NLWJC - Kagan

DPC - Box 028 - Folder 010

Health - Definitions

Health-defibrillation

Elizabeth Drye
04/28/97 01:24:00 PM

Record Type: Record

To: Elena Kagan

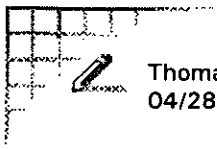
cc:
Subject: Re: defibrillation

Message Creation Date was at 28-APR-1997 13:24:00

After your meeting Friday before last, Mary Beth Donahue (Deputy COS) decided this had to be run out of the Secretary's office, ordered Jerrry NOT to talk to rest of HHS about it, and assigned the issue to a staff person at HHS "exec sec." Mary Beth promised a memo by tomorrow (thought that Corr had let you know last week they couldn't meet original deadline).

I am doing what I can w/out HHS. Jerry is following up with a police organization Dennis Burke put us in touch with, and I am trading phone calls with NHTSA. I'll have time to move the ball forward this week.

Health-defibrillator



Thomas L. Freedman
04/28/97 10:49:05 AM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Heart

I haven't heard from the HHS or FDA heart people, except last week to say their memo was going to take a while.

My general feeling is what we talked about before-- we just need a package of reasonable things to do, study the futureistic stuff, have orders on some concrete things-- and release a good war on heart attacks plan.

After I finish my New Ideas memo for this week, I could give you a menu memo of heart things we could do, at least as reference for what they finally come up with...

Health - defibrillators

Elizabeth Drye
04/17/97 06:32:53 PM

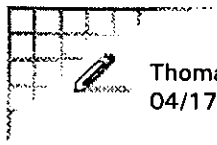
Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Laura Emmett/WHO/EOP, Jonathan Prince/WHO/EOP, Thomas L. Freedman/OPD/EOP
Subject: defibrillation

I've set up 11:00 meeting with you. FDA (Jerry Mande and possibly Bruce Burlington) will join us. They have some ideas about how to move forward we'd like to bounce off of you. FYI the doc running this for American Heart Assn. has very positive things to say about FDA's role to date and wasn't happy with the FDA bashing in the NYT article.

Health defibrillators



Thomas L. Freedman
04/17/97 09:58:02 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc: Elena Kagan/OPD/EOP
Subject: Take Heart

FYI. USA Today did a concise defibrillator item today on page 1, probably with the logical conclusion--- we should push to get the devices in ambulances/firefighting vehicles since most vehicles do not.

Office of Public Advocacy
1150 Connecticut Avenue Northwest Suite 810 Washington, DC 20036
Tel 202 822 9380
Fax 202 822 9883
http://www.americanheart.org

American Heart Association
Fighting Heart Disease and Stroke

Health - Defibrillators

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.

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.

AHA position

In a few weeks, Representative Cliff Stearns (R-FL-8) 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:

- 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 venticular fibrillation/ventricular tachycardia were discharged form 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.

CARDIAC ARREST SURVIVAL ACT

105th Congress

SECTION 1. SHORT TITLE

This Act may be cited as the "Cardiac Arrest Survival Act".

SEC. 2. FINDINGS

The Congress finds as follows:

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

(2) These cardiac arrest deaths occur primarily from occult underlying heart disease and from drownings, allergic or sensitivity reactions, electrical shocks, or motor vehicle injuries.

(3) Survival from cardiac arrest requires successful early implementation of a chain of events--the chain of survival--from the scene of the arrest to the hospital.

(4) A successful chain of survival requires the first person on the scene to take rapid and simple initial steps that will then lead to entry into the medical care system.

(5) The first persons on the scene when an arrest occurs are typically lay persons who are friends or family of the victim, firefighters, law enforcement officers, teachers, coaches and supervisors of sports or other extracurricular activities, providers of day-care, school-bus drivers, lifeguards, attendants at public gatherings, co-workers and other leaders within the community.

(6) A federal response to this epidemic is needed -- the development of a simple, short, convenient training program.

(7) The training program should be easily learned and easily retained and it should be nationally uniform.

Sec. 3 NATIONAL INSTITUTE OF HEALTH MODEL PROGRAM ON THE FIRST LINKS IN THE CHAIN OF SURVIVAL

Section 421(a)(1) of the Public Health Service Act (42 U.S.C. 285b-3(a)(1)) is amended by striking (E) and inserting in lieu thereof:

"(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases, **which shall include:**

"(I) development and dissemination, in coordination with the emergency services guidelines promulgated under Title 23, U.S. Code, § 402(a), by the Associate Administrator for Traffic Safety Programs, Department of Transportation, of a core content for a recommended model state training program for both first responders and bystanders in life saving interventions, including cardiopulmonary resuscitation;

(ii) the core content of such program shall include age-specific criteria for the use of particular techniques which shall include infants and children;

(iii) the core content of such program should be re-evaluated as additional interventions are shown to be effective;

(iv) operation of a demonstration project to provide training in such core content for first responders and bystanders;

"(v) definition and identification of both first responders and bystanders, by personal relationship, exposure to arrest or trauma, occupation (including health professionals), or otherwise, who could

provide benefit to victims of out-of-hospital arrest by comprehension of a core content;

"(vi) establishment of criteria for completion and comprehension of core content, including consideration of inclusion in health and safety educational curricula;

"(vii) identification and development of equipment and supplies that should be accessible to bystanders and first responders to permit life-saving interventions by pre-placement of such equipment in appropriate locations;

"(viii) development of model state legislation (or federal legislation applicable to federal territories, facilities, and employees), in cooperation with the Department of Justice, to ensure: (a) access to emergency medical services through consideration of a requirement for public placement of life-saving equipment and/or consideration of requirements for training in the core content and use of lifesaving equipment for State licensure or credentialing of health professionals or other licensed occupations or employment of other individuals who may be defined as first responders under clause (iv); and, (b) good samaritan immunity for: (1) bystanders; (2) first responders; (3) those involved with the instruction of the training programs; and, (4) owners and managers of property where equipment is placed.

"(ix) development of a national database for reporting and collecting information relating to the incidence of cardiac arrest, the circumstances surrounding such arrests, the rate of survival, the effect of age, and whether interventions, including bystander or first

responder interventions, or other aspects of the chain of survival, improve the rate of survival;

(x) publication of a biennial public report summarizing progress in life saving first aid;

SEC. 4 COMMISSION ON CARDIAC ARREST SURVIVAL

a) ESTABLISHMENT - There shall be established as an independent agency within the executive branch a commission to be known as the Commission on Cardiac Arrest Survival (hereinafter in this section referred to as the "Commission").

b) MEMBERSHIP

1) COMPOSITION - The Commission shall be composed of 15 members who shall be appointed by the President.

2) EXPERTISE REQUIREMENTS - The members of the Commission shall consist of individuals with expertise and experience in one or several of the following areas: emergency medical care, cardiology, state and local emergency medical services, delivery of state health services, public safety, trauma, public buildings or governmental facilities management, epidemiology, life-saving equipment design and manufacture, development of model state legislation, human factors engineering, and professional and public education. At least three of the members shall be qualified by scientific training and experience to evaluate the design or conduct of, and data derived from, clinical and educational research, in the risks and benefits of resuscitative modalities. Ex officio liaison to the commission shall be provided by the Department of Health and Human Services (National Institutes of Health), Department of

Education, Department of Transportation (National Highway Traffic Safety Administration), General Services Administration, Department of Defense and Department of Justice.

c) FUNCTION OF THE COMMISSION - The Commission shall, in consultation with the National Heart Lung and Blood Institute, evaluate and provide recommendations on effective methods to increase survival from cardiac arrest. Such recommendations may include recommendations on implementation of this Act, further studies on emergency medical systems or other modalities for early intervention in the chain of survival, or further legislation to improve access to cardiac arrest survival modalities.

d) REPORTS AND RECOMMENDATIONS - Not later than 18 months after the date of enactment of this Act, or during the interim when the Commission believes necessary, the Commission shall prepare and submit to the President and to the Congress a final report.

e) ADMINISTRATIVE POWERS OF THE COMMISSION - The commission may hold hearings, set and act at such time and places, take such testimony, receive such evidence as the Commission considers advisable to carry out the purpose of this section. The Commission may secure directly from any federal department or agency such information as the commission considers necessary to carry out the provisions of this section.

f) AUTHORIZATION OF APPROPRIATIONS - There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section.

March 11, 1997

TO: Writers, Editors, Broadcasters

FROM: Division of News Media Relations
Office of Communications

You are invited to cover the American Heart Association's symposium
"Public Access Defibrillation II: Strengthening the Chain of Survival,"
April 17-19, 1997, Hyatt Regency Crystal City in Arlington, Va.

Every day in the United States, 1,000 adults will experience sudden cardiac arrest, which is the sudden, abrupt loss of heart function in someone who may or may not have diagnosed heart disease. The condition can lead to sudden cardiac death, which kills about 250,000 people each year. In addition to the physical toll, it has enormous economic and social impacts because it claims many people during their most productive years and devastates families.

But people can survive sudden cardiac arrest when a particular sequence of events -- which the American Heart Association calls the "cardiac chain of survival" -- occurs as rapidly as possible. The cardiac chain of survival is: early access to emergency services; basic cardiopulmonary resuscitation (CPR); early defibrillation; and early advanced life support. Early defibrillation -- in which an electric shock is applied to an irregularly pulsating heart through the chest wall to restore its strong pumping action -- is the single most important life-saving maneuver in the chain of survival.

The AHA conference is designed to foster an exchange of information about various issues related to public access to defibrillation.

The program begins at 6 p.m. Thursday, April 17. A briefing for media will be held at 10 a.m. Thursday, in the hotel with conference chairman Myron Weisfeldt, M.D., chairman of the dept. of medicine at Columbia Presbyterian Medical Center in New York City, and others. A question-and-answer period will follow their remarks

Sessions include: FDA Update; Automatic External Defibrillator Technology Symposium; Current AED Features and the Future of AEDs in Public Access Defibrillation; AED Research Initiatives; Worldwide Presentations; 35 poster presentations and seven concurrent workshops.

Newsroom facilities will be available. Please return the accompanying form so we can best serve your needs. **For hotel reservations, contact the Hyatt Regency Crystal City at (703) 418-1234.**

*For more information, call News Media Relations, Dallas (214) 706-1173; Patricia Bowser (415) 637-8500; Robyn Landry, Washington, D.C. (202) 872-4240; Trish Moreis (202) 822-9380.

q/nmr/defib/invite.doc

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Note: If using a credit card, you can register by fax (301) 694-5124.

Workshop Request:

Indicate your first (1) and second (2) choice of workshop below: (See pages 5–6 for more information.)

___ #1 Established and Alternative Waveforms
___ #2 AHA Educational and Advocacy Initiatives
___ #3 Pediatric Issues Related to Public Access Defibrillation
___ #4 Population, Settings and Trial Design
___ #5 Trial Outcomes and Analysis, Including Utstein Criteria, Quality of Life Measures and Costs
___ #6 Interface of Public Access Defibrillation with the Emergency Medical System
___ #7 Training Challenges and Limitations

___ Check here if you require special assistance to fully participate in the conference. Attach a written description of your requirements.

CONFERENCE PROGRAM

Thursday, April 17

3:00–6:00 PM
Registration

6:00–7:00 PM
Conference Opening: Overall Progress Report
Myron L. Weisfeldt, MD
Chairman, Department of Medicine
Columbia Presbyterian Medical Center

Special Guest Speaker:
Claude Lenfant, MD
Director, National Heart, Lung and Blood Institute

7:00–9:30 PM
Session I: Key Clinical Research Highlights
Moderator: Martha N. Hill, RN, PhD
Associate Professor
Johns Hopkins University

Highest Rated U.S. Abstracts

Cardiac Arrest in Public Locations
Linda J. Becker
King County Health Department

Accuracy of an Automated External Defibrillator During Field Use for Out-of-Hospital Cardiac Arrest
Ronald E. Stickney
Physio-Control Corp.

Maintenance of Automated External Defibrillator Skills Using A Computer
John M. Jerin
King County Emergency Medical Services

Teaching Citizens to Use an AED During the AHA Heartsaver Course: Active vs. Passive Learning and Retention of Skills
Alidene M. Doherty, RN
University of Washington

Chairman's Invited Investigators

Use of Automated External Defibrillators by Police First Responders in Suburban Pittsburgh
Vince N. Mosesso Jr., MD, FACEP
University of Pittsburgh

Implementation of AEDs: Community Educational and Technical Implications
Max Harry Weil, MD, PhD
Institute of Critical Care Medicine

Estimating Effectiveness of Cardiac Arrest Interventions: A Logistic Regression Survival Model
Terence D. Valenzuela, MD, MPH
University of Arizona Health Science Center

Access to Rapid Defibrillation in a Combined Police/Paramedic Response System: Six Years' Experience in Rochester, Minnesota
Roger D. White, MD
Mayo Clinic

Outcomes of Cardiac Arrest Managed at or in the Vicinity of the Melbourne Cricket Ground Utilizing an Early Access to Defibrillation Strategy — A Forerunner to Public Access Defibrillation
Keane G. Wassertheil, MD
Epworth Hospital Richmond, Victoria, Australia

Friday, April 18

7:00–12:00 Noon
Registration

7:00–7:50 AM
Continental Breakfast

8:00–9:20 AM
Session II: Food and Drug Administration Update
Moderator: Richard E. Kerber, MD
Professor of Medicine
University of Iowa Hospital

Facilitating FDA Evaluation of AED Safety and Efficacy for Public Access Defibrillation
Richard E. Kerber, MD

The FDA's View of AEDs and Public Access Defibrillation
D. Bruce Burlington, MD
Director, Center for Devices & Radiological Health
U.S. Food and Drug Administration (FDA)

Informed Consent and CPR Research
Joseph P. Ornato, MD
Professor, Internal Medicine and Cardiology
Medical College of Virginia

9:45–12:00 Noon
Session III: Automatic External Defibrillator Technology Symposium
Moderator: Graham Nichol, MPH, MD
Assistant Professor
Loeb Medical Research Institute,
University of Ottawa

Current AED Features and the Future of AEDs in Public Access Defibrillation
Carl Morgan
Vice President of Research and Development
HeartStream, Inc

John Kuphal
Vice President, Product Support
Laerdal Medical Corporation

David Schlageter
Product Manager–Defibrillators
Marquette Electronics, Inc

Robert A. Niskanen
Director of Research
Physio-Control Corporation

James E. Brewer
Director, Research and Regulatory Affairs
SurVivaLink Corporation

Gary Freeman
Research Manager
Zoll Medical Corporation

12:00 Noon–1:00 PM
Lunch

An Open Discussion of Public Access Defibrillation

Robert R. Bass, MD, FACEP
National Association of State Emergency Medical Services Directors

Richard O. Cummins, MD, MPH, MSc
American Heart Association Emergency Cardiac Care Committee

James M. Atkins, MD
U.T. Southwestern Medical Center at Dallas

1:00–2:30 PM

Session IV: Public Access Defibrillation Research Initiative

Moderator: Michael J. Horan, MD, ScM
Director, Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute

Overview of AHA Public Access Defibrillation Research Initiative
Joseph P. Ornato, MD
Professor, Internal Medicine and Cardiology
Medical College of Virginia

Overview of Public Access Defibrillation Training Issues
Barbara Riegel, DNSc, FAAN
Associate Professor
San Diego State University

Measuring the Major Outcome Variables
Graham Nichol, MPH, MD
Assistant Professor
Loeb Medical Research Institute
University of Ottawa

Technical Challenges in Public Access Defibrillation Research
Alfred Hallstrom, PhD
Professor of Biostatistics
University of Washington

2:30–4:30 PM

Session V: Worldwide Abstract Presentations

Moderators: Sidney C. Smith Jr., MD
Professor and Chief, Division of Cardiology
University of North Carolina at Chapel Hill
and
Russell V. Leupker, MD
Professor and Head, Division of Epidemiology,
School of Public Health
University of Minnesota

Current AED Features and the Future of AEDs in Public Access Defibrillation
Carl Morgan
Vice President of Research and Development
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Robert A. Niskanen
Director of Research
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James E. Brewer
Director, Research and Regulatory Affairs
SurVivaLink Corporation

Gary Freeman
Research Manager
Zoll Medical Corporation

12:00 Noon–1:00 PM
Lunch

An Open Discussion of Public Access Defibrillation

Robert R. Bass, MD, FACEP
National Association of State Emergency Medical Services Directors

Richard O. Cummins, MD, MPH, MSc
American Heart Association Emergency Cardiac Care Committee

James M. Atkins, MD
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1:00–2:30 PM

Session IV: Public Access Defibrillation Research Initiative

Moderator: Michael J. Horan, MD, ScM
Director, Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute

Overview of AHA Public Access Defibrillation Research Initiative
Joseph P. Ornato, MD
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Overview of Public Access Defibrillation Training Issues
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Associate Professor
San Diego State University

Measuring the Major Outcome Variables
Graham Nichol, MPH, MD
Assistant Professor
Loeb Medical Research Institute
University of Ottawa

Technical Challenges in Public Access Defibrillation Research
Alfred Hallstrom, PhD
Professor of Biostatistics
University of Washington

2:30–4:30 PM

Session V: Worldwide Abstract Presentations

Moderators: Sidney C. Smith Jr., MD
Professor and Chief, Division of Cardiology
University of North Carolina at Chapel Hill
and
Russell V. Leupker, MD
Professor and Head, Division of Epidemiology,
School of Public Health
University of Minnesota

March 11, 1997

TO: Writers, Editors, Broadcasters

FROM: Division of News Media Relations
Office of Communications

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"Public Access Defibrillation II: Strengthening the Chain of Survival,"
April 17-19, 1997, Hyatt Regency Crystal City in Arlington, Va.

Every day in the United States, 1,000 adults will experience sudden cardiac arrest, which is the sudden, abrupt loss of heart function in someone who may or may not have diagnosed heart disease. The condition can lead to sudden cardiac death, which kills about 250,000 people each year. In addition to the physical toll, it has enormous economic and social impacts because it claims many people during their most productive years and devastates families.

But people can survive sudden cardiac arrest when a particular sequence of events -- which the American Heart Association calls the "cardiac chain of survival" -- occurs as rapidly as possible. The cardiac chain of survival is: early access to emergency services; basic cardiopulmonary resuscitation (CPR); early defibrillation; and early advanced life support. Early defibrillation -- in which an electric shock is applied to an irregularly pulsating heart through the chest wall to restore its strong pumping action -- is the single most important life-saving maneuver in the chain of survival.

The AHA conference is designed to foster an exchange of information about various issues related to public access to defibrillation.

The program begins at 6 p.m. Thursday, April 17. A briefing for media will be held at 10 a.m. Thursday, in the hotel with conference chairman Myron Weisfeldt, M.D., chairman of the dept. of medicine at Columbia Presbyterian Medical Center in New York City, and others. A question-and-answer period will follow their remarks

Sessions include: FDA Update; Automatic External Defibrillator Technology Symposium; Current AED Features and the Future of AEDs in Public Access Defibrillation; AED Research Initiatives; Worldwide Presentations; 35 poster presentations and seven concurrent workshops.

Newsroom facilities will be available. Please return the accompanying form so we can best serve your needs. **For hotel reservations, contact the Hyatt Regency Crystal City at (703) 418-1234.**

*For more information, call News Media Relations, Dallas (214) 706-1173; Patricia Bowser (415) 637-8500; Robyn Landry, Washington, D.C. (202) 872-4240; Trish Moreis (202) 822-9380.

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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.

CARDIAC ARREST SURVIVAL ACT
105th CONGRESS SUPPORTERS

American Heart Association
American Red Cross
American Association for Respiratory Care
American College of Cardiology
Citizen CPR Foundation
Consumer Federation of America
Emergency Nurses Association
Event Medical Services, Inc.
Hewlett-Packard Company
Heartstream, Inc.
International Association of Fire Chiefs
International Association of Firefighters
Laerdal Medical Corporation
Physio-Control Corporation
Save a Life Foundation
SOS Technologies & Oxygen Therapy Institute
SurVivaLink Corporation
The Institute of Critical Care Medicine
Wisconsin Indianhead Technical College, New Richmond Campus
Wyoming Department of Health

Office of Public Advocacy
1150 Connecticut Avenue Northwest Suite 810 Washington, DC 20036
Tel 202 822 9380
Fax 202 822 9883
http://www.americanheart.org

American Heart Association
Fighting Heart Disease and Stroke

Health – Defibrillation

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.

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.

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:

- 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 programs 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).**

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 venticular fibrillation/ventricular tachycardia were discharged form 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.

all steps in chain?

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.

CARDIAC ARREST SURVIVAL ACT

105th Congress

SECTION 1. SHORT TITLE

This Act may be cited as the "Cardiac Arrest Survival Act".

SEC. 2. FINDINGS

The Congress finds as follows:

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

(2) These cardiac arrest deaths occur primarily from occult underlying heart disease and from drownings, allergic or sensitivity reactions, electrical shocks, or motor vehicle injuries.

(3) Survival from cardiac arrest requires successful early implementation of a chain of events--the chain of survival--from the scene of the arrest to the hospital.

(4) A successful chain of survival requires the first person on the scene to take rapid and simple initial steps that will then lead to entry into the medical care system.

(5) The first persons on the scene when an arrest occurs are typically lay persons who are friends or family of the victim, firefighters, law enforcement officers, teachers, coaches and supervisors of sports or other extracurricular activities, providers of day-care, school-bus drivers, lifeguards, attendants at public gatherings, co-workers and other leaders within the community.

(6) A federal response to this epidemic is needed -- the development of a simple, short, convenient training program.

(7) The training program should be easily learned and easily retained and it should be nationally uniform.

Sec. 3 **NATIONAL INSTITUTE OF HEALTH MODEL PROGRAM ON THE FIRST LINKS IN THE CHAIN OF SURVIVAL**

Section 421(a)(1) of the Public Health Service Act (42 U.S.C. 285b-3(a)(1)) is amended by striking (E) and inserting in lieu thereof:

"(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases, **which shall include:**

"(I) development and dissemination, in coordination with the emergency services guidelines promulgated under Title 23, U.S. Code, § 402(a), by the Associate Administrator for Traffic Safety Programs, Department of Transportation, of a core content for a recommended model state training program for both first responders and bystanders in life saving interventions, including cardiopulmonary resuscitation;

(ii) the core content of such program shall include age-specific criteria for the use of particular techniques which shall include infants and children;

(iii) the core content of such program should be re-evaluated as additional interventions are shown to be effective;

(iv) operation of a demonstration project to provide training in such core content for first responders and bystanders;

"(v) definition and identification of both first responders and bystanders, by personal relationship, exposure to arrest or trauma, occupation (including health professionals), or otherwise, who could

provide benefit to victims of out-of-hospital arrest by comprehension of a core content;

"(vi) establishment of criteria for completion and comprehension of core content, including consideration of inclusion in health and safety educational curricula;

"(vii) identification and development of equipment and supplies that should be accessible to bystanders and first responders to permit life-saving interventions by pre-placement of such equipment in appropriate locations;

"(viii) development of model state legislation (or federal legislation applicable to federal territories, facilities, and employees), in cooperation with the Department of Justice, to ensure: (a) access to emergency medical services through consideration of a requirement for public placement of life-saving equipment and/or consideration of requirements for training in the core content and use of lifesaving equipment for State licensure or credentialing of health professionals or other licensed occupations or employment of other individuals who may be defined as first responders under clause (iv); and, (b) good samaritan immunity for: (1) bystanders; (2) first responders; (3) those involved with the instruction of the training programs; and, (4) owners and managers of property where equipment is placed.

"(ix) development of a national database for reporting and collecting information relating to the incidence of cardiac arrest, the circumstances surrounding such arrests, the rate of survival, the effect of age, and whether interventions, including bystander or first

responder interventions, or other aspects of the chain of survival, improve the rate of survival;

(x) publication of a biennial public report summarizing progress in life saving first aid;

SEC. 4 COMMISSION ON CARDIAC ARREST SURVIVAL

a) ESTABLISHMENT - There shall be established as an independent agency within the executive branch a commission to be known as the Commission on Cardiac Arrest Survival (hereinafter in this section referred to as the "Commission").

b) MEMBERSHIP

1) COMPOSITION - The Commission shall be composed of 15 members who shall be appointed by the President.

2) EXPERTISE REQUIREMENTS - The members of the Commission shall consist of individuals with expertise and experience in one or several of the following areas: emergency medical care, cardiology, state and local emergency medical services, delivery of state health services, public safety, trauma, public buildings or governmental facilities management, epidemiology, life-saving equipment design and manufacture, development of model state legislation, human factors engineering, and professional and public education. At least three of the members shall be qualified by scientific training and experience to evaluate the design or conduct of, and data derived from, clinical and educational research, in the risks and benefits of resuscitative modalities. Ex officio liaison to the commission shall be provided by the Department of Health and Human Services (National Institutes of Health), Department of

Education, Department of Transportation (National Highway Traffic Safety Administration), General Services Administration, Department of Defense and Department of Justice.

c) FUNCTION OF THE COMMISSION - The Commission shall, in consultation with the National Heart Lung and Blood Institute, evaluate and provide recommendations on effective methods to increase survival from cardiac arrest. Such recommendations may include recommendations on implementation of this Act, further studies on emergency medical systems or other modalities for early intervention in the chain of survival, or further legislation to improve access to cardiac arrest survival modalities.

d) REPORTS AND RECOMMENDATIONS - Not later than 18 months after the date of enactment of this Act, or during the interim when the Commission believes necessary, the Commission shall prepare and submit to the President and to the Congress a final report.

e) ADMINISTRATIVE POWERS OF THE COMMISSION - The commission may hold hearings, set and act at such time and places, take such testimony, receive such evidence as the Commission considers advisable to carry out the purpose of this section. The Commission may secure directly from any federal department or agency such information as the commission considers necessary to carry out the provisions of this section.

f) AUTHORIZATION OF APPROPRIATIONS - There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section.

Health - defibrillation

4/18 Defibrillation Mtg

1/4 of amb type p - firemen etc. — $2-8,000

costs

Legal barrier

- st sum acts — CA - only one that specif extends

- medical practice acts

National model act

2 legislation - to develop this.

Allow by FDA - Physician supervised

Not yet - Other

Heart Assoc study

DOT - Police

NITSE/DOT -

Health - defibrillation

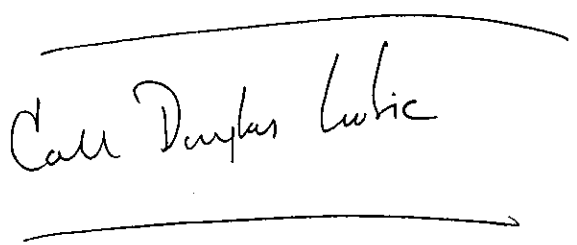
The elements of a good event I think we need, and that are defensible are:

1. Encourage all ambualnces and police to have these things

2. Create model legislation for what states can do, what training programs should look like. (Chairman of Columbia Presbyterian says it is laws and regulations that are holding cardiac care back).

3. Get airlines, public places to put in

4. Do model programs, studies,



Health –
defibrillators

Elizabeth Drye
04/09/97 05:02:36 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc: Jonathan Prince/WHO/EOP, Thomas L. Freedman/OPD/EOP, Christopher C. Jennings/OPD/EOP
Subject: Cardiac care /defibrillators

I've looked into this briefly and think it's worth pursuing -- I'm meeting with American Heart Assn. Friday. But I have no time to -- and I don't think we need to -- come up with an administration policy on this by AHA's conference next Friday. If the conference gets widespread coverage, any action we take within the next few weeks will still resonate. I'd like to put something together over the next month. Let me know if that's not acceptable.

DK – keep on