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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	Zoraida Pagett to Elizabeth Drye re: SSN and DOB (partial) (1 page)	05/27/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20465

FOLDER TITLE:

Portable Defibrillators

2012-0463-S

rc814

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

MEMORANDUM

TO: Tom Freedman, Mary Smith
FROM: David Hochschild
DATE: July 8, 1998
RE: AED's

Heart
Abstracts
GW

Who's buying AED's (besides the airlines):

- Chicago City Council has proposed an ordinance that would require most city-owned buildings and high-occupancy areas such as office skyscrapers, apartment buildings and sports stadiums to purchase AED's.
- AED's are becoming much more common in police and fire departments across the country. The results, however, have not necessarily matched the publicity. In Cincinnati, 32 police cruisers have carried AED's for a year but they have only been used twice and the patient died in both cases.
- Boston, in addition to equipping police and fire personnel with AED's, has installed the device in two of the biggest highrise buildings downtown (the John Hancock Tower and the Federal Reserve Bank Building). They have trained the buildings security guards how to use the equipment. At 24%, Boston's cardiac arrest survival rate is now second only to Seattle's (at 34%).
- Lifeguards, beginning with those in some counties in Florida, are now equipped with AED's.
- Ohio, Illinois and West Virginia are all beginning to use AED's in schools.

Bill Summary & Status for the 105th Congress

[NEW SEARCH](#) | [HOME](#) | [HELP](#)

H.R.4121SPONSOR: [Rep Stearns](#) (introduced 06/23/98)RELATED BILLS: [S.2196](#)

Jump to: [Titles](#), [Status](#), [Committees](#), [Amendments](#), [Cosponsors](#), [Summary](#)

TITLE(S):

- **SHORT TITLE(S) AS INTRODUCED:**
Cardiac Arrest Survival Act
 - **OFFICIAL TITLE AS INTRODUCED:**
A bill to amend the Public Health Service Act to provide for the establishment at the National Heart, Lung, and Blood Institute of a program regarding lifesaving interventions for individuals who experience cardiac arrest, and for other purposes.
-

STATUS: Floor Actions***NONE***

STATUS: Detailed Legislative Status**House Actions****Jun 23, 98:**

Referred to the House Committee on Commerce.

Jul 2, 98:Referred to the Subcommittee on Health and Environment.

STATUS: Congressional Record Page References***NONE***

COMMITTEE(S):

- **COMMITTEE(S) OF REFERRAL:**
[House Commerce](#)
 - **SUBCOMMITTEE(S):**
[Hsc Health and the Environment](#)
-

AMENDMENT(S):***NONE***

54 COSPONSORS:

<u>Rep Gekas</u> - 06/23/98	<u>Rep Serrano</u> - 06/23/98
<u>Rep Waxman</u> - 06/23/98	<u>Rep Frost</u> - 06/23/98
<u>Rep Mink</u> - 06/23/98	<u>Rep Filner</u> - 06/23/98
<u>Rep Hilliard</u> - 06/23/98	<u>Rep McCollum</u> - 06/23/98
<u>Rep Kennelly</u> - 06/23/98	<u>Rep Clement</u> - 06/23/98
<u>Rep Shays</u> - 06/23/98	<u>Rep Faleomavaega</u> - 06/23/98
<u>Rep Hastings, Alcee</u> - 06/23/98	<u>Rep Carson</u> - 06/23/98
<u>Rep Wolf</u> - 06/23/98	<u>Rep Walsh</u> - 06/23/98
<u>Rep Boehlert</u> - 06/23/98	<u>Rep Smith, Linda</u> - 06/23/98
<u>Rep Cook</u> - 06/23/98	<u>Rep Delahunt</u> - 06/23/98
<u>Rep Foley</u> - 06/25/98	<u>Rep Canady</u> - 06/25/98
<u>Rep Meehan</u> - 06/25/98	<u>Rep Bono, Mary</u> - 07/14/98
<u>Rep Slaughter</u> - 07/14/98	<u>Rep Mollohan</u> - 07/14/98
<u>Rep Davis, T.</u> - 07/14/98	<u>Rep Clayton</u> - 07/14/98
<u>Rep Pascrell</u> - 07/14/98	<u>Rep Hoyer</u> - 07/14/98
<u>Rep Eshoo</u> - 07/15/98	<u>Rep Green</u> - 07/16/98
<u>Rep Martinez</u> - 07/20/98	<u>Rep Lofgren</u> - 07/24/98
<u>Rep English</u> - 07/24/98	<u>Rep Thurman</u> - 07/24/98
<u>Rep Greenwood</u> - 07/24/98	<u>Rep Sanchez</u> - 07/24/98
<u>Rep Capps, Lois</u> - 07/30/98	<u>Rep Kind</u> - 07/30/98
<u>Rep Kelly</u> - 07/30/98	<u>Rep Matsui</u> - 07/30/98
<u>Rep Torres</u> - 08/06/98	<u>Rep McHugh</u> - 08/06/98
<u>Rep Murtha</u> - 09/09/98	<u>Rep Rahall</u> - 09/09/98
<u>Rep Price</u> - 09/17/98	<u>Rep LaHood</u> - 09/17/98
<u>Rep Hinchey</u> - 09/23/98	<u>Rep Woolsey</u> - 09/23/98
<u>Rep Kaptur</u> - 09/25/98	<u>Rep DeLauro</u> - 09/25/98
<u>Rep Mascara</u> - 09/25/98	<u>Rep Talent</u> - 10/01/98

SUMMARY:

(AS INTRODUCED)

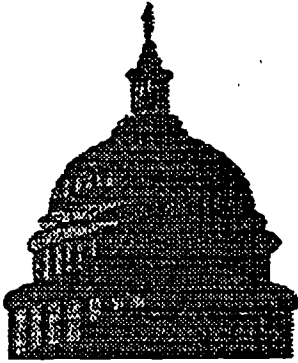
Cardiac Arrest Survival Act - Amends the Public Health Service Act with respect to emergency medical services (EMS). Requires programs for emergency medical services and preventive, diagnostic, therapeutic, and rehabilitative approaches to include: (1) development and dissemination of a core content for a model State training program applicable to cardiac arrest for inclusion in EMS educational curricula and training programs that address lifesaving interventions, including cardiopulmonary resuscitation and defibrillation; (2) a limited demonstration project to provide training in such core content; (3) identification of cardiac arrest care providers; (4) identification of equipment and supplies that should be accessible to such providers to permit lifesaving interventions; (5) development of model State and Federal legislation; and (6) coordination of a national database for reporting and collecting information on the incidence of cardiac arrest and related issues.

Prescribes guidelines for the core content of the model State training program.

Declares that the purpose of the model legislation is to ensure: (1) access to EMS through consideration

of a requirement for public placement of lifesaving equipment; and (2) good samaritan immunity for cardiac arrest care providers, those involved with the instruction of the training programs, and owners and managers of property where equipment is placed.

Heart Attacks



American Heart Association
Fighting Heart Disease and Stroke



OFFICE OF COMMUNICATIONS AND ADVOCACY

- ♥ Heart attack, stroke and other cardiovascular diseases remain the No. 1 killer in the United States.
- ♥ More than 1 in 5 Americans suffer from cardiovascular diseases at an estimated cost of \$259 billion in medical expenses and lost productivity in 1997.
- ♥ To fight these killers the AHA invests in research, education and community service programs.

Office of Communications and Advocacy
1150 Connecticut Ave., N.W., Suite 810
Washington, D.C. 20036

Date: 6/21

Time: 600

To: Tom Kresnow

Fax: 456-7431

From: Rich Wandy
AHA, Office of Communications and Advocacy

Tel: (202) 785-7900
Fax: (202) 785-7950

Number of pages including cover sheet: 17

Message Per a previous discussion. Please give me a call to discuss the AED issue. Perhaps we can sit down

Confirmation: yes no Free a mtg. as well.

Tom Kresnow



Office of Communications and Advocacy
1150 Connecticut Avenue Northwest, Suite 810
Washington, D.C. 20036
Tel 202 785 7900
Fax 202 785 7950

May 14, 1998

The Honorable Lois Capps
U.S. House of Representatives
Washington, DC 20515

Dear Representative Capps:

"Police Cardiac Machines Jolt Residents to Life (Greenwich Time)
"Defibrillator Saves Trans-Atlantic Flyer" (Chicago Tribune)
"Casino Security Guards Save Slot Player's Life" (Las Vegas Review Journal)
"Town Arms Cops With Defibrillators" (San Francisco Chronicle)

Perhaps you've seen these headlines in your newspapers and asked yourself what you can do to facilitate the use of life-saving devices such as the automatic external defibrillator (AED). On behalf of the American Heart Association, I am writing to ask you to become an original co-sponsor of the *Cardiac Arrest Survival Act*, currently HR 1679. The bill has bi-partisan support from over 80 members of the House.

In June, Representative Cliff Stearns (R-FL) will be re-introducing this legislation together with Senator Slade Gorton (R-WA). The new draft further simplifies the existing provisions of the current legislation.

Each year, more than 350,000 Americans suffer a sudden cardiac arrest. Less than 10 percent will be discharged from a hospital alive. Studies have found that, after as little as 10 minutes, very few resuscitation attempts are successful. Unfortunately, pre-hospital medical care (including training, equipment and standards of care) suffers from state-by-state variation, which condemns the public to inconsistent care.

The *Cardiac Arrest Survival Act* provides for the:

- development of a model state training program for cardiac arrest care providers in lifesaving interventions, including the use of AEDs;
- development of model state legislation to ensure access to emergency medical services; and
- coordination of a national database to track incidence of cardiac arrest to determine whether cardiac arrest care providers can improve survival rates.

Please call Veronica Crowe in Representative Stearns' office at 5-5744 to add your name to the list of co-sponsors of the *Cardiac Arrest Survival Act*.

Sincerely,

Martha N. Hill, RN, PhD
President

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Rodman D. Starke, M.D.

MEDIA ADVISORY

For Immediate Release: June 12, 1998
Contact: Erica L. Neufeld, 202-785-7927

News Conference Announcing Introduction of Cardiac Arrest Survival Act

WHAT: The Cardiac Arrest Survival Act will be introduced in the Senate by Slade Gorton (R-Wash.) and in the House by Cliff Stearns (R-Fla.).

Across the United States, approximately 250,000 people die each year from cardiac arrest. However, many of these lives could be saved if the general public had easier access to emergency cardiac care, such as automated external defibrillators (AEDs). The Cardiac Arrest Survival Act is designed to set a national standard for training first responders, ensuring access to AEDs, and tracking incidence of cardiac arrest and effectiveness of bystanders and first responders.

WHEN: Wednesday, June 17, 1998
11:30 a.m.

WHERE: 340 Cannon Building
Independence and First St.
Washington, DC

WHO: Speakers Include:

- Senator Slade Gorton (R-Wash)
- Representative Cliff Stearns (R-Fla)
- Paul Berlin, American Heart Association spokesperson
- Reed Klanderud, American Red Cross Spokesperson
- Chuck Kitchens, American Red Cross Spokesperson
- Jennie Collins representing the Congressional Fire Services Institute, will provide a demonstration of an AED.
- Bob Adams, a New York City attorney who was saved by an AED in Grand Central Station the day after they were installed, will speak about his experience.

Visual/Interview Opportunities

- Bob Adams, survivor from New York, will be available for interview.
- Jennie Collins will be demonstrating how AEDs are used and will be available for interview about the use of AEDs.
- Paul Berlin, active in EMS for 27 years, will be available to talk about the use of AEDs and how their use is changing the face of emergency cardiac care.

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READ 1:
CQ's WASHINGTON ALERT

06/29/98

*** FULL REPORT -- DIGEST, LEGISLATIVE ACTION, COSPONSORS, SPEECHES ***

MEASURE: HR4121

SPONSOR: Stearns (R-FL)

OFFICIAL TITLE: A bill to amend the Public Health Service Act to provide for the establishment at the National Heart, Lung and Blood Institute of a program regarding lifesaving interventions for individuals who experience cardiac arrest, and for other purposes

INTRODUCED: 06/23/98

COSPONSORS: 23 (Dems: 13 Reps: 10 Ind: 0)

COMMITTEES: House Commerce

RELATED BILLS: See S2196, HR1679

LEGISLATIVE ACTION:

05/20/97 *** Related measure (HR1679) introduced in House. ***

06/19/98 *** Related measure (S2196) introduced in Senate. ***

06/23/98 Referred to Committee on Commerce (CR p. H5064)

06/23/98 Original Cosponsor(s): 20

Boehlert (R-NY)	Frost (D-TX)	Serrano (D-NY)
Carson (D-IN)	Gekas (R-PA)	Shays (R-CT)
Clement (D-TN)	Hastings, A. (D-FL)	Smith, Linda (R-WA)
Cook, M. (R-UT)	Hilliard, E. (D-AL)	Walsh (R-NY)
Delahunt (D-MA)	Kennelly (D-CT)	Waxman (D-CA)
Faleomavaega (D-AS)	McCollum (R-FL)	Wolf (R-VA)
Filner (D-CA)	Mink (D-HI)	

06/25/98 Cosponsor(s) added: 3

Canady (R-FL)	Foley, M. (R-FL)	Meehan (D-MA)
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Bill Summary & Status for the 105th Congress**NEW SEARCH | HOME | HELP****S.2196****SPONSOR: Sen Gorton (introduced 06/19/98)**Jump to: Titles, Status, Committees, Amendments, Cosponsors, Summary**TITLE(S):**

- **SHORT TITLE(S) AS INTRODUCED:**
Cardiac Arrest Survival Act
- **OFFICIAL TITLE AS INTRODUCED:**
A bill to amend the Public Health Service Act to provide for establishment at the National Heart, Lung, and Blood Institute of a program regarding lifesaving interventions for individuals who experience cardiac arrest, and for other purposes.

STATUS: Floor Actions*****NONE*******STATUS: Detailed Legislative Status****Senate Actions****Jun 19, 98:**

Read twice and referred to the Committee on Labor and Human Resources.

STATUS: Congressional Record Page References06/19/98 Introductory remarks on Measure (CR S6699)06/19/98 Full text of Measure as introduced printed (CR S6699-6700)**COMMITTEE(S):**

- **COMMITTEE(S) OF REFERRAL:**
Senate Labor and Human Resources

<http://thomas.loc.gov/cgi-bin/bdquery/z?d105:SN02196:@@@L|/bss/6/29/98:ry.htm>

THE CASE FOR SUPPORT FOR THE CARDIAC ARREST SURVIVAL ACT

Background

Some time ago, the federal government established a program to develop nationally uniform standards for training curricula and procedures for local emergency medical services. This program is housed within the Department of Transportation, in the National Highway Traffic Safety Administration (NHTSA). NHTSA has done an admirable job in developing training materials that could be voluntarily implemented locally.

Ensuring heart disease and stroke focus -

There is significant concern that, as our knowledge about out-of-hospital cardiac arrest has expanded, NHTSA has not incorporated a heart disease and stroke focus in the standardized or proposed curricula for bystanders and first responders. Bystander and first responder CPR are essential to facilitating survival from out-of-hospital arrest, and we believe that the time has come for broadening of model EMS program to include both clinical evaluation of the results of proposed interventions - to ensure timely and appropriate changes in the curriculum - and development of a uniform national standard on the appropriate use of life-saving equipment for first responders, bystanders and other persons who may volunteer to resuscitate patients but are not trained paramedics or EMTs.

The current program, housed at NHTSA, while superb, has historically not engaged in these activities because its focus, properly so, has been on vehicular and traffic safety. NHTSA lacks clinical and research infrastructure in heart disease readily available at, for instance, the National Institutes of Health. But, the NHTSA program has been developed without significant clinical or scientific input from those components of the federal government directly involved in understanding heart disease and the potential that appropriate local management or, and training for, out-of-hospital arrest can have on mortality and disability from heart disease.

Removing barriers to care - In addition, legislative interventions can substantially affect the delivery of pre-hospital care, resulting in increased survival rates. The value of an unbroken *Chain of Survival* has been highlighted in cities such as Seattle, WA and Rochester, Minnesota, where early access to EMS, early CPR, early defibrillation and early advanced cardiac life support have dramatically increased survival rates. Unfortunately, the broad range of state statutes has resulted in pre-hospital care which suffers from state-by-state variation, condemning the public to inconsistent care. A 1995 poll of state EMS directors, published in the *Journal of Emergency Medical Services (JEMS)*, identified lack of enabling legislation (34%) as a prime obstacle to implementation of early defibrillation programs. According to data published in *JEMS* in 1997, non-EMT first responders are legally permitted to use AEDs in only half the states, and less than one half of EMTs and less than one quarter of non-EMT first responders in the U.S. are trained and equipped to defibrillate. If a national standard were developed by the federal government, states would likely be more receptive to changes.

Summary of provisions

The bill directs the National Heart, Lung, and Blood Institute (NHLBI), in cooperation with NHTSA, to develop and disseminate a model state training program for first responders and bystanders in lifesaving interventions, including CPR, and directs the development of model state legislation to ensure access to emergency medical services, including: consideration of the necessary training in, placement of, and good samaritan protection for the use of life-saving equipment for those choosing to intervene in out-of-hospital arrest. Finally, NHLBI is called upon to coordinate a national database for reporting and collecting data on the incidence of cardiac arrest and to evaluate the effectiveness of bystander and first responder lifesaving interventions.

Model
State
Training
Program

ANSWERS TO FREQUENTLY ASKED QUESTIONS ABOUT THE CARDIAC ARREST SURVIVAL ACT

Question

Is there organizational support for the proposal?

Answer

Support for the Cardiac Arrest Survival Act in the 105th Congress is broad. A diverse cross-section of national health and safety groups endorse the proposal, including the American Heart Association, American Red Cross, American Academy of Pediatrics, American College of Emergency Physicians, American Association for Respiratory Care, American College of Cardiology, Emergency Nurses Association, International Association of Firefighters, International Association of Fire Chiefs, the National Association of State EMS Directors, and the North American Society of Pacing and Electrophysiology.

Question

Is there congressional support for the proposal?

Answer

The legislation has over 80 House co-sponsors, representing a broad range of bi-partisan support. Senator Slade Gorton is expected to introduce a companion bill in June.

Question

Isn't this another burdensome federal mandate to the states?

Answer

The Congressional Budget Office has determined that the bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act of 1995, and would impose no costs on state, local or tribal governments.

Question

Isn't this issue more properly addressed at the state level. Aren't we ignoring what the public asked for during the 104th Congress when they voted for less federal bureaucracy?

Answer

Pre-hospital medical care (training, equipment, standards of care) suffers from state-by-state variation which condemns the public to inconsistent care. A 1995 poll of state EMS directors identified lack of enabling legislation as one of the primary obstacles to implementation of early defibrillation programs. If a model national standard were developed by DHHS, states would likely be more receptive to changes.

Development and dissemination of a core content for a recommended model state training program for first responders and bystanders (defined as cardiac arrest care providers) in lifesaving interventions, including cardiopulmonary resuscitation (CPR), throughout the U.S., in a standardized fashion using current science, would be an efficient use of federal government resources.

Question

How important is rapid access to basic and advanced cardiac life support?

Answer

In a recent study, when CPR was initiated in less than four minutes, and advanced cardiac life support in less than eight minutes, then the survival rate of the cardiac arrest patient was 43%. When CPR was initiated in less than four minutes but advanced cardiac life support was not initiated for 16 minutes, the rate of survival for the patient dropped precipitously to 10 percent. In general, it is estimated that for each minute of delay in administering defibrillation, survival rates drop by 10 percent.

Question

What are the critical links in the emergency treatment of sudden cardiac arrest?

Answer

More people can survive sudden cardiac arrest when a particular sequence of events occurs as rapidly as possible: 1) recognition of early warning signs, 2) early activation of the emergency medical system, 3) early basic cardiopulmonary resuscitation (CPR), 4) early defibrillation, and 5) early advanced cardiac life support. The American Heart Association has embraced the phrase "Chain of Survival" to communicate this concept in a useful way.

Question

Is the Chain of Survival effective?

Answer

In Houston, 40% of patients with ventricular fibrillation/ventricular tachycardia were discharged from the hospital if they had received bystander CPR, versus 19% for patients not given bystander CPR. Some communities have widely deployed AEDs (Richmond, Seattle, Rochester, MN). In such places survival rates have reached over 30 percent. In other large cities, such as Chicago and New York, rates run as low as 1-2 percent.

Question
Haven't most states implemented the links in the Chain of Survival?

Answer
According to recent surveys: (1) 31 percent of the population and 65 percent of the land area in the U.S. is not covered by the 911 system; (2) only a small percentage - about 10 to 15 percent in most studies - of witnessed cardiopulmonary emergencies have a citizen attempt resuscitation; and (3) only 28 states allow first responders to use an automatic external defibrillator. We have a long way to go!

Question
What is an example of life-saving equipment?

Answer
Automated external defibrillators (AED). An AED is a device that automatically analyzes heart rhythms and delivers an electric current to the heart if the heart is in ventricular fibrillation. In other words, an AED can restart a heart that has stopped beating. Ventricular fibrillation is an abnormal heart rhythm, or arrhythmia. When ventricular fibrillation develops, the heart quivers and ceases its pumping action. The only effective treatment for this condition is defibrillation, the delivery of a powerful electrical shock to the heart.

Question
Are AEDs safe in the hands of non-medical cardiac arrest care providers?

Answer
AEDs are already being widely deployed to cardiac arrest care providers. Recent breakthroughs in technology have resulted in AEDs which are easier to use and maintain; smaller, lightweight and rugged; and lower in cost. AEDs have built-in safeguards to protect both patient and user, and safety records are excellent. AEDs are programmed to administer a shock only when necessary, and have verbal and visual prompts that tell everyone near the victim to stand back before the shock is delivered. Cardiac arrest is a life or death situation. Without defibrillation, the patient has very little chance of survival.

Question
Aren't all ambulances already equipped with defibrillators?

Answer
Only about 50 percent of EMTs are trained and equipped to defibrillate. Less than 1 in 5 of non-EMT first responders (individuals trained to the U.S. Dept. of Transportation First Responder level or its equivalent) are trained and equipped.

Question
Even if first responders are authorized to use AEDs, won't the costs be prohibitive?

Answer
The expense and time involved in equipping emergency vehicles with AEDs and training all first responders how to use them is minimal in proportion to the number of lives that can be saved. A report from Richmond, VA found that the cost-per-life-year saved from sudden cardiac arrest with defibrillation was about \$2,200. Other cardiovascular interventions cost up to \$50,000 per year. The actual cost of some AEDs is now under \$3,000 and training has been incorporated into basic life support courses.

Question
But what are the chances for long-term survival by those after suffering a sudden cardiac arrest?

Answer
People who survive a sudden cardiac arrest have a very good chance at long term survival. Approximately 83 percent of sudden cardiac arrest survivors live at least one year and 57 percent survive for five years or longer.

Question
What if AEDs were more widely available to cardiac arrest care providers such as police officers and fire department personnel?

Answer
Up to 100,000 lives could be saved annually.

Question
Why does the legislation recommend the expansion of good samaritan protections for those involved in the use of lifesaving equipment?

Answer
The American Heart Association recommends providing liability protection to certain individuals in order to encourage greater availability and use of AEDs. It recommends that all designated responders, premise owners that have an AED, prescribing physicians and AED trainers should have at least some limited protection against liability for civil damages.

Question
How much training is required to use an AED?

Answer
The American Heart Association's HeartSaver-D program, which includes training in CPR and AEDs, can be completed in about three hours.

(May 1998)

105TH CONGRESS
2D SESSION

S. 2196

IN THE SENATE OF THE UNITED STATES

Mr. GORTON introduced the following bill; which was read twice and referred to the Committee on

(Mrs Murray, Mr. Grimes, Mr. Bingaman, Mr. Faircloth)

A BILL

To amend the Public Health Service Act to provide for the establishment at the National Heart, Lung, and Blood Institute of a program regarding lifesaving interventions for individuals who experience cardiac arrest, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the "Cardiac Arrest Sur-
5 vival Act".

6 SEC. 2. FINDINGS.

7 Congress makes the following findings:

1 (1) Each year more than 350,000 adults suffer
2 cardiac arrest, usually away from a hospital. More
3 than 95 percent of them will die, in many cases, be-
4 cause lifesaving defibrillators arrive on the scene too
5 late, if at all.

6 (2) These cardiac arrest deaths occur primarily
7 from occult underlying heart disease and from
8 drownings, allergic or sensitivity reactions, or elec-
9 trical shocks.

10 (3) Survival from cardiac arrest requires suc-
11 cessful early implementation of a chain of events,
12 the chain of survival which begins when the person
13 sustains a cardiac arrest and continues until the
14 person arrives at the hospital.

15 (4) A successful chain of survival requires the
16 first person on the scene to take rapid and simple
17 initial steps to care for the patient and to assure the
18 patient promptly enters the emergency medical serv-
19 ices system.

20 (5) The first persons on the scene when an ar-
21 rest occurs are typically lay persons who are friends
22 or family of the victim, fire services, public safety
23 personnel, basic life support emergency medical serv-
24 ices providers, teachers, coaches, and supervisors of
25 sports or other extracurricular activities, providers of

1 day care, school bus drivers, lifeguards, attendants
2 at public gatherings, coworkers, and other leaders
3 within the community.

4 (6) A coordinated Federal response is necessary
5 to ensure that appropriate and timely lifesaving
6 interventions are provided to persons sustaining non-
7 traumatic cardiac arrest. The Federal response
8 should include, but not be limited to—

9 (A) significantly expanded research con-
10 cerning the efficacy of various methods of pro-
11 viding immediate out-of-hospital lifesaving
12 interventions to the nontraumatic cardiac arrest
13 patient;

14 (B) the development of research-based, na-
15 tionally uniform, easily learned and well re-
16 tained model core educational content concern-
17 ing the use of such lifesaving interventions by
18 health care professionals, allied health person-
19 nel, emergency medical services personnel, pub-
20 lic safety personnel, and other persons who are
21 likely to arrive immediately at the scene of a
22 sudden cardiac arrest;

23 (C) an identification of the legal, political,
24 financial, and other barriers to implementing
25 these lifesaving interventions; and

1 (D) the development of model State legis-
2 lation to reduce identified barriers and to en-
3 hance each State's response to this significant
4 problem.

5 **SEC. 3. NATIONAL INSTITUTES OF HEALTH MODEL PRO-**
6 **GRAM ON THE FIRST LINKS IN THE CHAIN OF**
7 **SURVIVAL.**

8 Section 421 of the Public Health Service Act (42
9 U.S.C. 285b-3) is amended by adding at the end the fol-
10 lowing subsection:

11 “(c) Programs under subsection (a)(1)(E) (relating
12 to emergency medical services and preventive, diagnostic,
13 therapeutic, and rehabilitative approaches) shall include
14 programs for the following:

15 “(1) The development and dissemination, in co-
16 ordination with the emergency services guidelines
17 promulgated under section 402(a) of title 23, United
18 States Code, by the Associate Administrator for
19 Traffic Safety Programs, Department of Transpor-
20 tation, of a core content for a model State training
21 program applicable to cardiac arrest for inclusion in
22 appropriate current emergency medical services edu-
23 cational curricula and training programs that ad-
24 dress lifesaving interventions, including
25 cardiopulmonary resuscitation and defibrillation. In

1 developing the core content for such program, the
2 Director of the Institute may rely upon the content
3 of similar curricula and training programs developed
4 by national nonprofit entities. The core content of
5 such program---

6 “(A) may be used by health care profes-
7 sionals, allied health personnel, emergency med-
8 ical services personnel, public safety personnel,
9 and any other persons who are likely to arrive
10 immediately at the scene of a sudden cardiac
11 arrest (in this subsection referred to as ‘cardiac
12 arrest care providers’) to provide lifesaving
13 interventions, including cardiopulmonary resus-
14 citation and defibrillation;

15 “(B) shall include age-specific criteria for
16 the use of particular techniques, which shall in-
17 clude infants and children; and

18 “(C) shall be reevaluated as additional
19 interventions are shown to be effective.

20 “(2) The operation of a limited demonstration
21 project to provide training in such core content for
22 cardiac arrest care providers to validate the effec-
23 tiveness of the training program.

24 “(3) The definition and identification of cardiac
25 arrest care providers, by personal relationship, expo-

1 sure to arrest or trauma, occupation (including
2 health professionals), or otherwise, who could pro-
3 vide benefit to victims of out-of-hospital arrest by
4 comprehension of such core content.

5 “(4) The establishment of criteria for comple-
6 tion and comprehension of such core content, includ-
7 ing consideration of inclusion in health and safety
8 educational curricula.

9 “(5) The identification and development of
10 equipment and supplies that should be accessible to
11 cardiac arrest care providers to permit lifesaving
12 interventions by preplacement of such equipment in
13 appropriate locations insofar as such activities are
14 consistent with the development of the core content
15 and utilize information derived from such studies by
16 the National Institutes of Health on investigation in
17 cardiac resuscitation.

18 “(6) The development in accordance with this
19 paragraph of model State legislation (or Federal leg-
20 islation applicable to Federal territories, facilities,
21 and employees). In developing the model legislation,
22 the Director of the Institute shall cooperate with the
23 Attorney General, and may consult with nonprofit
24 private organizations that are involved in the draft-

1 ing of model State legislation. The model legislation
2 shall be developed in accordance with the following:

3 “(A) The purpose of the model legislation
4 shall be to ensure—

5 “(i) access to emergency medical serv-
6 ices through consideration of a require-
7 ment for public placement of lifesaving
8 equipment; and

9 “(ii) good samaritan immunity for
10 cardiac arrest care providers; those in-
11 volved with the instruction of the training
12 programs; and owners and managers of
13 property where equipment is placed.

14 “(B) In the development of the model leg-
15 islation, there shall be consideration of require-
16 ments for training in the core content and use
17 of lifesaving equipment for State licensure or
18 credentialing of health professionals or other oc-
19 cupations or employment of other individuals
20 who may be defined as cardiac arrest care pro-
21 viders under paragraph (3).

22 “(7) The coordination of a national database
23 for reporting and collecting information relating to
24 the incidence of cardiac arrest, the circumstances
25 surrounding such arrests, the rate of survival, the

1 effect of age, and whether interventions, including
2 cardiac arrest care provider interventions, or other
3 aspects of the chain of survival, improve the rate of
4 survival. The development of such database shall be
5 coordinated with other existing databases on emer-
6 gency care that have been developed under the au-
7 thority of the National Highway Traffic Safety Ad-
8 ministration and the Centers for Disease Control
9 and Prevention."



m e m o

May 27, 1997

TO: Elizabeth Drye
FROM: Rich Hamburg
Acting Director, Public Advocacy

SUBJECT: RECOMMENDATIONS FOR EXECUTIVE BRANCH

Per our previous conversations, what follows is a thumbnail sketch of our perception of favorable outcomes relative to the AED issue. At the core of our position is that a coordinated federal response is necessary to ensure that appropriate and timely lifesaving interventions are provided to persons sustaining non-traumatic out-of-hospital cardiac arrest

Potential Executive Orders:

- Direct NHTSA and NHLBI to collaborate in an effort to more effectively address cardiovascular disease, including sudden cardiac arrest, in a pre-hospital setting, including the expeditious development of curricula specifically addressing sudden cardiac arrest
- Direct the Dept. of Justice to develop model state good samaritan immunity for cardiac arrest care providers as well as those involved with the instruction of training programs and owners and managers of property where equipment is placed.
- Direct the NHLBI to immediately develop a national database for reporting and collecting information relative to the incidence of cardiac arrest, rates of survival and whether interventions, including cardiac arrest care provider interventions, improve the rate of survival
- Direct the establishment of a Presidential Commission on Cardiac Arrest Survival to evaluate and provide recommendations on effective methods to increase survival from cardiac arrest, including the development of model state legislation to ensure access to EMS through consideration of a requirement for public placement of lifesaving equipment and for the use of such equipment by cardiac arrest care providers

Among suggestions for immediate action:

- Public announcement of Presidential support for research initiatives that bring together the collaborative efforts of government, the non-profit sector and industry. This is exemplified by the broad-based clinical trial to evaluate whether targeted responders who use AEDs can improve survival of patients with out-of-hospital cardiac arrest compared to implementation of a usual community-based EMS system alone.
- Presidential support and recognition of the expanded role of the police force to better serve the community. This is exemplified by the groundbreaking work done by the police force in Rochester, MN under the director of Dr. Roger White, where the prompt use of AEDs by the police force dramatically improved survival from out-of-hospital sudden cardiac arrest.

MEMORANDUM

Heart
attacks
- 60

TO: Tom Freedman, Mary Smith
FROM: David Hochschild
DATE: July 7, 1998
RE: Improving the nation's response to Heart Attacks

Heart attacks

More than 350,000 adults suffer cardiac arrest each year, mostly away from the hospital. 95% of these victims die as a result. But studies show that a victim's chance of survival increases dramatically if advanced life support (defibrillation) is initiated rapidly after a heart attack. There is a 43% survival rate in cases where advanced life support is given in less than 8 minutes. When advanced life support is given after 16 minutes, the survival rate falls to 10%. So the loss of life from cardiac arrest can be greatly reduced by increasing access to defibrillators.

The Forerunner

In 1996, the FDA approved a device called the Forerunner, an automatic external defibrillator (AED) which is said to have the potential to be the most accessible advanced lifesaving tool yet developed. The Forerunner itself is light and small, about the size of a large paperback book. It works by sensing the electrical currents from the heart and deciding whether a heart attack is, in fact, occurring and whether defibrillation is needed. At \$3,000, it's about 40% cheaper than standard defibrillators. But the most important difference between the Forerunner and its predecessors is that it can be used with very little training. A recording provides instructions and there are only two buttons to use. As a result, it can be used by police officers, EMT's, security guards, flight attendants and other first-responders while most ordinary defibrillators are only used by doctors and paramedics.

Many major airlines, including American, Delta and Alaska Airlines, are now equipping their planes with the Forerunner. An American Airlines spokesman claimed that since his company began putting Forerunners on planes about a year ago, they have been used 49 times but in only three cases did the device decide that shocks were needed. The victim survived in only one of these cases (which remains the only documented incident thus far of a life being saved in the air by Forerunner). But the number is sure to climb as other airlines follow suit. There are roughly 150 heart attacks in the air each year on US carriers.

The American Heart Association estimates that a total of 100,000 lives can be saved annually with this device if it is made widely available. To make the device more accessible, the AHA is lobbying for the passage of the Cardiac Arrest Survival Act. A description of this and other legislation related to AED's follows:

Bill	Date	Sponsors	Description/Status
<p><i>HR1679 and S2196 The Cardiac Arrest Survival Act</i></p>	<p><i>5/29/97 reintroduced on 6/22/98</i></p>	<p><i>House: Stearns (R-FL) 80 cosponsors 53 Dem 27 Rep</i> <i>Senate: Gorten (R-FL) 6 co-sponsors 4 Dem 2 Rep</i></p>	<p><i>Directs the National Heart, Lung and Blood Institute in cooperation with the National Highway Traffic Safety Administration to develop a model state training program for cardiac arrest care providers in lifesaving interventions, including the use of automated external defibrillators (AED's). Directs the agencies to create model state legislation to reduce identified barriers to emergency medical service such as training and placement of AED's and good samaritan protection for those who help respond to cardiac arrests. Requires the creation of a national cardiac arrest database to track the incidence of cardiac arrest and to determine whether cardiac arrest care providers can improve survival rates.</i></p> <p><i>House version: 5/20/97 Referred to the House Committee on Commerce</i> <i>5/29/97 Referred to the Subcommittee on Health and Environment. No action.</i> <i>6/23/98 Reintroduced (as HR4121) and Referred to the House Committee on Commerce</i> <i>Senate Version: 6/19/98 Referred to the Committee on Labor and Human Resources</i></p>
<p><i>HR1670 Airline Passenger Safety Act of 1997</i></p>	<p><i>5/20/97</i></p>	<p><i>Kennelly (D-CT) 10 co-sponsors 10 Dem</i></p>	<p><i>Establishes a routine set of procedures to be followed during in-flight emergencies. Requires airlines to keep automated external defibrillators or an equivalent cardiac device on board for use during emergencies.</i></p> <p><i>5/20/97 Referred to the House Committee on Transportation and Infrastructure.</i> <i>6/2/97 Referred to the Subcommittee on Aviation.</i> <i>Hearings Held by Subcommittee on Aviation Prior to Referral (May 21, 97).</i></p>
<p><i>HR 2843 Aviation Medical Assistance Act of 1998</i></p> <p><i>Public Law 105-170</i></p>	<p><i>11/6/97</i></p>	<p><i>Duncan (R-TN) 5 co-sponsors 2 Dem 3 Rep</i></p>	<p><i>Directs the FAA to reevaluate the medical equipment required on aircraft operated by air carriers. Requires the FAA administrator to decide whether or not to require automatic external defibrillators on passenger aircraft and in airports. Provides good samaritan protection from liability lawsuits for the air carrier and any passengers who assist in good faith during a cardiac arrest.</i></p> <p><i>3/24/98 Passed House by voice vote</i> <i>4/3/98 Passed Senate by unanimous consent</i> <i>4/24/98 Signed by the President</i></p>

5-31-98

heart attacks — ew

The New York Times

WEDNESDAY, APRIL 16, 1997

Cardiologists Say Portable Defibrillators Can Save Time and Lives

By JANE FRITSCH

When Tony Cox's heart stopped beating, he was working out on a treadmill at the Reebok Club on the Upper West Side.

Theoretically, his odds of survival were as high as 60 percent or 70 percent. A doctor was exercising nearby and a club employee was a trainee paramedic; they began working on him immediately. Others called 911. And the club was only 10 blocks from St. Luke's-Roosevelt Hospital, whose ambulances respond to 911 calls.

But Winston Hill (Tony) Cox, a 55-year-old father of four and the former chairman of Showtime, died that Saturday afternoon last September.

He might have had a chance, doctors said, if emergency medical workers had arrived sooner with a defibrillator, a machine that delivers

RACING THE AMBULANCE

A special report.

an electric shock to restart the heart. But it took 16 excruciating minutes for the ambulance to arrive that day, far more than the 5- or 6-minute window of hope.

In New York City, in fact, the likelihood of being revived after cardiac arrest is only about one percent. The congealed traffic in New York — and in most American cities — and the vast distances ambulances must travel in rural areas mean that emergency workers simply cannot reach most cardiac arrest victims in time.

Cardiologists estimate that a half or more of the 350,000 people who die of cardiac arrest in the United States each year could have been saved.

Cardiologists now argue that it is time to give up on emergency medi-

cal squads as the chief means of reviving heart patients. In the last year, the American Heart Association has begun to push for much wider availability of defibrillators. The devices should be placed just about everywhere, the association contends — in factories, health clubs, apartment buildings, and even in private homes, and available for use by a variety of nonmedical people, like security guards and doormen. Within a decade, the association hopes, the devices should become as common as fire extinguishers.

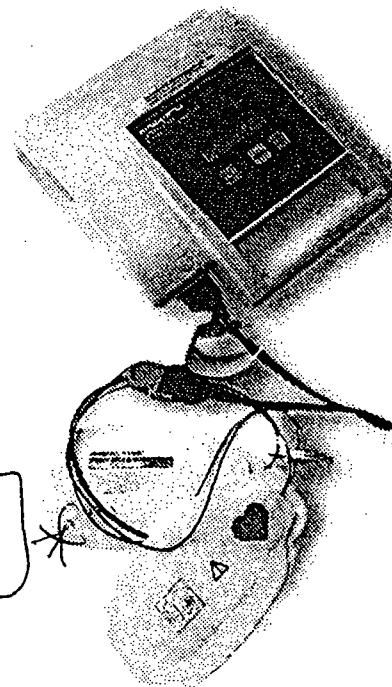
While the heart association's proposal may seem simple, state laws and Federal regulations are in the way.

The Food and Drug Administration, which regulates the machines, has not considered whether they are safe and effective for use by the general public.

State emergency medical directors have joined together to oppose the widespread use of defibrillators, saying that the matter needs more study.

Still, the heart specialists plan to

Continued on Page A22, Column 1



Librado Romero/The New York Times

The Lifepak 500 is made by Physio-Control, one of four companies offering a new defibrillator.

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fight aggressively for plan, kicking it off at a meeting this Washington.

Not too long ago, defibrillators were so complicated that the operator had to be specially trained to the screens and interpret the waves. But the heart association says a new generation of automatic, easy-to-use machines has been developed that can be operated by almost anyone. The new lightweight machines analyze heart rhythms, decide whether a shock is needed, and give simple voice instructions. The machines will not shock a person who does not need it, the manufacturers say.

What this means, the machines practical, the association says, are five-year minimum batteries that eliminate the need for regular maintenance. The Food and Drug Administration approved several of the new lightweight models last fall, but only for prescription use.

The average cost is about \$3,000 but the price is expected to drop significantly if the market is opened to all who want to buy them.

The collection of data on deaths cardiac arrest is haphazard, making the rates difficult to compare. But experts generally agree that dismal survival rates apply to all but a few American cities and suburban and rural areas.

This is an area that has been hobbled by rules and laws and regulations, said Dr. Myron J. Weisfeldt, the chairman of the Department of Medicine at Columbia Presbyterian Medical Center and the of the heart association's task force on defibrillators.

"If the defibrillators aren't there and the survival rate is less than 5 percent, then you'd better find a way to get them there," Dr. Weisfeldt said.

*
J R

The Newest Models Come on the Market

Use of defibrillators by the public generally not covered by "good samaritan" laws, which protect amateur rescuers from liability. But cardiologists are afraid that at some point, health clubs, office buildings and other public buildings, as well as airlines could be found negligent if they did not have defibrillators.

American Airlines recently became the first airline in this country to order defibrillators for its planes and other domestic airlines are considering it because it is all but impossible to land a plane and get a defibrillator to a victim in time. Metro North has ordered defibrillators to be placed on its east of emergency medical supplies in Grand Central Station, and a few casinos in Las Vegas have also bought defibrillators.

Dr. La Pook can legally have his own defibrillator because he is a physician. Under current Federal regulations and the law in most states, including New York, only doctors or people authorized by doctors may buy and operate defibrillators, even the simplest models.

Last fall, the National Association of State Emergency Services Directors became so concerned with the push for public access to defibrillators that it passed a resolution calling on the heart association to postpone its defibrillator campaign until data show that use by the public is effective and safe.

"They are potentially wonderful devices," said Dr. Robert R. Bass, the executive director of the Maryland Institute for Emergency Medical Services. "But we don't see any evidence that the devices are going to be effective in the hands of the public. Before we call for a national movement to place these devices everywhere, we need to know how safe they are and what the cost benefits are."

Manufacturers of the devices say they are completely safe, and the heart association says they are all but foolproof. And, they add, if the choice is between defibrillation by an amateur and no defibrillation at all, the answer is clear.

But Food and Drug Administration officials say some safety and ethical considerations have yet to be addressed.

"There's a question of whether you can do as much harm as you can do good," said Thomas J. Callahan, the Food and Drug Administration official who oversees the evaluation of such devices. "In the hands of a lay person, are there going to be more disasters than there are benefits?"

He said he was not certain that in all cases the new machines could distinguish a heart rhythm that should be shocked from those that should not. To evaluate fine distinctions, he said, trained technicians are necessary.

Late-stage resuscitation by amateurs, he said, might restore a heart beat and do little more, leaving the victim with little brain function and permanently dependent on life support systems.

Advocates of greater distribution of defibrillators say such results are rare and no more likely to happen when rescuers are amateur than when they are highly trained.

"The reality is that none of it is that good as it," said Dr. Alex Koehl, the chairman of the New York City medical advisory emergency services and the head of the city's emergency services agency.

"There's always a danger you're going to shock a living rhythm, but that brain is going to be dead," he said. "But if we can get the very few of us play God in who lives and who dies. We'll back the one thing that we want, which is the heart, and that the brain is intact."

And those who are brain not linger on life supports, he adding, "Two days later on the respirator."

The Condition

The Heart And Its Problems

Like Mr. Cox, about half of all those who die of heart disease die suddenly and unexpectedly, without ever having shown any symptoms, the heart association says. Many are unaware that they have clogged arteries or other types of heart disease.

In Mr. Cox's case, an autopsy showed that three coronary arteries were blocked, but there was no sign of the muscle damage that would have been present if he had had a heart attack.

Dr. Cox's heart had been reorganized, he said, and been started again. He had been a candidate for cardiac bypass surgery. Dr. Nicholas J. Fortuin, a professor of medicine at Johns Hopkins, said that procedure restores blood flow to the heart and can add decades to a life. But Mr. Cox might have died even with early defibrillation, Dr. Fortuin said.

Cardiac arrest does not necessarily mean a heart attack occurred. Arterial blockages alone can cause the heart's electrical impulses to become disorganized and incapable of coordinating the contractions that keep the heart beating normally.

The disorganized electrical activity, called ventricular fibrillation, can last for about five minutes. During that time, a shock from a defibrillator can reorganize the electrical impulses so that the heart resumes normal beating.

But with each passing minute, the likelihood of successful defibrillation drops significantly. Expertly done cardiopulmonary resuscitation can buy the victim a little more time, but it is useless unless a defibrillator arrives quickly, before all electrical activity in the heart has ceased.

It is a common notion, suggested by television shows and movies that defibrillation is not done until a flat line appears on a heart monitor, but that is not so. A flat line indicates that there is no electrical activity in the heart at all, and therefore no

electrical impulses to be reorganized by a shock from a defibrillator.

Dr. John La Pook, a Manhattan internist and friend of Mr. Cox, was so disturbed by his friend's unexpected death that he has since purchased a defibrillator and keeps it at his apartment on Central Park West.

Sometimes, he even takes his defibrillator to his regular basketball game in Brooklyn, where he plays with an friends with ages ranging from the 30's into the 50's. At first they laughed at him, Dr. La Pook said, but they seem to have come to appreciate having the thing around.

2/3

York City was published in the Journal of the American Medical Association and was based on 1991 data.

Since then, the department has gradually equipped all fire engines in Brooklyn, Queens, the Bronx and Staten Island with defibrillators, on the theory that firetrucks are more likely to reach victims in time than are ambulances. Similar plans are under way in Manhattan.

The latest statistics show that the average response time for fire engines on cardiac arrest calls is only five minutes, according to Deputy Commissioner Edward M. Dolan. It takes another five minutes for an ambulance to arrive, he said.

The firefighters are using virtually the same models that the heart association is advocating for public use.

The Suffolk County Police Department has ordered the models for its police cars because the county is almost entirely served by volunteer ambulance squads, which have great difficulty reaching victims in time.

Four companies are now manufacturing the machines, and are in fierce competition for what they hope will be an exploding market over the next decade. They are Heartstream, of Seattle; Laerdal Medical Corporation, a Norwegian company with American headquar-

ters in Wappingers Falls, N.Y.; Physio-Control Corporation of Redmond, Wash., and Survivalink Corporation, of Minneapolis.

Their machines, all similar, weigh about five pounds and were designed in consultation with the heart association to be as simple as possible for amateurs to use. The recent advance that makes them practical, according to cardiologists, is the inclusion of a lithium battery with a five-year life. The batteries eliminate the need for constant maintenance or recharging, and computer chips perform complete tests of the operating systems each day.

When the machine is turned on, it gives a series of simple voice instructions, so that panicked users do not need to stop to read complex directions. The rescuer is told to attach two plastic leads to the victim's chest and then stand back.

The machine analyzes the heart rhythm and determines whether the victim's heart is in fibrillation. If so, it charges up, instructs the rescuer to stand clear, and then to push a red button that delivers a shock. The machine may call for a second or third shock if necessary, then a period of cardio-pulmonary resuscitation, followed by another cycle of shocks.

Present Practice

A Few New Models But Most Are Old

For the near future, at least, New Yorkers must depend on the Fire Department's emergency services for help with cardiac arrests. The department has worked aggressively for the last three years to improve response time, and there are indications that the efforts are working. But no statistics have been compiled to show whether the survival rate has improved. The study that showed a one percent survival rate in New

3/3

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Newly OK'd defibrillator could save 100,000 lives

By Doug Levy
USA TODAY

A lightweight, less expensive and easier-to-use device to start the heart beating again has been approved by the Food and Drug Administration.

Seattle-based Heartstream announced the approval Thursday, saying its ForeRunner automatic defibrillator now can be available to the people most likely to reach a cardiac

arrest victim first, such as police or office security guards.

Less than 25% of emergency vehicles carry defibrillators, but using one within four minutes of a cardiac arrest increases survival rates to 30% from less than 5%.

Defibrillators, which shock a heart into normal rhythm, have long been carried by paramedics.

But their use has been limited by the cost, size and need

for maintenance. Even automated versions, in use by some fire and police departments, cost \$5,000 or more.

ForeRunner "has some very definite advantages," says Dr. Roger White of the Mayo Clinic, who urged defibrillators be put in police cars in the clinic's hometown of Rochester, Minn.

It now has the USA's highest cardiac arrest survival rate.

The American Heart Association estimates 100,000 lives

could be saved if defibrillators were more widely used.

Heartstream plans to sell ForeRunner for \$3,000 to \$4,000. A recording provides instructions, and there are only two buttons to use. Powered by a 'long-life' battery, the four-pound device is about the size of a large paperback.

ForeRunner was not approved for use on airplanes because its ability to function at high altitude is unstudied.



By Robert Bork
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Friday 9/13/96 p.1

HHS Comments Related to the Draft Legislation on
The Cardiac Arrest Survival Act and Cardiac Survival Activities
the Department Could Support

- o HHS/The National Institutes of Health/National Heart, Lung and Blood Institute (NHLBI), supports the "chain of survival" concept and the position that all emergency medical personnel should be trained to use a defibrillator and that all medical vehicles should be equipped with a manual or automated external defibrillator (AEDs).
- o With respect to the proposed legislation, it contains a number of provisions that are of concern to the Department. For example, it provides for the development and dissemination of a "core content" for a model state training program in lifesaving interventions, including cardiopulmonary resuscitation. Organizations such as the American Red Cross and the American Heart Association are currently involved in developing and disseminating training programs for cardiopulmonary resuscitation. We believe it is not appropriate for the NHLBI to assume this function and thus duplicate the ongoing efforts of private entities.
- o The legislation also proposes a demonstration project to provide training in the core content to first responders and bystanders. While we would support such a project, we are concerned that implementation of a demonstration project of this type through the Department would require additional funding and staff resources.
- o HHS supports the development of a nation database related to the incidence of cardiac arrest. This is an important area that is not currently addressed. This also would involve the investment of substantial resources, both human and financial, that are not currently planned for within the Department. The proposed legislation does not address financial support in this regard.
- o We believe there is merit in developing model state legislation to ensure access to emergency medical services for basic life support. However, we have a concern about the appropriateness of the NHLBI in developing such legislation. The NHLBI has a research and education mandate. Thus, we do not believe NHLBI should be involved in the development of legislation at the state level especially legislation that may establish requirements for state licensure or credentials of health professionals.

- o We strongly believe that any advances in this area should address research needs in cardiac arrest. For example, although the NHAAP supports the concept of placing AEDs in public places, it has emphasized the need for additional research before this occurs.
- o There is also a need for additional research on resuscitation. Electrical instability of the heart remains a vexing problem and research into understanding mechanisms and therapies to prevent it and or restore normal health rhythm, particularly following cardiac arrest, is urgently needed.
- o Additional studies of the feasibility and efficacy of public programs to treat cardiac arrest are also highly desirable and should precede implementation of any nation emergency action programs.
- o The Department will work with our health professional training programs in the Health Resources and Services Administration and the Health Care Financing Administration to explore the possibility of putting greater emphasis on the chain of survival training activities and the use of AEDs in their grant and contract training programs.
- o We also will explore with Public Health Service Agencies in the Department, including the Food and Drug Administration, the possibility of broadening the use of AEDs so that more non-EMT and other health professionals, who are first responders, are able to use AEDs.

Emergency Cardiac Care

Case for Support

More than 350,000 Americans suffer a sudden cardiac arrest each year. Less than ten percent will be discharged from a hospital alive. The key to survival is timely initiation of a series of events, coined the "Chain of Survival." The chain includes early activation of the emergency medical system; basic cardiopulmonary resuscitation (CPR); rapid defibrillation; and early advanced cardiac life support. Weakness in any link lessens the chance of survival and condemns the efforts of an emergency medical system to poor results. After as little as 10 minutes, very few resuscitation attempts are successful.

Chain of Survival

Unfortunately, pre-hospital medical care (including training, equipment and standards of care) suffers from state-by-state variation, which condemns the public to inconsistent care. It is clear that legislative interventions can substantially affect the delivery of pre-hospital care, resulting in increased survival rates. In cities such as Seattle, WA and Rochester, MN, where early access to EMS, early CPR, and early defibrillation have dramatically increased survival rates. However, according to data recently published in the Journal of Emergency Medical Services (JEMS), non-EMT first responders are legally permitted to use AEDs in only half the states and less than one half of EMTs, and less than one quarter of non-EMT first responders, in the U.S. are trained and equipped to defibrillate. As for basic life support training, more than half the states in a recent study had no secondary school curriculum requirements for first aid and CPR.

*automated external
defibrillators*

AHA position

In a few weeks, Representative Cliff Stearns (R-FL-6) will be introducing the Cardiac Arrest Survival Act. This legislation, drafted in large part by the American Heart Association, in partnership with the American Red Cross and nearly two dozen national organizations, establishes a federal program regarding training in lifesaving interventions and the use of lifesaving equipment, including automated external defibrillators (AEDs) to assist individuals experiencing cardiac arrest. Specifically, the legislation calls for:

*Cardiac
Arrest
Survival
Act*

- the National Heart, Lung, and Blood Institute (NHLBI), in cooperation with the National Highway Traffic Safety Administration (NHTSA), to develop and disseminate a model state training program for first responders and bystanders in lifesaving interventions, including cardiopulmonary resuscitation (CPR).
- the development of model state legislation to ensure access to emergency medical services, including consideration of the necessary location and placement of lifesaving equipment, including AEDs; the development of requirements for training in the core content and use of life-saving equipment, including AEDs; and the provision of good samaritan immunity for bystanders first responders instructors and owners and owners and managers of property where equipment is placed.
- the development of a national database for reporting and collecting information relating to the incidence of cardiac arrest and whether interventions, including bystander or first responder, improve the rate of survival.

Action requested

- Co-sponsor the Cardiac Arrest Survival Act, sponsored by Rep. Cliff Stearns (R-FL).

THE CASE FOR SUPPORT FOR THE CARDIAC ARREST SURVIVAL ACT

Background

Some time ago, the federal government established a program to develop nationally uniform standards for training curricula and procedures for local emergency medical services. This program is housed within the Department of Transportation, in the National Highway Traffic Safety Administration (NHTSA). NHTSA has done an admirable job in developing training materials that could be voluntarily implemented locally.

Ensuring heart disease and stroke focus -

There is significant concern that, as our knowledge about out-of-hospital cardiac arrest has expanded, NHTSA has not incorporated a heart disease and stroke focus in the standardized or proposed curricula for bystanders and first responders. Bystander and first responder CPR are essential to facilitating survival from out-of-hospital arrest, and we believe that the time has come for broadening of model EMS program to include both clinical evaluation of the results of proposed interventions - to ensure timely and appropriate changes in the curriculum - and development of a uniform national standard on the appropriate use of life-saving equipment for first responders, bystanders and other persons who may volunteer to resuscitate patients but are not trained paramedics or EMTs.

The current program, housed at NHTSA, while superb, has historically not engaged in these activities because its focus, properly so, has been on vehicular and traffic safety. NHTSA lacks clinical and research infrastructure in heart disease readily available at, for instance, the National Institutes of Health. But, the NHTSA program has been developed without significant clinical or scientific input from those components of the federal government directly involved in understanding heart disease and the potential that appropriate local management or, and training for, out-of-hospital arrest can have on mortality and disability from heart disease.

AHA (March 1997)

Removing barriers to care - In addition, legislative interventions can substantially affect the delivery of pre-hospital care, resulting in increased survival rates. The value of an unbroken *Chain of Survival* has been highlighted in cities such as Seattle, WA and Rochester, Minnesota, where early access to EMS, early CPR, early defibrillation and early advanced cardiac life support have dramatically increased survival rates. Unfortunately, the broad range of state statutes has resulted in pre-hospital care which suffers from state-by-state variation, condemning the public to inconsistent care. A 1995 poll of state EMS directors, published in the *Journal of Emergency Medical Services (JEMS)*, identified lack of enabling legislation (34%) as a prime obstacle to implementation of early defibrillation programs. According to new data published in *JEMS* (January 1997), non-EMT first responders are legally permitted to use AEDs in only half the states, and less than one half of EMTs and less than one quarter of non-EMT first responders in the U.S. are trained and equipped to defibrillate. As for basic life support, more than half of the states in a recent study reported having no secondary school curriculum requirements for first aid and CPR. If a national standard were developed by the federal government, states would likely be more receptive to changes.

Summary of provisions

The bill directs the National Heart, Lung, and Blood Institute (NHLBI), in cooperation with NHTSA, to develop and disseminate a model state training program for first responders and bystanders in lifesaving interventions, including CPR, and directs the development of model state legislation to ensure access to emergency medical services, including: consideration of the necessary training in, placement of, and good samaritan protection for the use of life-saving equipment for those choosing to intervene in out-of-hospital arrest. Finally, NHLBI is called upon to develop a national database for reporting and collecting data on the incidence of cardiac arrest and to evaluate the effectiveness of bystander and first responder lifesaving interventions.

ANSWERS TO FREQUENTLY ASKED QUESTIONS ABOUT THE CARDIAC ARREST SURVIVAL ACT

Question

Is there support for the proposal?

Answer

Support for the Cardiac Arrest Survival Act in the 104th Congress was broad. A diverse cross-section of national health and safety groups endorsed the proposal, including the American Heart Association, American Red Cross, American Association for Respiratory Care, American Association of Critical Care Nurses, American College of Cardiology, American Nurses Association, Citizen CPR Foundation, Emergency Nurses Association, North American Society of Pacing and Electrophysiology, National Safety Council, Save a Life Foundation, Society for Academic Emergency Medicine, and The Institute of Critical Care Medicine.

Question

How important is rapid access to basic and advanced cardiac life support?

Answer

A recent study found that if CPR is initiated in less than four minutes, and advanced cardiac life support in less than eight minutes, then the survival rate of the cardiac arrest patient is 43%. When CPR is initiated in less than four minutes but advanced cardiac life support is not initiated for 16 minutes, the rate of survival for the patient drops precipitously to 10 percent.

Question

What is the "Chain of Survival"?

Answer

More people can survive sudden cardiac arrest when a particular sequence of events occurs as rapidly as possible: 1) recognition of early warning signs, 2) activation of the emergency medical system, 3) basic cardiopulmonary resuscitation (CPR), 4) defibrillation, and 5) advanced cardiac life support. The American Heart Association has embraced the phrase "Chain of Survival" to communicate this concept in a useful way. This legislation makes a concerted effort to remove the barriers to the Chain of Survival in order to increase the likelihood of people surviving sudden cardiac arrest.

Question

Is the Chain of Survival effective?

Answer

In Houston, 40% of patients with ventricular fibrillation/ventricular tachycardia were discharged from the hospital if they had received bystander CPR, versus 19% for patients not given bystander CPR. Some communities have widely deployed AEDs (Richmond, Seattle, Bay Area). In such places survival rates run as high as 30 percent. In other large cities, such as Chicago and New York, rates run as low as 1-2 percent. Up to 100,000 lives could be saved annually through removal of barriers to the chain of survival.

Question

Haven't most states implemented the links in the Chain of Survival?

Answer

According to a 1995 survey, 31% of the population and 65% of the land area in the U.S. is not covered by the 911 system; only 14 states offer CPR training as part of their secondary school curricula; and only 22 states allow first responders to use an automatic external defibrillator. We have a long way to go!

Question

Isn't this just another burdensome federal mandate to the states?

Answer

The bill simply directs the National Heart, Lung, and Blood Institute to develop and disseminate a model state training program for first responders and bystanders in lifesaving first aid, including CPR, and directs the development of model state legislation to ensure access to emergency medical services, including consideration of mandatory location and placement of life-saving equipment and requirements for training in the core content and use of life-saving equipment for first responders.

Question

What is an example of life-saving equipment?

Answer

Automated external defibrillators. The vast majority of sudden cardiac arrests are due to an electrical malfunction of the heart called ventricular fibrillation (VF). In VF, the heart's electrical signals, which normally induce a coordinated heartbeat, suddenly become chaotic, and the heart's function as a pump abruptly ceases. Consciousness is quickly lost and unless this condition is reversed, death follows within a matter of minutes. The only effective treatment for this condition is defibrillation, the delivery of a powerful electrical shock to the heart. Defibrillation -- which can be compared to rebooting a 'frozen' computer -- eliminated VF and allows a coordinated rhythm to resume.

Question

Isn't this issue more properly addressed at the state level. Aren't we ignoring what the public asked for during the 104th Congress when they voted for less federal bureaucracy?

Answer

Pre-hospital medical care (training, equipment, standards of care) suffers from state-by-state variation which condemns the public to inconsistent care. A 1995 poll of state EMS directors identified obstacles to implementation of early defibrillation programs. Among the major obstacles identified was a lack of enabling legislation (34%). If a national standard were developed by DHHS, states would likely be more receptive to changes.

Development and dissemination of a core content for a recommended model state training program for first responders and bystanders in lifesaving first aid, including cardiopulmonary resuscitation (CPR) throughout the U.S., in a standardized fashion using current science, would be an efficient use of government resources.

(AHA - 12/96)

Question

With Congress moving to cut federal appropriations, won't additional funds be scarce for implementing this legislation?

Answer

Existing resources at DHHS can be used if the leadership mission were assigned, because industry, academia, and the medical community would all be available to contribute to the development of the legislation's recommendations.

Question

Aren't all ambulances already equipped with defibrillators?

Answer

AEDs are designed for trained basic life support (BLS) personnel. Currently, only 25 percent of BLS responders have defibrillators. First responders include fire rescue, police, BLS, flight attendants, or security personnel with a minimum of four hours AED training.

Question

Even if first responders are authorized to use AEDs, won't the costs be prohibitive?

Answer

The expense and time involved in equipping emergency vehicles with AEDs and training all first responders how to use them is minimal in proportion to the number of lives that can be saved. A Tucson, Arizona study showed the cost per year of life saved for care of sudden cardiac arrest by paramedics to be \$8,000. The actual cost of some AEDs is now under \$3,000 and training in its use takes less than four hours per person.

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CO-CHAIRMAN

Congress of the United States House of Representatives

March 14, 1996

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COSPONSOR THE CARDIAC ARREST SURVIVAL ACT



Dear Colleague:

Each year, approximately 250,000 people die when they suffer cardiac arrest. Less than seven percent of those who suffer cardiac arrest outside of a hospital survive.

The evidence is clear, however, that when more people are trained in cardiopulmonary resuscitation (CPR), more lives can be saved. For example, in Seattle, where CPR training is required for high school students, cab drivers and Seattle sports arena vendors, and is offered free to anyone who wants it, a person

is five times more likely to survive a cardiac arrest than in most other parts of the country. The average survival rate for cardiac arrest is 29 percent and rises to 40 percent for victims who receive the quickest emergency response.

Current programs to teach CPR have been successful in many areas, but have been limited to a relatively small segment of the population. Legislation that I have recently introduced -- the Cardiac Arrest Survival Act -- would increase training of citizens and first responders to victims who suddenly suffer cardiac arrest and in other serious trauma injury.

H.R. 3022 would potentially expand the number of health professionals and members of the general public who are trained to perform life saving techniques, such as CPR, rescue breathing, relieving airway obstruction and other first aid techniques. It would require the Secretary of Health and Human Services to make recommendations to the states on policies regarding the provision of first aid, CPR training and access to emergency medical services through the 911 system. In making these recommendations, the Secretary would consider the merits of requiring lifesaving training for law enforcement officers, fire fighters, teachers, athletic coaches, day care providers and other first responders.

The Secretary would be required to carry out demonstration projects in these and

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American Heart
Association
Fighting Heart Disease
and Stroke



For Release: March 7, 1996

Contact: Trish Morels
(202) 822-9380

NEWS

American Heart Association Supports Cardiac Arrest Survival Act Cardiac Defibrillation Should be More Accessible

WASHINGTON, DC -- The American Heart Association announced its support for the Cardiac Arrest Survival Act, HR 3022, being introduced today by Rep. Gerry Studds (D-MA). This legislation would recommend making automated external defibrillators (AEDs) more accessible to professionals who regularly respond to emergency situations, especially those involving cardiac arrest.

According to the AHA, each year more than 250,000 people die when they suffer cardiac arrest. Fewer than 7 percent of those suffering cardiac arrest outside a hospital survive.

The Cardiac Arrest Survival Act, supported by the AHA and a number of other organizations, would require the Secretary of Health and Human Services to make recommendations to the states on policies regarding the provisions of first aid, CPR training and access to emergency medical services through the 911 system. The Secretary would also be required to carry out demonstration projects dealing with the use of automated external defibrillators. These projects would result in recommendations about whether states should require that defibrillators be located in public places, such as office buildings, stadiums, and arenas.

Dr. Joseph Ornato, chair of the American Heart Association's Emergency Cardiac Care Committee explained, "Every day in the United States, 1,000 adults will become victims of sudden cardiac arrest. States need to be encouraged to adopt policies and programs that will significantly improve the survival rate of people suffering from cardiac arrest. This legislation recognizes that full public access to automated external defibrillators (AEDs) is essential for increased survival of cardiac arrest victims."

More people can survive sudden cardiac arrest when a particular sequence of events occurs as rapidly as possible. The American Heart Association developed the phrase "cardiac chain of survival" to communicate this concept in a useful way. Weakness in any link lessens the chance of survival and condemns the efforts of an emergency medical system (EMS) to poor results. The cardiac chain of survival is:

1) *early access* -The legislation would ensure that more people are trained to recognize the warning signs of cardiac arrest, to be able to adequately perform CPR, to promptly call 911, and to ensure that emergency personnel are dispatched to the scene.

- more-

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
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001. email	Zoraida Pagett to Elizabeth Drye re: SSN and DOB (partial) (1 page)	05/27/1997	P6/b(6)
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COLLECTION:

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Devorah Adler
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FOLDER TITLE:

Portable Defibrillators

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Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
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- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

To: Elizabeth_Drye@oa.eop.gov
 Cc:
 Bcc:
 From: Zoraida Pagett@IOS.IO@OS.DC
 Subject: Defibrillators
 Date: Tuesday, May 27, 1997 14:12:54 EDT
 Attach:
 Certify: N
 Forwarded by:

As per Mary Beth's request, I am forwarding the waive information of the participants attending the WH meeting tomorrow, May 28, 1997 at 10:00.

Mary Beth Donahue
 Deputy Chief of Staff (HHS)

[Redacted] P6(b)(6)

[001]

Jerry Mande (FDA)

[Redacted] P6(b)(6)

Bruce Burlington (FDA)

[Redacted] P6(b)(6)

Michael Friedman (FDA)

[Redacted] P6(b)(6)

Claude Lenfant (NIH)

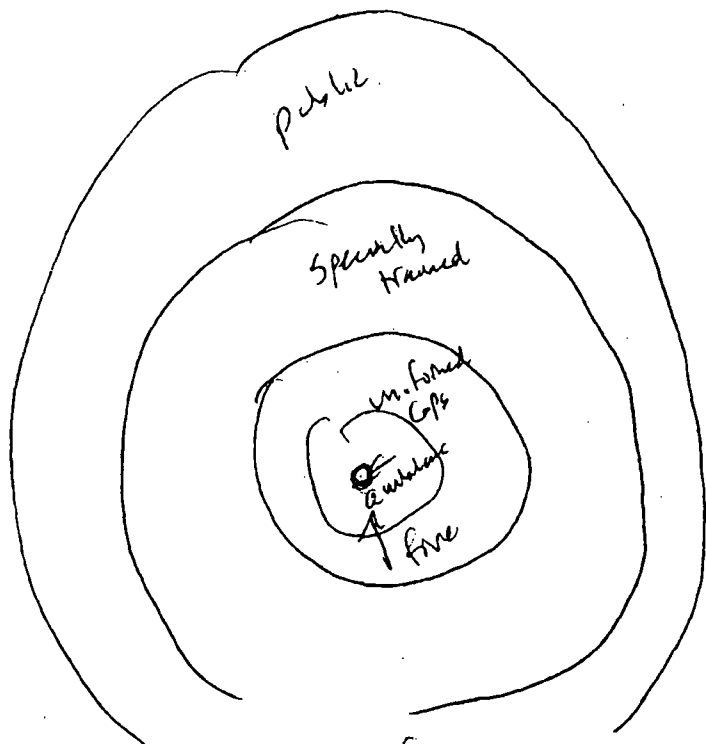
[Redacted] P6(b)(6)

David Snyder (HRSA)

[Redacted] P6(b)(6)

Kathy Buto (HCFA)

[Redacted] P6(b)(6)



Thank you.

Most

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