FOIA Number: 2008-1524-F

FOIA MARKER

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Subgroup/Office of Origin: Office of Science and Technology Policy

Series/Staff Member: Jerold Mande

Subseries:

OA/ID Number: 13034

FolderID:

Folder Title:
Automatic External Defibrillators:Cardiac Arrests

Stack:	Row:	Section:	Shelf:	Position:
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Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. fax	WAVES Confirmation to Elizabeth Drye, appt date 05/28/1997 (partial) (1 page)	05/27/1997	b(7)(C), b(6)

COLLECTION:
Clinton Presidential Records
Office of Science and Technology Policy
Jerold Mande
OA/Box Number: 13034

FOLDER TITLE:
Automatic External Defibrillators: Cardiac Arrests

2008-1524-F
kc1219

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]

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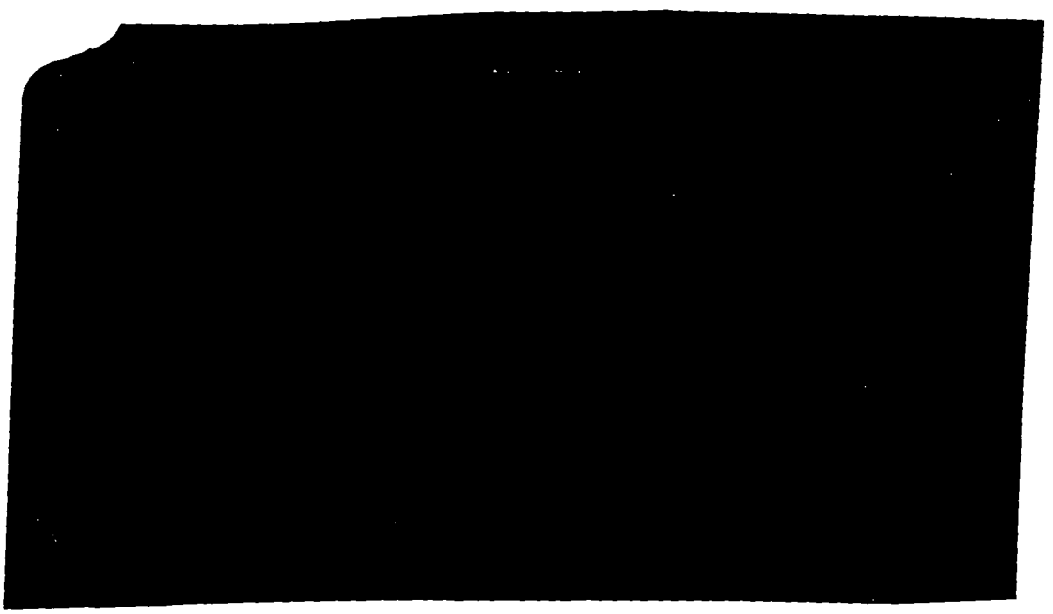

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the Critical Moment

When resuscitation depends on rapid defibrillation

A EMS/FIREFIGHTER'S NEWS Supplement on Early Defibrillation

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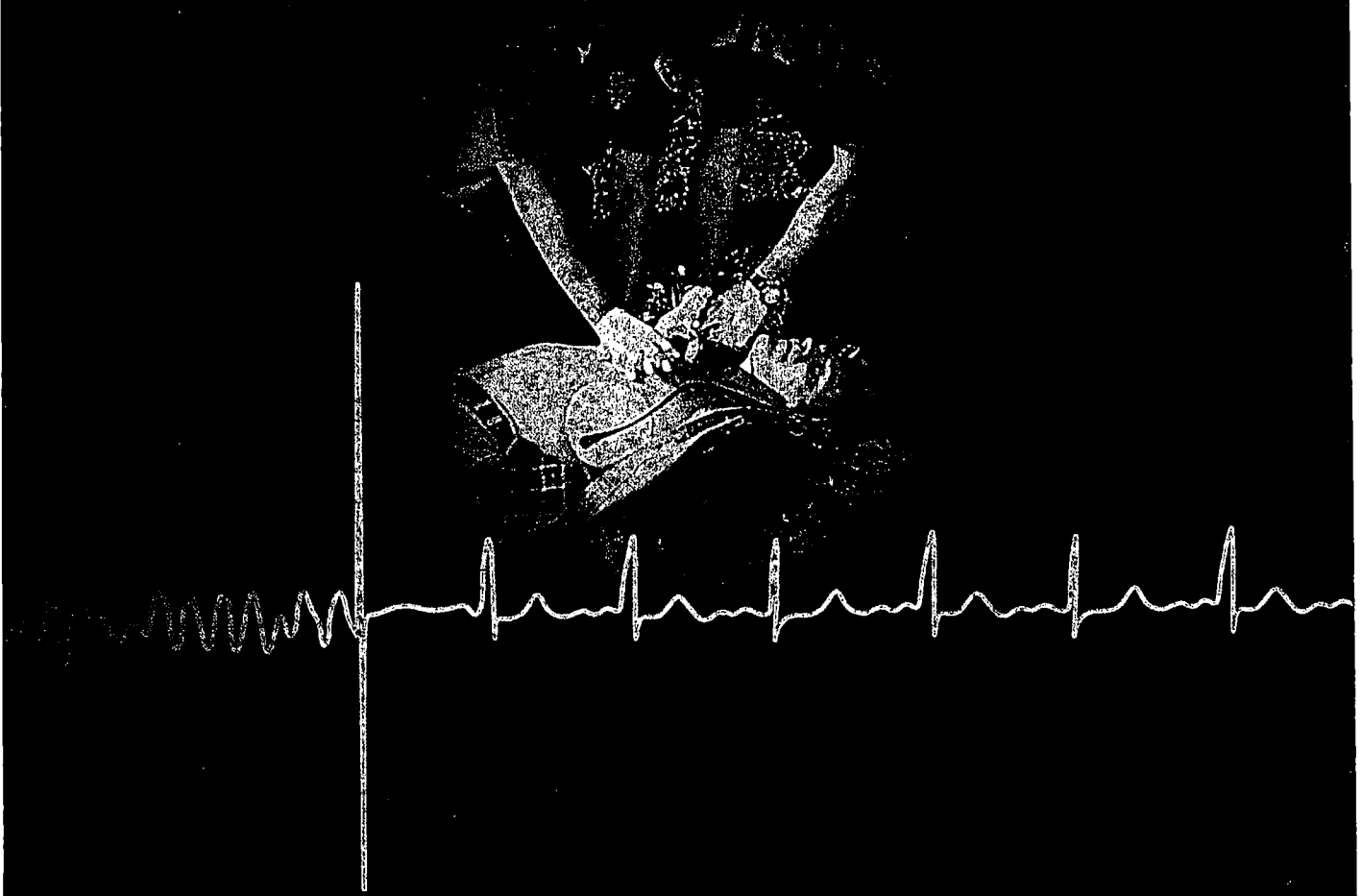
the Critical Moment

When resuscitation depends on rapid defibrillation



A JEMS/FIREFIGHTER'S NEWS Supplement on Early Defibrillation

STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
Alabama	Ala. Code §6-5-332 (Supp. 1991)	Immunity from civil damages; medically trained personnel and public education employees	Gratuitous, good faith, emergency care at the scene of an accident.
Alaska	Alaska Stat. §09.65.090 (1991)	Immunity from civil damages; any person	Emergency aid in a hospital or any location; excepts gross negligence, reckless or intentional misconduct.
Arizona	Ariz. Rev. Stat. Ann. §32-1471 (1986)	Immunity from civil or other damages; health care provider or any other person	Emergency call, gratuitous, in good faith; excepts gross negligence.
	Ariz. Rev. Stat. Ann. §32-1473 (Supp. 1991)	Physician not liable to pregnant patient, child delivered, or family for medical malpractice related to labor and delivery	Emergency, patient was not previously treated by physician or a physician in a group practice with the delivering physician; patient's medical information is not reasonably available to the physicians attending the labor and delivery.
	Ariz. Rev. Stat. Ann. §12-571 (1992)	Immunity from malpractice suit; health care professional	Health care professional who provides services, without compensation in a nonprofit clinic; excepts gross negligence.
	Annual appropriation to Department of Health Services; not in statute	Malpractice premium subsidy; Physicians who provide obstetrical services in under served areas	Physician must provide obstetrical care in State-defined underserved area; Department of Health Services creates distribution requirements through rulemaking.
Arkansas	Ark. Stat. Ann. §17-93-101 (1987)	Immunity from civil damages; physician or any other person	Good faith, emergency care without compensation at the scene of an emergency.

STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
California	Cal. Health & Safety Code §1799.102 (West 1990)	Immunity from civil damages; any person	Good faith, without compensation, rendering emergency care at the scene of an emergency; excludes emergency departments and other places where medical care is usually offered.
	Cal. Bus. & Prof. Code §2395 (West 1990)	Immunity from civil damages; physician	Care at scene of emergency (scene of emergency shall include, but not be limited to, the emergency rooms of hospitals in the event of a state declared medical disaster); excludes wilful acts or omissions.
	Cal. Bus. & Prof. Code §2395.5 (West 1990)	Immunity from civil damages/ obstetrical care; physicians	Physicians also serve on an "on-call" basis to a hospital emergency room who in good faith render emergency medical services; statute inapplicable when there is an existing duty to treat or a reasonable expectation of payment, and additional requirements.
	Cal. Bus. & Prof. Code §2396 (West 1990)	Immunity from civil damages; physician	Good faith, renders emergency care at the the request of another physician for medical complications arising from prior care of another.
	Cal. Bus. & Prof. Code §2397 (West 1990)	Immunity from civil damages; physician	Emergency situation in physician's office or hospital on account of failure to inform patient of consequences of a medical procedure for reasons set forth in statute.
Colorado	Colo. Rev. Stat. §13-21-108 (1989 & Supp. 1991)	Immunity from civil damages; physician or any person	Good faith, without compensation, emergency care rendered at the place of the emergency. Person needing assistance must not presently be physician's patient, place of emergency may be a health care institution; excepts gross negligence, wilful, wanton conduct.
Connecticut	Conn. Gen. Stat. Ann. §52-557b (1991)	Immunity from civil damages; physician or trained medical personnel	Gratuitous, not in course of employment, emergency medical assistance; excludes gross, wilful or wanton negligence.
Delaware	Del. Code Ann. tit. 16, §6801 (Supp. 1990)	Immunity form civil damages; any person	Good faith, emergency care, without compensation, at the scene of an accident, or any other place; excepts

STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
Delaware (Cont'd)			gross negligence, wilful, reckless or wanton misconduct; also excludes premises of hospital or clinic.
	Del. Code Ann. tit. 10, §8135 (Supp. 1990)	Immunity from civil damages; unless volunteer physician or nurse has insurance coverage for negligent acts or omissions	Nonprofit clinics; excluding doctor's office or hospital; also excludes wilful, wanton or grossly negligent conduct.
District of Columbia	D.C. Code Ann. §2-1344 (1988)	Immunity from civil damages; any person	Good faith, scene of accident or emergency, outside a hospital, no remuneration; excepts gross negligence.
	D.C. Code Ann. §2-1344 (Supp. 1992)	Immunity from civil damages; physician, nurses, nurse-midwives who volunteer in free clinics	Provision of obstetric or gynecologic care; good faith, without compensation; excepts intentional wilful, wanton conduct.
Florida	Fla. Stat. Ann. §768.13(2)(a) (Supp. 1992)	Immunity from civil damages; any person	Gratuitous, good faith, emergency care at scene of emergency outside a hospital or doctor's office, or other place with proper medical equipment.
	Fla. Stat. Ann. §768.13(2)(b)(1) (Supp. 1992)	Immunity from civil damages; physician	Physician in hospital, who in good faith, renders emergency care, in emergency room; excludes reckless, disregard for care of the life or health of others does not apply to patient who has been stabilized.
	Fla. Stat. Ann. §768.13(4)(3) (Supp. 1992)	Immunity from civil damages; physician	Physician who is staff member or has clinical privileges at nonprofit medical facility, other than hospitals; care must be gratuitous.
	Fla. Stat. Ann. §766.303 (Supp. 1992)	Birth-related neurological compensation plan.	Applies to births after Jan. 1, 1989; exclusive remedy against any person or entity involved in labor and delivery when injury occurs; excludes bad faith, malicious purpose or wilful and wanton disregard of human rights, safety or property.
Georgia	Ga. Code. Ann. §51-1-29 (1982)	Immunity from civil damages; any person	Good faith, emergency care at the scene of an accident or emergency, without compensation.

STAT	CITATION	TYPE/PROTECT	REQUIREMENTS
Georgia (Cont'd)	Ga. Code Ann. §51-1-29.1 (Supp. 1991)	Immunity from civil damages; licensed health care provider	Health care provider who voluntarily provides health care services for hospital, public school, non-profit organization, or state agency; excludes gross negligence, wilful or wanton misconduct.
Hawaii	Haw. Rev. Stat. §663-1.5(a) (1988)	Immunity from civil damages; any person	Good faith, emergency care, without remuneration, at the scene of an accident or emergency; excepts gross negligence or wanton acts.
	Haw. Rev. Stat. §663-1.5(c) (1988)	Immunity from civil damages; physician	Physician who renders emergency medical care in good faith in a hospital, to a person in immediate danger of loss of life, without remuneration or expectation of remuneration.
	Annual appropriation; not in statute	Premium subsidy	State provides a premium subsidy to physicians who provide obstetrical care in underserved areas.
Idaho	Idaho Code §5-330 (1990)	Immunity from civil damages; anyone	Good faith, scene of accident; excepts gross negligence, immunity ends upon delivery to hospital, office or facility, or ambulance.
	Idaho Code §6-1605 (1990)	Immunity from civil liability; nonprofit organization, officers, directors, volunteers	Nonprofit organization, officers, directors, and volunteers who serve the nonprofit, without compensation, excepts wilful, wanton conduct, fraud, or knowing violation of the law; does not limit immunity to the extent of coverage for such conduct under a policy of liability insurance, whether policy is purchased by organization, officer, director, volunteer or third party; does not limit liability for any breach of fiduciary duty, or for acts not in good faith, or intentional misconduct, fraud or knowing violation of the law.
Illinois	Ill. Ann. Stat. ch. 111, §4400-30 (Smith-Hurd Supp. 1991)	Immunity from civil damages; physician	Good faith, without prior notice of illness or injury provides emergency care, without a fee; excepts wilful or wanton misconduct.

STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
Illinois (Cont'd)	Ill. Ann. Stat. ch.ill, §4400-31 (Smith-Hurd Supp. 1991)	Immunity from civil damages; physician	Good faith, provision of medical treatment in a free medical clinic to medically indigent patients who do not require the services of a licensed hospital or ambulatory surgical center, receives no compensation; excepts wilful or wanton misconduct. Free medical clinic must post in a conspicuous place an explanation of the exemption from liability.
Indiana	Ind. Code Ann. §34-4-12-1 (Burns 1986)	Immunity from civil damages; any person	Good faith, gratutiously rendering emergency care at the scene of an accident; except gross negligence, wilful or wanton misconduct.
	Ind. Code Ann. §34-4-12-2 (Burns 1986)	Immunity from civil damages; anyone trained in CPR and rendering CPR	Person trained in CPR rendering CPR without compensation; excepts gross negligence, wilful or wanton misconduct.
Iowa	Iowa Code Ann. §613.17 (West Supp. 1991)	Immunity from civil damages; any person	Good faith, emergency care without compensation, at the place of the emergency or accident; excepts recklessness.
Kansas	Kan. Stat. Ann. §65-2891(a) (Supp. 1991)	Immunity from civil damages; health care provider	Good faith, renders emergency care, at scene of an emergency or accident; excepts gross negligence or wilful or wanton acts.
	Kan. Stat. Ann. §65-2891(c) (Supp. 1991)	Immunity for civil damages other than negligence; health care provider	Good faith, emergency care within a hospital or elsewhere, with or without compensation, until such time as the physician employed by the patient or by the patient's family or guardian assumes responsibility for such patient's care.
	Kan. Stat. Ann. §75-6102 (1989 & Supp. 1991)	Indemnity; charitable health care providers are employees of the State for purposes of the Kansas Tort Claims Act	Charitable health care provider means someone licensed to practice medicine who has entered into an agreement with the secretary of health and environment, renders gratuitous professional services to medically indigent and who is considered a State employee or who renders care pursuant to an agreement with the local health department.

STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
Kentucky	Ky. Rev. Stat. Ann. §411.148 (Michie 1992)	Immunity from civil damages; physician	Emergency care at the scene of an emergency outside a hospital, doctor's office, or other place having proper medical equipment, excluding house calls; excludes wilful or wanton misconduct. Does not apply where there is an expectation of remuneration.
Louisiana	La. Rev. Stat. Ann. §37:1731 (West Supp. 1992)	Immunity from civil damages; physician or nurse	Good faith, gratuitous, emergency care at the scene of an emergency, except in a public or private hospital.
	La. Rev. Stat. Ann. §40:1299.153 (West Supp. 1992)	Indemnity; health care providers meeting statutory requirements	State indemnifies a health care provider who provides charity care in at least 10% of the health care provider's patient encounters. "Charity care" is limited to defined State programs or care provided at federally funded nonprofit clinics. Health care providers can be a person, partnership or corporation that is reimbursed by the State for care. Providers must maintain liability insurance, and insurer must defend action. State's liability is for actual damages. State's liability is limited. Excludes gross negligence, intentional misconduct.
	La. Rev. Stat. Ann. §40:1299.161 (West Supp. 1992)	Liability premium discount; certain health care providers	State-mandated premium discount for health care providers who at least 10% or more of the patient encounters are charity care, and additional statutory requirements are met.
	La. Rev. Stat. Ann. §40:1299.39 (West 1992)	Indemnity; "State health care provider"	"State health care provider" means the State, its departments and employees, also includes contract employees, and persons performing voluntary professional services in a health care facility on behalf of the State, and physicians who gratuitously treat "any patient referred to him from a state facility without compensation," or gratuitously treats a patient who is certified by a state facility to be eligible for admission to a state facility. Physician must signify in writing by the end of the next business day that all medical and hospital fees are waived. Excludes gross negligence, or any wilful or wanton act or omission.

STAT	CITATION	TYPE/PROTECT	REQUIREMENTS
Louisiana (Cont'd)	La. Rev. Stat. Ann. §9:2793 (West 1991)	Immunity from civil damages; any person	Good faith, gratuitous, renders emergency care, at the scene of an emergency; Act does not apply to care rendered incidental to a business relationship, also excludes intentional or grossly negligent acts or omissions.
Maine	Me. Rev. Stat. Ann. tit. 14, §164 (1980)	Immunity from civil damages; any person	Voluntary, without expectation of compensation, emergency care; excepts wilful, wanton reckless, or grossly negligent conduct. Excludes care in hospital or clinic.
	Me. Rev. Stat. Ann. tit.24, §2904 (1990)	Immunity from civil damages; physician	Voluntary, without compensation, provides professional services to a nonprofit organization or agency of the State; excepts wilful, wanton, reckless, or grossly negligent conduct.
	Me. Rev. Stat. Ann. tit. 14 §158-A (Supp. 1991)	Immunity from civil damages; charitable directors, officers and volunteers	Charitable organization means a non-profit organization, applies to persons rendering services or serving without compensation.
	Me. Rev. Stat. Ann. tit. 24-A §6301 (Supp. 1991)	Premium subsidy; physicians who practice obstetrics in underserved areas	Physician must serve Medicaid patients, provide complete obstetrical services, and must practice at least 50% of the time in a state-defined underserved area.
Maryland	Md. Cts. & Jud. Proc. Code Ann. §5-309 (1989)	Immunity from civil damages; licensed medical personnel	Without compensation, at the scene of an emergency or in transit to a medical facility; excludes gross negligence.
Montgomery County, Maryland	No statute	Indemnification from County; obstetricians employed by County on part-time basis to provide obstetrical care	Qualified obstetricians employed on a part-time basis by County to perform obstetrical services, indemnified by County; County's liability is limited by law to $500,000. Excludes actions with actual malice.
Massachusetts	Mass. Ann. Laws ch.112, §12B (Law. Co-op. 1991)	Immunity from civil damages; physician	Good faith, as a volunteer without a fee, rendering emergency care, other than in the ordinary course of his practice.

STAT	CITATION	TYPE/PROTECTION	REQUIREMENTS
Massachusetts (Cont'd)	Mass. Ann. Laws ch 112, §12C (Law. Co-op. 1991)	Immunity from civil damages; physician	No physician administering immunization or other protective programs under public programs shall be liable.
Michigan	Mich. Comp. laws Ann. §691.1501 (West Supp. 1991)	Immunity from civil damages; physician	Good faith, renders emergency care at the scene of an emergency, no prior physician/patient relationship existed; excepts gross negligence, or wilful and wanton misconduct.
	Mich. Comp. laws Ann. §691.1502 (West 1987)	Immunity from civil damages; hospital or other medical care facility personnel	In instances where the actual hospital duty of that person did not require a response to that emergency situation, persons responding in good faith to life-threatening emergency within a hospital or other licensed medical facility not liable; excepts gross negligence, or wilful and wanton misconduct. Cannot be a prior physician/patient relationship.
Minnesota	Minn. Stat. Ann. §604.05 (West 1988 & Supp. 1992)	Immunity from civil damages; any person	Without compensation, renders emergency care at the scene of an emergency or during transit; excepts wilful and wanton or reckless care. Excludes anyone rendering emergency care in the regular course of employment and receiving compensation for such care. Excludes care in hospital, or other institution with hospital facilities or physicians office.
Mississippi	Miss. Code Ann. §73-25-37 (1989)	Immunity from civil damages; physician, or any other person	Good faith, with reasonable care, renders emergency care at the scene of an emergency or transporting a person.
	Miss. Code Ann. §11-46-1 (Supp. 1991) §11-46-15 (Supp. 1991)	Indemnifies physicians who provide care under an agreement with State government. Physician is considered a State employee	Limits liability claims against government or government employee.
Missouri	Mo. Ann. Stat. §537.037 (Vernon 1988)	Immunity from civil damages; physician	Good faith, emergency care, without compensation; excepts gross negligence or wilful or wanton acts.

STATE	CITATION	TYPE/PROTECTI	REQUIREMENTS
Missouri (Cont'd)	Mo. Ann. Stat. §105.711 (Vernon Supp. 1992)	Indemnity; physician who is employed by the State	State legal expense fund covers payment claims against physicians who provide obstetrical or child care pursuant to contract for local health departments who receive minimal or no compensation.
Montana	Mont. Code Ann. §27-1-714 (1991)	Immunity from civil damages; physician, any other person	Good faith, renders emergency care, with out compensation, at the scene of an emergency; excepts gross negligence, or wilful or wanton conduct.
	Mont. Code Ann. §27-1-734 (1991)	Immunity from civil damages; health care providers	Good faith, physician rendering care to a patient of a nurse midwife in an emergency obstetrical situation; excepts gross negligence, or wilful or wanton acts.
Nebraska	Neb. Rev. Stat. §25-21,186 (1989)	Immunity from civil damages; any person	Scene of accident or emergency, care rendered gratuitously.
Nevada	Nev. Rev. Stat. Ann. §41.505 (Michie Supp. 1991)	Immunity from civil damages; physician	Good faith, gratuitous, scene of emergency or transport; excepts gross negligence. Also excludes acts or omissions in a licensed medical facility where there is a pre-existing patient relationship.
	Nev. Rev. Stat. Ann. §41.485 (Michie 1991)	Immunity from civil damages; volunteer of a charitable organization	Volunteer, performs services without compensation; excludes intentional, wilful, wanton or malicious conduct. Definition of charitable organization includes licensed medical facility.
	Nev. Rev. Stat. Ann. §442.1192 (Michie 1991)	Malpractice insurance premium subsidy; physician providing certain obstetrical care	Physician must attend continuing education on risk management or patient care relating to prenatal services; collect certain required data; provide prenatal care without regard to her economic status or ability to pay; refer the pregnant woman if he or she cannot provide necessary care; carry out the plan for inproving the health care of local pregnant women.

STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
New Hampshire	N.H. Rev. Stat. Ann. §508:12 (Supp. 1991)	Immunity from civil damages; any person	Good faith, emergency care, excludes wilful or wanton negligence; no compensation permitted for Act to apply.
	N.H. Rev. Stat. Ann. §329:25 (1984)	Immunity from civil damages; physician	Physician who renders emergency aid in good faith at the scene of an emergency, without compensation.
	N.H. Rev. Stat. Ann. §508:17 (Supp. 1991)	Immunity from civil damages; volunteers of nonprofit organizations or government entities	Volunteer must have prior written approval from the organization to act on its behalf. Good faith; excepts wilful, wanton or grossly negligent misconduct. Liability of nonprofit organization based on negligence of volunteers is limited to $250,000 for a single person or $1,000,000 for injury substained by a group of persons.
New Jersey	N.J. Stat. Ann. §2A:62A-1 (West Supp. 1991)	Immunity from civil damages; any person	Good faith, emergency care rendered at the scene of an accident or emergency, or during transport.
New Mexico	N.M. Stat. Ann. §24-10-3 (1991)	Immunity from civil damages; any person	Emergency care rendered in good faith, at or near the scene of an emergency; excepts gross negligence, and does not apply to care rendered for remuneration or the expectation of remuneration.
New York	N.Y. Educ. Law §6527 (2) (McKinney 1985)	Immunity from civil damages; physician	Voluntarily, without the expectation of compensation, renders aid at the scene of an accident or emergency; outside a hospital, doctor's office, or other place having necessary medical equipment excepts gross negligence; excepts physician's professional services in the normal course of practice.
North Carolina	N.C. Gen. Stat. §90-21.14 (Supp. 1991)	Immunity from civil damages; any person, including a volunteer medical or health care provider at a facility of a local health department or at a nonprofit community health center.	Voluntary, no compensation, immediate health care services necessary; excepts gross negligence, wanton conduct or intentional wrong doing. Does not apply to the rendering of health care services in the normal and ordinary course of a person's business or profession. However, a health care provider who receives no compensation

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STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
North Carolina (Cont'd)			for voluntarily rendered services in local health department facilities or nonprofit community centers are deemed not to be in the health care provider's normal and ordinary course of the of the person's business or profession.
		State subsidy	Legislature appropriated funding for a rural obstetrical care incentive program. Program offsets higher malpractice premiums for providing delivery services in medically under served areas.
North Dakota	N.D. Cent. Code §39-08-04.1 (1987)	Immunity from civil damages; any person	Unpaid volunteer, good faith, renders emergency services at or near the scene of an emergency, or during transport; exempts conduct related to intoxication, wilful misconduct or gross negligence. Act does not apply if emergency care rendered for remuneration or with the expectation of remuneration.
	N.D. Cent. Code §32-03.1-02 (Supp. 1991)	Immunity from suit or liability; any person, or their employers	Rendering emergency aid; excepts gross negligence or intentional misconduct.
	N.D. Cent. Code §32-03.1-02.1 (Supp. 1991)	Immunity from civil damages; physician	Physician rendering emergency care to woman in active labor, no prior patient relationship, whose medical records are not reasonably available; excepts intentional misconduct or gross negligence. Act does not apply to physician who accepts remuneration or collects a fee for rendering such care.
	N.D. Cent. Code §32-03.1-02.2 (Supp. 1991)	Immunity from civil damages; licensed health care provider	Licensed health care provider who voluntarily (without remuneration) provides care at a free clinic; excepts intentional misconduct or gross negligence.
	N.D. Cent. Code §32-03.1-04 (Supp. 1991)	Immunity from civil damages; physician or surgeon	Act does not apply if care rendered in expectation of remuneration.
Ohio	Ohio Rev. Code Ann. §2305.23 (1991)	Immunity from civil damages; any person	Emergency care, outside of a hospital or doctor's office, or other place having proper medical equipment; excepts wilful or wanton misconduct. Act does not apply if there is remumeration, or the expectation of remuneration for care given.

STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
Oklahoma	Okla. Stat. Ann. tit. 76, §5 (West 1987)	Immunity from civil damages; physician	No prior contractual relationship, emergency circumstances, good faith, voluntarily and without compensation; excepts gross negligence, or wilful and wanton wrongs. Also covers performance of surgery upon victim.
	Okla. Stat. Ann. tit. 59, §518 (West 1989)	Immunity from civil damages, immunity from criminal statutes for treating a minor without consent of minor's parent or guardian, when treatment performed under emergency conditions	Good faith, emergency care or treatment at the scence of an emergency.
	Okla. Stat. Ann. tit. 51, §152 (West Supp. 1992)	Indemnification; state indemnifies physicians who are designated State employees	Physicians who perform prenatal, delivery or infant care services pursuant to a contract with the State, to State Department of Health clients; definition of employee also includes physicians acting in administrative capacities, residents, in terms in State hospitals, and faculty members and staff while teaching in State hospitals. Limits placed on amount of statutory liability.
Oregon	Or. Rev. Stat. Ann. §30.800 (1988)	Immunity from suit; physician	Applies any place where emergency care is not regularly available, voluntarily and without expectation of compensation. Immunity attaches unless alleged and proven that the standards of reasonable care were violated.
Pennsylvania	42 Pa. Cons. Stat. Ann. §8331 (Purdon 1982)	Immunity from civil damages; physician	Scene of emergency, good faith, excepts intentional harm or grossly negligent acts.
	42 Pa. Cons. Stat. Ann. §8332.4 (Purdon Supp. 1991)	Immunity from civil damages; any person	Without compensation, volunteer, renders public services for a nonprofit organization or a government agency. Immunity only applies as long as the volunteer's conduct does not fall below the standards generally practiced and accepted in like circumstances by similar persons rendering such services.

STAT	CITATION	TYPE/PROTECT	REQUIREMENTS
Rhode Island	R.I. Gen. Laws §5-37-14 (Supp. 1991)	Immunity from civil damages; physician	Voluntariiy, gratuitously renders emergency care, and other than in the ordinary course of his or her employment or practice; excludes gross, wilful, or wanton negligence, or when rendered at any hospital, doctors' offices or clinic where such services are normally rendered.
	R.I. Gen. Laws §9-1-34 (1985)	Immunity from civil damages; any person properly trained in CPR	Gratuitously renders emergency cardiopulmonary resuscitation; excludes gross, wilful or wanton negligence.
South Carolina	S.C. Code Ann. §15-1-310 (Law. Co-op. 1977)	Immunity from civil damages; any person	Good faith, gratuitously, renders emergency care at the scene of an accident or or emergency; excepts gross negligence, wilful and wanton misconduct.
	S.C. Code Ann. §15-78-20 (Law. Co-op. 1991)		Includes state-employed physicians under provisions of state tort claims act.
	S.C. Code Ann. §15-78-30(c) (Law. Co-op. Supp. 1991)		Caps damages amount.
	S.C. Code Ann. §15-78-120 (Law. Co-op. Supp. 1991)		Limitation on liability.
	S.C. Code Ann. §33-55-210(A) (Law. Co-op. 1990)	Recovery against charitable organization limited, recovery against employee of charitable organization barred if action taken against charitable organization.	Recovery against charitable organization for tortious act of employee limited to actual damages. If action is taken against the charitable organization, claimant is barred from recovery of employee of the charitable organization; except if employee's action was reckless, wilful or grossly negligent, then employee may be joined as a party defendant.
	S.C. Code Ann. §33-55-210(B) (Law. Co-op. 1990)	Immunity from civil damages; physician	Voluntarily, without compensation or the expectation of compensation; excepts gross negligence or wilful misconduct. The agreement to provide voluntary non-compensated care must be made prior to the provision of such care.

STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
South Dakota	S.D. Codified Laws Ann. §20-9-3,-4 (1987)	Immunity from civil damages; physician	Good faith, emergency care at the scene of an emergency.
Tennessee	Tenn. Code Ann. §63-6-218 (1990)	Immunity from civil damages; any person	Good faith, renders emergency care at the scene of an accident, or en route to a medical facility excludes gross negligence.
Texas	Tex. Civ. Prac. & Rem. Code Ann. §74.001 (Vernon 1986)	Immunity from civil damages; any person	Good faith, scene of emergency or in a hospital; excludes acts that are wilfully or wantonly negligent. Act does not apply if care given for remuneration, if care given by person who regularly administers care in a hospital emergency room or by an admitting physician of the patient bringing a health-care liability claim.
	Tex. Civ. Prac. & Rem. Code Ann. §110.001 (Vernon Supp. 1992)	Indemnification; certain physicians	Physician indemnified by State for defined "charity care" if physician renders charity care in at least 10% of the patient encounters during the year a claim is made; excludes intentional acts or gross negligence. Amount of recovery is limited.
	Tex. Ins. Code Ann. art. 5.15-4 (Vernon Supp. 1992)	Reduction in professional liability premium; physician	Physician entitled to premium discount for medical professional liability insurance for providing services for selected charity care programs, continuing education requirements also.
Utah	Utah Code Ann. §58-12-23 (1990)	Immunity from civil damages; physician	Good faith, renders emergency care at the scene of an emergency.
	Utah Code Ann. §78-19-1 (1992)	Immunity from liability; volunteer for nonprofit organization	Volunteer receives nothing of value for services, good faith; excludes intentional on knowing act which constitutes illegal, wilful or wanton misconduct. Nonprofit must provide a financially secure source of recovery for individuals who suffer injuries as a result of actions by volunteers for act to apply.

STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
Vermont	Vt. Stat. Ann. tit. 12 §519 (1973)	Immunity from civil damages; any person	Creates duty to provide reasonable assistance in terms of emergency medical care; excludes gross negligence, does not apply if remuneration expected or received; also does not alter law related to tort liability for practitioners of healing Arts commited in the ordinary course of practice. $100 fine for violating the Act.
	Vt. Stat. Ann. tit. 24-§2687 (Supp. 1991)	Immunity from civil damages; volunteer emergency medical personnel	Protections apply whether or not personnel receive or expect to receive nominal payments; protections of tit. 12 §519 apply, however, personnel shall not be considered practitioners of the healing acts for purposes of tit. 12 §519; excludes gross negligence and wilful misconduct.
Virginia	Va. Code Ann. §8.01-225 (Supp. 1991)	Immunity from civil damages; any person	Good faith, renders emergency care, without compensation, at the scene of an accident or emergency, or en route to hospital or doctor's office. Act also applies to any person who in the absence of gross negligence provides emergency obstetrical care to a woman who the aider has not given previous care to and whose medical records are not reasonably available to. Immunity only applies to emergency care given.
	Va. Code Ann. §54.1-106 (1991)	Immunity from civil damages; health care professionals at certain clinics	Rendering of health care services by health care professional, voluntarily and without compensation, at a free clinic; excludes gross negligence and wilful misconduct.
	Va. Code Ann. §38.2-5000 (1990)	Birth-related neurological injury compensation fund; provides immunity from suit for participating physicians	Participating physicians who sign the required agreements with the State Commissioner of Health are granted protections under the act. Compensation provided from fund for birth-related neurological injuries. Rights and remedies of infant granted by act exclude all other rights and remedies of infant. Act inapplicable when physician or hospital acted intentionally or wilfully to cause the birth-related neurological injury.

STATE	CITATION	TYPE/PROTECTION	REQUIREMENTS
Washington	Wash. Rev. Code Ann. §4.24.300 (1988)	Immunity from civil damages; any person	Without compensation or the expectation thereof, renders emergency care at the scene or during transport; excludes gross negligence, or, wilful or wanton misconduct. Also excludes any person rendering emergency care during the course of regular employment and receiving conpensation for rendering care.
West Virginia	W. Va. Code §55-7-15 (1991)	Immunity from civil damages; any person	Good faith, renders emergency care at the scene of an accident, without remuneration.
	W. Va. Code §29-12-5c (Supp. 1991)	Provision of malpractice insurance for obstetricians participating in State malpractice insurance program; State-created obstetrical/gynecological liability pool.	Physician must be part of State malpractice insurance program, only applies to obstetric patients whose care is paid for out of State Medicaid funds. (NOTE: Although enacted, this piece of legislation has not been put into effect and will not be in effect in the foreseeable future.)
Wisconsin	Wis. Stat. Ann. §895.48 (West (Supp. 1991)	Immunity from civil damages; any person	Good faith, emergency care at the scene of an accident; immunity does not attach to health care employees rendering care for compensation within the scope of their usual and customary employment in a hospital or similarly equipped facility, or en route to such a facility or at a physician's office.
	Wis. Stat. Ann. §146.89 (West Supp. 1991)	Indemnification; certain volunteer health care providers are considered agents of state	Health care provider submits an application with nonprofit agency to the State. Health care provider volunteers to provide services in a nonprofit agency. The nonprofit cannot provide emergency care, hospitalization, or surgery. The volunteers are considered State agents.
Wyoming	Wyo. Stat. Ann. §1-1-120 (1988)	Immunity from civil damages; any person	Good faith, renders emergency care, without compensation at the place of an emergency or accident.

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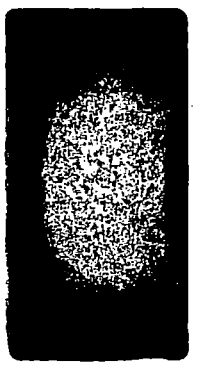
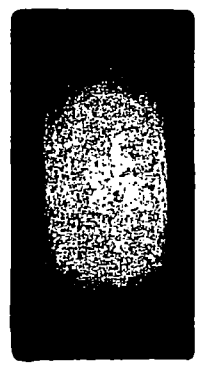
Wyoming	Wyo. Stat. Ann. §1-1-120 (1988)	Immunity from civil damages; any person	Good faith, renders emergency care, with-out compensation at the place of an emergency or accident.





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;

I am skeptical that targeting [illegible] at them will be helpful

(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. (5) what @ manus.?

How effective is this w/o duty?

"(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.

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.

which are the most crucial steps? — #1 + #4 ?

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!

doesn't necessarily mean that they are trained to do so.

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.

Bruce — unsettled / uncertain

— I like what I'm doing
- efficient
- good issues

— Tom Freedman

6-5692

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

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

AGENDA

Cardiac Arrest Survival

I. Overview -- opportunity for lifesaving.
- AEDs
- Other

II. Effectiveness of AEDs in different settings
- Advanced Life Support (paramedics)
- EMTs (less than half of non-paramedic EMTs have AEDs)
- Non-EMT first responders (police/firefighters; 19% trained/equipped)
- "Designated" responders (flight attendants; security guards; occupational)
- Trained bystanders (CA city)

- supervision

III. Goals
- Research
- Access

IV. Actions

a) Research
- scope, timing, immediate effect on access, funding

b) Training
- core content for first responders and bystanders (NHTSA/NHLBI)

c) Other actions to increase access (beyond research/training)
- AED's in every ambulance? who pays? cost-effectiveness?
- Advocated AED's in for every police force / firefighter?

d) National Database

e) Commission to increase survival from cardiac arrests

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

- 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).

- 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.

- 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.

- 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.

- 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.

- 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.

- 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.

- 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.

- 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.

- 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.

Core content for Model State training

Barriers
- labeling
- good samaritan laws.

Model State
- training
- access

- NHLBI
- HRSA
- HCFA
- FDA (Bruce Burlington / Jerry)
- NHTSA

Research
- AED's

Pilot Project
- research efficacy
- training

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- Trained bystanders (CA city)

Medical 911 Respondas

- supervision

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- AED's in every ambulance? who pays? cost-effectiveness?
- Advocated AED's in for every police force / firefighter?

d) National Database

e) Commission to increase survival from cardiac arrests

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001. fax	WAVES Confirmation to Elizabeth Drye, appt date 05/28/1997 (partial) (1 page)	05/27/1997	b(7)(C), b(6)

COLLECTION:
Clinton Presidential Records
Office of Science and Technology Policy
Jerold Mande
OA/Box Number: 13034

FOLDER TITLE:
Automatic External Defibrillators: Cardiac Arrests

2008-1524-F
kc1219

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]

[001]

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05/27/97 07:32:48 PM

Record Type: Record

To: ELIZABETH DRYE

cc:
Subject: WAVES Confirmation

BEG HDR:
ADDRESSEES: ELIZABETH_DRYE
SUBJECT: CONFIRMATION: APPT. REQUEST FOR DRYE, ELIZABETH
END HDR:
FROM: WAVES OPERATIONS CENTER - ACO: (b)(7)c, (b)(6)
Date: 05-27-1997
Time: 19:31:38

This message serves as confirmation of an appointment for the visitors listed below.

Appointment With: DRYE, ELIZABETH
Appointment Date: 5/28/97
Appointment Time: 10:00:00 AM
Appointment Room: 211
Appointment Building: OEOB
Appointment Requested by: DRYE ELIZABETH
Phone Number of Requestor: 65573

WAVES APPOINTMENT NUMBER: U34662

If you have any questions regarding this appointment, please call the WAVES Center at 456-6742 and have the appointment number listed above available to the Access Control Officer answering your call.

****
TOTAL NUMBER OF NAMES SUBMITTED FOR ENTRY : 9
TOTAL NUMBER OF NAMES OF CLEARED FOR ENTRY: 9
****

BURLINGTON, BRUCE
BUTO, KATHY
DONAHUE, MARY
FRIEDMAN, MICHAEL
LENFANT, CLAUDE
MANDE, JEROLD
MICHAEL, JEFF
RECHT, PHIL

(b)(6)

2x10^8
5x10^6
2.5x10^3
2500
~5000
2000?
2x10^3
2.5x03
5x10^6

Jeff Michaels —

Neutral facilitator - technical resource
NHTSA — voluntary Emer. Response standard.
- make it a consensus-driven product

paramedic — Advanced life support ambulance — 1000 hrs.
intermediate — couple hundred.
basic — 100 hours — accompany basic life support ambulances
first responder — basic level 40 hours — police or firemen

Most influential role

paramedic guideline under revision now — 1000
"first responder" — 40 hour course. — police, some fire people
400,000 in the US.

NHTSA develops the curriculum
states define who can be a paramedic/first responder — usually by whether they've taken this course

— partly public safety / partly medical. —

Also do system development / technical assistance
- e.g. developed model quality improvement program.
- influence through leadership — get that from progressive people in field. —

Factions involved: ER docs, nurses, surgeons. Nat Assn EMTs
Trauma nurses
EMS educators
Firefighters / Chiefs

National registry of EMTs
- Joint review cmte – national accreditation service
- Air-medical, wilderness medical
- law enforcement grps.

working on EMS agenda for the future. —
- create a vision for EMS in changing health care environment
- now doing an implementation plan. —

Vision
EMS needs to integrate w/rest of community health care system – trauma ~~prot~~ triage protocols, equipment located strategically. Feedback btw EMS and acute care.

EMS community wants paramedics to be more highly trained – locating health/injury hazards, diagnostic, patient follow-ups. ⇒ expansion of education. Career path to nursing.

Enhance emer. access – automatic location info for wireless phones.

Defibrillators —

- State EMS directors key —
- Have first responders in each of their states
- Think it could be done w/some of their first responders — controlled exposure to grp that would get initial training
  - periodic refreshers
  - quality assurance
  - physician oversight
- Some meet these criteria —
  e.g. firefighters

If we tried to respond ~~to~~ first responder curriculum — would have a big debate —
— Because as de facto std — would bring out many of their concerns —

Start w/something first — dialogue w/state directors — which first responders may be appropriate.

Basic curriculum does include AED use by reference first responder curriculum. — does not

Concern - ~~basic~~ invasive medical procedure done by individuals w/training/oversight link to physician. —

JEMS - Survey — 20% of first responders

Jeff

have defibrilators -
- wants to build confidence in an incremental
to go faster?
. demonstration programs / clinical trials
- State directors (regulators)

Response Time
- Emergency must dispatch program
-

Traffic - ITS - Intelligent Traffic System - notification -

5/09 Confirmed - still reservations — have late October mtg.
- State emergency medical directors
- regulate delivery of EM services in each State
- want to move ahead at reasonable rate consider through demonstration or other evaluation
- take the next step - getting training in defibrilators to first responder communities
- police officers; firemen. -
"first responder" in system that has re-training and some medical oversight.

Dr. Buss? State EMS director for MD. —

Elena — let's discuss tomorrow — Liz

Elizabeth — (+ Helen)
Where are we on this? It seems to me that someplace underneath the bureaucratic mumbo-jumbo, there's probably something to do here.
Elena

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

- 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).

- 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.

- 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.

- 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.

- 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.

so what?

- 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.

- 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.

- 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.

- 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.

- 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.

American Heart Association℠
Fighting Heart Disease and Stroke

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 the by police force dramatically improved survival from out-of-hospital sudden cardiac arrest.

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 Sorb
New model: Smallest, che

today 9/13/96 p.1

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.

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American Heart Association
Fighting Heart Disease and Stroke

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 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).**

Defibrulation

PERF [redacted]

— Police Executive Research Forum
Chuck Wexler
- Indian Creek Island, FL —
outfitted police cars w/devices —
Capt. — religious on this.

HHS — Glen Harrelson / exec sec.

Florine Martinez

— Nat Assn of EMS physicians - cautious
— Model State laws —
- lead agency for curriculum for EMS —
—
—
- after the crash
— make the right call
— first responder program —
- growth of EMS came from cardiac care —
- happy to look at incorporating that into the code. —
- David Brice / Jeff Michaels —

May 19th Buckle up America
National EMS week. —

High Discharge Survival Rate After Out-of-Hospital Ventricular Fibrillation With Rapid Defibrillation by Police and Paramedics

Roger D White, MD[*‡]
Brent R Asplin, MD[§]
Thomas F Bugliosi, MD[*‡]
Daniel G Hankins, MD[*‡]

From the Mayo Clinic and Medical School and Mayo Gold Cross Ambulance Service, Incorporated†, Rochester, Minnesota; and the Affiliated Residency in Emergency Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania.*[§]

Received for publication March 8, 1996. Accepted for publication April 3, 1996

Presented at the Society for Academic Emergency Medicine Annual Meeting, Denver, May 1996.

Study objective: To assess outcome in patients with ventricular fibrillation (VF) treated by defibrillator-equipped police and emergency medical technician-paramedics in an advanced life support (ALS) emergency medical services (EMS) system.

Methods: We carried out a retrospective observational outcome study of all consecutive adult patients with atraumatic cardiac arrest treated from November 1990 through July 1995. The study was carried out in a city with a population of 76,865 in an area of 32.6 square miles. Central 911 dispatched police and an ALS ambulance simultaneously. Accurate intervals were obtained with the synchronization of all defibrillator clocks with the 911 dispatch clock. The personnel who arrived first delivered the initial shock. After shocks delivered by police, paramedics provided additional treatment if needed. Main outcome measures were time elapsed before delivery of the first shock, restoration of spontaneous circulation (ROSC), and survival to discharge home.

Results: Of 84 patients, 31 (37%) were first shocked by police. Thirteen of the 31 demonstrated ROSC, without need for ALS treatment. All 13 survived to discharge. The other 18 patients required ALS; 5 (27.7%) survived. Among the 53 patients first shocked by paramedics, 15 had ROSC after shocks only, and 14 survived. The other 38 needed ALS treatment; 9 survived. Call-to-shock time for all patients was less in the police group than in the paramedic group (5.6 versus 6.3 minutes, $P=.038$). For all patients, call-to-shock time was less in those with ROSC after shocks only than in those who needed ALS (5.4 versus 6.3 minutes, $P=.011$). Survival to discharge was 49% (41 of 84), with 18 of 31 (58%) in the police group and 23 of 53 (43%) in the paramedic group. Call-to-shock time for survivors was 5.8 minutes; it was 6.4 minutes for the nonsurvivors ($P=.020$). Neither ROSC nor discharge survival was significantly different between police- and paramedic-shocked patients. ROSC after initial shock and call-to-shock time were major determinants of survival, whether the first shocks were administered by police or by

paramedics. With ROSC after shocks only, 27 of 28 (96%) survived, whereas 14 of 56 (25%) needing ALS survived ($P<.001$).

Conclusion: A high discharge-to-home survival rate was obtained with early defibrillation by both police and paramedics. When shocks resulted in ROSC, the overwhelming majority of patients survived (96%). Even brief time decreases (eg, 1 minute) in call-to-shock time increase the likelihood of ROSC from shocks only, with a consequent decrease in the need for ALS intervention. Short call-to-shock time and ROSC response to shocks only are major determinants of a high rate of survival after VF.

[White RD, Asplin BR, Bugliosi TF, Hankins DG: High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. *Ann Emerg Med* November 1996;28:480-485.]

INTRODUCTION

Rapid defibrillation after out-of-hospital cardiac arrest (OHCA) caused by ventricular fibrillation (VF) is the single most important determinant of outcome.[1,2] Other variables such as witnessed arrest, rapid access to emergency medical services (EMS), prompt bystander CPR, and initial VF maximum amplitude have been shown to improve survival.[3-10] However, the interval between collapse and delivery of defibrillatory shocks is the most critical variable influencing outcome.[1] Incorporation of early defibrillation into EMS systems has been followed by demonstrable benefit in most settings[11-16], although this has not always been observed.[17-19] Also, in large metropolitan areas survival from OHCA has been shown to be very low.[20,21] In one city, survival in patients with an initial rhythm of VF was 3%[20]; in another, survival of bystander-witnessed VF arrest was 5.3%.[21] For rapid defibrillation to be provided in such settings, substantial changes in EMS systems, or the innovative institution of alternative methods for making early defibrillation more accessible, will have to be carried out. In 1994 we reported our first 2 years of experience with the addition of early defibrillation provided by city police to an existing advanced life-support (ALS) EMS system.[22] In that study we emphasized acquisition of accurate times for the calculation of intervals likely to be critical determinants of patient outcome after VF OHCA. Our findings also indicated that short critical intervals, most importantly call-to-shock time, might account for the relatively high survival rate (47.7%) we noted during that study of time intervals. We now report our experience with an additional 33 months of ongoing observation of outcome from VF OHCA in this EMS system in which both defibrillator-equipped police officers and ALS emergency medical technician-paramedics (EMT-Ps; referred to in this article as paramedics) respond to all in-city OHCA events.

MATERIALS AND METHODS

The city of Rochester, Minnesota (1993 population, 76,865; area, 32.6 square miles), is served by a private ambulance service (Gold Cross Ambulance Service, Incorporated). Patient care personnel are nationally registered EMT-Ps. Rochester Police Department police officers are trained as first responders in accord with the US Department of Transportation First Responder Training Program.[23] All officers are trained to operate automated external defibrillators (AEDs) with the American Heart Association Early Defibrillation Training Program as the format, with modifications to accommodate the versions of AED used.[24] At approximate 90-day intervals the officers undergo a brief skills-retention assessment.

In November 1990 the police defibrillation program was begun with four AEDs (First Medic 510 semiautomatic defibrillator; Physio-Control Corporation). In March 1993, four additional identical units were added, and in April 1995 four more AEDs were provided by the manufacturer for assessment purposes (VivaLink semiautomatic defibrillator; SurVivaLink Corporation). Thus for the first 27 months 4 AEDs were available, during the next 25 months 8 AEDs were in service, and for the final 5 months as many as 12 AEDs were in service at one time in police cars distributed throughout the city.

In Rochester, all 911 calls are received at a central law enforcement dispatch console. When a 911 medical emergency call is received at central dispatch, it is immediately transferred to an EMS dispatcher at the ambulance dispatch center by telephone hotline. While this call is being processed, central dispatch locates the nearest available police car for dispatch to the site of the emergency. Thus dispatch of police and paramedics to medical emergency calls is nearly simultaneous. Ambulances are located at and dispatched from two ambulance stations. The first personnel to arrive at the scene began standard assessment procedures, connected an AED in pulseless and apneic patients, and delivered defibrillatory shocks if indicated. In the first 39 months of the study period, paramedics used AEDs (HeartStart 2000 semiautomatic defibrillator; Laerdal Medical Corporation). On a few occasions an AED was not available and a backup manual defibrillator was used (LifePak 5 cardioscope/recorder/DC defibrillator; Physio-Control Corporation). In the last 18 months of the study

period, paramedics used an ALS version of AED (First Medic 710 semiautomatic defibrillator; Physio-Control Corporation). At weekly intervals, central and EMS dispatch clocks were synchronized with the universal time coordinate and all defibrillator clocks, police and paramedic, were synchronized to this time. Thus all times used to calculate intervals were derived from synchronized times taken from central and ambulance dispatch Dictaphone time recordings and defibrillator clocks. Defibrillator clock times were obtained from memory modules, PCMCIA memory cards, or, in the case of the VivaLink AED, from internal memory. Significant error has resulted from lack of time synchronization in an EMS system.[25] Such error affects assessment of intrasystem performance and raises questions about the validity of time-dependent cardiac arrest clinical research.[25] All adult patients found in atraumatic VF cardiac arrest in the city were included in the data analysis. No change in patient treatment protocol was involved, and the methods and procedures used qualified for institutional review board approval. Confirmation of a cardiac origin as the cause of the arrest was obtained from in-hospital follow-up and review of all diagnostic studies or from findings at autopsy.

Patients were categorized as demonstrating ROSC if initial shocks restored a spontaneous circulation, with or without 1 minute or less of CPR, after initial shocks. No epinephrine or other vasoactive drug was needed in any of these patients. In accord with our current standard cardiac care protocol, ROSC patients received high-flow oxygen with a nonrebreather mask, IV line placement, and prophylactic lidocaine before or during transport. Patients classified as needing ALS required additional interventions, including epinephrine in all instances, and endotracheal intubation, in accordance with American Heart Association Advanced Cardiac Life Support guidelines incorporated into our ALS protocols.

All patients with ROSC at the scene were transported to a single receiving hospital. The target outcome was defined as survival to discharge home, with a functional status not requiring assistance for daily living. Any patient with neurologic impairment necessitating discharge to a nursing home for prolonged or permanent care was considered a nonsurvivor.

Interval comparisons between various subgroups were examined univariately with the two-sided Wilcoxon rank-sum test. Discrete variables were examined univariately with the two-sided χ^2 test. The main study endpoints were time to shock, ROSC, and survival to discharge.[26] Potential predictors were age, sex, bystander CPR, witnessed event, and paramedics as first responders. We used linear and logistic regression analyses to determine which variables were most strongly associated with the endpoints, using a stepwise selection process.[27,28] We considered *P* values less than .05 significant.

RESULTS

During the 57-month study period, 84 OHCA patients presented with VF as the initial rhythm. Seventy-four patients in non-VF arrest (40 in asystole and 34 in pulseless electrical activity) were encountered but were excluded from this analysis for obvious reasons. All arrests included in the study occurred before the arrival of police or paramedics. None of the 74 survived. No patients were excluded because of insufficient, inaccurate, or unavailable data.

Thirty-one patients were first shocked by police. Because of the numbers of AEDs after the first 2 years, the first police car to arrive at a cardiac arrest scene carried an AED in 90% of cases. Of the 31 patients, 13 (42%) had ROSC from shocks only. All 13 survived. The other 18 patients (58%) required ALS treatment by paramedics. Five of the

Table 1.
Patient and arrest data.

Variable	All (N=84)	Police-Treated (n=31)	Paramedic-Treated (n=53)	Relative Risk of Police-Treated	95% CI for Relative Risk	*P*
Median age (range) [years]	65 (29–91)	65 (29–91)	64 (35–87)	1.1*	.7–1.5	.827
No. male (%)	65 (77)	25 (81)	40 (75)	1.4	.5–4.0	.584
No. of witnessed arrests (%)	69 (82)	26 (84)	43 (81)	1.2	.4–3.9	.752
No. given bystander CPR (%)	36 (43)	16 (52)	20 (38)	1.8	.7–4.3	.215
No. with ROSC (%)	28 (33)	13 (42)	15 (28)	1.8	.7–4.6	.201
No. of survivors (%)	41 (49)	18 (58)	23 (43)	1.8	.7–4.4	.194

*Per 10-year increase in age.

18 (28%) survived. Among 53 patients first shocked by paramedics, 15 (28%) had ROSC with shocks only; 14 survived. The one nonsurvivor in this group made a complete neurologic recovery, but recurrent intractable VF developed 2 days after admission. The other 38 patients in the paramedic group (72%) required ALS treatment, with 9 survivors (24%). Three patients classed as nonsurvivors sustained neurologic impairment necessitating discharge to a nursing home for permanent or prolonged care.

Patient and arrest data for all patients are presented in Table 1. We detected no statistically significant differences between the police- and paramedic-treated groups among the variables in Table 1. Table 2 depicts association of categoric factors with discharge survival. Among these factors, only initial response to shock—whether ROSC or need for ALS—was significant. Bystander CPR did not increase discharge survival, and survival was not significantly higher among patients with witnessed arrests. When police and paramedic patient groups were analyzed individually, neither bystander CPR nor witnessed arrest significantly increased survival.

Call-to-shock times for all patients are shown in Table 3. This interval was significantly shorter in patients in whom spontaneous circulation was restored by the initial shock than in patients who needed ALS intervention to regain spontaneous circulation. Likewise, call-to-shock time was significantly shorter in the survivors than in the nonsurvivors.

Table 4 depicts call-to-shock times in the police and the paramedic groups. For all patients this interval was shorter in the police-defibrillated group. In the police group, call-to-shock time was significantly shorter in patients with ROSC after shock than in those who required ALS. This time difference was not significantly different between ROSC and ALS patients treated first by paramedics. The time spread was wider in both ROSC and ALS patients first treated by paramedics.

We performed logistic regression to determine which variables were most strongly associated with the endpoints of survival to discharge and ROSC from shocks only. After ROSC from shocks only was added to the logistic model, no other variable predicted who would survive to discharge. After addition of time to shock, no other variable predicted who would have ROSC from shocks only. The major determinants of outcome were call-to-shock time and ROSC from shocks only, regardless of who delivered the shocks.

DISCUSSION

Our observations extend and affirm the conclusions of our earlier preliminary study.[22] In that study, as in this one, we chose to use the call-to-shock interval rather than the collapse-to-shock interval because the latter is almost always, at best, an estimate. We prefer to use an interval that is precise and quantitative and can be correlated with outcome. The call-to-shock interval also can be used for accurate intersystem data comparisons, provided all EMS system clocks are synchronized at regular intervals. In our earlier evaluation of a police defibrillation program our primary objective was accurate measurement of critical time intervals considered important for improved survival from VF OHCA.[22] As part of that study of intervals we noted a relatively high survival rate after VF OHCA (21 of 44 patients [47.7%]). The objective of this study was to assess patient outcome over a much longer period, thereby including more patients. We continued to acquire accurate synchronized times for calculation of call-to-shock intervals

Table 2.
Association of categoric factors with discharge survival.

Variable	Provider of Care	No. of Patients	No. of Survivors (%)	Relative Risk of Surviving	95% CI of Relative Risk	P
Initial shocks	Police	31	18 (58)	1.8	.7–4.4	.194
	Paramedics	53	23 (43)			
Sex	Male	65	33 (51)	1.4	.5–4.0	.506
	Female	19	8 (42)			
Witnessed arrest	Unwitnessed	15	4 (27)	.3	.1–1.1	.058
	Witnessed	69	37 (54)			
Bystander CPR	No CPR	48	23 (48)	.9	.4–2.2	.850
	CPR	36	18 (50)			
Response to shock	ROSC	28	27 (96)	81.0	10.1–652.0	<.001
	ALS	56	14 (25)			

as we had done earlier. Our results confirm that early defibrillation not only increases survival from VF OHCA but increases the likelihood that initial shocks will result in ROSC, without need for costly and time-consuming on-scene ALS care to restore stable circulation. Although we did not analyze other variables in this outcome study, it is probable that additional benefits are derived from early defibrillation with ROSC from shocks only (eg, shorter, less expensive hospitalizations).

In contrast to generally accepted and reported experience we could not confirm a significant impact of bystander CPR or of witnessed arrest on discharge survival. This lack of confirmation does not diminish the important role these variables may contribute to survival in many settings.[3,29] With regard to witnessed arrest, it is possible that in our study the smaller number of patients in the unwitnessed-arrest group (15 of 84) limited the statistical power to detect a significant difference. Swor and associates[30,31] observed that patients who received bystander CPR were more often found in VF and had a higher discharge survival rate. Although their data included response times, accurate call-to-shock times were not available. In our system the very short time from call to shock may negate a demonstrable benefit of bystander CPR. A similar observation has been reported in patients with VF OHCA in an EMS system with apparently short response times.[32] With regard to unwitnessed arrests it can be assumed that some of these patients, if still in VF when found, may in fact have had a short "down time" and therefore might still be candidates for successful defibrillation and discharge survival. These observations further support the critical role rapid defibrillation assumes as a determinant of outcome from VF OHCA.

As noted above, the call-to-shock time in the police-defibrillated patients was shorter than in the patients first treated by paramedics. Likewise, in the police-defibrillated group the time to shock was shorter for ROSC patients than for those who required ALS treatment after initial shocks. In the paramedic group this time difference was not significant. A greater spread of data in both the ROSC and ALS patients in the paramedic group, compared with those in the police group, is evident. These findings are consistent with shorter and less variable call-to-shock times made possible by citywide distribution and mobile rapid availability of police defibrillators. Extension of these observations to other means of providing short call-to-shock times appears to be substantiated by these findings. Our data lend credence to movement toward widespread implementation of rapid defibrillation by means of placement of AEDs in a variety of nontraditional settings that would make short call-to-shock times possible.[33] The documented expectations from short call-to-shock times are high survival rates from VF and ROSC from shocks only, without need in the ROSC patients for time-consuming and costly on-scene ALS interventions.

Our experience with a combined police/paramedic rapid-defibrillation EMS system confirms that short call-to-shock times are accompanied by frequent ROSC from shocks only and by a relatively high discharge survival rate. The critical determinant of these outcomes is the rapidity with which initial shocks are delivered rather than who provides those shocks. The additional benefit of ALS care by paramedics is for patients who do not achieve ROSC from shocks only, among whom a smaller, although significant, number of patients survive. In this system, rapid defibrillation is achieved by the combination of widespread citywide availability of defibrillators in mobile police cars along with paramedic-provided defibrillation and back-up ALS care. Extrapolation of these observations to other EMS systems and to alternative modes of delivery of rapid defibrillation, including implementation of study of the American Heart Association Public Access Defibrillation proposal, is both rational and timely.

Table 3.
Call-to-shock times for all patients.

Patient Group	Median Time (Range) [Minutes]	*P*
All	6 (2.0–12.1)	
ROSC	5.4 (2.0–7.9)	.011
ALS	6.3 (2.8–12.1)	
Survivors	5.8 (2.0–8.2)	.020
Nonsurvivors	6.4 (2.8–12.1)	

Table 4.
Call-to-shock times in police and paramedic groups (median [range]).

Patient Group	Police-Treated	Paramedic-Treated	*P*
All	5.6 (3.5–8.2)	6.3 (2.0–12.1)	.038
ROSC	5.0 (3.5–7.8)	6.0 (2.0–7.9)	.140
ALS	6.1 (3.5–8.2)*	6.4 (2.8–12.1)†	.317
Survivors	5.3 (3.5–7.8)	6.0 (2.0–8.2)	.156
Nonsurvivors	6.0 (3.5–8.2)‡	6.7 (2.8–12.1)§	.302

*P=.024 between police-treated ROSC and ALS groups.
†P=.213 between paramedic-treated ROSC and ALS groups.
‡P=.123 between police-treated survivors and nonsurvivors
§P=.146 between paramedic survivors and nonsurvivors

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USE OF THE AUTOMATIC EXTERNAL DEFIBRILLATOR IN THE MANAGEMENT OF OUT-OF-HOSPITAL CARDIAC ARREST

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Abstract The automatic external defibrillator is a simple device that can be used by nonprofessional rescuers to treat cardiac arrest. In 1287 consecutive patients with out-of-hospital cardiac arrest, we assessed the results of initial treatment with this device by firefighters who arrived first at the scene, as compared with the results of standard defibrillation administered by paramedics who arrived slightly after the firefighters. Of 276 patients who were initially treated by firefighters using the automatic defibrillator, 84 (30 percent) survived to hospital discharge (expected rate according to a logistic model, 17 percent; $P<0.001$), as compared with 44 (19 percent) of 228 patients when firefighters delivered only basic cardiopulmonary resuscitation and the first defibrillation was performed after the arrival of the paramedic team. Few patients with conditions other than ventricular fibrillation survived.

In a multivariate analysis of characteristics that influenced survival after ventricular fibrillation, a better survival rate was related to a witnessed collapse (odds ratio, 3.9; 95 percent confidence interval, 2.0 to 7.6), younger age (odds ratio, 1.2; 95 percent confidence interval, 1.0 to 1.4), the presence of "coarse" (higher-amplitude) fibrillation (odds ratio, 4.2; 95 percent confidence interval, 1.6 to 11.0), a shorter response time for paramedics (odds ratio, 1.4; 95 percent confidence interval, 1.0 to 2.1), and initial treatment by firefighters using an automatic external defibrillator (odds ratio, 1.8; 95 percent confidence interval, 1.1 to 2.9).

These findings support the widespread use of the automatic external defibrillator as an important part of the treatment of out-of-hospital cardiac arrest, although the overall impact of the use of this device on community survival rates is still uncertain. (N Engl J Med 1988; 319:661-6.)

THE early use of defibrillators by those providing first aid has been demonstrated to improve both survival and neurologic recovery after out-of-hospital cardiac arrest.[1-3] In spite of the importance of these findings, considerable difficulties have precluded the widespread use of standard defibrillator–monitors by first-aid personnel other than paramedics. One deterrent is the need for legislation in some states to authorize such treatment and to confer immunity from civil suits on providers of such care. Another is the requirement that physicians endorse and support the implementation of this new type of emergency cardiac care. Finally, the training required to use conventional devices, particularly to acquire and maintain the skill to interpret disorders of cardiac rhythm, is extensive and therefore costly. As an alternative to conventional defibrillator–monitors, the automatic external defibrillator is a relatively simple device that requires only a modest amount of training and thus appears ideally suited for use by persons whose skills are limited to basic life support. These devices require the application of adhesive monitor–defibrillator electrodes and the activation of the detector–defibrillator; the operator does not need to be able to interpret the cardiac rhythm.

Automatic external defibrillators have obvious advantages in rural settings where paramedics' services are not available. However, the contribution of automatic defibrillators to the overall management of cardiac arrest has not been clearly ascertained, particularly in cities with established emergency medical systems. Because of the potential importance of this device and the need for a careful examination of its efficacy, we evaluated the outcome of patients treated for cardiac arrest with use of the automatic defibrillator in an urban emergency medical system with several levels, or tiers, of care.

Methods

The automatic external defibrillator consists of adhesive electrodes used for both monitoring and defibrillation, a rhythm detector, and a defibrillator that is connected to the detector. The device is ideally suited for use by first-aid personnel, because its operation is simple and the recognition of cardiac rhythms need not be taught. A pilot evaluation of early defibrillation given by first-aid personnel in Seattle found that patients whom paramedics took a long-

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er time to reach and for whom first-aid personnel initially used standard defibrillator monitors to manage cardiac arrest had improved outcomes, as compared with other patients.[1] Accordingly, we thought that a randomized controlled trial of the efficacy of the automatic external defibrillator was not desirable, even though this device is new and its performance characteristics have not been extensively described.[4-7] Instead, we evaluated the device in a prospective study and used multivariate analysis to adjust for the effect of factors thought likely to influence survival rates and also to test for the effectiveness of early defibrillation with the automatic defibrillator.

Automatic defibrillators were provided to firefighters working in districts of Seattle in which paramedics' response times averaged at least three minutes longer than the response time of the first fire department unit on the scene. In order to choose the districts, we tabulated the response times of the fire department and paramedic units for each cardiac arrest in the city between 1978 and 1982. On the basis of these findings, 22 of 40 selected engine companies and all 6 first-aid rescue units were provided with automatic external defibrillators. These units typically responded to five or more cardiac arrests each year; the average difference in response time between firefighters and paramedics was more than three minutes. Thus, there would be sufficient time for an automatic external defibrillator to be used before paramedics arrived.

More than 400 firefighters were trained to use a prototype automatic external defibrillator in four hours of instruction over two or three days. During the training, the operation of the device, a protocol, and standing orders were taught. The protocol provided for the delivery of up to three 200-J shocks (the output of the device was not adjustable) to patients with ventricular fibrillation. Firefighters were instructed to use the device until paramedics arrived and continued care with standard defibrillator–monitors, tracheal intubation, and medications as needed. The performance of the automatic external defibrillator was assessed after the first year, and the device was modified in an effort to increase the sensitivity of the automatic detector in recognizing ventricular fibrillation. The modified device was used during the second year of the study.[8]

Information was recorded for all episodes of cardiac arrest treated in the city by paramedics. Specifically, we determined response times for each rescue unit, whether the collapse was witnessed, whether cardiopulmonary resuscitation had been initiated by a bystander before the arrival of the firefighters, the patient's age, and the initial cardiac rhythm, all of which had been previously demonstrated to influence survival.[9] Outcome was determined from hospital records.

During the first 20 months, patients who had had cardiac arrest and available witnesses to the event were interviewed by telephone (this was possible in approximately two thirds of the cases) to verify the patient's age and the circumstances of the collapse. We expected that in about 40 percent of cases (those treated by firefighters who had not been provided with automatic defibrillators), only cardiopulmonary resuscitation would be provided until paramedics arrived. The difference in response time between firefighters and paramedics in these cases was expected to be small, because the automatic defibrillators had been placed in stations with larger differences between the response time of the first fire department unit and the paramedics. The study was approved in 1984 by the University of Washington Human Subjects Review Committee.

Discrete variables were analyzed by means of the chi-square or Fisher's exact test and continuous variables by the t-test. A logistic-regression analysis was used to determine the influence of clinical factors and characteristics of emergency care on outcome after cardiac arrest due to ventricular fibrillation. The logistic model was also used to estimate the survival rates for two groups of patients: those treated initially with an automatic defibrillator and those for whom the paramedics were the first responding unit capable of providing defibrillation.

Results

Patients

In 25 months, beginning in May 1984, 1287 consecutive patients with cardiac arrest were enrolled in this prospective study. Of this group, 687 (53 percent) received initial treatment from firefighters using automatic external defibrillators before paramedics arrived; the remaining 600 patients (47 percent) were also treated by firefighters and paramedics, but an automatic external defibrillator was not available for use. Figure 1 shows the cardiac condition of patients when first-aid personnel arrived. Table 1 compares patients found to be in ventricular fibrillation and initially treated with an automatic external defibrillator with those who were not treated with this device. As would be expected from the design of the study, the mean response time (±SD) for paramedics was substantially longer when patients were initially treated by firefighters using the automatic defibrillator than when patients received only basic life support before paramedics arrived (8.8±3.3 vs. 5.1±2.3 minutes). The automatic defibrillator permitted defibrillation to be provided to the former group 5.1±3.2 minutes sooner than would have been possible if only paramedics had been equipped with defibrillators. In the subset of patients for whom determinations could be made, there were no differences between patients who were treated initially by firefighters with the automatic defibrillator and those who were first treated by paramedics using standard defibrillators, in terms of either the time elapsed from the collapse to the report of the emergency (the call to emergency number 911) or the time required to deliver the first shock.

The Automatic Defibrillator

The prototype automatic defibrillator used in the first year of the study was somewhat insensitive to ventricular fibrillation; it delivered shocks to only 92 (77 percent) of 119 patients with fibrillation (documented on magnetic-tape records made by the device). Fine fibrillation amplitude (≤200 mV) was particularly difficult for the detection algorithm to interpret; in only 11 of 62 cases (18 percent) were rhythm segments correctly identified and the patients given a shock, as compared with 135 of 218 (62 percent) episodes of coarse fibrillation (amplitude >200 mV; $P<0.001$).

Modification of the detector at the end of the first year substantially improved its performance, so that 150 of 157 patients (96 percent) who were discovered in ventricular fibrillation received shocks from the devices. Also, 26 of 37 episodes (76 percent) of fine fibrillation and 212 of 228 episodes (93 percent) of coarse fibrillation were appropriately detected and shocks were delivered ($P<0.001$, as compared with the results during the first year). Because of the lower sensitivity of the device used during the first year, only 242 of all 276 patients (88 percent) who had ventricular fibrillation actually received one or more shocks from the device. During the second year of the study, the improved performance of the device allowed the first shock to be delivered sooner and more shocks to be given per patient before the arrival of paramedics (Table 2). The first 200-J shock converted the cardiac rhythm in 66 percent of cases. The device and its performance in a

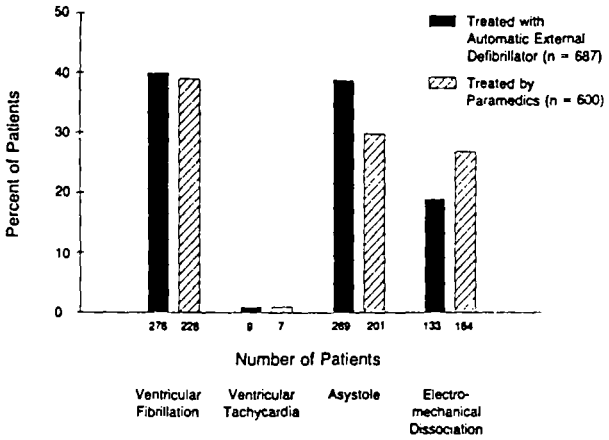

Figure 1. Condition of Patients on the Arrival of the First Responding Unit.

Of 1287 patients with cardiac arrest, 687 received treatment first from firefighters who were equipped with automatic defibrillators, whereas the other 600 were first treated only with cardiopulmonary resuscitation by firefighters before the arrival of paramedics. About 40 percent of each treatment group were discovered in ventricular fibrillation. Only 16 patients were discovered in cardiac arrest with ventricular tachycardia.

subset of these patients has been described previously in greater detail.[8]

Survival

Few patients with conditions other than ventricular fibrillation were successfully resuscitated in the field or survived to discharge from the hospital after resuscitation (Fig. 2). Resuscitation rates (the proportion of patients with cardiac arrest admitted to the hospital) were similar for patients treated by firefighters using the automatic defibrillator and those who received only cardiopulmonary resuscitation until the paramedics arrived. In the two treatment groups, resuscitation rates for patients with ventricular fibrillation were 59 and 53 percent, respectively; for patients with asystole, 9 and 9 percent; and for patients discovered with electromechanical dissociation, 20 and 34 percent. There was a lower survival rate for patients with ventricular tachycardia who were treated initially with the automatic defibrillator, but the number of patients with this condition was very small and the meaning of this observation is uncertain.

Survival rates were significantly higher for patients who were discovered in ventricular fibrillation if firefighters used automatic external fibrillators than if only basic life support was provided until paramedics arrived (30 vs. 19 percent; $P<0.01$). The survival rate for the subset that received one or more shocks from the automatic defibrillator was 33 percent (unlike the device using the present detection algorithm, the prototype device used in the first year failed to recognize and give shocks to all patients with ventricular fibrillation). Sixty-six patients given shocks by the automatic defibrillator had regained pulse and blood pressure by the time paramedics arrived.

We evaluated survival in association with the use of an automatic external defibrillator in two ways: first, by using a multivariate logistic-regression model to predict survival (expected survival rates), and second, by performing a multivariate analysis to discover the contribution of automatic defibrillators to survival, over and above that of other major factors.

The multivariate logistic-regression equation for the prediction of survival was developed on the basis of data on all patients discovered in ventricular fibrillation. The model treated as covariates the patient's age, whether the cardiac arrest was witnessed, whether a bystander initiated cardiopulmonary resuscitation, and the response time of personnel with a defibrillator. These variables could be determined in 201 (90 percent) of the cases in which defibrillation was initially provided by paramedics and in 260 (94 percent) of the cases in which early treatment was given by firefighters with automatic defibrillators.

The expected and observed survival rates for the patients first given defibrillation by paramedics, with firefighters providing only basic life support, were 24 and 22 percent, respectively (P not significant). The expected survival rate — based on the response time of the personnel with defibrillators — and the observed rate were both 30 percent for the patients treated initially with automatic defibrillators. When, instead, the response time of the paramedics was used in the multivariate model to predict survival rates for these same patients, early treatment with an automat-

Table 1. Characteristics of Patients with Out-of-Hospital Cardiac Arrest and Ventricular Fibrillation, Treated by Firefighters Using Automatic External Defibrillators, as Compared with Those First Treated with Defibrillation by Paramedics.

Characteristic	Early Defibrillation by Firefighters (N = 276)*	First Defibrillation by Paramedics (N = 228)	P Value†
Mean age ±SD (yr)	65.4±13.2	65.9±12.6	NS
	no. (%)		
Male sex	223 (81)	186 (82)	NS
Previously recognized heart disease‡	140 (69)	98 (66)	NS
Witnessed collapse	208 (79)	149 (71)	0.06
Resuscitation initiated by bystander	98 (36)	64 (29)	0.11
Collapsed at home	126 (60)	99 (65)	NS
Coarse ventricular fibrillation	240 (87)	195 (86)	NS
	mean ±SD		
Response time (min)			
First responding unit	3.2±1.2	3.4±1.4	NS
Defibrillator-equipped team	3.6±1.5	5.1±2.3	0.001
Paramedics	8.8±3.3	5.1±2.3	0.001
Difference in response time			
First unit vs. paramedics	5.6±3.3	1.7±2.2	0.001
Defibrillator-equipped unit vs. paramedics	5.1±3.2	0	0.001

*Thirty-four of the 276 patients did not receive a shock from the automatic external defibrillator but are included here on the basis of the intention to treat.

†P values for differences between the two groups are shown when $P \leq 0.15$; otherwise they are listed as not significant (NS).

‡Includes a history of angina, myocardial infarction, congestive heart failure, or hypertension. The percentages have been adjusted for the number of cases in which the history was obtained from either hospital records or interviews with family members.

ic defibrillator significantly improved survival rates; the estimated survival rate based on the response times of paramedics was 17 percent, as compared with an observed survival rate of 30 percent ($P<0.01$). Thus, the major benefit of the automatic defibrillator is associated with a reduction in the time elapsed between cardiac arrest and the availability of a defibrillator to be used by first-aid personnel.

The results of a multivariate analysis of the factors influencing the survival of all patients who were discovered in cardiac arrest due to ventricular fibrillation are shown in Table 3. Initial treatment with automatic external defibrillators was associated with higher survival rates (odds ratio, 1.8; 95 percent confidence interval, 1.1 to 2.9). In addition to the factors shown in Table 3, survival rates were also higher for patients who were treated with cardiopulmonary resuscitation by bystanders, as compared with those who did not receive such treatment (40 percent vs. 30 percent; $P = 0.04$ by univariate analysis, $P = 0.17$ by multivariate analysis).

An additional multivariate analysis of survival, restricted to the group of patients treated with automatic defibrillators, showed that the response time of paramedics was still an important determinant of survival ($P = 0.05$). This finding indicates an independent contribution of the care given by paramedics over and above that of defibrillation by first-aid personnel (either because of the delivery of adjunctive therapy or because of the continuation of efforts at defibrillation).

Table 2. Characteristics of Patients Discovered in Ventricular Fibrillation and Treated with the First and Second Prototype Automatic External Defibrillator (AED) Used during the Two-Year Study.

Characteristic†	Treated with the 1st Prototype (N = 119)	Treated with the 2nd Prototype (N = 157)	P Value*
Mean age ±SD (yr)	63.6±13.6	66.8±12.8	0.05
	no. (%)		
No. of shocks delivered (±SD)	1.3±1.0	1.6±0.9	0.01
Witnessed collapse	85 (79)	114 (78)	NS
Resuscitation initiated by bystander	42 (36)	56 (36)	NS
Shocked by AED	92 (77)	150 (96)	0.001
Admitted to hospital	61 (51)	102 (65)	0.03
Discharged from hospital	33 (28)	51 (32)	NS
	mean ±SD		
Response time (min)			
First responding unit	3.3±1.3	3.2±1.2	NS
Defibrillator-equipped team	3.9±1.6	3.4±1.4	0.02
Paramedics	9.1±3.7	8.5±3.0	NS
Time from collapse to 911 call (min)	2.2±2.4	2.2±3.5	NS
Arrival time to delivery of first shock (min)	3.9±1.7	2.8±1.4	0.001
Duration of AED use (min)	5.0±3.0	4.9±2.8	NS

*P values are shown when $P<0.15$; otherwise they are listed as not significant (NS).
†Means and percentages have been adjusted for known cases.

Discussion

Although compelling evidence exists that early defibrillation has benefit, widespread implementation of this treatment is hampered by the need for additional training when standard defibrillator–monitors are used. In addition, it has not been clear from past studies how effective defibrillation by first-aid personnel might be in tiered emergency medical systems, which include paramedic teams. The findings in this study in Seattle's tiered emergency medical system show that early defibrillation by firefighters using automatic external defibrillators was associated with higher survival rates than when defibrillation was provided only by paramedics. We assessed the effect of early defibrillation by multivariate analysis, in which we considered other clinical characteristics surrounding the cardiac arrest that were of univariate significance. A randomized trial was not justified, given the results of earlier studies that showed that defibrillation by the first responding unit was beneficial. By design, the response time of defibrillator-equipped personnel was 1.5 minutes shorter for the group of patients initially treated with the automatic defibrillator than those for whom early automatic defibrillation was not available, and permitted defibrillation 5 minutes sooner than if defibrillation had been available only from paramedic teams. Although on the surface and on the basis of the medical information available to us, there is no reason to suspect underlying clinical differences between the two treatment groups, bias could have resulted from this grouping. For the most part, the automatic defibrillators were placed with fire companies located in residential areas or with busy fire department first-aid units that serve the central and industrial areas of the city. The paramedic units are also located both in the downtown area and either in or near residential areas of the city.

Using the response time of paramedics in the multivariate model, we estimated that the survival rate for patients discovered in ventricular fibrillation would have been 17 percent if automatic defibrillators had not been available. Instead, we observed a survival rate of 30 percent. Resuscitation rates were similar for both treatment groups, suggesting that the major benefit of early defibrillation was in reducing in-hospital mortality after resuscitation. One quarter of the patients with ventricular fibrillation who were treated initially with the automatic defibrillator had regained pulse and blood pressure even before paramedics arrived on the scene, and 25 of 163 (15 percent) of those who were resuscitated were conscious by the time they were admitted to the hospital.

On the basis of this study, it is not possible to assess the full impact of the use of automatic external defibrillators on outcome and morbidity after out-of-hospital cardiac arrest. Although this study shows a survival benefit from the use of the automatic defibrillator, the overall survival rate of patients with out-of-hospital ventricular fibrillation during the two years

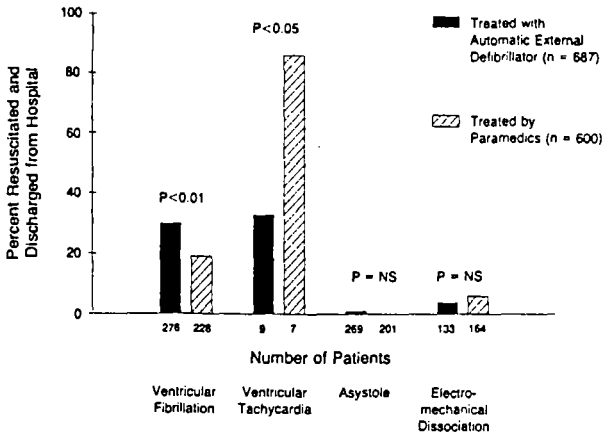

Figure 2. Survival Rates in the Two Treatment Groups, According to Cardiac Condition.

Only 18 (2 percent) of the 767 patients discovered with asystole or electromechanical dissociation were resuscitated and discharged from the hospital. Survival rates for patients discovered in ventricular fibrillation were significantly higher when firefighters used automatic external defibrillators, even though the average delay from the arrival of the first responding unit to the arrival of paramedics was significantly longer than for the group of patients to whom firefighters gave only basic life support and all shocks were given after the paramedics arrived. On the basis of a multivariate model, the expected survival rate calculated from the response time of paramedics was 17 percent for the group initially treated with automatic defibrillators. Thus, the observed survival rate of 30 percent after treatment with automatic defibrillators is significantly higher than the estimated rate without early defibrillation.

of our study was 26 percent, within the annual survival rates of 21 to 30 percent that have been recorded in our emergency medical system over the past 15 years. The results of our analyses, in which we controlled for previously recognized characteristics thought to influence survival, strongly argue for the importance of this treatment in the absence of a randomized, controlled trial. At this time, however, the magnitude of the benefit is difficult to quantify.

The first prototype defibrillator failed to recognize many cases of ventricular fibrillation; however, when the detection algorithm for the defibrillator was modified, 96 percent of all episodes of fibrillation were automatically detected. The most difficult rhythm for these devices to identify is ventricular fibrillation of very low amplitude. In practice, failure to provide a shock in response to this rhythm may have little clinical relevance, since survival rates for patients with fine fibrillation are extremely low, even when shocks are delivered by conventional devices.[10] Low-amplitude fibrillation is most often the result of a long delay between the patient's collapse and the initiation of treatment; consequently, survival is unusual.

We also found that paramedic care made an independent contribution to survival, over and above that conferred by the use of the automatic defibrillator by the first responding personnel. This may simply have been an effect of paramedics' providing additional shocks to patients who remained in fibrillation after the initial treatment by firefighters; alternatively, it may demonstrate the salutary effects of intubation and drug therapy before the patient reaches the hospital. Unfortunately, we are unable to determine which of these factors explains the benefit of care given by paramedics. These findings emphasize, however, that early defibrillation given by first-aid personnel with minimal training is not a substitute for the full services of paramedics. On the other hand, the likelihood of survival after cardiac arrest is increased in tiered emergency systems when the first responding unit is equipped and trained to use automatic defibrillators while awaiting the arrival of paramedics.

The findings in this study suggest that to maximize the benefits associated with early defibrillation, automatic defibrillators and training in their use should be provided to many types of responding personnel, including police, ambulance attendants, firefighters, attendants in public assemblies, and others who provide first aid in a medical emergency. There are, however, several requirements for extending this new type of health care. A supervising physician is needed to establish standing orders and protocols, to certify skill levels, and to provide periodic retraining and assessment of the service. All of the automatic external defibrillators currently available generate either a tape or digital recording of the electrocardiographic rhythm and voice or a paper-strip chart of the rhythm in order to facilitate quality assurance. In addition, it will be necessary in many instances for state legislatures to authorize such services and to provide immunity to trained providers who are working under the direction of a physician.

The use of automatic external defibrillators is an improvement in emergency cardiac care delivered outside the hospital. Their widespread use has obvious benefits in communities with only basic emergency services. Our findings also support the use of these

Table 3. Multivariate Determinants of Survival after Cardiac Arrest and Ventricular Fibrillation.*

Factor	Intention to Treat with AED	Shocked by AED
	odds ratio (95% CI)	
Witnessed collapse	3.9 (2.0–7.6)	3.8 (1.9–7.5)
Coarse vs. fine fibrillation	4.2 (1.6–11.0)	3.6 (1.3–9.8)
Younger patient age†	1.2 (1.0–1.4)	1.2 (1.0–1.4)
Shorter paramedic response time†	1.4 (1.0–2.1)	1.5 (1.0–2.1)
Initial shock from AED vs. paramedics	1.8 (1.1–2.9)	2.0 (1.3–3.3)

*The odds ratios are derived from two analyses of survival rates, one based on intention to treat and the other on the treatment delivered. In the analysis based on intention to treat, a patient in the automatic external defibrillator (AED) group is one for whom an AED was used, regardless of whether the device delivered a shock. Only 242 (88 percent) of the patients in the AED group actually received a shock from the device. Most cases in which no shock was delivered resulted from the failure of the first prototype device to detect ventricular fibrillation. In both analyses, odds ratios indicate the probability of survival for patients with a given factor, as compared with those in the group without that factor. CI denotes confidence interval.

†In calculating the odds ratios, age was evaluated in 10-year decrements and paramedic response time in 5-minute decrements. The coefficients and the contents of the analysis are available on request.

devices in cities with well-established tiered emergency medical systems that include paramedics.

We are indebted to the many firefighters of the Seattle Fire Department, without whose outstanding cooperation this study would not have been possible; to Physio-Control Corporation, which provided both the automatic defibrillators and generous support for the study; and to Janet Atlas for assistance in the preparation of the manuscript.

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ALCOHOL CONSUMPTION AND WITHDRAWAL IN NEW-ONSET SEIZURES

Stephen K.C. Ng, M.B., B.S., Dr.P.H., W. Allen Hauser, M.D., John C.M. Brust, M.D., and Mervyn Susser, M.B., Ch.B., D.P.H., F.R.C.P.(E)

Abstract We studied alcohol use before the onset of a first seizure in 308 patients with seizures and 294 controls. The risk of seizures increased with increasing current alcohol use. For unprovoked seizures (i.e., seizures occurring without an antecedent event, such as a recent stroke), the adjusted odds ratios rose from 3-fold at intakes of 51 to 100 g of ethanol per day (95 percent confidence limits, 1.3 and 6.3), to 8-fold at 101 to 200 g per day (95 percent confidence limits, 3.3 and 18.7), and to almost 20-fold at 201 to 300 g per day (95 percent confidence limits, 6.1 and 62). For provoked seizures, the odds ratios were lower and statistically significant only above 200 g per day (odds ratio, 10.1; 95 percent confidence limits, 2.3 and 43.8 at 201 to 300 g per day; odds ratio, 7.4; 95 percent confidence limits, 1.8 and 30.5 above 300 g per day). Among exdrinkers (abstention ≥1 year), no increased risk was detected.

Alcohol withdrawal was not associated with the onset of seizures in this study; 16 percent of first seizures in drinkers fell outside the conventionally defined withdrawal period, and the remainder exhibited a seemingly random timing after the last drink.

We conclude that the relation of seizures to alcohol use is dose dependent and appears to be causal, and that seizures can be interpreted as a disorder induced by the ingestion of alcohol, independently of alcohol withdrawal. (N Engl J Med 1988; 319:666-73.)

THE prevailing view of the long-recognized relation of seizures to an excessive intake of alcohol[1] is that they usually result from abrupt withdrawal.[2-4] Until the 1950s, however, alcohol abuse or its consequences were generally held responsible.[5,6] In either case, sustained excess is deemed a necessary condition. It is remarkable, therefore, that we know little about the relation of the duration, magnitude, and type of alcohol use to the risk of incurring seizures. The few studies that report frequencies do not distinguish first episodes of seizure from recurrent episodes.[7-11] Therefore, we studied new-onset seizures in a hospitalized population of adults to quantify alcohol as a risk factor and test the withdrawal hypothesis.

From the G.H. Sergievsky Center (S.K.C.N., W.A.H., M.S.), Faculty of Medicine, the Division of Epidemiology (S.K.C.N., W.A.H., M.S.), School of Public Health, and the Department of Neurology (W.A.H., J.C.M.B.), Faculty of Medicine, Columbia University; and the Department of Neurology (W.A.H., J.C.M.B.), Harlem Hospital Center, New York. Address reprint requests to Dr. Ng at the G.H. Sergievsky Center, Columbia University, 630 W. 168th St., New York, NY 10032.

Supported in part by a research grant (R01 NS 17236-04A1) from the National Institute of Neurological and Communicative Disorders and Stroke. Dr. Ng is the recipient of a Clinical Investigator Award (K08 HD00702) from the National Institute of Child Health and Human Development.

Methods

Patients with Seizures

Cases were drawn from Harlem Hospital, the sole municipal hospital serving some 120,000 poor, predominantly black people in New York City. Eligible persons were all those over 15 years of age admitted with first seizures between December 1981 and February 1984 (n = 341); each of these patients was admitted for a neurologic workup. A first seizure was defined as the first ever experienced by the patient (or the first cluster within a 24-hour period), but we did not count childhood febrile seizures (n = 4) or medically unevaluated seizures that had occurred up to 12 months before admission (n = 59) as previous seizures. In 90 percent a witness described the seizure; the remaining 10 percent met three of four criteria: loss of consciousness, urinary or fecal incontinence, laceration of tongue or cheek, and postictal confusion or Todd's paralysis.

A search of the admissions logs, with a chart review of all first seizures and suspicious diagnoses, yielded 95 percent of the cases; after admission, referrals to the neurology service yielded 5 percent.

To: Elizabeth Dirr

Pages: 2

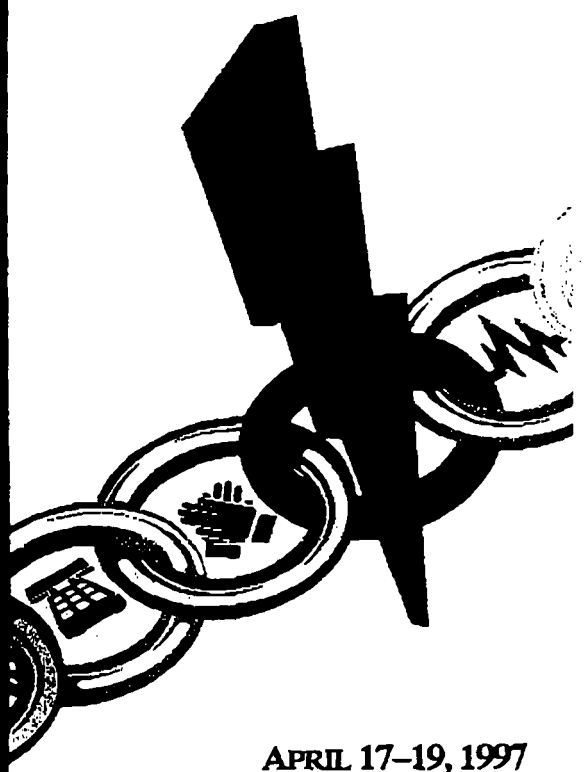
From: Alice Blair

Re: Information
Public defibrillation
Conference

American Heart Association
Fighting Heart Disease and Stroke

public access defibrillation III

STRENGTHENING *THE* CHAIN *OF* SURVIVAL



APRIL 17–19, 1997
HYATT REGENCY CRYSTAL CITY
OF WASHINGTON, D.C.
NATIONAL AIRPORT

GENERAL INFORMATION

Conference Description

This conference consists of five state-of-the-art sessions, seven concurrent workshops and a poster session. The conference will focus on public access defibrillation research; results to date and the AHA's planned initiative. The FDA role and the latest in devise technology will also be covered. Workshops will provide an opportunity for attendees to participate in discussion about various issues related to public access defibrillation.

* 10:00 am press conference

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, Australi

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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.

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John M. Jerin
King County Emergency Medical Services

Options

- programs in HHS that affect Cardiac arrest/ first responders
  - who sets standards?
  - who funds?

NHTSA –

Justice – good samaritan laws; medical practice
- who can a doctor extend their license to in what States

1. Research

2. Actions in legislation

3. Steps relating to police (Jerry) and other efforts to

$? OTHER HHS Opportunities

FDA - labeling / otc sales
- safety / efficacy

HLBI - systems research ?

NHTSA - Model state codes

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 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.

RACING THE AMBULANCE

A special report.

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 medical 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.

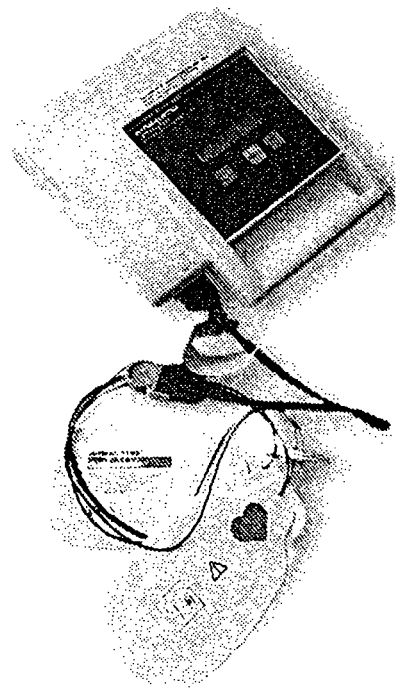
While the heart association's proposal may seem simple, state laws and Federal regulations are in the way.

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.

1/3

Continued From Page A1

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

Not too long ago, defibrillators so complicated that the operators had to be specially trained to read the screens and interpret the heart waves. But the heart associa- says a new generation of automatic, easy-to-use machines has 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 has made the machines practical, the association says, are five-year lithium 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 from cardiac arrest is haphazard, making the rates difficult to com- 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 hidebound by rules and laws and regulations," said Dr. Myron L. 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.

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.

Mr. Cox's heart had been re- garded as likely to have 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.

The Device

The Newest Models Come on the Market

Use of defibrillators by the public is generally not covered by state "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 eart 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 state 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's the cost benefit."

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 heart rhythms 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 heartbeat 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 us that good at it," said Dr. Alexan Kuehl, the chairman of the New Y City medical advisory committee emergency services the forn head of the city's emergency se ices agency.

"There's always a danger, th you're going to shock a ba into a living rhythm, but that t brain is going to be dead," he sa "But if we can get the bac very few of us play God in t who lives and who dies. We bri back the one thing that we can bri back, which is the heart, and ho that the brain is intact."

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

2/3

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 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 headquarters 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 panicky 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.

3/3

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

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.

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 Scott

New model: Smallest, che

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

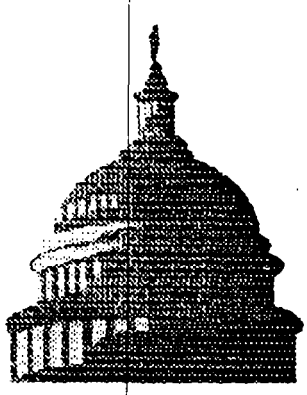
Measuring the Major Outcome Variables
Graham Nichol, MPH, MD
Assistant Professor
Loeb Medical Research Institute
University of Ottawa

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



American Heart Association℠

Fighting Heart Disease and Stroke

OFFICE OF PUBLIC ADVOCACY

"actively working to change the political, social, legal, and medical environment to reduce heart disease and stroke"

- ♥ 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 Public Advocacy
1150 Connecticut Ave., N.W.
Suite 810
Washington, D.C. 20036

Tel: (202) 822 9380
Fax: (202) 822 9883

Date: 4/ /97 **Time:** 1100

To: Jon Friedman **Fax:** 456-7431

From: **Trish Moreis** / Nick Hansen
AHA, Office of Public Advocacy

Tel: (202) 822 9380
Fax: (202) 822 9883

Number of pages including cover sheet: 16

Message Here's some information on our conference and the AED legislation.

Confirmation: ☐ **yes** ☐ **no**

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http://www.americanheart.org

American Heart Association
Fighting Heart Disease and Stroke

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 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).**

Emerging Cardiac Care

For Bruce Bullington - Company "Heartstream"
" ForeRunner "device

Actions

- No commission through legislation
- Admin action - Departments willing to make commitment

Bruce Burlington

American Heart Assn.

Early defibrillation produces better results
"Heartstream" and other highly-automated.
a less-trained person can use it.

Products all labeled for professional use —
variety of investment in viewpoints.

- is it a wise investment to place these devices everywhere,

Earls shock — saves lives by trained personal — (inductive reasoning)
SO we should get these out to less-trained person

- less trained people may not the device on
people who don't have cardiac arrest
- if you don't know much about this —
have to spend time.

Need to learn proper positioning of these for results. —
Heart Assn. — sponsor — Consortium would contribute
2-3 years.
- Mike Weissfield. — Am. Heart Assn
Dean at Columbia. —

- others who do resuscitation research

Next level - beyond police/fireman to
- Security guards.

Accruing data —

- General

- If you put a lot of input-ar in Seattle — Uniformed first ~~safety~~ responders. —

- major improvements in prevention of sudden cardiac arrests — implantable defibrulators, drugs, other forms of care

Mike Weisfield - Columbia - Med - Chair, Dept. of Medicine
Richard Cummins - Univ of Washington, Seattle - Chairman

Claude L'enfant, Director of NHLBI

- role of medical professionals vis a vis level of supervision —

- CDC / Heart Lung — technical advice — basic — not applied - research

ACTRR - not a priority —

Working w/ Heart Association to say how should they be appropriately labeled — now labeled for supervised systems

Am Red Cross — private fund

4/16/97

Dr. Chandra — #1 killer

- Not recognizing warning signs
  - particular older people

- automatic external defibrillators.
  - non medical

100,000 die from out of hospital arrests. —

Variability — across ~~states~~ cities.

NHTSA - safety emphasis —

National Heart Lung Blood — Pg3 said get more involved in systems research —

NHTSA — Statutory — develop emergency services guidelines
paramedic } model guideline.
EMT
First-responders (policemen — but no heart focus — trauma oriented.
bystanders

911 — 45-50% penetration.

Early recognition
early Notification
CPR
Defibrilation
Advanced Care.

Good Samaritan legislation varies across states.

Public Access Conf. —

Papers

Roger White — police force trained did better than ~~EMT~~

Quantas — AED's are the right way to go. —

Use by lay people has been shown to be safe under strict medical supervision.

NIH's — National heart attack alert program — charged w/ responsibility to ↓ death/illness from heart attack.

States are passing legislation to authorize first responders. —

model immunity legislation —

Early Access – call 911

Early CPR – 1st person on scene does CPR.

Early Defibrillation – ** SAVES LIVES

EARLY ADVANCED CARE.

Improved neurologic recovery and survival after early defibrillation

W. DOUGLAS WEAVER, M.D., MICHAEL K. COPASS, M.D., DEBBIE BUFI, R.N., ROBERTA RAY, M.S., ALFRED P. HALLSTROM, PH.D., AND LEONARD A. COBB, M.D.

ABSTRACT Eighty-seven patients who had out-of-hospital cardiac arrests received defibrillating shocks delivered by minimally trained first responders before the arrival of paramedics in a city with short emergency response times. Their outcomes were compared with those of 370 other victims who received only basic life support by first responders until paramedics arrived. Survival was improved by early defibrillation in cases in which there was a delay in initiating cardiopulmonary resuscitation and in which paramedic response times exceeded 9 min: there was 62% survival after early defibrillation by first responders and 27% if first responders provided only basic life support ($p < .02$). Neurologic recovery was also improved after early defibrillation. Eighteen of 46 resuscitated patients (39%) receiving early defibrillation were awake at 24 hr compared with 49 of 204 patients (24%) who received only basic life support while awaiting paramedics ($p < .02$). Incorporating defibrillation as part of basic life support can reduce both mortality and morbidity from cardiac arrest, even in cities with established, rapidly responding emergency care systems.
Circulation 69, No. 5, 943–948, 1984.

THE TRAINING of emergency medical technicians to deliver defibrillating shocks in conjunction with cardiopulmonary resuscitation (CPR) has been demonstrated to improve the survival of patients suffering out-of-hospital cardiac arrests in communities without access to paramedic services.[1] This is not surprising, since out-of-hospital conditions make it difficult to administer effective basic life support during transport to the hospital.

We sought to determine the benefit of early defibrillation delivered by first responders, who in the past have delivered only CPR until the arrival of promptly responding paramedic services. We suspected that early defibrillation delivered before the arrival of paramedics could produce salutary effects.

Methods

Seattle, a city of 235 square kilometers with a population of one-half million people, has an efficient paramedic system that responds approximately 14,000 times each year to medical emergencies, including approximately 300 cases of cardiac arrest caused by ventricular fibrillation.[2] The system's response for life-threatening emergencies is tiered. Basic life support for cardiac arrest is initially managed by firefighters responding from the nearest fire station. Advanced life support is subsequently delivered by paramedics from one of five rescue vehicles staffed by paramedics, located at four stations in the city. Response times for the first-responding units average 3.2 ± 1.8 min (mean ± SD) and those for paramedic units average 7.2 ± 3.5 min.

We provided a 10 hr training program to first responders. Training included a refresher course in CPR techniques, electrocardiographic rhythm interpretation, with emphasis on recognition of ventricular fibrillation, and the use and maintenance of a defibrillator. Cardiac rhythms were considered in two broad groups: ventricular fibrillation and those rhythms that were not ventricular fibrillation. First responders had been previously trained or certified emergency medical technicians.[3]

From December 1980 to November 1982, firefighters on four selected first-responding units were authorized to deliver up to three shocks for ventricular fibrillation. These four units (three first aid rescue vehicles and one engine company) were selected becauses they served areas of the city known to have relatively long paramedic response times. In suspected cases of cardiac arrest, two fire department units (the nearest engine and aid car) were dispatched to the location to begin basic life support before the arrival of paramedics. The selected first responders were instructed to first provide conventional basic life support. After establishing adequate CPR, one of the rescuers connected the patient monitoring cable with silver–silver chloride electrodes in the standard lead II configuration. First responders used modified defibrillator-monitors (Physio Control Corp., Lifepak 5 model) that included a two-channel magnetic tape recorder which continuously recorded the electrocardiographic rhythm and voice during the resuscitation attempt. After the electrodes were in place, cardiac rhythm was determined and a shock was administered in cases of ventricular fibrillation. CPR was then resumed and the rhythm again was assessed in approximately 30 sec. If ventricular fibrillation persisted or recurred, the sequence

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was repeated up to three times. Initial shocks used either 175 or 320 J of delivered energy, according to a previously described protocol.[4] After arrival of paramedics, all further efforts were directed by the advanced life support team. In cases of cardiac arrest associated with rhythms other than ventricular fibrillation, first responders provided only basic life support and all further treatment was directed by the paramedics.

During the 2 years beginning April 1980 in which there were approximately 500 additional victims of ventricular fibrillation, we were able to obtain similar magnetic tape recordings in 370 of these episodes. These patients, serving as a comparative treatment group, received only CPR by first responders, and defibrillation was administered only after the arrival of paramedics. Cardiac histories were similar for both treatment groups, and as far as we could ascertain, only the emergency system logistical factors were different.

The magnetic tapes were used to determine the times when all therapy was delivered and to document the rhythm present before and after each defibrillatory shock. Rhythms were grouped as follows: (1) ventricular fibrillation, (2) supraventricular (includes any rhythm with atrial activity), (3) idioventricular (includes wide QRS rhythms at any rate in the abence of atrial activity), and (4) asystole or the absence of both atrial and ventricular electrical activity during the assessment period. Rhythms were determined as early as possible after a defibrillatory shock, during CPR if possible, or at times when CPR was interrupted by the rescuers themselves to assess the rhythm.

The time of collapse was estimated by interviewing bystanders. The times of emergency dispatch, arrival of the rescue unit, and each treatment were recorded on magnetic tape. Resuscitated patients were admitted to any of 14 hospital coronary care units in the city. Hospital and physician records were reviewed to determine survival, time of awakening, and other clinical information. Because we could not personally examine all of the patients, we used the time of awakening, as determined from the medical records, to assess neurologic recovery. This has proved to be a reliable indicator of ultimate neurologic outcome.[5]

The protocol for this study was approved by the Human Subjects Review Committee of the University of Washington. During the first year, a committee reviewed short- (resuscitation rate) and long-term (percentage discharged alive) outcome to ensure the safety of the trial.

Differences in discrete variables between the groups receiving early defibrillation (shocked by first responders) and CPR only (shocked by paramedics) were compared by chi-square analysis. Continuous variables were analyzed by Student's t test. Tests for differences in variance were done, and when appropriate, the t test was modified.[6] Differences in outcome variables between the two groups were assessed with one-sided tests. A multivariate logistic model was used to examine the effects of clinical characteristics, emergency system factors, and treatment group. The form of the model is

$$p = \frac{1}{1 + e^{-(b_0 + b_1 \text{ age} + b_2 \text{ DTCPR} + b_3 \text{ CPRT} + b_4 \text{ GB})}}$$

where p is the probability of survival, DTCPR is the duration of time from collapse to initiation of CPR, CPRT is the duration of CPR before application of the first shock, and GB is the type of rescuer who shocked the patient (first responder or paramedic). To compare the two treatment groups, we stratified the patients by both the minutes until initiation of CPR and by interval of response times of paramedics. We determined survival and neurologic recovery in each strata. We had used this technique previously to evaluate the effect of CPR administered by bystanders.[7] By design there were differences in the paramedic response times for both treatment groups, and we could not choose intervals of response times that would provide equal proportions of cases in each interval. We therefore arbitrarily divided the response time into equal 3 min intervals to measure treatment effect.

Results

Clinical and logistical characteristics. Before the arrival of paramedics, first responders began CPR and administered initial defibrillation shocks to 87 patients discovered in cardiac arrest. The average time from collapse to start of CPR was 3.8 ± 2.4 min (SD) in 46 witnessed episodes in which times were known. The duration of CPR until the first shock averaged 5 min. In 370 similar patients, first responders provided only CPR and defibrillation was accomplished by paramedics. The delay from collapse to start of CPR in these patients was similar to that observed in patients receiving early defibrillation. As expected, the delay from collapse until defibrillation was significantly longer (almost 3 min) in patients who received only CPR from first responders (table 1).

The location of the cardiac arrest, proportion of witnessed cases, and incidence of bystander-initiated CPR were comparable for both groups of patients.

In patients receiving early defibrillation given by first responders, the delay until administration of the initial shock was shortened an average of 5 min compared with what would be expected (defibrillator-equipped first responder on scene 4.5 ± 2.2 min after the alarm; paramedic unit on scene 9.5 ± 3.3 min after dispatch).

Results of defibrillatory shocks. Twenty-eight of 87 patients defibrillated early (32%) received all the shocks required during the resuscitation effort before the arrival of paramedics; of these 28 patients, 22 (79%) developed organized rhythms that produced palpable arterial pulses. Six of the 28 patients were shocked into asystole or pulseless rhythms and died despite further treatment by paramedics. In the other 59 patients receiving early defibrillation, additional shocks and drug therapy were administered to treat persistent or recurrent episodes of ventricular fibrillation after the arrival of paramedics (figure 1).

One incorrect assessment of the rhythm was made by one of the first responding firefighters in a pulseless patient with an idioventricular rhythm. A shock was delivered that had no effect on the underlying rhythm. In reviewing the tape recordings of all other uses, we found no other instance in which a shock was given for a rhythm other than ventricular fibrillation.

The total number of shocks required during the resuscitation effort were similar for patients receiving early defibrillation and those shocked only after arriv

TABLE 1
Clinical and system variables in patients shocked by first responders and in patients receiving only CPR by first responders

Variable	Initial shocks delivered by: First responders (n = 87)[A]	Paramedic (n = 370)[A]	p value[B]
Collapsed at home n (%)	56 (64)[C]	207 (56)	NS
Witnessed arrest n (%)	52 (60)	233 (63)	NS
Bystander CPR n (%)	26 (30)	133 (36)	NS
Age (yr)	68.4 ± 11.4[D]	65.4 ± 13.3	.05
Collapse to initiation of CPR (min)	3.8 ± 2.4	4.2 ± 3.2	NS
Alarm time to arrival of firefighters (min)	3.0 ± 1.1	3.1 ± 1.8	NS
Alarm time to arrival of paramedics (min)	9.5 ± 3.3	6.7 ± 3.3	.001
Collapse to first shock (min)	8.8 ± 2.8	11.5 ± 4.2	.001
Duration of CPR to first shock (min)	4.9 ± 3.0	7.7 ± 5.0	.001

[A]The number of patients with known values for each variable varies for each determination and percentages have been adjusted accordingly.

[B]Probability values are expressed when $p \leq .1$; higher values are expressed as not significant (NS).

[C]Data expressed as number of patients, with percentage of total number of patients in parentheses.

[D]Data expressed as mean ± SD.

of paramedics (4.4 ± 3.8 vs 4.3 ± 3.5 shocks, respectively). However, patients shocked by first responders more frequently developed a supraventricular rhythm after the initial shock (figure 2).

Survival and neurologic recovery after early defibrillation. On the whole, survival for patients receiving early defibrillation was identical to that for patients in the comparative treatment group in which only CPR was administered by first responders and shocks were delivered after arrival of paramedics (table 2). However, when we stratified the delay in the start of CPR and paramedic response times for both groups of patients,

TABLE 2
Hospital course in patients receiving early defibrillation by first responders vs standard paramedic treatment

Variable	Initial shocks delivered by: First responders (n = 87)[A]	Paramedics (n = 370)[A]	p value[B]
Resuscitated and admitted (n)	51 (59%)	217 (59%)	NS
Discharged alive (n)	26 (30%)	105 (28%)	NS
Awake by 24 hr (n)	18 (39%)[C]	49 (24%)[C]	.02
Highest CK, day 1 (IU ± SD)			
All (n)	331 ± 471 (37)	587 ± 1345 (158)	NS
LTS (n)	391 ± 571 (24)	638 ± 1529 (86)	NS
Highest CK, day 2 (IU ± SD)			
All (n)	1325 ± 1221 (30)	1687 ± 1947 (150)	NS
LTS (n)	1220 ± 1190 (20)	1905 ± 2244 (86)	NS
Highest CK, day 3 (IU ± SD)			
All (n)	1548 ± 1065 (16)	1489 ± 1616 (90)	NS
LTS (n)	1412 ± 986 (9)	1586 ± 1852 (56)	NS
Peak CK_2 (IU ± SD)			
All (n)	66 ± 112 (23)	33 ± 47 (73)	NS
$LDH_1 > LDH_2$			
All (n)	8 (16%)	49 (23%)	NS
CHF at discharge			
LTS (n)	7 (27%)	40 (40%)	NS
No. of hospital days	13.2 ± 14.3	12.1 ± 16.4	NS

CHF = congestive heart failure; CK = creatine kinase (total) and CK_2 = myocardial fraction; LTS = long-term survivor (i.e., survived and was discharged alive); LDH = serum lactate dehydrogenase, fractions 1 and 2.

[A]The number of known patients for each variable in both groups varies and percentages have been adjusted accordingly.

[B]Probability values are expressed when $p \leq .1$.

[C]Values in parentheses indicate percent of resuscitated patients.

TABLE 3

Long-term survival and neurologic recovery after cardiac arrest: patients receiving early defibrillation by first responders vs those in whom only CPR was provided until paramedic arrival

	Witnessed cases									
	Collapse until initiation of CPR (min)									
	0-1		2-3		4-5		6-7		≥8	
	PM	FR	PM	FR	PM	FR	PM	FR	PM	FR
Paramedic response time (min)										
0-3										
LTS	5 (71)[A]	—	7 (64)	—	0 (0)	1 (100)	—	—	0 (0)	—
Awake at 24 hr	1 (14)	—	4 (36)	—	0 (0)	0 (0)	—	—	0 (0)	—
3-6										
LTS	11 (55)	0 (0)	11 (65)	1 (33)	10 (45)	0 (0)	1 (13)	—	1 (14)	—
Awake at 24 hr	5 (25)	0 (0)	4 (24)	1 (33)	5 (23)	0 (0)	0 (0)	—	0 (0)	—
6-9										
LTS	8 (50)	2 (67)	5 (42)	1 (33)	11 (46)	2 (40)	2 (25)	1 (100)	1 (33)	—
Awake at 24 hr	2 (13)	2 (67)	2 (17)	0 (0)	6 (25)	0 (0)	2 (25)	1 (100)	0 (0)	—
>9										
LTS	1 (13)	1 (17)	3 (30)	1 (17)	5 (29)[B]	5 (63)	1 (33)	2 (67)	1 (17)	1 (50)
Awake at 24 hr	0 (0)	1 (17)	1 (10)	2 (33)	2 (12)	2 (25)	1 (33)	1 (33)	0 (0)	1 (50)
Total cases	51	10	50	12	67	16	19	4	17	2

FR = defibrillation by trained first responders and before arrival of paramedics; LTS = long-term survivor, resuscitated, admitted to the hospital, and later discharged alive; PM = standard first response and defibrillation after arrival of paramedics.

[A]Data expressed as number of patients, with percentage of total number of patients in parentheses.

[B]When delays until initiating CPR ≥ 4 min and paramedic response times exceeded 9 min, early defibrillation was associated with significantly improved survival rates (8 of 13 [62%] vs 7 of 26 [27%]; $p < .02$) (boxed data).

[C]$p = .05$.

survival was significantly improved after early defibrillation in cases in which CPR was begun 4 min or more after collapse and paramedic response times exceeded 9 min (62% vs 27%; $p < .02$, table 3). We found no difference in survival for shorter paramedic response times, but there were too few cases in each stratum to make meaningful observations.

There was a marked improvement in neurologic recovery as determined by the rate of awakening at 24 hr in patients receiving early defibrillation, both in witnessed and unwitnessed cases of cardiac arrest. This improvement was particularly marked when the paramedic response time exceeded 9 min. Seven (39%) of 18 patients who received early defibrillation and who were admitted to the hospital were awake and responsive by 24 hr, compared with only four of 24 (17%) comparable patients who received basic life support from first responders and initial shocks only after paramedic arrival ($p = .05$). Neurologic recovery was also better in unwitnessed cases of cardiac arrest in which patients received early defibrillation, presumably because of inherently longer delays until initiation of both basic and advanced life support (figure 3).

The clinical and logistical variables influencing survival were examined in victims ($n = 244$) for whom all information was available. Two variables were associated with improved outcome: shorter delays to initiation of CPR ($p < .01$) and early defibrillation by first responders ($p < .005$). Survival was not related to patient age, nor was it dependent on the training of the rescuer who administered the shock (first responder or paramedic). Long delays until defibrillation, independent of when CPR was begun, were associated with poorer survival. In the 87 patients receiving early defibrillation, the odds for survival were 2.15 times greater than expected if CPR alone had been done by first responders and initial defibrillatory shocks had been delivered after arrival of paramedics.

Early defibrillation had no observable effect on the peak level of serum enzymes, findings of congestive heart failure, and total days of hospitalization (table 2).

Discussion

Early defibrillation, administered by minimally trained first-responding rescuers such as firefighters is feasible, safe, and beneficial, even in cities with sophisticated paramedic emergency response systems. After a total of 10 hr of additional training in which CPR skills were refreshed, simple rhythm recognition skills (to identify ventricular fibrillation) were taught,

TABLE 3
(Continued)

Witnessed cases				Unwitnessed cases	
Total					
PM		FR		PM	FR
12 (52)		1 (100)		1 (8)	—
5 (22)		0 (0)		1 (8)	—
34 (46)		1 (17)		9 (14)	2 (33)
14 (19)		1 (17)		5 (8)	2 (33)
27 (43)		6 (50)		9 (18)	4 (33)
12 (19)		3 (25)		4 (8)	3 (25)
11 (25)		10 (40)		2 (7)	2 (10)
4 (9)[c]		7 (28)[c]		4 (13)	2 (10)
204		44		157	38

and practical sessions with a mannequin were carried out, rescuers stationed in four of the areas of the city with longer paramedic response times were given standing orders to apply required defibrillatory shocks to victims of cardiac arrest. Inappropriate delivery of shocks occurred only once. In fact, the commentary on the magnetic tapes revealed that there was initial hesitation to deliver the shock until the rescuers had reassured one another. CPR was never inappropriately interrupted to allow for rhythm interpretation.

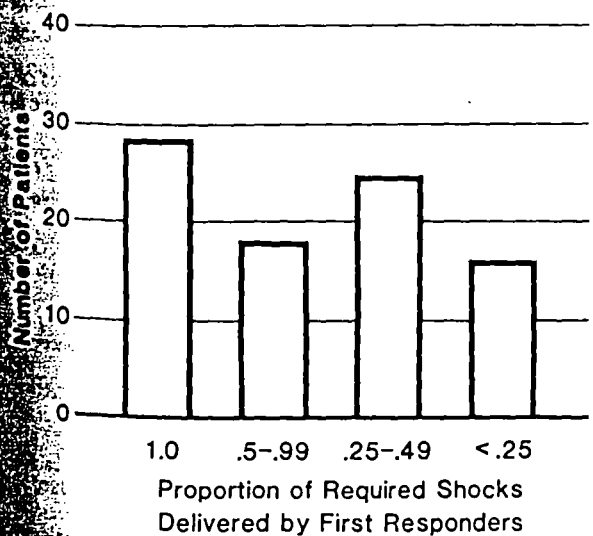

FIGURE 1. Proportion of the total number of required defibrillatory shocks delivered by first responders to 87 patients. In two-thirds of patients additional shocks along with other advanced life support measures were administered by paramedics for episodes of persistent or recurrent ventricular fibrillation. In 28 patients the first responders terminated the episode of cardiac arrest before arrival of paramedics. Twenty-two (80%) of these 28 patients developed an organized rhythm.

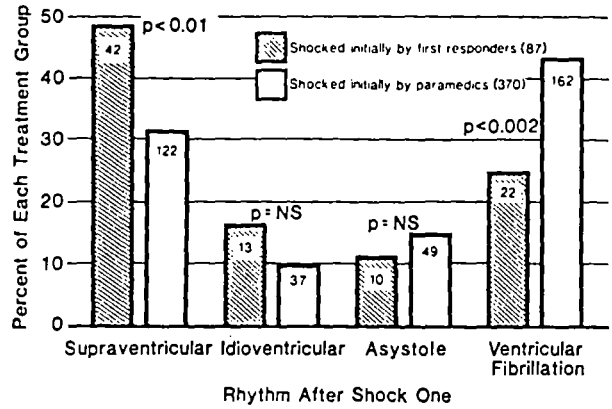

FIGURE 2. Electrocardiographic rhythm after the initial defibrillatory shock in both treatment groups. When early defibrillation was delivered by first responders, a supraventricular rhythm was more often restored than when first responders provided only CPR and shocks were delivered after arrival of paramedics. The proportion of witnessed collapses, bystander-initiated CPR, and delay until initiation of CPR were similar for both treatment groups.

We found by multivariate analysis and by stratifying the delays in beginning CPR and in paramedic response that early defibrillation delivered by first responders improved survival after cardiac arrest; this was particularly evident when paramedic response times exceeded 9 min. In the study areas of the city, where paramedic response time averaged 9.5 min, we calculated that survival rates when early defibrillation was provided by first responders were over 2 times greater than that expected if only CPR was provided before arrival of paramedics.

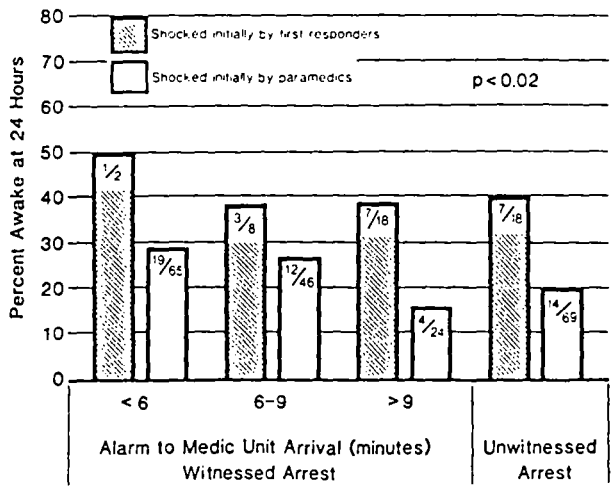

FIGURE 3. Effect of early defibrillation on neurologic recovery in resuscitated patients. Both in the witnessed and unwitnessed arrests, early defibrillation delivered by first responders was associated with a significantly greater proportion of patients awake 24 hr after hospital admission than when first responders provided only CPR before arrival of paramedics.

Equally important, we also found a significant improvement in neurologic recovery after early defibrillation. When paramedic response times exceeded 9 min the rate of awakening by 24 hr after cardiac arrest was 3 times greater in patients receiving early defibrillation than that in patients who received only CPR by first responders and defibrillation after arrival of paramedics. Both in this and an earlier study[8] the conventional tiered response of first basic and then advanced life support teams resulted in approximately 20% of the resuscitated patients resuming consciousness by the time of hospital admission and in 25% resuming consciousness at 24 hr. In contrast, when patients received CPR plus defibrillatory shocks by the first-responding rescuers, 39% of patients admitted to the hospital were awake by 24 hr. It seems possible that early defibrillation may have other beneficial effects on cerebral recovery that we did not attempt to measure in this study, such as prompt return of full cognitive and motor activities. The time of awakening has been shown in a previous study of similar patients to correlate closely with the full return of neurologic function.[5] Furthermore, early defibrillation more often resulted in an organized rhythm after the first shock, possibly the result of attenuated myocardial ischemia and injury. These findings provide evidence that early defibrillation results in lower morbidity and mortality after cardiac arrest.

Delays in initiation of CPR and in arrival of advanced life support teams have a great effect on the potential for survival of victims of cardiac arrest.[9-13] Rapid initiation of CPR and defibrillation (e.g., in the coronary care unit or during an exercise rehabilitation program for primary episodes of ventricular fibrillation[14, 15]) usually result in rapid restoration of an organized rhythm and consciousness. This is not true for victims of cardiac arrest for whom resuscitation efforts are delayed or prolonged, both of which occur frequently in the out-of-hospital situation.[4] Early defibrillation by first responders can improve both neurologic recovery and survival of patients treated by efficient paramedic-level care systems but is clearly still inferior to immediate treatment. Delays could be further reduced by placing the defibrillator closer to the victim — in the hands of bystanders. Lay bystanders have shown their willingness to perform basic life support,[7, 16, 17] and these efforts have been associated with improved outcome.[8] This additional step would require the development of a small defibrillator that is portable, inexpensive, safe, and easy to operate; it must also have a reliable, adequately tested automatic ventricular fibrillation detector. Widespread use of such a device will require proven methods of user training and safeguards to prevent inappropriate use. They could be placed in the homes of high-risk patients, public places, police and fire vehicles, ambulances, airliners, and physicians' offices. Early defibrillation by bystanders might dramatically improve both survival and neurologic recovery of victims of sudden cardiac death syndrome.

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