtronic CR Plus	Open lid button	Pre-connected, pull handle to release	Simple	Flashing lights, voice prompt, audible tone	Step by step	CPR Timer, audio instruction to check breathing, if not breathing to start CPR
Phillips Heartstart OnSite	Large pull handle	Under cover, pull handle to release	Detailed	Flashing light, voice prompt, audible tone	Step by step	Detailed voice instructions, button to push for detailed help with CPR instructions
Welch Allyn AED 10	On/off button (inside zippered case ^b)	Pre-connected, in pouch on top of case	Simple	Button illuminates, voice and audio prompt	Prompt to start	Audio instruction to check airway, check breathing, start CPR
Zoll AED Pro	On/off button (inside zippered case ^b)	Pre-connected, in pouch on top of case	Simple	Button illuminates, voice prompt, audible tone	Prompt to start	

^a All devices provide visual prompts on pads, packaging, device or all three. See methods for definition of simple and detailed.

^b Case required to stow pads.

Table 2
Participant characteristics.

	Cardiac science	Heartsine	Medtronic	Phillips	Welch Allyn	Zoll	All AEDs	P-Value
Age (years)								
Median (range)	21.5 (18–59)	25.5 (19–61)	23.0 (18–66)	27.0 (18–77)	24.5 (18–60)	32.0 (18–64)	25.0 (18–77)	
Average	28.7	29.5	28.2	35.5	33.8	35.6	31.9	0.663
Sex								
Male (%)	9	13	9	9	9	15	64 (53)	
Female (%)	11	7	11	11	11	5	56 (47)	0.166
Language ^a								
English (%)	18	19	19	19	18	20	113 (94)	
Other (%)	2	1	1	1	1	0	7 (6)	0.527
Education ^a								
Some high school (%)	1	0	0	0	0	0	1 (1)	
High school (%)	3	2	1	2	4	3	15 (12)	
Some college (%)	9	9	9	7	8	6	48 (40)	
Bachelors (%)	4	5	6	5	5	6	31 (26)	
Masters (%)	1	2	2	5	2	2	14 (12)	
Doctorate (%)	2	2	1	1	0	1	7 (6)	
Other (%)	0	0	0	0	0	2	2 (2)	0.888
Medical training ^a								
None (%)	8	9	13	11	11	8	60 (50)	
CPR (%)	3	4	1	2	3	3	16 (13)	
First aid (%)	4	2	1	1	0	2	10 (8)	
Both (%)	5	5	5	6	6	7	34 (28)	0.982

^a One participant in the Welch Allyn group did not report a primary language, level of education, or medical training.

or post-graduate degree. Nearly half (42%) of participants reported prior CPR training (Table 2).

Most subjects (91%) were able to deliver shock. The most common individual step leading to failure to deliver shock was failure to power-on device (eight of 11 subjects) (Table 3). One hundred and eight (90%) subjects delivered shock within 180 s of starting the scenario. Median time from start to shock was 79 s (IQR: 67–99) but varied by device model (56–103 s, $p=0.001$) (Table 4 and Fig. 1).

Feature-based analysis (Table 5) revealed that time to power-on was shorter in devices with open lid (median 12 s; IQR 8–27 s) and pull handle (median 17 s; IQR 9–20 s) mechanisms than with a push button (median 37 s; IQR 18–69 s) ($p=0.000$). Pad position was judged adequate for 86 (77%) of the 111 subjects who placed pads. Devices which gave detailed audio instruction for pad placement had higher rates of adequate position [36/38 (95%) versus 50/73 (68%), $p=0.001$].

Only 75/109 (69%) subjects began CPR after shock delivery. With AEDs that provided step-by-step CPR instruction, 49/58 (84%) subjects began CPR compared to 26/51 (51%) among those who used AEDs that only prompted to start CPR ($p=0.01$) (Table 5).

Participants rated all the models easy to use (overall median 1, IQR 1–2). However statistical differences were noted among the devices when participants were asked how easy it was to turn the device on ($p=0.049$), ease of removing the backing from the AED pads ($p=0.002$), when to call 911 ($p=0.003$), and the ease of understanding the instructions for appropriate pad placement ($p=0.019$).

4. Discussion

Many cardiac arrest victims who now die can be saved with prompt defibrillation.⁵ For this to occur, laypersons must be able to use AEDs quickly and effectively. Our study found that a high per-

Table 3
Subject performance of individual steps by device model.

Device (N)	Powered on, N (%)	Pads placed on chest, N (%)	Adequate pad location ^a , N (%)	Shock delivered, N (%)	CPR started, N (%)
Cardiac science (20)	19 (95)	18 (90)	16 (89)	18 (90)	16 (80)
Heartsine (20)	16 (80)	17 (85) ^b	11 (65)	16 (80)	9 (45)
Medtronic (20)	20 (100)	20 (100)	17 (85)	20 (100)	15 (75)
Phillips (20)	20 (100)	20 (100)	20 (100)	20 (100)	18 (90)
Welch Allyn (20)	19 (95)	17 (85)	12 (70)	17 (85)	8 (40)
Zoll (20)	18 (90)	19 (95) ^b	10 (53)	18 (90)	9 (45)
All models (120)	112 (93)	111 (92)	86 (77)	109 (91)	75 (62)

^a Percentage reflects only the number of participants who placed the pads on the manikin.

^b One participant in each group placed the pads on the chest without turning the device on.

Table 4
Comparison of individual step time intervals by device model – median times (s (IQR)).

Device	Start to on	On to pad placement	Pad placement to shock	Overall time to shock	Shock to CPR
Cardiac science	8 (5–9)	68 (57–80)	34 (32–35)	101 (90–110)	45 (38–69)
Heartsine	32 (13–51)	43 (21–44)	23 (21–25)	62 (62–70)	34 (34–45)
Medtronic	25 (17–38)	48 (40–53)	26 (24–32)	76 (67–86)	44 (35–51)
Phillips	17 (9–20)	59 (51–65)	25 (25–26)	84 (77–97)	44 (34–55)
Welch Allyn	37 (19–54)	27 (18–45)	21 (16–28)	56 (36–74)	47 (40–48)
Zoll	66 (25–112)	74 (63–106)	25 (23–28)	103 (74–137)	39 (28–42)
All models	20 (10–44)	51 (39–67)	25 (23–33)	79 (67–99)	42 (35–53)

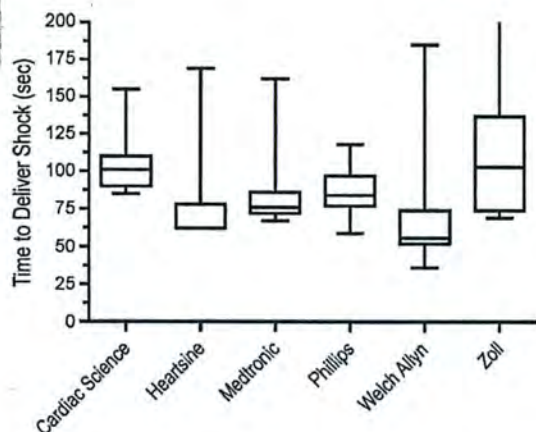


Fig. 1. Time intervals from start of scenario to shock delivery (median, IQR, and range shown).

centage of participants were able to deliver a shock within 180 s, which was also reported by other studies.⁵⁻¹² Other studies found that removing unnecessary voice prompts can shorten the amount of hands off time for the performance of CPR, and efforts to decrease the time to delivery of first shock and to encourage chest compressions after the first shock are likely to improve resuscitation success.^{13,14} Prior studies have compared different models of AEDs but this study is unique in its findings that specific device features impact AED operation and subsequent initiation of CPR. Our study found that ergonomic features had the greatest impact on three actions: powering on device, proper pad placement, and starting CPR after shock.

The devices with the open lid and pull handle power-on mechanisms had large identifying words or indicators easily noticed by the participants. The start buttons proved to be more difficult to locate and when the device was housed in a zipper case the amount of time it took for the study participant to push the start button increased by doubling their task load. Only two models took users significantly longer than the others to deliver a shock and one of the devices also took subjects longer to power-on by pushing a button. Overall, powering on the device on was the single most rate limiting step as eight participants were unable to accomplish this task.

Proper pad placement is likely affected by multiple variables, including visual and audible instructions, location of pads in device or device case, and ease of backing removal. Pad placement was deemed adequate more often when the device gave more detailed voice instruction. One exception was the Medtronic device, which was associated with high rate of adequate pad placement but was judged pre-trial to have less detailed voice instructions. This device has color coded visual prompts on pads and packaging which may have increased proper positioning. Pad placement was also found to be adequate more often when the storage location of the pads was

sitting on top of the device than when underneath the device or in a pouch or carrying case. This may be due to the layperson's ability to see the pads immediately upon opening the device. The device with both pads adhered to one backing tended to take rescuers longer to apply compared to those with separate backing. Inadequate pad placement was reported by Andre, who found that voice instruction and visual aids available to the lay rescuer led to more optimal pad placement for an adequate shock to be delivered.³ While pad placement was often deemed inadequate by independent evaluators, it must be recognized that shock efficacy for some placements deemed inadequate is not known.

Laypersons (with or without prior CPR training) were more likely to start CPR when using devices that provided more specific instructions on doing CPR. Although this would seem to take longer, time from shock to beginning CPR did not significantly differ between the devices with more detailed instruction (Cardiac Science, Medtronic, Phillips) and those that simply stated to start CPR (Heartsine, Welch Allyn, Zoll). It is important to note that during this study there was a time delay for the AEDs to re-analyze after a shock, as the AEDs were programmed according to the 2000 American Heart Association Guidelines. Initiation of CPR was looked at in another study, which had similar findings that the key factors for failure to do CPR were the content and the volume of the voice prompts, and that lay rescuers placed a great deal of trust in device prompts.⁸

While all participants rated the devices easy to use, there were some significant differences reported in the post scenario survey. Being able to turn the device on is critical to operation of any AED. The pull handle and push to open (devices started automatically once the lid was opened) AEDs were rated easier to use when compared to the AEDs with an on/off button. Our participants found that most of the devices provided clear prompt to call 911, but they rated the Zoll unit less clear than the others.

The ability of participants to remove the backing from the pads varied among the models of AEDs as well. This may have had to do with instruction on removing the backing from the pads, pad adherence to the backing material, or the participants' lack of understanding that some of the pads are placed back to back with one piece of material in between them. The Cardiac Science and Zoll pads were rated as the most difficult to remove, whereas the Heartsine and Medtronic pads were deemed the easiest.

Based on our findings, the authors propose combining the best features from different models into an "optimal" AED. The open lid or pull handle are superior to the push button in ease and speed of powering on the device. Design not requiring a separate case, such as the zippered cases, also decreases time to power-on. Device design should allow immediate visibility of pads upon initiation of use, and pads should have separate backing which is clearly marked with a removal tab. Pad placement instruction should be as detailed as possible, as the more detailed the pad placement instruction the more likely pad placement is to be adequate to deliver a successful shock. CPR instruction should be given as step-by-step instruc-

Table 5
Subject performance of individual steps by device feature.

Feature	Participant success, N (%)	P-Value	Median time (s (IQR))	P-Value
Power-on mechanism (N = all subjects)	Powered on			
Open lid (40)	39 (97)		12 (8-27)	
Pull handle (20)	20 (100)		17 (9-20)	
Push button (60)	53 (88)	0.079	37 (18-69)	0.000
Pad placement instruction (N = subjects who turned on device)	Adequate placement			
Simple voice instruction (73)	50 (68)			
Detailed voice instruction (38)	36 (95)	0.001		
CPR instruction (N = subjects who delivered shock)	CPR initiated			
Start CPR only (51)	26 (51)			
Step-by-step instruction (58)	49 (84)	0.01		

tion, including talking the user through chest compressions, as lay rescuers are more likely to perform CPR with instruction than without, as concluded in another study.¹⁵ The visibility of power-on mechanism, the ease of finding pads, clarity and preciseness of pad placement instructions and step-by-step CPR instruction are ergonomic features that can be modified to assist the lay rescuer in increasing the ease and speed of use of the AED. We suggest that for each step of AED operation, both the clarity and completeness of instructions (aural and visual) and the intrinsic ergonomic attributes of the device should be optimized.

Device features associated with increased performance rate were not always associated with shorter times to shock. This may reflect benefit of more detailed instructions for untrained users. Trained users may be able to deliver shock faster with less intensive verbal instruction.

Our study has a number of important limitations. Performance in a simulated setting may not reflect actions in an actual cardiac arrest. Subjects may not have represented the general US population, as 45% completed college, only 2 were over the age of 65, and none were under the age of 18. We presumed all subjects were truthful and did not use an AED or have any prior AED training. In six cases English was not the primary language and this may have impeded those subjects' ability to follow the instructions and prompts correctly. Some photos of pad placement were not labeled properly so we could not determine the number of subjects who both delivered shock and placed pads in adequate position. Features not assessed in this study may also impact device use; we tried to select those that seemed most important.

Future studies could explore the effect of non-standard pad location on shock success, factors that might improve the location of pad placement and the ability of untrained individuals over the age of 65 or under the age of 18 to operate an AED.

5. Conclusion

In a simulated cardiac arrest setting, most untrained AED users were able to deliver a shock within 180 s. Pad placement was often inadequate. Device features were found to have the most impact on time to power-on, accuracy of pad placement and initiation of CPR.

Conflicts of interest

VNM receives compensation for serving as medical director from the Sudden Cardiac Arrest Association, Washington, DC, a non-profit organization which promotes greater awareness and prevention and better treatment of sudden cardiac arrest.

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AED devices were loaned and disposable supplies provided by the manufacturers of the six devices used in the study. The final study design and manuscript were solely determined by the authors. Manufacturers did not have access to the study database.

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AUTOMATED EXTERNAL DEFIBRILLATOR USE BY UNTRAINED BYSTANDERS:

CAN THE PUBLIC-USE MODEL WORK?

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ABSTRACT

Objective. For automated external defibrillators (AEDs) to be practical for broad public use, responders must be able to use them safely and effectively. This study's objective was to determine whether untrained laypersons could accurately follow the visual and voice prompt instructions of an AED. **Methods.** Each of four different AED models (AED1, AED2, AED3, and AED4) was randomly assigned to a different group of 16 untrained volunteers in a simulated cardiac arrest. Four usability indicators were observed: 1) number of volunteers able to apply the pads to the manikin skin, 2) appropriate pad positioning, 3) time from room entry to shock delivery, and 4) safety in terms of touching the patient during shock delivery. **Results.** Some of the 64 volunteers who participated in the study failed to open the pad packaging or remove the lining, or placed the pads on top of clothing. Fifty-percent of AED2 pads and 44% of AED3 pads were not placed directly on the manikin skin compared with 100% of AED1 and AED4 pads. Adjacent pad displacements that potentially could affect defibrillation efficacy were observed in 6% of AED1, 11% of AED2, 0% of AED3, and 56% of AED4 usages. Time to deliver a shock was within 3.5 minutes for all AEDs, although the median times for AED1 and AED4 were the shortest at 1.6 and 1.7 minutes, respectively. No significant volunteer contact with the manikin occurred during shock delivery. **Conclusions.** This study demonstrated that the AED user interface significantly influences the ability of untrained caregivers to appropriately place pads and quickly deliver a shock. Avoiding grossly inappropriate pad placement and failure to place AED pads directly on skin may be correctable with improvements in the AED instruction user interface. **Key words:** automated external defibrillators; cardiac arrest; resuscitation; emergency medical services.

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Sudden cardiac arrest (SCA) is a leading cause of death in the United States, resulting in 250,000 to 450,000 deaths per year.^{1,2} Unlike many other life-threatening illnesses and conditions, sudden cardiac arrest due to ventricular fibrillation (VF) often occurs outside of a medical setting. The estimated national survival rate is less than 5%.³ Survival from SCA has been well correlated with the rapidity of delivering a successful defibrillatory shock. In most instances, survival is limited by the arrival time of an emergency medical service with the capacity to provide rapid defibrillation. If no bystander CPR is provided, survival decreases dramatically for every minute that transpires between collapse and successful defibrillation.³

Recently, access to automated external defibrillators (AEDs) has increased in public and corporate environments. For example, AEDs have been placed in airports, airplanes, shopping malls, government buildings, and various other public places.⁴ In most of these environments, selected individuals (e.g., flight attendants) are trained to use the devices. However, it is clear that, to make an impact on the SCA mortality rate, these devices must be made accessible to and usable by bystanders, who may not have received prior AED training. Moreover, for these devices to be practical for broad public use, they must be designed in a way that allows people to use them quickly, easily, and effectively in the context of an unexpected and dramatic emergency medical situation. This premise represents an important challenge to AED manufacturers, many of whom have historically designed devices to be used by trained medical professionals (e.g., nurses or emergency medical technicians (EMTs)) and, more recently, by selected and trained lay individuals (e.g., flight attendants, lifeguards, or security personnel). Current-generation AEDs all have voice prompts and graphical instructions to guide the user. But it is not known whether these interfaces are sufficient in supporting a public-use model for untrained bystanders.

Given that success with lay users is a critical goal for the broad public deployment of AEDs, it is important to determine whether AEDs can be used effectively, and without undue difficulty, by the average layperson.^{5,6} Our objectives were, first, to determine whether laypersons with no prior exposure or training with AEDs could accurately follow the voice and graphical prompts in a simulated cardiac arrest, and, second, to

determine if there were observable differences between four AEDs in terms of usability. The primary goal of this study was to gain insight into AED usage with untrained volunteers. This information could then be incorporated into the design improvements of AEDs. The four usability factors evaluated were: 1) number of volunteers able to remove pads from packaging, remove the liner, and apply the pads to the manikin skin, 2) appropriate pad placement as guided by the manufacturer's pad icon, 3) time from room entry to shock, and 4) safety in terms of touching the patient during shock delivery.

METHODS

Volunteer Selection and Randomization

The study was conducted in April 2003 at the Usability Testing Research Facility of Interface Analysis Associates, a human factors, ergonomics, and usability consulting firm. Adult participants between the ages of 35 and 55 years were recruited via public advertisement and direct-mail letters to local businesses. Participants were prescreened via phone interview and excluded if they worked in medical or related fields, or had any exposure to, prior training, or familiarity with AEDs. Participants were also excluded if they self-disclosed any of the following: poor English comprehension, cardiopulmonary resuscitation (CPR) training within the last 24 months, sight or hearing impairment (that was not corrected), or injuries or disabilities that would prevent the participant from bending down, kneeling on the ground, or holding a package. All participants granted written permission and received \$50 for participation. The study was exempted from institutional review board approval because it did not meet the criteria of an investigational study and was determined to have nonsignificant risk.

Volunteers were assigned to one of the four AED groups using a stratified random sampling technique, where gender and age were equally distributed across the four groups. Within the block randomization strata, volunteers were sequentially assigned to an AED in the order they presented for testing. Each of the four AEDs was used by a different group of 16 participants.

AEDs Used

To examine our assumption that AEDs differ in the quality of voice and graphical prompts, thus affecting usability, four different AEDs were studied: AED1 was the Philips HeartStart OnSite (Seattle, WA), AED2 was the Zoll AED Plus (Chelmsford, MA), AED3 was the Cardiac Science Powerheart (Irvine, CA), and AED4 was the Medtronic CRPlus (Minneapolis, MN). To make the simulation more realistic, clinical AEDs were used as opposed to AED trainers. The AEDs were



FIGURE 1. The manikin with wires stitched into the skin covering the right and left sides from the upper chest through the abdomen. The wires were attached inside the manikin to a rhythm simulator to provide the electrocardiographic (ECG) ventricular fibrillation (VF) signal. The wires allowed transmission of impedance and ECG signals to the electrode pads simulating a patient in VF.

modified so that, when the shock button was pressed, no actual shock was delivered. No other modifications were made to the AEDs. Fully charged batteries and clinical pads were used throughout the study.

Resuscitation Simulation Setup

The volunteers were asked to rush into a room and attempt to use an AED to resuscitate a victim of sudden cardiac arrest. Volunteers were provided with only basic information about the main functions of an AED (Appendix-A) before they entered the room where they found a fully clothed, full-sized adult manikin (Resusci Anne; Laerdal Medical, Wappingers Falls, NY) on the floor and one of the four AEDs nearby. The volunteers were guided only by the instructions (the AED voice and graphical prompts) specific to that AED. The manikin was dressed in pants, a button-front shirt, and zippered jacket. Wires were stitched into the plastic skin covering the right and left sides of the manikin from the upper chest through the abdomen and attached to a rhythm simulator (Symbio AED Simulator; Symbio Corporation, Beaverton, OR) to provide the electrocardiograph (ECG) VF signal (Figure 1). The wires allowed transmission of impedance and ECG signals to the electrode pads simulating a patient in VF. The AEDs were able to detect that the

pads had been placed and analyze the signal when one pad was placed on the right side of the chest, and the other pad placed on the left side of the chest. Note that the wires intentionally covered a large area of the manikin so that the volunteers would not deduce correct pad position. The AED would then analyze the signal and advise a shock. Note that a limitation of the test setup was that if both pads were placed on the same side of the chest, only an asystolic signal was transmitted to the AED (so no shock was advised). In addition, any pad placed in the middle of the chest (where no wires were present) or with only a small portion making contact with the wire, resulted in an inability of the AED to recognize that the pads had been placed on the manikin. Two remote-controlled video cameras were used to record the AED use; three observers were located in a control room behind a one-way mirror.

Assessment of Usability Factors

The number of volunteers who were able to remove pads from packaging, remove the liner, and apply the pads to the manikin skin was recorded for each AED and volunteer. The "ideal" pad position was determined before the study began based on each manufacturer's recommended location, as depicted on the pad icon for each AED. The position was agreed on by three observers (ADA, DBJ, JEP) and then a template defining the "ideal" pad location for each AED was created from a plastic sheet laid over the manikin thorax. This was then used to measure pad displacement from the ideal by placing the sheet over the pads after each trial and measuring the discrepancy between actual pad placement and the template-indicated ideal pad location. Measurements were made from the ideal center of the template pad to the actual center of the pad placed by the volunteer on the manikin. Electrode pad placement measures were collected immediately after each trial. Digital photos were also taken of pad positions after each trial, and these were later reviewed to further record and verify pad displacement, contact with manikin skin, and removal of pad liners.

The number of volunteers who were able to proceed through the trial to the point of pushing the shock button was recorded for each of the AEDs tested. The time from entry into the room until the AED was

turned on, pads were positioned, a shock was advised, and the shock was delivered was recorded. Timing was accomplished via video recording and stopwatch. Safety was defined in terms of instances of users' touching the manikin during shock delivery. The trial ended after the volunteer had successfully delivered a shock, 5 minutes had elapsed from entry into the room, the device did not advise a shock or entered the CPR pause mode, or the volunteer expressed a desire to stop.

Statistical Analysis

The statistical analysis was performed with StatXact, version 5 (Cytel Software, Cambridge, MA) and Statistica, version 6 (StatSoft, Tulsa, OK). Outcome variables were tested for statistical significance of overall effect using exact nonparametric methods. The Fisher-Freeman-Halton test was employed for categorical data, and the Kruskal-Wallis analysis of variance was used for continuous variables. If a statistically significant overall effect was identified, between-group comparisons were performed using Fisher's exact test for categorical data and exact Mann-Whitney tests for continuous data.

RESULTS

Volunteer Demographics

There were 64 volunteers who participated in the study. The occupations of the volunteers spanned a wide range of industries and activities, including teachers, security guards, sales representatives, software developers, office administrators, waitresses, and truck drivers. Each AED group comprised eight male and eight female participants. Table 1 summarizes the demographic characteristics of the four volunteer groups. The median age of the volunteers was 44 years; the distributions of ages were not statistically significantly different between the groups ($p = 0.70$). The educational levels of volunteers were not statistically significantly different between the groups ($p = 0.77$).

Simulation Setup and Data Collection

In several instances, pads were placed on the manikin in areas where no wires were present. One volunteer (using AED4) placed the right sternal pad over the sternum where there were no wires; we included the pad-placement data from this case, but time-to-shock data were not available. In two other cases (one AED1 and one AED4), both pads were placed on the same side of the chest, so again pad-placement data were included but there were no time-to-shock data. In a final case (AED1), pads were properly placed on the

TABLE 1. Demographics of Study Participants

Device	AED1	AED2	AED3	AED4
Age in years (mean \pm SD, $n = 16$)	44 \pm 7	43 \pm 7	45 \pm 6	43 \pm 5
High school/vocational	3	3	5	5
Post-high school	13	13	11	11

AED = automated external defibrillator; SD = standard deviation.

TABLE 2. Shock Delivery and Pad Placement Measures

Device	AED1	AED2	AED3	AED4
Pads applied to skin	*100% (16/16)	50% (8/16)	56% (9/16)	*100% (16/16)
Pad displacement error (cm)	†S 4.8 [3.0–5.9] A 4.5 [2.3–7.0]	†S 3.5 [2.8–5.5] A 3.5 [2.4–5.5]	S 6.5 [3.8–8.4] A 6.5 [4.4–10.0]	S 7.5 [4.6–16.3] A 12.3 [2.8–17.4]
Separation of pads (cm)	‡16.0 [12.0–17.9]	‡15.0 [13.0–15.3]	11.0 [7.3–12.8]	5.5 [3.8–13.8]
% Pads placed adjacent	†6% (1/16)	†11% (1/9)	†0% (0/13)	56% (9/16)
% Successful shock delivery	*100% (14/14)	§44% (7/16)	75% (12/16)	*100% (14/14)
Time to shock (sec)	*99 [84–109] n = 14	§210 [170–287] n = 7	132 [96–196] n = 12	*93 [78–115] n = 14

S = right upper parasternal pad; A = left apex pad, median [interquartile].

*p < 0.05 vs AED2 and AED3.

†p < 0.05 vs. AED4.

‡p < 0.05 vs. AED3 and AED4.

§p < 0.05 vs. AED3.

manikin chest, but the AED did not recommend a shock; this was subsequently identified as caused by an ECG artifact originating within the test setup, so only pad-placement data were included.

In terms of the number of volunteers able to remove pads from packaging, remove the liner, and apply the pads to the manikin skin, Table 2 contains a summary of the pad-placement results. Significant proportions of volunteers were unable to attach pads directly to the manikin skin (50% AED2 and 44% AED3). Many volunteers did not remove the pads from the packaging, placed the pads on top of clothing, or left liners on the pads. Two of the AED2 users and three of the AED3 users never managed to open the pad package. Another two AED2 users and four AED3 users failed to remove the liner from one or both electrode pads. Five AED2 users placed the pads directly over the victim's clothes (see Figure 2). Further, we observed that, in 31% of AED4 uses, participants inadvertently pulled the pad connector plug out of its socket while attempting to open the pad package.

In terms of appropriate pad location placement as guided by the manufacturer's pad icon, Table 2 summarizes the average displacement from ideal center for apical and right sternal pads for all four AEDs tested. The greatest displacement error (12.3 cm) was noted with AED4. More important was the observation that, in some instances, pads were placed in positions that were *adjacent* to each other, meaning locations 1) side by side, 2) on the same side of the chest, 3) at the same vertical level, or 4) touching each other. Our results demonstrated inappropriate pad adjacency in 56% of uses of AED4 (Figure 3) uses versus a range of 0% to 11% with the other devices. Table 2 also contains the measured separation between the pads. Median separation was as low as 5.5 cm (AED4). The close proximity of the pads resulted primarily from placement of the apical pad medially and cranially.

For the time from room entry to shock delivery, nine of the 16 users of AED2 (56%) and four of the 16 users of AED3 (25%) failed to administer a shock to the simulated victim (Table 2). Three of the four AED3 users who failed to remove the liner from one of the pads still received a shock command, because the AED3 liner has small holes that allow a fraction of the pad to contact the skin even with the liner left on. These were counted as successful shock deliveries, though appropriate energy delivery for defibrillation would likely be severely compromised.

In contrast, AED1 and AED4 users were successful in delivering a shock in all valid trials. In the time it took users to deliver a shock, AED1 and AED4 were mathematically similar (Figure 5, Table 2). The median times were well under 2 minutes, at 99 and 93 seconds, respectively. The other two devices were significantly slower, with users of AED3 taking 132 seconds (just over 2.0 minutes), and users of AED2 taking 210 seconds (or 3.5 minutes). We also looked at time per AED task for each of the four AEDs, broken down into



FIGURE 2. An example of electrode pads placed over the victim's clothes.

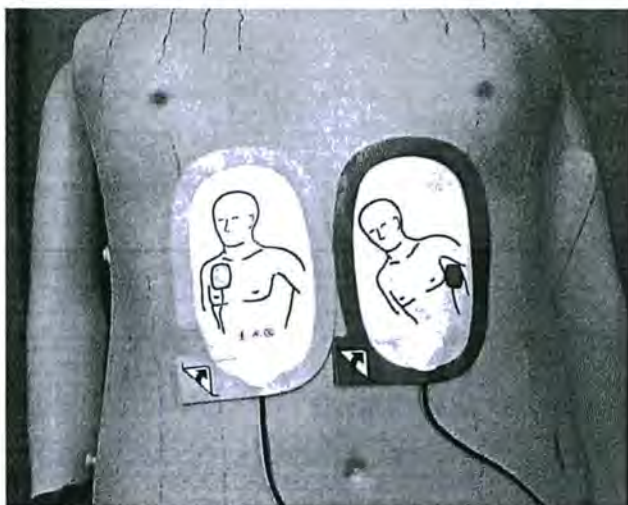


FIGURE 3. An example of electrode pads placed adjacent to each other.

five time segments: AED power on, first pad on (attached), second pad on, shock command given, and shock delivered. As shown in Figure 5, the "lost" time for AED2 and AED3 compared with AED1 and AED4 was primarily in achieving pad placement.

For safety in terms of touching the patient during shock delivery, in three cases the volunteer was in contact with the manikin during shock delivery. In two cases (AED4), the contact was clothing to clothing, with the participant's right knee touching the manikin's right arm and the participant's right knee touching the manikin's right knee. In one case (AED2), the participant's right knee touched the manikin's right hand (clothing-to-skin contact).

DISCUSSION

Success with untrained users is a critical goal for the broad public deployment of AEDs. We investigated the ability of untrained volunteers to use an AED without prior exposure or training with an AED. Specifically, we wanted to observe how well a layperson could initiate usage of the AED and follow through with the given directions to the point of delivering a shock. Previous studies have suggested that this is possible with some AEDs.⁷⁻¹¹ For example, the majority of patients who survived a sudden cardiac arrest in Chicago airports over a two-year period were saved by persons who had no duty to act and no prior training in the use of AEDs.⁷ Another study showed that naive 6th graders could successfully employ an AED.⁸ A recent study by Eames et al. compared ease of use of three AEDs by untrained laypeople.⁹ They found statistically significant differences among AEDs, including time to shock and pad position. The Eames study differs from this study in that they used AED training devices (Larsen P, personal communication,

2003), they scored all pad positions against the same criteria regardless of manufacturer's instructions, and volunteers randomly used all devices, thus introducing learning effects.

In this study of simulated cardiac arrest, we observed several important mistakes made by untrained volunteers when attempting to follow the voice and visual AED prompts. A specific focus of this study was the ability of participants to correctly position pads on the manikin. Obvious errors that would affect defibrillation success included failure to remove the pads from the packages or to remove the pad backings, or placing the pads on top of the clothes. Pad location was evaluated and compared with the manufacturer ideal location as directed by the pad icons. "Correct" or "ideal" position varies between the four AEDs, but they share the similarity of a right upper sternal and a left apical pad position. Displacement from ideal center may not have a clinical significance as long as an appropriate vector for defibrillation can be maintained. We therefore highlighted pad displacement that might raise concerns in a true clinical setting. Those were the instances when pads were placed adjacent to each other, often at the same level on the chest or on the same side of the chest. One of the AEDs (AED2) has a fixed connection between the apical and sternal pads that prevented the two pads from being placed in adjacent positions. Whether a fixed pad position would be adequate for a variety of different thorax sizes is unknown.

Another observation was the tendency to displace the left apical pad medially and cranially, which if anything would be more likely to decrease defibrillation efficacy as the two pads come into proximity of each other and the apical pad moves away from overlying the left ventricular myocardium, particularly in patients with dilated hearts. One wonders if this tendency, as well as the instances of pad adjacency, is derived from television scenarios of defibrillation where handheld paddles are usually placed in right upper and left upper parasternal positions. The risk of current shunt between the pads is a function of distance and the resulting vector defined by the specific pad placement. Catherine et al. found that, when one electrode was placed in the right parasternal position and the other within 2 cm in the left parasternal position, the theoretical percentage of current traversing the heart was significantly reduced.¹²

Pad placement has been well documented as the Achilles' heel for lay responders and those with advanced training alike.¹³⁻¹⁵ Heames et al. tested the ability of doctors to position paddles correctly on a manikin and found 35% of the sternal and 78% of the apical paddle placements to be incorrect.¹³ Meischke et al. reported that the most difficult task in a simulation study with seniors was correct pad placement.¹⁴

Approximately 17% following initial training and 48% at the retesting three months later did not correctly place the pads on the manikin. Mattei et al. tested untrained nurses and physiotherapists and reported that 53% failed to initially position the pads correctly, although all participants were able to place the pads appropriately following training.¹⁵ This study is consistent with these previous findings and extends them to the realm of public use. We found that the least pad placement error occurred with AED1 both in terms of displacement from ideal center and in no instances of pad adjacency error. This probably is because of the very specific voice prompt "Look carefully at the pictures on the white adhesive pads ... place pads exactly as shown in the picture" and the fact that both pad placement icons are shown on each pad, giving users a good sense of the relative placement of the two pads (Figure 4). This was also true of AED2 and AED3, which had a low instance of pads' being placed in adjacent positions. In addition, AED1 includes sensor technology that detects the current action of the user and adjusts the voice instructions to match that action. We observed many instances with the other three devices where the audio instruction and the user's current action were incongruent.

An important issue in AED usage is how quickly a shock can be delivered. Brillhart et al. used AED recordings and emergency medical services (EMS) reports to study the time elapsed for EMTs to arrive on scene and recognize cardiac arrest to shock delivery.¹⁶ They found the median time for the EMTs was 51 seconds. The investigators suggested a 1-minute goal and a 90-second minimum standard for time to first shock by EMTs using AEDs in the field. Although most of the users of the AEDs in this study were able to deliver a shock in less than 2.0 minutes, the users of AED2 took 3.5 minutes. One difference is that users of this AED found it difficult even to turn on the device (Figure 5). Nevertheless, the time to shock for all the devices tested, if used in an actual SCA, would likely result in a significant time reduction compared with that which can be achieved by awaiting the arrival of most EMS responders.¹⁷

One concern that has been raised regarding layperson usage of an AED is whether the rescuer might inadvertently receive a shock by touching the victim. We observed only three instances of participants' contacting the manikin during the simulated shock; none of these instances would likely cause serious harm. In each case, the volunteer's knee or hand made a single point of contact with the victim's clothes during shock delivery.

Resuscitating a victim of cardiac arrest involves much more than operation of an AED. Recognizing the cardiac arrest, calling EMS, and performing CPR as a bystander are all important steps; however, timely



FIGURE 4. Icon for AED1 (one of the four automated external defibrillators studied) depicting the relative locations for both pads.

defibrillation is a critical factor for those patients in VF. Defibrillators that are to be used by lay responders should be designed from a human-centered perspective. That is, they should provide useful, timely guidance, include effective and salient graphics, and induce acceptable levels of workload and stress. This study demonstrated that all AEDs share a common set of functionality and, if used correctly, result in the delivery of a shock to the victim, but the objective experiences of the users are likely to vary greatly based on the presence or absence of critical usability design attributes.

To be effectively used by untrained laypersons, AEDs targeted for use by the lay public must be tested to determine whether they are intuitive enough. In the present study, we found that performance suffered for AEDs that 1) had to be manually turned on, 2) provided a minimal and implicit set of instructions, 3) incorporated components that easily became loose or detached, 4) did not provide an image of both pads on the pad placement graphic, and 5) failed to guide the user explicitly through the pad-placement process. These five critical usability design attributes accounted for nearly all performance and behavioral deficiencies observed in this study.

LIMITATIONS

This study is limited in that it was a simulation of a cardiac arrest. However, an actual emergency situation would likely increase the stress and confusion of the rescuer and amplify some of the results found here. A limited number of volunteers participated in this observational study, which was not powered to test any specific hypothesis. Training would likely increase the ability of users to place pads appropriately and deliver a shock and is recommended in all AED manufacturers' labeling. However, in the context of public access, defibrillation users may very well be

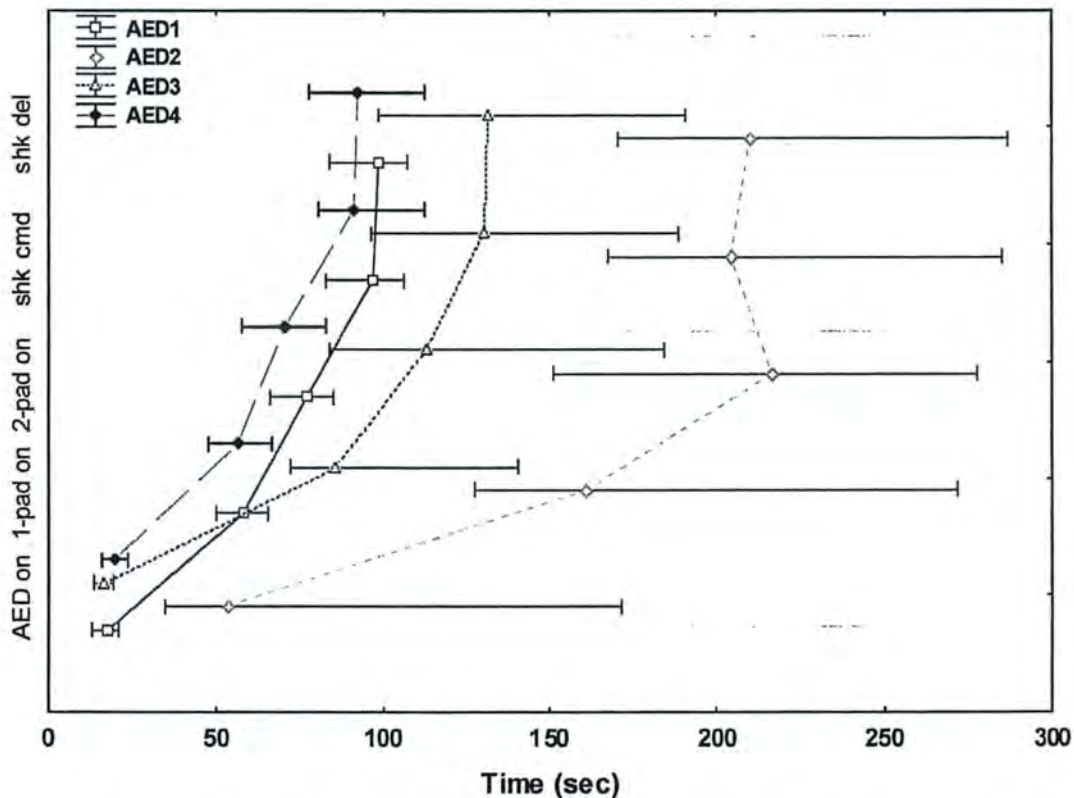


FIGURE 5. Breakdown of automated external defibrillator (AED) tasks and timing for each device, median [interquartile range]. Note that pad application times are inclusive of all uses with pads placed on clothes and liners left in place, even if shocks were not delivered.

untrained.⁷ Further, issues with training retention may limit the ability of a previously trained caregiver to use an AED.

CONCLUSIONS

Because laypersons and innocent bystanders with no prior exposure to, training with, or understanding of AEDs may use them in public settings during an unexpected emergency, the devices must be intuitive to use. We found observable differences among the AEDs we studied and have identified a number of AED pad-placement errors that could theoretically lead to ineffective defibrillation. Untrained laypersons require a categorically different level of guidance and design support than do traditional medical professionals or trained laypersons. Pad icon graphics, voice prompts, and industrial design significantly influence the ability of caregivers to deliver a shock appropriately and quickly. Although the majority of our study's rescuer volunteers were able to deploy the AED to the point of shock delivery, not all AEDs were able to guide the rescuer through AED use in a manner that would ensure the highest likelihood of successful defibrillation. We conclude that untrained laypersons can safely and effectively use an AED in the public-use context

simulated in this study only when a clear, comprehensive, and explicit instruction scheme is employed.

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APPENDIX A

PARTICIPANT INSTRUCTIONS

This is a study of your response in a simulated emergency to a victim of sudden cardiac arrest. Sudden cardiac arrest is a condition that occurs unexpectedly when the heart stops pumping effectively. Soon you will be asked to enter a room across the hall where you will find a simulated cardiac arrest victim (a mannequin). I hope this is never the case, but let's assume it is a friend of yours who suffered a cardiac arrest while you were out shopping together. You should assume the following:

- 9-1-1 has already been called.
- The victim is not breathing and does not have a pulse.

In the room you will also find an Automatic External Defibrillator, or AED device. Defibrillation with an AED is the delivery of an electrical shock to a patient's heart. Defibrillation is intended to allow the heart to restart itself and begin pumping again. Unless a shock is successfully delivered, your friend will die in minutes. I want you to use this AED to attempt to save your friend's life.

People will be observing and videotaping your actions; but you may not ask them questions or ask for help until after you have saved your friend. During the test we will be timing you. Keep in mind that we would like you to act in the same manner as you might during an actual emergency where timing is important and every second counts.

Note that this is a simulation; you will not actually deliver a shock, but the product will work in all other aspects. You cannot pass or fail this test. I only ask that you act with the same sense of urgency, determination, and care that you would bring to a real emergency situation of this kind.

Some final things to note:

- When you enter the room, the victim will be lying on the floor in the center of the room.
- The AED device will be located on a chair to your left.
- You already know that the victim is not breathing and has no pulse and therefore you should immediately use the AED rather than initiate any form of CPR. 9-1-1 has already been called.
- Remember, when I open the door for you across the hall, you are about to attempt to save a life. Your goal should be to deliver a shock to your friend's heart as quickly as possible. Every second counts.