No. S207313

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

ROSEMARY VERDUGO, mother, successor and heir of MARY ANN VERDUGO, Decedent and MICHAEL VERDUGO, brother of Decedent

Plaintiffs/Appellants

v.

TARGET STORES, a division of TARGET CORPORATION, a Minnesota corporation

Defendant/Appellee.

Following Certification of a Question of California Law from the U.S. Court of Appeals, Ninth Circuit, in Appeal No. 10-57008

SUPREME COURT
FILED

AUG 12 2013

Frank A. McGuire Clerk

Deputy

RESPONDENT'S REQUEST FOR JUDICIAL NOTICE

Donald M. Falk (SBN 150256)
Foster C. Johnson (SBN 289055)
MAYER BROWN LLP
Two Palo Alto Square, Suite 300
3000 El Camino Real
Palo Alto, CA 94306-2112
Tel.: (650) 331-2000
Fax: (650) 331-2060

Attorneys for Respondent Target Stores

REQUEST FOR JUDICIAL NOTICE

Pursuant to Evidence Code sections 452 and 459 and California Rules of Court, rules 8.252(a) and 8.520(g), respondent Target Stores hereby requests that this Court take judicial notice of the following documents, attached as Exhibits 1 through 19:

1. Assembly Committee on Judiciary, Background Information Request, Sen. Bill 911 (1999–2000 Reg. Sess.);
2. Cal. Health and Human Services Agency, Enrolled Bill Rep. on Assem. Bill No. 1312 (2009–2010 Reg. Sess.) prepared for Governor Schwarzenegger (Sept. 29, 2009);
3. California Employment Development Dept., Size of Business Data For California (Quarterly), Payroll and Number of Businesses by Size of Business – Classified by Industry (Table 2A) (Qtr. 2, 2012), available at http://www.labormarketinfo.edd.ca.gov/Content.asp?pageid=1045;
4. Loran Sheley, MA, California Department of Public Health, Heart Disease Mortality Data Trends, California 2000-2008 (Jan. 10, 2011), available at http://www.cdph.ca.gov/programs/ohir/Pages/Heart2008PrinterVersion.aspx;

5. U.S. Food and Drug Administration, Center for Devices and Radiological Health, External Defibrillator Improvement Initiative Paper (Nov. 2010), available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/ExternalDefibrillators/ucm232621.htm;

6. U.S. Food and Drug Administration, Class 2 Recall Phillips and Laerdal Brands of HeartStart HS1 Defibrillator Family, Recall No. Z-0643-2013 (Jan. 4, 2013), available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=113133;

7. Occupational Safety and Health Administration, *Automated External Defibrillators*, available at http://www.osha.gov/SLTC/aed/;

8. Linda Becker, M.A., et al., *Public Locations of Cardiac Arrest: Implications for public access defibrillation*, Circulation 97:2106-2109 (1998), available at http://circ.ahajournals.org/content/97/21/2106.long;

9. Hoag Levins, *The Automated External Defibrillator: Medical Marvel But Measurement Mystery*, U. Penn. LDI Health Economist (May 2012), available at http://ldihealtheconomist.com/he000019.shtml;

10. Mary F. Hazinski, et al., *Lay Rescuer Automated External Defibrillator Programs*, Circulation 111: 3336-3340 (2005), available at http://circ.ahajournals.org/content/111/24/3336.full;

11. JA Drezner, KJ Rogers, & JG Horneff, *Automated External Defibrillator Use at NCAA Division II and III Universities*, Brit. J Sports Med, 45: 1174-1178 (2011), available at http://bjsm.bmj.com/content/early/2010/11/15/bjsm.2009.070052.abstract;

12. Larry M. Starr, *Automated External Defibrillation in the Occupational Setting*, J. of Occupational & Emergency Med. Vol. 54 No. 9 1170 (Sept. 2012), available at http://www.acoem.org/uploadedFiles/Public_Affairs/Policies_And_Position_Statements/Guidelines/Position_Statements/Automated%20External%20Defibrillation%20in%20Occup%20Setting.pdf;

13. Terence D. Valenzuela, M.D., et al., *Outcomes of Rapid Defibrillation by Security Officers after Cardiac Arrest in Casinos*, New Eng. J. Med. 2000, 343:1206-1209 (Oct. 2000), available at http://www.nejm.org/doi/full/10.1056/NEJM200010263431701;

14. Myron L. Weisfeldt, M.D., et. al, *Ventricular Tachyarrhythmias After Cardiac Arrest in Public Versus at Home*, New Eng. J. Med. 2011, 364:313-21 (Feb. 2011), available at

http://www.medpagetoday.com/upload/2011/1/26/nejmoa1010663.pdf;

15. Comilla Sasson, M.D., et. al, *Predictors of Survival From Out-of-Hospital Cardiac Arrest: A Systematic Review and Meta-Analysis, Circulation: Cardiovascular Quality and Outcomes 2010*; 3:63-81, available at http://circoutcomes.ahajournals.org/content/3/1/63.long;

16. American Heart Association, *First Aid*, Circulation (112: III-115-III-125) at III-115 (Nov. 29, 2005), available at http://circ.ahajournals.org/content/112/22_suppl/III-115.full;

17. American Heart Association, *Defibrillation*, 112 Circulation III-17, available at http://circ.ahajournals.org/content/112/22_suppl/III-17.full.pdf+html;

18. Mary P. Larsen, et al., *Predicting Survival From Out-of-Hospital Cardiac Arrest: A Graphic Model*, Annals of Emergency Med. 1652 (Nov. 1993), available at http://www.annemergmed.com/article/S0196-0644(05)81302-2/abstract;

19. American Heart Association, *CPR & Sudden Cardiac Arrest (SCA) Fact Sheet* (April 24, 2013), available at http://www.heart.org/HEARTORG/CPRAndECC/WhatisCPR/CPRFactsandStats/CPR-Statistics_UCM_307542_Article.jsp.

This motion for judicial notice is based on the accompanying Memorandum of Points and Authorities and the Declaration of Foster C. Johnson.

MEMORANDUM OF POINTS AND AUTHORITIES

This Court has the same ability as a trial court to take judicial notice of appropriate materials. (See Evid. Code § 459; *Smith v. Rae-Venter Law Group* (2002) 29 Cal.4th 345, 459.) Under sections 451 and 452 of the Evidence Code, the Court "may judicially notice a variety of matters" relevant to the legal question at hand. (*Mangini v. R.J. Reynolds Tobacco Co.* (1994) 7 Cal.4th 1057, 1063, overruled on other grounds by *In re Tobacco II Cases* (2007) 41 Cal.4th 1257.)

This case presents the following certified question from the United States Court of Appeals for the Ninth Circuit: "Under what circumstances, if ever, does the common law duty of a commercial property owner to provide first aid to invitees require the availability of an Automated External Defibrillator ('AED') for cases of Sudden Cardiac Arrest?" Target requests that the Court take judicial notice of the documents described below, which are pertinent to the Court's resolution of that question. None of the exhibits for which Respondent requests judicial notice were noticed in the federal court proceedings; all pertain to matters occurring before judgment. (California Rules of Court, rule 8.252(a)(1).) The exhibits' authenticity is supported by the Declaration of Foster C. Johnson, one of Target's attorneys. (See *People v. Connor* (2004) 115 Cal.App.4th 669, 681; *Whaley v. Sony Computer America, Inc.* (2004) 121 Cal.App.4th 479, 487.)

1. Exhibit 1 is an Assembly Committee on Judiciary Background Information Request for legislation enacting Civil Code Section 1714.21 and 1797.196. This legislative history sheds light on the Legislature's intent in extending limited civil immunity to Good Samaritans who install and use AEDs in an emergency situation. "Background Information Requests are a proper source of legislative history." (*Kachlon v. Markowitz* (2008) 168 Cal.App.4th 316, 338 (citing (*Armijo v. Miles* (2005) 127 Cal.App.4th 1405, 1415, fn. 5).)

2. Exhibit 2 is an Enrolled Bill Report on Assembly Bill No. 1312 prepared for Governor Arnold Schwarzenegger by the California Health and Human Services Agency. "[E]nrolled bill reports, prepared by a responsible agency contemporaneous with passage and before signing, [are] instructive on matters of legislative intent." (*Elsner v. Uveges* (2004) 34 Cal.4th 915, 934 fn. 19.)

3. Exhibit 3 is a publication of the California Employment Development Department regarding the size and number of businesses in California. Similarly, Exhibit 4 is a publication by the California Department of Public Health regarding heart disease mortality trends in the state of California.

The Court could "consider[]" these publications even absent a "formal" request for judicial notice, because they contain information that bears on the incidence of cardiac arrest and is thus relevant to the "purpose of determining" whether "'a no-duty rule is appropriate'" in this case. (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 775 fn.5 [quoting Restatement (Third) of Torts § 7 cmt. b].) Because official publications of state agencies are also the proper subject of judicial notice, and acting, Target requests out of an abundance of caution that the Court take judicial notice of them. (See *Javor v. State Bd. of Equalization* (1974) 12 Cal.3d 790, 796 [publications of state agencies are subject to judicial notice as "official acts"]; *Board of Ed. of City of L.A. v. Watson* (1966) 63 Cal.2d 829, 836 ["[W]e may take judicial notice of this data since they are contained in a publication issued by an agency of the state."].)

4. Exhibits 5 and 6 are publications of the United States Food and Drug Administration, and Exhibit 7 is a publication of the United States Department of Labor. These publications provide background information regarding the failure rates of AEDs, the general effectiveness of AEDs, and governmental recalls of such devices. As with the state publications discussed above, the Court could consider these federal publications "as background to [its] determination of the law without taking formal notice of it." (*Cabral*, 51 Cal.4th at 775 fn.5.) These publications demonstrate the wide variation in reported results from AED use and thus bear on the question whether the Court should recognize a duty to install AEDs. As relevant publications of federal agencies, both documents are also the proper subject of a request for judicial notice. (*E.g.*, *Etcheverry v.*

Tri-Ag Serv., Inc. (2000) 22 Cal.4th 316, 330-31; *Smiley v. Citibank* (1995) 11 Cal.4th 138, 145 n.2.)

5. Exhibits 8 through 19 are scholarly articles concerning sudden cardiac arrest, the efficacy of AEDs, and the rarity with which business invitees suffer cardiac arrest in retail establishments. These articles provide highly relevant "viewpoints and generalized statements about the state of the world" (*Cabral*, 51 Cal.4th at 775 fn.5), illustrating both the low probability that retail customers will require an AED and the low probability that a customer suffering from cardiac arrest will be saved by an AED; They thus serve "as an aid to the court's work of interpreting, explaining and forming the law" and could also be considered even absent a request for judicial notice. (*Ibid.*)

Respondent requests judicial notice of these articles only out of an abundance of caution. Because these articles have been published, judicial notice is not required: "Citation to the material is sufficient." *Quelimane Co. v. Stewart Title Guaranty Co.*, (1998) 19 Cal.4th 26, 46 fn. 9 ["A request for judicial notice of published material is unnecessary."]). To the extent necessary, however, the articles may also be judicially noticed. (See, *e.g.*, *Gavin W. v. YMCA of Metropolitan L.A.* (2003) 106 Cal.App.4th 662, 672 n.6 [taking notice of research articles providing relevant background in a negligence action].)

CONCLUSION

For the foregoing reasons, Respondent Target Stores respectfully requests this Court take judicial notice of Exhibits 1 through 19.

Dated: August 9, 2013

Respectfully submitted,

Donald M. Falk (SBN 150256)
Foster C. Johnson (SBN 289055)
MAYER BROWN LLP
Two Palo Alto Square, Suite 300
3000 El Camino Real
Palo Alto, CA 94306-2112

Attorneys for Respondent Target Stores

DECLARATION OF FOSTER C. JOHNSON

I, Foster C. Johnson, declare as follows:

1. I am a member of the State Bar of California, and counsel for respondent Target Stores.

2. I am familiar with the facts represented in this Request for Judicial Notice, and declare that they are true and correct. I personally obtained the documents accompanying this Request for Judicial Notice from reliable sources.

3. Exhibit 1 is a true and correct copy of Assembly Committee on Judiciary, Background Information Request, Sen. Bill 911 (1999–2000 Reg. Sess.). This document was obtained by the staff of Legislative Research & Intent LLC from the designated official, public sources. A sworn authentication of this document by Lisa Hampton, Research Director of Legislative Research & Intent LLC, is attached.

4. Exhibit 2 is a true and correct copy of Cal. Health and Human Services Agency, Enrolled Bill Rep. on Assem. Bill No. 1312 (2009–2010 Reg. Sess.) prepared for Governor Schwarzenegger (Sept. 29, 2009). This document was obtained by the staff of Legislative Research & Intent LLC from the designated official, public sources. A sworn authentication of this document by Lisa Hampton, Research Director of Legislative Research & Intent LLC, is attached.

5. Exhibit 3 is a true and correct copy of a publication of the California Employment Development Department entitled “Size of Business Data For California (Quarterly), Payroll and Number of Businesses by Size of Business – Classified by Industry (Table 2A) (Qtr. 2, 2012).” I personally obtained this document from the state agency website, available at http://www.labormarketinfo.edd.ca.gov/Content.asp?pageid=1045

6. Exhibit 4 is a true and correct copy of a publication by the California Department of Public Health entitled “Heart Disease Mortality Data Trends, California 2000-2008.” I personally obtained this document from the state agency website, available at http://www.cdph.ca.gov/programs/ohir/Pages/Heart2008PrinterVersion.aspx.

7. Exhibit 5 is a true and correct copy of a publication of the United States Food and Drug Administration entitled “External Defibrillator Improvement Initiative Paper.” I personally obtained this document from the FDA’s website, available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/ExternalDefibrillators/ucm232621.htm

8. Exhibit 6 is a true and correct copy of a publication of the United States Food and Drug Administration entitled “Class 2 Recall Phillips and Laerdal Brands of HeartStart HS1 Defibrillator Family.” I personally

obtained this document from the FDA's website, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=113133

9. Exhibit 7 is a true and correct copy of a publication of the United States Department of Labor, Occupational Safety and Health Administration, *Automated External Defibrillators.* I personally obtained this document from the Department of Labor's Website, available at http://www.osha.gov/SLTC/aed/.

9. Exhibit 8 is a true and correct copy of an article by Linda Becker, M.A., et al., *Public Locations of Cardiac Arrest: Implications for public access defibrillation*, Circulation 97:2106-2109 (1998). I personally obtained this document from the American Heart Association website, available at http://circ.ahajournals.org/content/97/21/2106.long

10. Exhibit 9 is a true and correct copy of an article by Hoag Levins, *The Automated External Defibrillator: Medical Marvel But Measurement Mystery*, U. Penn. LDI Health Economist (May 2012). I personally obtained this document from the LDI Health Economist website, available at http://ldihealtheconomist.com/he000019.shtml

11. Exhibit 10 is a true and correct copy of an article by Mary F. Hazinski, et al., *Lay Rescuer Automated External Defibrillator Programs*, Circulation 111: 3336-3340 (2005). I personally obtained this document from the American Heart Association website, available at http://circ.ahajournals.org/content/111/24/3336.full

12. Exhibit 11 is a true and correct copy of an article by JA Drezner, KJ Rogers, & JG Horneff, *Automated External Defibrillator Use at NCAA Division II and III Universities*, Brit. J Sports Med., 45: 1174-1178 (2011). I personally obtained this document from the British Journal of Sports Medicine website, available at http://bjsm.bmj.com/content/early/2010/11/15/bjsm.2009.070052.abstract

13. Exhibit 12 is a true and correct copy of an article by Larry M. Starr, *Automated External Defibrillation in the Occupational Setting*, J. of Occupational and Emergency Med. Vol. 54 No. 9 1170 (Sept. 2012). I personally obtained this document from the American College of Occupational and Emergency Medicine website, available at http://www.acoem.org/uploadedFiles/Public_Affairs/Policies_And_Position_Statements/Guidelines/Position_Statements/Automated%20External%20Defibrillation%20in%20Occup%20Setting.pdf

14. Exhibit 13 is a true and correct copy of an article by Terence D. Valenzuela, M.D., et al., *Outcomes of Rapid Defibrillation by Security Officers after Cardiac Arrest in Casinos*, New Eng. J. Med. 2000, 343:1206-1209 (Oct. 2000). I personally obtained this document from the New England Journal of Medicine website, available at http://www.nejm.org/doi/full/10.1056/NEJM200010263431701

15. Exhibit 14 is a true and correct copy of an article by Myron L. Weisfeldt, M.D., et. al, *Ventricular Tachyarrhythmias After Cardiac Arrest*

in Public Versus at Home, New Eng. J. Med. 2011, 364:313-21 (Feb. 2011). I personally obtained this article from the New Journal of Medicine website, available at http://www.medpagetoday.com/upload/2011/1/26/nejmoa1010663.pdf

16. Exhibit 15 is a true and correct copy of an article by Comilla Sasson, M.D., et. al, *Predictors of Survival From Out-of-Hospital Cardiac Arrest: A Systematic Review and Meta-Analysis, Circulation: Cardiovascular Quality and Outcomes 2010*; 3:63-81. I personally obtained this document from the American Heart Association website, available at http://circoutcomes.ahajournals.org/content/3/1/63.long

17. Exhibit 16 is a true and correct copy of an article published by the American Heart Association, *First Aid*, Circulation (112: III-115-III-125) at III-115 (Nov. 29, 2005). I personally obtained this document from the American Heart Association website, available at http://circ.ahajournals.org/content/112/22_suppl/III-115.full

18. Exhibit 17 is a true and correct copy of a publication of the American Heart Association, *Defibrillation*, 112 Circulation III-17. I personally obtained this document from the American Heart Association website, available at http://circ.ahajournals.org/content/112/22_suppl/III-17.full.pdf+html

19. Exhibit 18 is a true and correct copy of an article by Mary P. Larsen, et al., *Predicting Survival From Out-of-Hospital Cardiac Arrest: A Graphic*

Model, Annals of Emergency Med. 1652 (1993). I personally obtained this document from the Annals of Emergency Medicine website, available at http://www.annemergmed.com/article/S0196-0644(05)81302-2/abstract

20. Exhibit 19 is a true and correct copy of a publication by the American Heart Association entitled "CPR & Sudden Cardiac Arrest (SCA) Fact Sheet." I personally obtained this document from the American Heart Association website, available at http://www.heart.org/HEARTORG/CPRAndECC/WhatisCPR/CPRFactsandStats/CPR-Statistics_UCM_307542_Article.jsp.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on August 9, 2013, at Palo Alto, California.

By: Foster C. Johnson

Legislative Research & Intent LLC

1107 9th Street, Suite 220, Sacramento, CA 95814
(800) 530.7613 · (916) 442.7660 · fax (916) 442.1529
www.lrihistory.com · intent@lrihistory.com

Authentication of the Records and Table of Contents

Legislative History Research Report Regarding:
CALIFORNIA CIVIL CODE § 1714.21
As Added By Statutes of 1999, Chapter 163, § 2, SB 911 – Figueroa

I, Lisa Hampton, declare that this report includes:

- *Historical documents relating to the above legislation.* These documents were obtained by the staff of Legislative Research & Intent LLC and are true and correct copies of the originals obtained from the designated official, public sources in California unless another source is indicated, with the following exceptions: In some cases, pages may have been reduced in size to fit an 8 ½" x 11" sized paper. Or, for readability purposes, pages may have been enlarged or cleansed of black marks or spots. Lastly, paging and relevant identification have been inserted.

  Since 1983 LRI has specialized in the historical research surrounding the adoption, amendment and/or repeal of California statutes, regulations and constitutional provisions pursuant to California Code of Civil Procedure § 1859 which states in pertinent part: "In the construction of a statute the intention of the Legislature ... is to be pursued, if possible ...." Our research and expert witness services have assisted the courts in understanding and applying the underlying purpose of enactments in countless cases, such as *Redlands Community Hospital v. New England Mutual Life Insurance Co,* 23 Cal. App.4th 899 at 906 (1994). LRI also provides similar research for other states and at the federal level. (Formerly Legislative Research Institute and Legislative Research, Incorporated.)

- *A table of contents itemizing the documents.* This table of contents cites the sources of the documents.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct and that I could and would so testify in a court of law if called to be a witness.

Executed March 12, 2013, in Sacramento, California.

Lisa Hampton, Research Director

Table of Contents

PRIMARY SOURCE RECORDS (UNPUBLISHED HARDCOPY): At least one official California source is cited for the primary source records provided in this report. Multiple copies may have been obtained from various sources (primarily State Archives, the state library system and/or legislative offices), but the clearest/most legible version was selected for this report.

ENACTMENT HISTORY

GENERAL

DOCUMENTS GENERATED DURING
SENATE DELIBERATIONS

NOTE: The Senate reported the bill off the *floor* and to the Assembly on "Consent," signifying lack of controversy, no debate or discussion, with the roll-call substituting for the vote.

DOCUMENTS GENERATED DURING ASSEMBLY DELIBERATIONS

NOTE: The Assembly reported the bill off the *floor* and to the Senate on "Consent," signifying lack of controversy, no debate or discussion, with the roll-call substituting for the vote.

SENATE "CONCURRENCE" DOCUMENTS

NOTE: If the bill was amended "in the other house" (i.e., an Assembly Bill amended in the Senate or vice versa) it must return to the house of origin for "concurrence" on the other house's amendment(s). Concurrence results in immediate passage to the enrolled bill file (to the Governor). Nonconcurrence forces the bill into a joint house "conference committee."

Here there was concurrence.

NOTE: The Senate reported the bill off the *floor* and to the Governor on "Consent," signifying lack of controversy, no debate or discussion, with the roll-call substituting for the vote.

ENROLLED (GOVERNOR) MATERIALS
FROM STATE ARCHIVES

UNITEMIZED CORRESPONDENCE/MATERIALS
BY SOURCE FROM STATE ARCHIVES

FAILED LEGISLATION

PREDECESSOR (From a Previous Session)
Assembly Bill 2371 - Leonard

UNITEMIZED MATERIALS BY SOURCE

Legislative Research & Intent LLC

1107 9th Street, Suite 220, Sacramento, CA 95814
(800) 530.7613 · (916) 442.7660 · fax (916) 442.1529
www.lrihistory.com · intent@lrihistory.com

Authentication of the Records and Table of Contents

Legislative History Research Report Regarding:
CALIFORNIA HEALTH & SAFETY CODE § 104113
As Amended By Statutes of 2010, Chapter 500, § 1, SB 127 – Calderon

I, Lisa Hampton, declare that this report includes:

- *Historical documents relating to the above legislation.* These documents were obtained by the staff of Legislative Research & Intent LLC and are true and correct copies of the originals obtained from the designated official, public sources in California unless another source is indicated, with the following exceptions: In some cases, pages may have been reduced in size to fit an 8 ½" x 11" sized paper. Or, for readability purposes, pages may have been enlarged or cleansed of black marks or spots. Lastly, paging and relevant identification have been inserted.

  Since 1983 LRI has specialized in the historical research surrounding the adoption, amendment and/or repeal of California statutes, regulations and constitutional provisions pursuant to California Code of Civil Procedure § 1859 which states in pertinent part: "In the construction of a statute the intention of the Legislature ... is to be pursued, if possible ...." Our research and expert witness services have assisted the courts in understanding and applying the underlying purpose of enactments in countless cases, such as *Redlands Community Hospital v. New England Mutual Life Insurance Co,* 23 Cal. App.4th 899 at 906 (1994). LRI also provides similar research for other states and at the federal level. (Formerly Legislative Research Institute and Legislative Research, Incorporated.)

- *A table of contents itemizing the documents.* This table of contents cites the sources of the documents.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct and that I could and would so testify in a court of law if called to be a witness.

Executed March 13, 2013, in Sacramento, California.

Lisa Hampton, Research Director

Table of Contents

PRIMARY SOURCE RECORDS (UNPUBLISHED HARDCOPY): At least one official California source is cited for the primary source records provided in this report. Multiple copies may have been obtained from various sources (primarily State Archives, the state library system and/or legislative offices), but the clearest/most legible version was selected for this report.

GUIDING COMMENTS: The language of interest did not enter the bill until the June 1, 2010, amendment, when the entire bill was gutted while in the Assembly. Prior to this amendment, the bill dealt with a different subject matter: mortgages. Because the earlier documents were off-topic, we have done our best to eliminate them from this report, including only those documents that relate to the subject of the amended bill.

ENACTMENT HISTORY

GENERAL

DOCUMENTS GENERATED DURING ASSEMBLY DELIBERATIONS

SENATE "CONCURRENCE" DOCUMENTS

NOTE: If the bill was amended "in the other house" (i.e., an Assembly Bill amended in the Senate or vice versa) it must return to the house of origin for "concurrence" on the other house's amendment(s). Concurrence results in immediate passage to the enrolled bill file (to the Governor). Nonconcurrence forces the bill into a joint house "conference committee."

Here there was concurrence.

ENROLLED (GOVERNOR) MATERIALS
FROM STATE ARCHIVES

UNITEMIZED CORRESPONDENCE/MATERIALS
BY SOURCE FROM STATE ARCHIVES

PUBLISHED AND/OR MISCELLANEOUS MATERIALS

FAILED LEGISLATION

CONCURRENT (Same Session)
Assembly Bill 1312 - Swanson

UNITEMIZED MATERIALS BY SOURCE

FAILED LEGISLATION

PREDECESSOR
Assembly Bill 2130 - Hayashi

UNITEMIZED MATERIALS BY SOURCE

Legislative Research & Intent LLC

1107 9th Street, Suite 220, Sacramento, CA 95814
(800) 530.7613 · (916) 442.7660 · fax (916) 442.1529
www.lrihistory.com · intent@lrihistory.com

General Enactment History

Legislative Research & Intent LLC hereby certifies that the accompanying record/s is/are true and correct copies of the original/s obtained from one or more official, public sources in California unless another source is indicated, with the following exceptions : In some cases, pages may have been reduced in size to fit an 8 ½" x 11" sized paper. Or, for readability purposes, pages may have been enlarged or cleansed of black marks or spots. Lastly, for ease of reference, paging and relevant identification have been inserted.

SENATE COMMITTEE ON JUDICIARY
Adam Schiff, CHAIRMAN

BACKGROUND INFORMATION REQUEST

Measure: SB 911

Author : Senator Figueroa

1. Origin of the bill:

a. Who is the source of the bill? What person, organization, or governmental entity requested introduction?

____

____

b. Has a similar bill been before either this session or a previous session of the legislature? If so, please identify the session, bill number and disposition of the bill.

____

c. Has there been an interim committee report on the bill? If so, please identify the report.

____

2. What is the problem or deficiency in the present law which this bill seeks to remedy?

____

____

____

____

3. Please attach copies of any background material in explanation of the bill, or state where such material is available for reference by committee staff.

____

4. Please attach copies of letters of support or opposition from any group, organization, or governmental agency who has contacted you either in support or opposition to the bill.

5. If you plan substantive amendments to this bill prior to the hearing, please explain briefly the substance of the amendments to be prepared.

____

6. List the witnesses you plan to have testify.

____

____

____

____

RETURN THIS FORM TO: SENATE COMMITTEE ON JUDICIARY
Phone (916) 445-5957

STAFF PERSON TO CONTACT: ______________________________

Senate Bill 911

1.

a. American Heart Association. Marc Burgat, Director of Public Affairs. 446-6505

b. AB 2371 (Leonard) from the previous session (1997-98) addressed the same issue. This bill was passed by the Assembly Health Committee on April 21, 1998, on a 16-0 vote. The bill was later defeated in the Assembly Judiciary Committee on May 5, 1998, by a 6-1 vote missing the nine votes necessary to pass. This was the last Judiciary committee hearing of the year and reconsideration could not be granted. The only opposition to AB 2371 was the Consumer Attorneys of California. CAOC's concern regarding training requirements has been fully addressed by this legislation.

c. N/A

2. Over 2,900 people suffer sudden cardiac arrest in California every month (37,500 nationally). It is estimated that over 460 of these occur in public places and some 440 of those people will die. Survival rate for victims of sudden cardiac outside of a hospital setting without defibrillation is less than 1%. The only realistic these victims have for survival is to be defibrillated. The window of opportunity for resuscitation is extremely short. Brain damage occurs within 4 minutes and resuscitation is possible for no more than 10 minutes, possibly 12-13 minutes if CPR is administered correctly. In cases of sudden cardiac arrest, CPR is merely a maintenance tool; defibrillation must take place to "shock" the patient's heart into a proper working rhythm.

Senate Bill 911 extends Good Samaritan protections to those who use an AED in an emergency situation under certain specified conditions. To date, 21 states have passed legislation Good Samaritan protection for AED lay-users.

The question of liability when using an AED in an emergency situation under current Good Samaritan laws was posed to the Legislative Counsel in 1998, and the response was equivocal. The law is silent when discussing civil liability and AED use. In practice, California businesses are reluctant to incorporate the use of AEDs in their facilities until this issue is addressed adequately and directly. Risk managers are often advising businesses that the purchase and use of an AED could expose the business to liability lawsuits. Arco Arena in Sacramento is one example of a business that would like to have AEDs at their facility but have concerns over liability issues.

By granting Good Samaritan protections for good faith use of AEDs many more locations will be able to make these life saving devices available. It is estimated that resuscitation rates can be raised to 30-60% when a defibrillator is available and used by a trained Good Samaritan.

3. See attached

4. See attached

5. No

6. American Heart Association
   American Red Cross
   California Labor Federation
   AED Survivor
   EMSA representative and will be available for technical questions

Staff Person to Contact: Monica Pacheco - 445-6671

L:Sen Judiciary Background

American Heart Association[SM]
Fighting Heart Disease and Stroke

SB 911
Senator Figueroa (D, Fremont)
AED Good Samaritan Liability Protections

FACT SHEET

What SB 911 does: Senate Bill 911 extends Good Samaritan protections to individuals who use an *automated external defibrillator* (AED) in an emergency situation under certain specified conditions. The bill is patterned after the national American Heart Association model Good Samaritan legislation.

This legislation has three main points: 1) Protections from civil liability; 2) Training requirements; 3) Requires notification of local Emergency Medical Services. To date, 23 states have passed legislation Good Samaritan protection for AED lay-users.

The need: Over 2,900 people suffer sudden cardiac arrest (SCA) in California every month. It is estimated that over 460 of these occur in public places and some 440 of those people will die. Survival rate for victims of SCA outside of a hospital setting is less than 5 percent.

Technology has come a long way to make these medical devices safe and easy-to-use. The new generation of AEDs contain microcomputers to accurately identify sudden cardiac arrests and make extensive use of audible prompting and signals to provide trained operators with clear and concise instruction, making their use uncomplicated, intuitive, and nearly foolproof. Safeguards are built in to protect both operator and victim and to ensure that the AED will only deliver a shock if the victim is in SCA.

Principal Co-author: Assemblyman Oller (R, San Andreas); **Senate Co-authors:** Alarcon (D, Sylmar), Morrow (R, Oceanside), Peace (D, El Cajon), Perata (D, Alameda), Rainey (R, Walnut Creek), Solis (D, El Monte); **Assembly Co-authors:** Baugh (R, Huntington Beach), Cardoza (D, Merced), Romero (D, Los Angeles), Torlakson (D, Antioch), Wildman (D, Los Angeles), Zettle (R, Poway)

Organizational support for SB 911: American Red Cross, California Labor Federation (AFL-CIO), California Chamber of Commerce, California Medical Association, Emergency Medical Services Administrators' Assoc., Kaiser Permanente, Emergency Nurses Association, American College of Cardiology, and City and County of San Francisco.

Public support: 86 percent of Californians favor giving civil liability protection to trained individuals who use an automated external defibrillator as Good Samaritans. (Feb. 1999)

Status: Introduced February 25, 1999; Senate Judiciary Committee hearing April 13, 1999

For more information, contact Marc Burgat at 916/446-6505 or marcb@heart.org, or Kirk Kleinschmidt at 415/433-2273 or kirkk@heart.org.

4/6/99

ENROLLED BILL MEMORANDUM TO GOVERNOR

BILL: AB 1312 **AUTHOR:** Swanson **DATE:** 09/29/09 **DUE:** 10/11/09
ASSEMBLY: 77-0 **SENATE:** 24-9 **CONCURRENCE:** 76-2
PRESENTED BY: Jennifer Kent **RECOMMEND:** Sign ☐ Veto ☐

SUMMARY

This bill extends the existing sunset date from July 21, 2012 to July 1, 2014, on the requirement that every health studio to acquire, maintain, and train personnel on the use of an automatic external defibrillator (AED). The bill also extends the AED requirement to golf courses and permanent amusement parks commencing July 1, 2010, with the latter under the jurisdiction of the Cal/OSHA program.

SPONSOR: Author

SUPPORT: Health and Human Services Agency
Emergency Medical Services Authority
Labor and Workforce Development Agency
Department of Industrial Relations

OPPOSITION: None Received

FISCAL IMPACT

This bill would have no fiscal impact on the State. This bill would increase costs to golf courses and amusement parks. Each defibrillator is estimated to cost between $1,000 and $3,000, with training costs approximately $32 per person.

PREVIOUS ACTION/SIMILAR LEGISLATION

AB 1507 (Pavley, Chapter 431, Statutes of 2005) established the requirement that health studios acquire, maintain, and train personnel in the use of AEDs. This law also extended immunity to health studios for proper use of an AED during emergency situations.

NOTES

CHHS
California Health & Human Services Agency

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY

ENROLLED BILL REPORT

CONFIDENTIAL-Government Code §6254(l)		
Department/Board: Emergency Medical Services Authority	Author: Asm. Swanson	Bill Number/Version Date: AB 1312 September 1, 2009
Sponsor: Author ☐ Admin Sponsored Proposal No.	Related Bill(s)	Chaptering Order (if known) ☐ Attachment
Subject: Defibrillators		

SUMMARY

This bill would extend to July 1, 2014 the sunset date for existing law requiring health studios to acquire automated external defibrillators (AEDs), train personnel in proper use, and maintain cardio-pulmonary resuscitation (CPR) and AED-trained personnel on site during all operating hours. This bill would add golf courses and permanent amusement parks to the current health studio requirement to implement AED programs.

RECOMMENDATION AND SUPPORTING ARGUMENTS

Sign. This bill would facilitate the increased availability and use of AEDs in venues known to involve heightened risk of cardiac arrest. It would also limit potential civil liability for golf courses and permanent amusement parks that implement AED programs.

PURPOSE OF THE BILL

The purpose of this bill is to extend the lifesaving benefits of early AED use during cardiac arrest for a greater length of time and to additional recreational facilities where the likelihood of cardiac arrest is increased. The bill would also extend, to golf courses and permanent amusement parks, the limited civil liability immunity for AED use currently covering health studios.

Departments That May Be Affected	
☐ New or Increased Fee ☐ Governor's Appointment ☐ Legislative Appointment ☐ State Mandate ☐ Urgency Clause ☐ Legislative Report ☐ Regulations Required	
Dept/Board Position ☒ Sign ☐ Veto ☐ Defer to:	Agency Secretary Position ☑ Sign ☐ Veto ☐ Defer to:
Director Date 9/11/09 R. Steven Tharratt, MD, MPVM	Agency Secretary Date 9/13/09 Kimberly Belshé, Secretary

ANALYSIS

Existing Law:

Existing law requires defibrillators and trained staff to be available in a variety of public venues. Under current law, through July 1, 2012, every health studio is required to have and maintain an AED, to train staff on CPR and AED use within 30 days of employment, and to have a written emergency plan that includes procedures related to use of the AED. The law additionally provides limited civil liability protection for an employee who renders emergency medical care related to AED use, attempted use or non-use as well as to the health studio owners, managers and boards of directors.

This bill would make the following changes:

- Commencing July 1, 2010, this bill would require golf courses and permanent amusement parks to:
  1) Acquire AEDs;
  2) Train all employees in CPR and AED use;
  3) Test and maintain the AED every 30 days and after every deployment;
  4) Activate EMS system upon use of AED;
  5) Immediately report deployment of AED to the AED provider's medical director and the local EMS agency; and
  6) Create a written emergency plan to describe procedures to be followed in the event of an emergency that may involve the use of an AED.

  The above provisions are required to start a public access defibrillation program and are currently required, in law, for other mandated facilities.

  Extending the requirement to other recreational sites will make AEDs more available in public areas where cardiac arrests tend to be increased. By placing AEDs on golf courses and permanent amusement parks, locations where these devices tend to be more in need, clientele may be assisted with early defibrillation by trained employees or lay rescuers while waiting for EMS to arrive on scene. However, depending on the size and layout of the course, AEDs may be ineffective unless they are strategically and proximally located. An AED may not be effective unless it can be applied to the patient within 4 minutes of cardiac arrest.

  The Golf Course Superintendents Association of America's website states that sudden cardiac arrest is the number one killer on courses. According to the Red Cross, golf courses and sports stadiums are two of the top five most likely spots for cardiac arrest. Most large amusement parks and aquatic facilities already have AEDs on site in multiple locations.

- This bill would also extend the sunset date for existing AED requirements by an additional five years, to July 1, 2014. Extending the sunset date of the requirement for health clubs to maintain AED programs would ensure that individuals experiencing cardiac arrest have access to immediate, life-saving emergency medical assistance.

- This bill would require that records be maintained for two years after the AED is checked for readiness.

LEGISLATIVE HISTORY

AB 3037 (Chandler), Chapter 217, Statutes of 1988, created Section 1797.190 of the H&SC. that requires the EMS Authority to establish minimum standards for the training and use of AEDs. This Section also requires involvement of a licensed physician to authorize individuals to use an AED.

SB 911 (Figueroa), Chapter 163, Statutes of 1999, created Section 1714.21 of the Civil Code and Section 1797.196 of the H&SC. This new section of the Civil Code provides immunity from civil liability to trained AED users. This section of the H&SC requires the involvement of a physician in AED programs, compliance with all regulations governing training, use and placement of AEDs, and certain maintenance requirements.

AB 2041 (Vargas), Chapter 718, Statutes of 2002, deleted the requirement that a physician specifically authorize in writing every individual to use an AED. The new requirement in the H&SC requires a minimum number of AED trained individuals be present during normal operating hours when an AED program is established, deletes the requirement for CPR and AED training for all individuals using the AED, and provides immunity from civil liability for AED users under specified conditions until January 1, 2008.

AB 1507 (Pavley), Chaper 431, Statutes of 2005, stated that health club facilities will be included in the immunity from civil liability that is contained in Section 1714.21 of the Civil Code.

AB 254 (Nakanishi), Chapter 111, Statutes of 2005, allows public or private K-12 schools to have AEDs and specifies conditions that will ensure that they are covered by the existing immunity from civil liability when implementing an AED program in their schools.

AB 2083 (Vargas) of 2006, Ch. 85 of 2006, extends the sunset date for another five years on the operative provisions of existing law which provide immunity from civil damages for persons or entities that acquire automatic external defibrillators (AEDs) and comply with maintenance, testing, and training requirements.

AB 2130 (Hayashi) of 2008, would have exempted health studios that do not maintain personnel on the premises from the requirements of maintaining personnel trained in AED at all times on site. This bill would have required, as a condition of that exemption, that such studios have a telephone on premises; as well as signs that (a) warn of the potential health and safety risks of exercising alone, (b) provide instructions in CPR and AED use, and (c) indicate the location of all AEDs on the premises. The bill died in the Senate Judiciary Committee.

AB 142 (Hayashi) of 2009, would exempt health studios that do not maintain personnel on the premises from the requirements of maintaining personnel trained in AED at all times on site. This bill would require that those health studios provide members with a device that when activated would contact emergency services. Those health studios would also be required to install live video surveillance so that the person monitoring the live-feed would notify law enforcement or emergency services in the case of an emergency.

PROGRAM BACKGROUND

AEDs are compact, lightweight medical devices that, when properly applied, can analyze and determine if a cardiac arrest victim can be defibrillated, and, if so, prompt the rescuer to administer a defibrillatory shock. The American Heart Association (AHA) estimates that a cardiac arrest victim has seven to ten percent decrease in their chances of surviving a cardiac arrest for every minute that passes without being defibrillated. After ten minutes without defibrillation, a cardiac arrest victim's chances of survival are approximately zero to thirty percent.

The EMS Authority is responsible for adopting, amending and/or repealing regulations (H&SC, Division 2.5, Section 1797.190) that pertain to establishing minimum standards for training and use of AEDs. The EMS Authority has developed and implemented three chapters of regulations (California Code of Regulations, Title 22, Division 9) that establishe the training and implementation requirements for AED programs. Those chapters are:

- Chapter 1.5 – First Aid Standard for Public Safety Personnel (peace officers, firefighters, public lifeguards).
- Chapter 1.8 – Lay Rescuer Automated External Defibrillator Regulations.
- Chapter 2 – Emergency Medical Technician - I

OTHER STATES' INFORMATION

Delaware - FY 02 and 03 Budget, the state allocated $752,000 for 2001 and $375,000 for 2002 to buy defibrillators at a cost of $2,500 to $3,500 each as part of the *First State, First Shock!* Public Access Defibrillation Program. For FY'03 an additional $141,400 has been allocated from tobacco settlement funds. Schools, businesses and other public places must apply to the state Emergency Medical Services office, which determines how many defibrillators are needed based on the number of athletic programs or people congregating at a particular location.

Illinois - H4232 of 2004, required every physical fitness facility to have at least one AED on premises, by mid-July 2006, with exceptions.

Massachusetts, S 2631 of 2006, required an AED on health club premises during business hours; volunteer exemption from liability to users. Clubs with 6+ employees must comply by 2008, clubs with few than 5 employees must comply by 2009.

New York - A 8779 of 2002, establishes requirements for public school facilities with more than 1000 persons to provide and maintain on-site AED equipment. Also requires that all school sponsored activities have at least one AED trained staff person present.

Pennsylvania - HB 4 of 2001, established a one-time program to assist school entities to acquire AEDs. The funds were appropriated by the General Assembly and after a bidding process the statewide contract for two AEDs per school district was awarded - each school district was offered two free AEDs and each intermediate unit and area vocational-technical school was offered one free AED. In addition, AEDs are made available to other school entities including non-public, private, charter and independent schools that meet program requirements.

FISCAL IMPACT

The EMS Authority would have no fiscal impact.

ECONOMIC IMPACT

California golf courses and permanent amusement parks would have to implement and maintain AED programs at their facilities. The costs of an AED vary by manufacturer and by the accessories that are ordered with each AED unit. Costs can range from $1,000 to $2,000 per AED unit. Actual costs will vary throughout the state and will differ depending on the manufacturer and number of AEDs purchased as well as additional defibrillator patches (typically a two year shelf life), spare AED batteries (typically a five year life), AED cases or cabinets, other supplies such as barrier devices, scissors to remove clothing, gloves, and training accessories. Additional costs, which also vary throughout California, include training and retraining, maintenance, and physician oversight.

LEGAL IMPACT

This bill will protect golf courses and permanent amusement parks from civil liability that would result from any acts or omissions in rendering emergency care via AED and/or CPR.

APPOINTMENTS

No appointments.

SUPPORT/OPPOSITION

Support:
American Red Cross
California Professional Firefighters
City of Sacramento
Sudden Cardiac Arrest Association

Opposition: None on file.

ARGUMENTS

Pro:

- Requiring AEDs and trained staff at golf courses and permanent amusement parks would [illegible] availability and use of AEDs in venues known to involve heightened risk of cardiac arrest.
- The bill would reduce the risk to golf courses and permanent amusement parks that implement AED programs by limiting potential civil liability associated with AED use.

- Extending the sunset date of the requirement for health clubs to maintain AED programs would ensure that individuals experiencing cardiac arrest have access to immediate, life-saving emergency medical assistance.

Con:

- The cost of implementing an AED program would result in increased costs for operators of golf courses and permanent amusement parks and be extended for health club operators.
- Depending on the size and layout of the course, AEDs may be ineffective unless they are strategically and proximally located. An AED may not be effective unless it can be applied to the patient within 4 minutes of cardiac arrest.

VOTES

	DATE	RESULT	TALLY
Assembly Concurrence	9/9/09	Pass	Y:76 N:2
Senate Floor	9/2/09	Pass	Y:24 N:9
Senate Fiscal – NA non-fiscal			
Senate Policy	7/14/09	Pass	Y:4 N:0
Assembly Floor	5/18/09	Pass	Y:77 N:0
Assembly Fiscal – N/A non-fiscal		Pass	
Assembly Policy	5/5/09	Pass	Y:10 N:0

LEGISLATIVE STAFF CONTACT

Contact
Kim Belshé, CHHSA Secretary
Scott Carney, CHHSA Legislative Director
Dr. Steve Tharratt, Director
Dan Smiley, Chief Deputy Director
June Iljana, Legislative Coordinator

VETO MESSAGE

To the Members of the California State Assembly:

I am returning Assembly Bill 1312 without my signature.

This bill would increase costs for operators of golf courses and permanent amusement parks by requiring them to provide, maintain and train employees to use automatic external defibrillators with no clear evidence that the availability of these devices would save lives. Due to the size and layout of a course or park, AEDs may be ineffective unless it can be applied to the patient within 4 minutes of cardiac arrest.

Sincerely,

Arnold Schwarzenegger

Size of Business Data for California (Quarterly)

These tables are from "**California Size of Business -- Number of Businesses by Employment Size, and Industry**" for 2009 - 2012.

Definitions of Terms and Source Notes.

Description	2012 (Excel)	2011 (Excel)	2010 (Excel)	2009 (Excel)
Charts - Number of Businesses and Number of Employees by Size of Business (Based on Table 1 – Adobe Acrobat format)	Qtr 1 Qtr 2	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4
Number of Businesses, Number of Employees, and Payroll by Size of Business (Table 1)	Qtr 1 Qtr 2	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4
Payroll and Number of Businesses by Size of Business - Classified by Industry (Table 2A)	Qtr 1 Qtr 2	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4
Number of Employees by Size Category – Classified by Industry (Table 2B)	Qtr 1 Qtr 2	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4

For a explanation of what industries are included.

Annual statewide and county Size of Business Data for third quarter

Additional size of business data by county and industry are available from the U.S. Census Bureau in their "County Business Patterns" report. The data for 1998 to the present are available by NAICS and 1994 to 1997 by Standard Industry Classification.

Table 2A: Second Quarter Payroll and Number of Businesses by Size Category
Classified by North American Industry Classification System (NAICS) for California
Second Quarter, 2012

NAICS Code	Industry	Second Quarter Payroll (in thousands)	Total	Number of Businesses by Size Category								
				0-4	5-9	10-19	20-49	50-99	100-249	250-499	500-999	1000+
	Total All Industries	$200,160,799	1,419,942	1,021,350	155,593	108,635	80,418	31,704	15,896	3,944	1,489	913
11	Agriculture, Forestry, Fishing, Hunting	$2,784,082	16,421	8,352	2,767	2,055	1,615	723	516	243	101	49
111	Crop Production	$1,285,260	9,600	5,341	1,589	1,127	820	349	244	82	(2)	(2)
112	Animal Production	$227,754	2,664	1,244	557	450	341	50	18	4	0	0
113	Forestry and Logging	$23,425	298	156	59	(2)	(2)	9	4	0	(1)	0
114	Fishing, Hunting and Trapping	$5,876	196	168	20	(2)	(1)	0	0	0	0	0
115	Agric and Forestry Support Activities	$1,241,766	3,663	1,443	542	430	425	315	250	157	(2)	(2)
21	Mining	$787,733	736	285	118	119	111	50	26	17	6	4
211	Oil and Gas Extraction	$434,210	178	69	28	28	24	9	11	5	(1)	(1)
212	Mining, except Oil and Gas	$91,108	219	72	39	46	35	20	3	(2)	(1)	0
213	Support Activities for Mining	$262,414	339	144	51	45	52	21	12	(2)	3	(1)
22	Utilities	$1,436,854	1,173	478	227	134	139	73	75	28	9	10
23	Construction	$8,076,596	62,109	38,382	10,681	6,721	4,344	1,285	539	112	34	11
236	Construction of Buildings	$1,980,110	20,087	13,971	2,973	1,727	1,005	278	107	22	(2)	(1)
237	Heavy & Civil Engineering Construction	$1,358,825	3,471	1,686	564	499	436	151	92	27	(2)	(2)
238	Special Trade Contractors	$4,737,661	38,551	22,725	7,144	4,495	2,903	856	340	63	21	4
31-33	Manufacturing	$22,600,057	39,371	15,095	7,208	6,356	5,809	2,511	1,666	459	175	92
311	Food Manufacturing	$1,504,452	3,408	1,065	591	585	556	260	232	71	38	10
312	Beverage and Tobacco Products	$573,287	1,495	489	289	271	243	113	63	19	(2)	(1)
313	Textile Mills	$71,942	366	135	60	60	65	29	14	(1)	(1)	0
314	Textile Product Mills	$74,396	623	324	122	82	53	27	(2)	(1)	0	0
315	Apparel Manufacturing	$492,881	2,854	1,215	624	460	346	118	68	14	6	3
316	Leather and Allied Products	$28,347	152	69	25	25	15	12	(2)	(1)	(1)	0
321	Wood Products	$191,218	960	376	151	178	154	59	36	6	0	0
322	Paper Products	$296,894	491	121	77	55	101	68	61	(2)	(1)	0
323	Printing and Related Support Activities	$458,508	3,251	1,711	652	419	292	110	54	10	3	0
324	Petroleum and Coal Products	$491,670	244	105	31	41	29	13	10	7	(2)	(2)
325	Chemical Products	$1,664,540	1,761	584	305	308	293	136	89	28	12	6
326	Plastics and Rubber Products	$491,517	1,223	334	182	197	267	132	85	23	3	0
327	Nonmetallic Mineral Products	$363,186	1,189	378	210	235	230	82	45	(2)	(1)	0
331	Primary Metal Mfg	$279,133	539	177	87	77	98	48	44	4	4	0

Table 2A: Second Quarter Payroll and Number of Businesses by Size Category
Classified by North American Industry Classification System (NAICS) for California
Second Quarter, 2012

NAICS Code	Industry	Second Quarter Payroll (in thousands)	Total	Number of Businesses by Size Category								
				0-4	5-9	10-19	20-49	50-99	100-249	250-499	500-999	1000+
332	Fabricated Metal Products	$1,560,782	6,138	2,184	1,277	1,136	1,003	329	161	44	4	0
333	Machinery	$1,282,976	2,683	1,008	487	464	419	171	104	19	5	6
334	Computer and Electronic Products	$8,684,162	3,760	1,164	548	575	609	380	285	111	48	40
335	Electrical Equipment and Appliances	$443,592	961	299	166	161	174	86	61	(2)	(1)	0
336	Transportation Equipment	$1,994,162	1,550	505	277	248	238	112	97	37	22	14
337	Furniture and Related Products	$297,585	1,969	978	343	262	245	79	53	(2)	(1)	0
339	Misc Manufacturing	$1,354,827	3,754	1,874	704	517	379	147	87	26	11	9
42	Wholesale Trade	$10,777,108	57,292	32,153	10,753	7,188	4,854	1,432	710	140	52	10
423	Durable Goods Wholesalers	$5,423,661	25,148	12,614	5,286	3,662	2,487	710	305	57	21	6
424	Nondurable Goods Wholesalers	$3,494,480	18,514	9,973	3,496	2,374	1,701	556	323	65	26	0
425	Electronic Markets, Agents, Brokers	$1,858,968	13,630	9,566	1,971	1,152	666	166	82	18	5	4
44-45	Retail Trade	$12,457,544	95,054	39,861	23,482	15,339	9,404	4,260	2,229	434	37	8
441	Motor Vehicle and Parts Dealers	$2,017,848	9,101	3,245	2,211	1,759	1,004	561	299	18	(2)	(1)
442	Furniture and Home Furnishings	$411,396	4,889	2,526	1,042	748	450	89	25	6	3	0
443	Electronics and Appliance Stores	$1,320,560	5,512	2,829	1,520	577	300	163	109	(2)	(1)	0
444	Building Materials and Garden Supplies	$922,325	6,250	2,745	1,420	967	600	160	348	(2)	(1)	0
445	Food and Beverage Stores	$2,276,357	15,794	6,885	3,006	1,992	1,366	1,882	635	24	(1)	(1)
446	Health and Personal Care Stores	$1,011,145	10,255	4,159	2,518	2,125	1,345	69	(2)	5	(1)	(1)
447	Gasoline Stations	$290,774	6,174	2,000	2,679	1,180	247	49	(2)	(1)	(1)	0
448	Clothing and Clothing Accessories	$907,640	14,700	5,242	4,633	2,869	1,314	537	88	(2)	(1)	0
451	Sporting Goods, Hobby, Books, Music	$353,326	5,336	2,055	1,441	900	772	140	22	(2)	(1)	0
452	General Merchandise Stores	$1,672,720	3,786	894	311	418	820	411	594	319	16	3
453	Misc Store Retailers	$593,474	10,308	5,688	2,116	1,395	950	120	31	(2)	(1)	0
454	Nonstore Retailers	$679,979	2,949	1,593	585	409	236	79	29	14	(2)	(1)
48-49	Transportation and Warehousing	$4,813,135	17,942	8,533	3,336	2,496	2,093	797	480	120	54	33
481	Air Transportation	$676,509	491	183	62	89	75	31	27	9	8	7
482	Rail Transportation	$3,397	7	(2)	0	0	0	(1)	(1)	0	0	0
483	Water Transportation	$102,961	134	60	18	21	(2)	10	7	0	(1)	(1)
484	Truck Transportation	$1,156,354	7,343	3,881	1,312	923	791	273	125	25	7	6
485	Transit & Ground Passenger Transport	$298,366	1,610	680	283	234	211	99	(2)	17	(1)	0
486	Pipeline Transportation	$67,784	105	(2)	17	27	22	6	(1)	0	(1)	0
487	Scenic and Sightseeing Transportation	$35,896	266	122	59	38	26	11	10	0	0	0
488	Support Activities for Transportation	$1,061,004	4,581	2,187	964	659	530	150	64	17	6	4

Employment Development Department
Labor Market Information Division

Table 2A: Second Quarter Payroll and Number of Businesses by Size Category
Classified by North American Industry Classification System (NAICS) for California
Second Quarter, 2012

NAICS Code	Industry	Second Quarter Payroll (in thousands)	Total	Number of Businesses by Size Category								
				0-4	5-9	10-19	20-49	50-99	100-249	250-499	500-999	1000+
491	Postal Service	$3,877	104	71	18	9	(2)	(1)	0	0	0	0
492	Couriers and Messengers	$637,331	1,617	747	335	205	131	87	76	13	12	11
493	Warehousing and Storage	$769,656	1,684	567	268	291	286	(2)	83	39	(2)	(2)
51	Information	$10,837,020	18,341	11,204	2,294	1,860	1,606	718	427	122	65	45
511	Publishing Industries, except Internet	$2,532,460	3,177	1,633	535	392	320	131	115	25	17	9
512	Motion Picture and Sound Recording	$2,970,185	6,962	5,426	503	354	355	191	63	22	22	26
515	Broadcasting, except Internet	$977,579	1,056	418	153	149	141	89	70	27	6	3
517	Telecommunications	$1,806,838	4,368	2,126	685	659	541	201	112	26	15	3
518	Data Processing, Hosting and Related	$578,003	1,065	615	158	121	100	40	22	6	(1)	(1)
519	Other Information Services	$1,971,956	1,713	986	260	185	149	66	45	16	(2)	(1)
52	Finance and Insurance	$11,085,396	42,422	24,285	8,015	5,665	2,893	848	463	164	64	25
521	Monetary Authorities--Central Bank	$37,334	16	5	4	3	(1)	0	0	(1)	0	(1)
522	Credit Intermediation and Related	$4,300,181	15,720	5,598	4,259	3,749	1,503	318	174	71	33	15
523	Financial Investment and Related	$3,090,936	10,172	7,519	1,224	686	491	156	71	18	(2)	(2)
524	Insurance Carriers and Related Activity	$3,411,905	15,466	10,419	2,388	1,156	841	350	209	72	27	4
525	Funds, Trusts, Other Financial Vehicles	$245,040	1,048	744	140	71	(2)	24	9	(1)	(1)	(1)
53	Real Estate and Rental and Leasing	$3,091,321	40,317	28,690	6,600	2,878	1,436	466	210	(2)	6	(1)
531	Real Estate	$2,326,939	34,674	26,051	5,050	2,069	1,009	315	(2)	15	6	(1)
532	Rental and Leasing Services	$683,416	5,406	2,498	1,511	780	412	144	48	13	0	0
533	Lessors of Nonfinancial Intangible Assets	$80,966	237	141	39	29	15	7	(2)	(1)	0	0
	Services	$76,201,421	914,219	726,498	75,092	52,816	38,253	13,072	6,113	1,457	566	352
541	Professional and Technical Services	$24,984,377	115,355	79,486	16,642	9,692	6,085	1,995	1,028	282	95	50
551	Mgmt of Companies and Enterprises	$4,875,986	4,219	1,304	702	638	731	387	294	105	38	20
56	Administrative and Waste Services	$8,697,937	42,053	22,801	7,123	4,809	3,805	1,716	1,175	390	168	66
561	Administrative and Support Services	$8,123,611	40,322	22,173	6,794	4,531	3,523	1,596	1,097	378	164	66
562	Waste Mgmt and Remediation Services	$574,326	1,731	628	329	278	282	120	78	12	4	0
611	Educational Services	$3,508,770	11,157	4,952	1,901	1,587	1,637	620	343	66	31	20
62	Health Care and Social Services	$20,101,632	92,292	47,411	21,561	11,709	6,849	2,539	1,589	335	140	159
621	Ambulatory Health Care Services	$10,066,501	69,056	38,634	17,054	7,733	3,810	1,080	534	136	(2)	(2)
622	Hospitals	$6,552,867	630	96	43	32	50	41	71	89	79	129

**Table 2A: Second Quarter Payroll and Number of Businesses by Size Category
Classified by North American Industry Classification System (NAICS) for California
Second Quarter, 2012**

NAICS Code	Industry	Second Quarter Payroll (in thousands)	Total	Number of Businesses by Size Category								
				0-4	5-9	10-19	20-49	50-99	100-249	250-499	500-999	1000+
623	Nursing and Residential Care Facilities	$1,918,481	7,895	2,407	1,561	1,276	1,006	829	749	63	(2)	(1)
624	Social Assistance	$1,563,783	14,711	6,274	2,903	2,668	1,983	589	235	47	(2)	(1)
71	Arts, Entertainment and Recreation	$2,721,490	17,343	11,737	1,771	1,311	1,435	705	284	60	21	19
711	Performing Arts and Spectator Sports	$1,556,458	11,047	9,425	761	405	275	98	47	21	(2)	(2)
712	Museums, Historical Sites and Similar	$153,917	628	301	119	87	50	36	23	7	(2)	(1)
713	Gambling, Recreation, Amusement	$1,011,115	5,668	2,011	891	819	1,110	571	214	32	9	11
72	Accommodation and Food Services	$6,545,078	69,212	18,529	13,150	17,216	14,663	4,373	1,059	159	48	15
721	Accommodation	$1,483,602	5,988	1,781	985	1,314	1,107	372	286	96	37	10
722	Food Services and Drinking Places	$5,061,476	63,224	16,748	12,165	15,902	13,556	4,001	773	63	11	5
81	Other Services	$4,766,151	562,588	540,278	12,242	5,854	3,048	737	341	60	25	3
811	Repair and Maintenance	$1,337,906	21,410	13,299	4,633	2,085	1,107	235	43	5	3	0
812	Personal and Laundry Services	$938,531	18,884	11,212	4,431	2,012	(2)	(2)	113	19	(2)	(1)
813	Religious, Civic, Professional & Similar	$1,426,016	13,312	7,529	2,510	1,695	1,046	295	185	36	(2)	(1)
814	Private Households	$1,063,697	508,982	508,238	668	62	(2)	(1)	0	0	0	0
999	Nonclassifiable Establishments (3)	$951,788	80,516	80,034	251	140	75	8	(2)	(1)	0	0
	Federal, State and Local Government	$34,260,743	34,029	7,500	4,769	4,868	7,786	5,461	2,435	618	320	272

(1) Data are confidential if there are fewer than 3 businesses in a category or one employer makes up 80 percent or more of the employment in a category.
(2) Data are suppressed because confidential data could be extrapolated if these totals were included.
(3) Businesses are designated as "Nonclassifiable Establishments" when there is insufficient information to determine the appropriate industry classification.

Definitions of Terms and Source Notes

Heart Disease Mortality Data Trends, California 2000-2008

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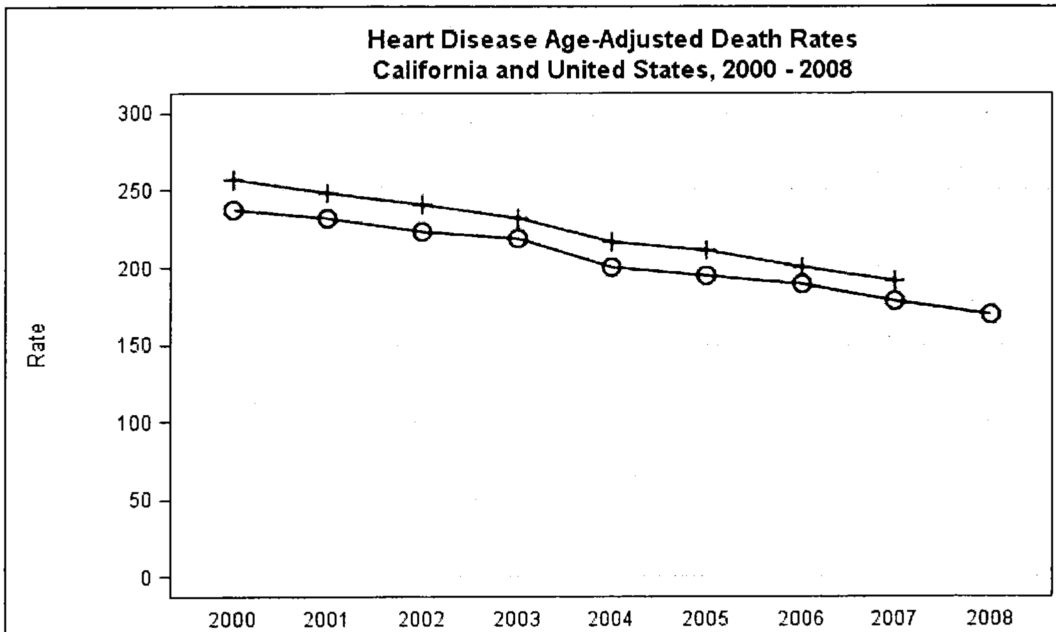
At a Glance

- Heart disease was California's number one leading cause of death every year from 2000 through 2008. Heart disease deaths accounted for more than one quarter (28.1 percent) of all California deaths during the same period.
- The age-adjusted heart disease death rate was lower in California than the United States every year from 2000 through 2007. National-level data is not available for 2008.
- There was a statistically significant downward trend in the California heart disease mortality rate. California's age-adjusted heart disease death rate dropped from 237.6 in 2000 to 169.5 in 2008, a 28.7 percent decrease.
- More than two-thirds of all heart disease deaths during this time occurred to persons aged 75 and older. However, the proportions of deaths under age 75 varied considerably by sex and race/ethnicity.
- Men had consistently higher age-adjusted heart disease death rates than women, but both men and women exhibited statistically significant decreasing trends.
- Blacks had the highest age-adjusted mortality rates among race/ethnic groups.
- All race/ethnic groups had statistically significant decreasing trends with the exception of Two or More Races, which showed a statistically significant increase, possibly due to improved race reporting on the death certificate.
- Statistically significant decreasing trends were seen in 40 of California's 58 counties. Sutter County demonstrated the greatest numerical and percentage decreases when comparing 2000 to 2008 data.
- For the study period, the lowest average age-adjusted heart disease death rate occurred in Marin County. The highest average age-adjusted heart disease death rate occurred in Kern County.

This report was authored by Loran Sheley, MA, Research Program Specialist. Please contact PDATrends@cdph.ca.gov for further information.



	2000	2001	2002	2003	2004	2005	2006	2007	2008
California	237.6	232.4	223.5	218.5	200.1	194.1	189.3	177.7	169.5
United States	257.6	247.8	240.8	232.3	217.0	211.1	200.2	190.9	

—O— California —+— United States

Background

Heart disease has historically been the leading cause of death in the United States (U.S.) and in California. Heart disease accounted for more than one quarter of all California deaths between 2000 and 2008. Health care services, medications, and lost productivity due to heart disease will cost the U.S. $316.4 billion in 2010.[1]

Some disparities have been identified in heart disease mortality. The heart disease death rate has historically been higher in males than in females and higher in the Black population than in the White population.[2]

According to the Centers for Disease Control and Prevention, there are several factors that can increase the risk of heart disease. These include high cholesterol, high blood pressure, diabetes, cigarette smoking, overweight and obesity, poor diet, physical inactivity, and alcohol use.[1]

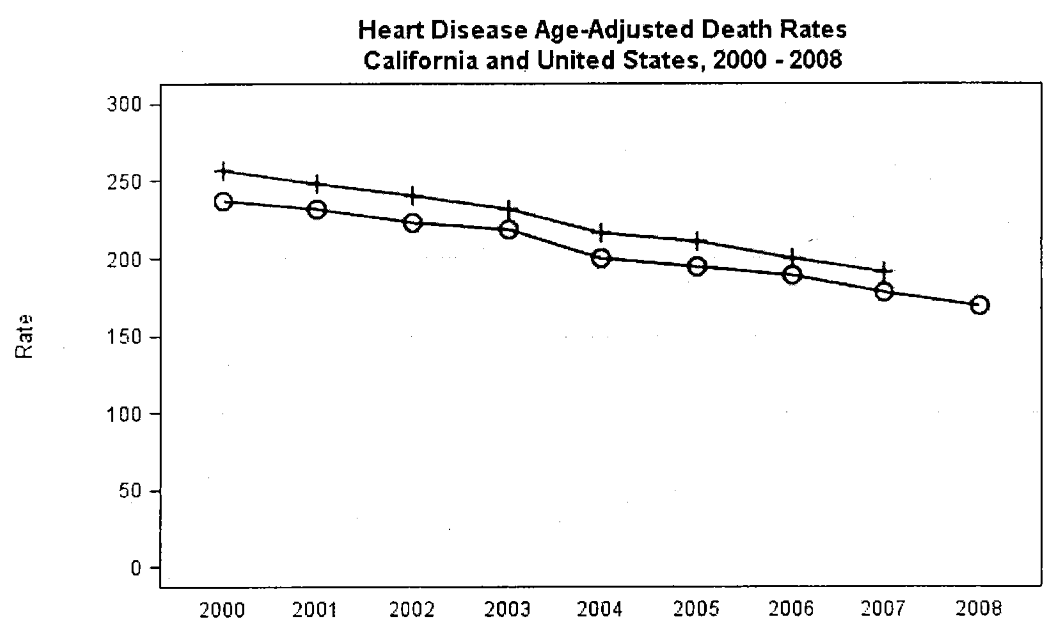
The definition of heart disease used in this report is based on the International Classification of Diseases, Tenth Revision (ICD-10) codes I00-I09, I11, I13, and I20-I51 currently presented in National Center for Health Statistics (NCHS) reports.[3] The national health objective for heart disease as defined by the Healthy People 2010 initiative[2] pertains only to coronary heart disease, which is a subset of heart disease. Therefore, California's progress in meeting this objective is not discussed in this report. However, it is presented in other Health Information and Strategic Planning reports.[4]

This report examines heart disease mortality trends for the years 2000 though 2008 and presents data in five major sections. The first section discusses heart disease mortality for the total California resident population. The second section analyzes male and female populations separately. The third section describes differences in heart disease mortality by race/ethnic groups. Sex differences within race/ethnic groups are discussed in the fourth section. Each of these sections includes information about the numbers and age distributions for heart disease deaths and mortality trends over time. The final section reviews trends in heart disease mortality by county of residence and includes trend charts for each county.

California Total Population

Heart disease was California's leading cause of death from 2000 through 2008 and the number one leading cause of death nationally from 2000 through 2007, the most recent year for which national data is available.

The age-adjusted heart disease death rate was lower in California than the United States each year from 2000 through 2007. The chart below displays California's age-adjusted death rates for 2000 through 2008, compared with the available United States rates.



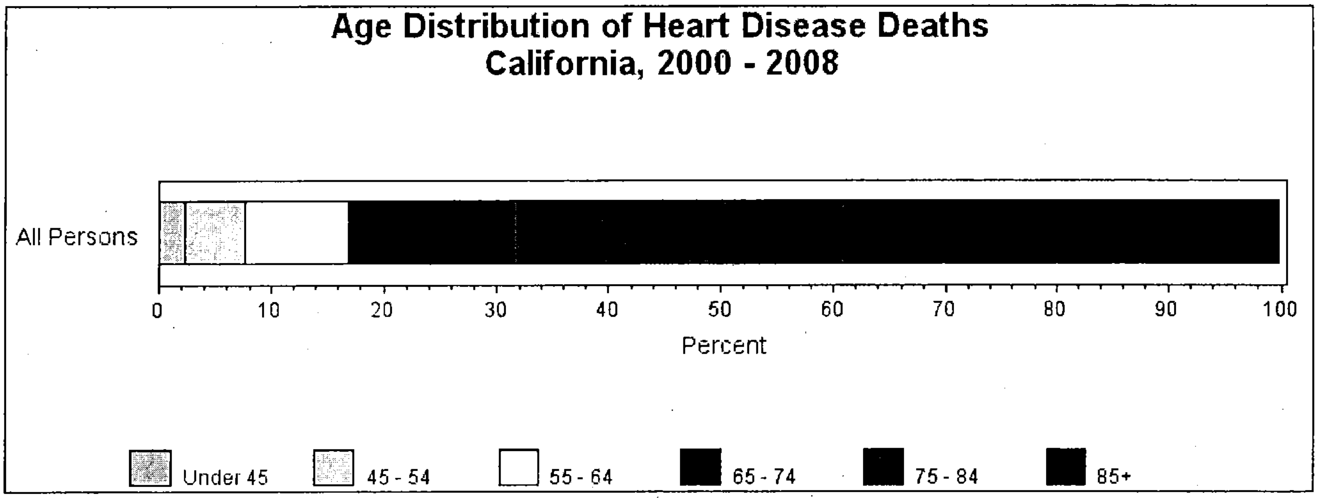
	2000	2001	2002	2003	2004	2005	2006	2007	2008
California	237.6	232.4	223.5	218.5	200.1	194.1	189.3	177.7	169.5
United States	257.6	247.8	240.8	232.3	217.0	211.1	200.2	190.9	

—O— California —+— United States

California's age-adjusted heart disease death rate decreased every year during the study period, and the decline over time became statistically significant. The rate dropped from 237.6 in 2000 to 169.5 in 2008, a 28.7 percent decrease. A similar pattern can be observed in the national-level data. Annual age-adjusted death rates are shown in Table 3 (PDF).

There were 592,235 heart disease deaths in California from 2000 through 2008. This represented more than one quarter (28.1 percent) of all California deaths during the same period.

The average age of death due to heart disease was 78.1 years. More than two-thirds of all California heart disease deaths during this time occurred to persons aged 75 and older. The chart below shows the age distribution of heart disease deaths for all California residents.



The risk of dying from heart disease increases with age, with the exception of infants under 1 year of age, whose rates are higher than all ages through the age of 24. The minimum and maximum annual age specific death rates per 100,000 population for 2000 through 2008 and age groups that had reliable rates during each study year were as follows:

- Under 1 year (4.8, 12.8)
- 15-24 years (1.5, 2.1)
- 25-34 years (5.1, 6.3)
- 35-44 years (16.3, 22.9)
- 45-54 years (61.8, 76.5)
- 55-64 years (157.2, 218.5)
- 65-74 years (380.8, 583.8)
- 75-84 years (1,167.8, 1,646.8)
- 85+ years (4,263.3, 5,903.5)

* Please Note: Age groups 1-4 years and 5-14 years were not shown due to unreliable rates.

All age groups for ages 35 and older displayed statistically significant downward trends during the period. There were no statistically significant trends in groups under age 35.

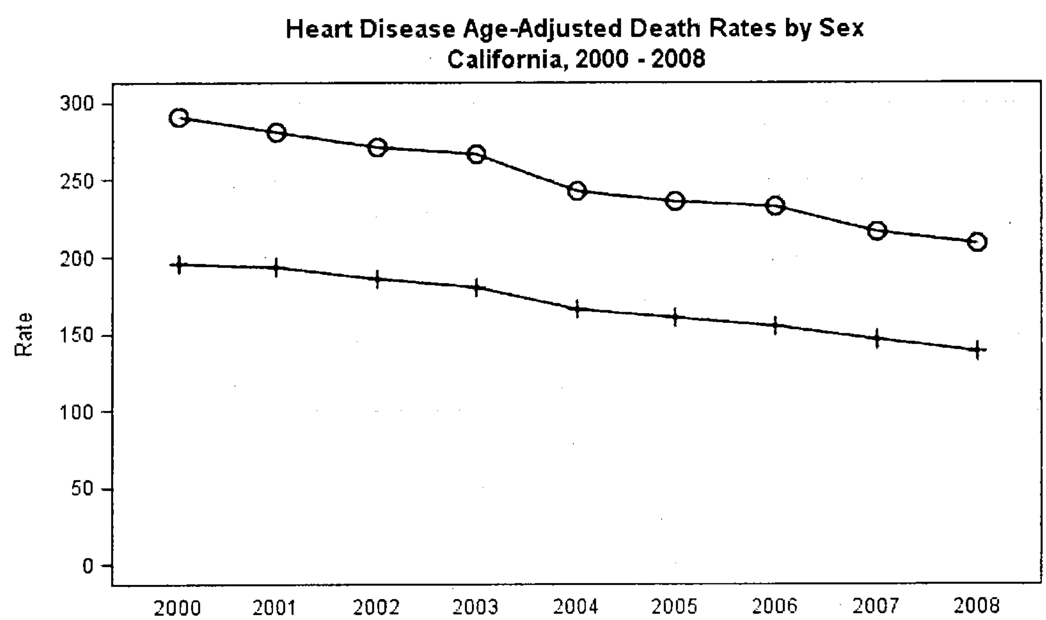
During the study period, the actual risk of dying (or crude death rate) from heart disease ranged from 158.8 to 200.9 per 100,000 population. Annual heart disease crude death rates for the California population are displayed in Table 2a (PDF) under the "All Ages" column.

See the Technical Notes for information about rate calculation and trend analysis.

Male and Female Populations

Heart disease was the number one leading cause of death for both men and women during all years studied in this report.

The chart below presents 2000 through 2008 age-adjusted death rates for California residents by sex.



	2000	2001	2002	2003	2004	2005	2006	2007	2008
Male	291.1	281.5	271.9	266.8	243.3	236.8	233.0	216.8	208.7
Female	195.9	193.7	185.3	180.3	165.8	160.0	154.5	146.3	138.1

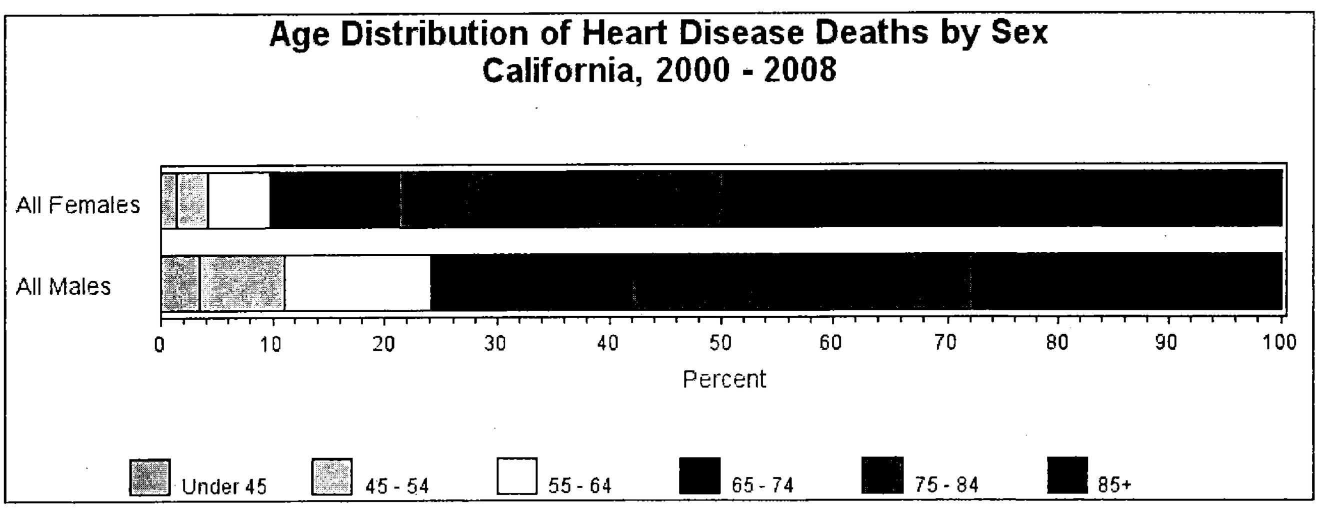
The age-adjusted heart disease death rate was lower for women than men throughout the study period, but both males and females experienced statistically significant rate decreases. For males, the age-adjusted rate fell from 291.1 in 2000 to 208.7 in 2008, a 28.3 percent decrease. The female rate dropped from 195.9 in 2000 to 138.1 in 2008, a 29.5 percent decrease. Annual heart disease age-adjusted death rates are shown in Table 3 (PDF).

Of California's 592,235 total heart disease deaths from 2000 through 2008, the proportions were about equal between males and females (296,957 deaths in males; 295,278 deaths in females).

The average age of death due to heart disease during this time was 74.4 years for men and 81.9 years for women. This means that, on average, men died more than seven years earlier from heart disease than women.

Although most heart disease deaths occurred to persons over age 75 in both sexes, the proportion of deaths that occurred to people under age 75 was larger for males. Approximately 42.0 percent of male heart disease deaths occurred to men under age 75 compared to 21.1 percent of female heart disease deaths in that age group.

The chart below shows the age distribution of heart disease deaths by sex.



The risk of dying from heart disease increases with age for both sexes. Age-specific death rates for both males and females were higher in older age groups. Annual age-specific heart disease death rates are displayed in Table 2b (PDF) for males and Table 2c (PDF) for females.

During the study period, the actual risk of dying (or crude death rate) from heart disease ranged from 199.7 to 163.0 deaths per 100,000 population for males. The female rate ranged from 202.2 to 154.7. Both males and females experienced consistent decreases in crude heart disease death rates during the study period. Annual rates are displayed in Table 2b (PDF) for males and Table 2c (PDF) for females under the "All Ages" column.

See the Technical Notes for information about rate calculation and trend analysis.

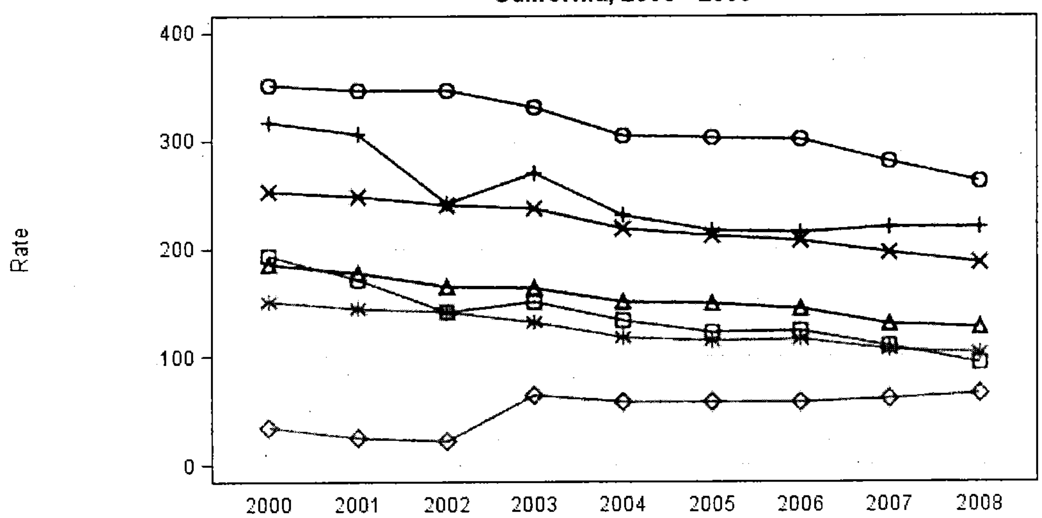
Race/Ethnic Group Differences

Heart disease was the leading cause of death for all race/ethnic groups in all years from 2000 through 2008 with the following exceptions:

- For Asians, heart disease was second to cancer in all years except 2002.
- For Hispanics, heart disease was the leading cause from 2000 through 2006 and was second to cancer in 2007 and 2008.
- For Two or More Races, heart disease was second to cancer in 2006 and 2007.

The chart below presents 2000 through 2008 age-adjusted death rates for California residents by race/ethnicity.

Heart Disease Age-Adjusted Death Rates by Race/Ethnicity California, 2000 - 2008



	2000	2001	2002	2003	2004	2005	2006	2007	2008
Black	351.2	347.3	347.1	331.3	304.5	302.1	301.8	280.4	262.2
Pacific Islander	317.3	306.0	241.2	269.4	230.1	216.4	215.0	220.1	219.0
White	251.8	248.2	240.2	236.4	218.1	211.1	206.6	196.2	187.3
Hispanic	184.8	177.0	165.4	163.3	150.3	148.5	143.8	130.1	127.4
American Indian	192.6	170.3	142.0	150.1	133.7	123.0	123.8	110.1	93.8
Asian	150.2	144.7	142.0	132.1	117.0	114.5	115.6	106.5	103.9
Two or More Races	34.1	25.5	22.7	64.7	58.7	58.0	58.2	60.9	65.8

Blacks had the highest age-adjusted heart disease death rates throughout the study period. All race/ethnic groups experienced statistically significant rate decreases except Two or More Races, which had a statistically significant increase, possibly due to improved race reporting on the death certificate. Rate changes between 2000 and 2008 varied among race/ethnic groups:

- The age-adjusted death heart disease rate for Blacks decreased by 25.3 percent.
- The rate for Whites decreased by 25.6 percent.
- The rate for Asians decreased by 30.8 percent.
- The Pacific Islander rate decreased by 31.0 percent.
- The Hispanic rate decreased by 31.1 percent.
- The American Indian rate decreased by 51.3 percent.
- The Two or More Races rate increased by 93.0 percent.

Annual heart disease age-adjusted death rates and 95 percent confidence intervals are shown in Table 3(PDF).

The average age of death due to heart disease during the study period varied among the race/ethnic groups. Pacific Islanders had the lowest average age of 65.3 years and Whites had the highest average of 79.8 years. This means on the average Pacific Islanders died more than 14 years earlier from heart disease when compared to Whites. The average age of death from heart disease between 2000 and 2008 was:

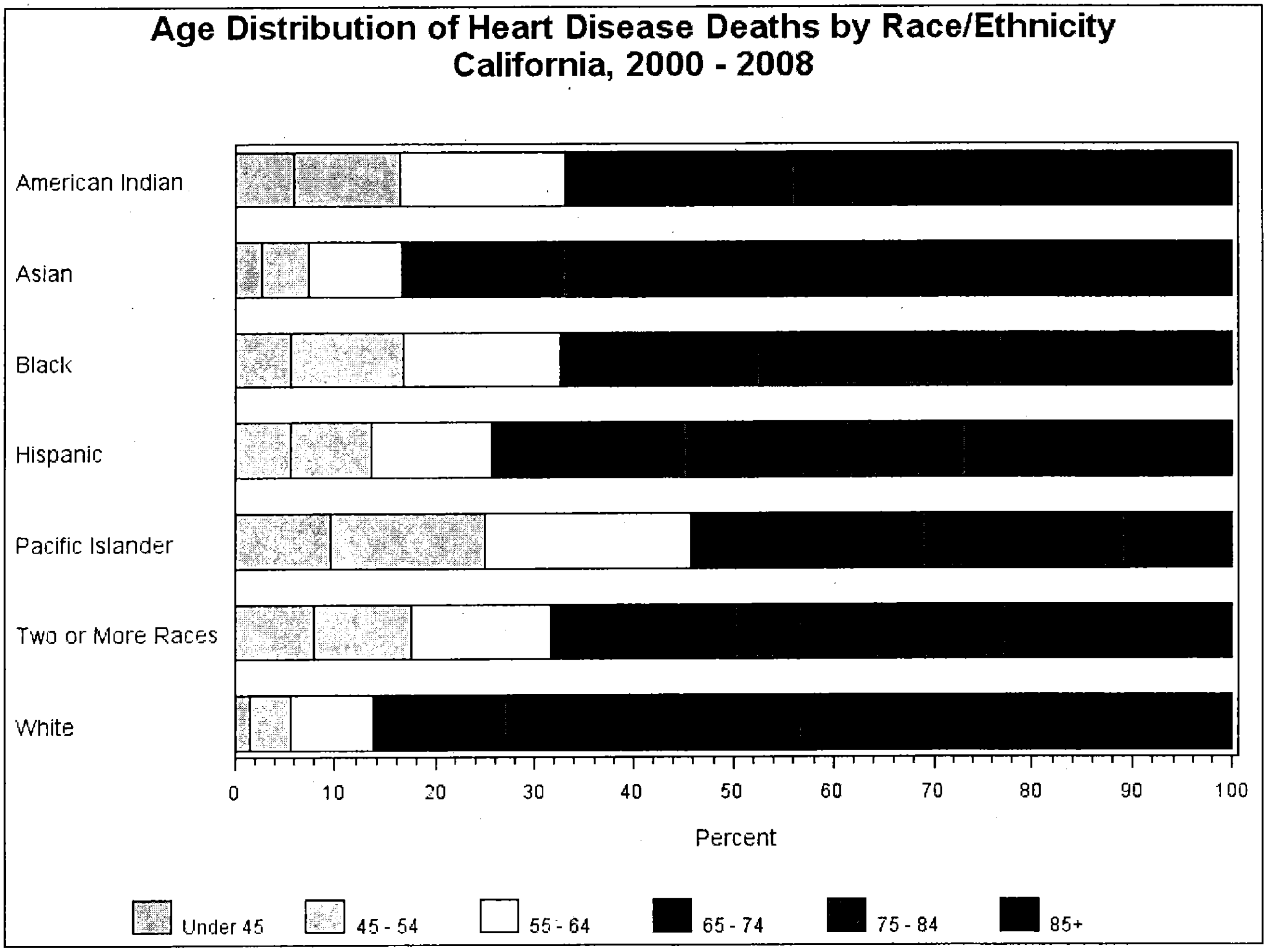
- 65.3 years for Pacific Islanders.
- 70.7 years for American Indians and Two or More Races.

- 71.3 years for Blacks.
- 73.4 years for Hispanics.
- 77.6 years for Asians.
- 79.8 years for Whites.

While the majority of all heart disease deaths occurred to people over age 75, the proportions that occurred to people under age 75 varied considerably among race/ethnic groups. Specifically, the proportion of heart disease deaths before age 75 was:

- More than 60 percent among Pacific Islanders.
- Between 50 and 60 percent for American Indians and Blacks.
- Between 40 and 50 percent for Hispanics and Two or More Races.
- Less than 40 percent among Whites and Asians.

The chart below shows the age distribution of heart disease deaths by race/ethnicity.



Age-specific death rates for all race/ethnic groups were generally higher in older age groups. Annual age-specific heart disease death rates are displayed in Table 2a (PDF).

During the study period, the actual risk of dying per 100,000 population, or crude death rate, for race/ethnic groups ranged as follows:

- American Indian, 88.6 to 113.4
- Asian, 93.7 to 103.8
- Black, 207.2 to 241.5
- Hispanic, 56.7 to 63.1
- Pacific Islander, 130.4 to 154.6
- Two or More Races, 10.6 to 38.3
- White, 261.7 to 323.8

Annual heart disease crude death rates by race/ethnic group are displayed in Table 2a (PDF) under the "All Ages" column.

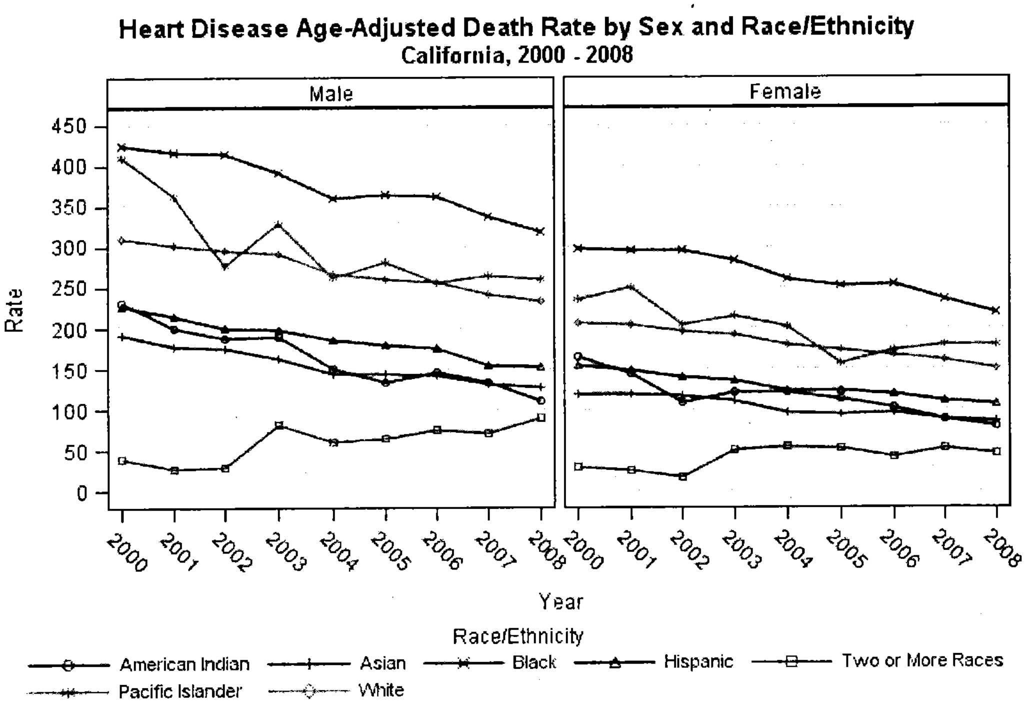
See the Technical Notes for information about rate calculation and trend analysis.

Sex Differences Within Race/Ethnic Groups

Heart disease was the leading cause of death for most race/ethnic groups regardless of sex during the study period with the following exceptions where cancer death rates exceeded those for heart disease:

- For American Indian females in 2002 and 2007.
- For Asian males from 2004 through 2008.
- For Asian females in all study years.
- For Hispanic females from 2006 through 2008.
- Heart disease and cancer alternated as the leading cause of death for Pacific Islander females and females of Two or More Races during the study period.
- For males of Two or More Races in 2007.

The chart below displays age-adjusted heart disease death rates by sex and race/ethnicity for the years 2000 through 2008.



Refer to Table 3 for rate values.

Age-adjusted heart disease death rates were generally higher for females than males within the same race/ethnic group. Black males had the highest age-adjusted rates among males, and Black females had the highest rates among females. Males and Females of Two or More Races had the lowest age-adjusted heart disease death rates over the period.

Both sexes within all race/ethnic groups with the exception of Two or More Races demonstrated statistically significant downward trends during the study period. Males of Two or More Races showed a statistically significant increase and females of Two or More Races did not exhibit a statistically significant trend.

Annual age-adjusted heart disease death rates by sex and race/ethnicity are shown in Table 3 (PDF).

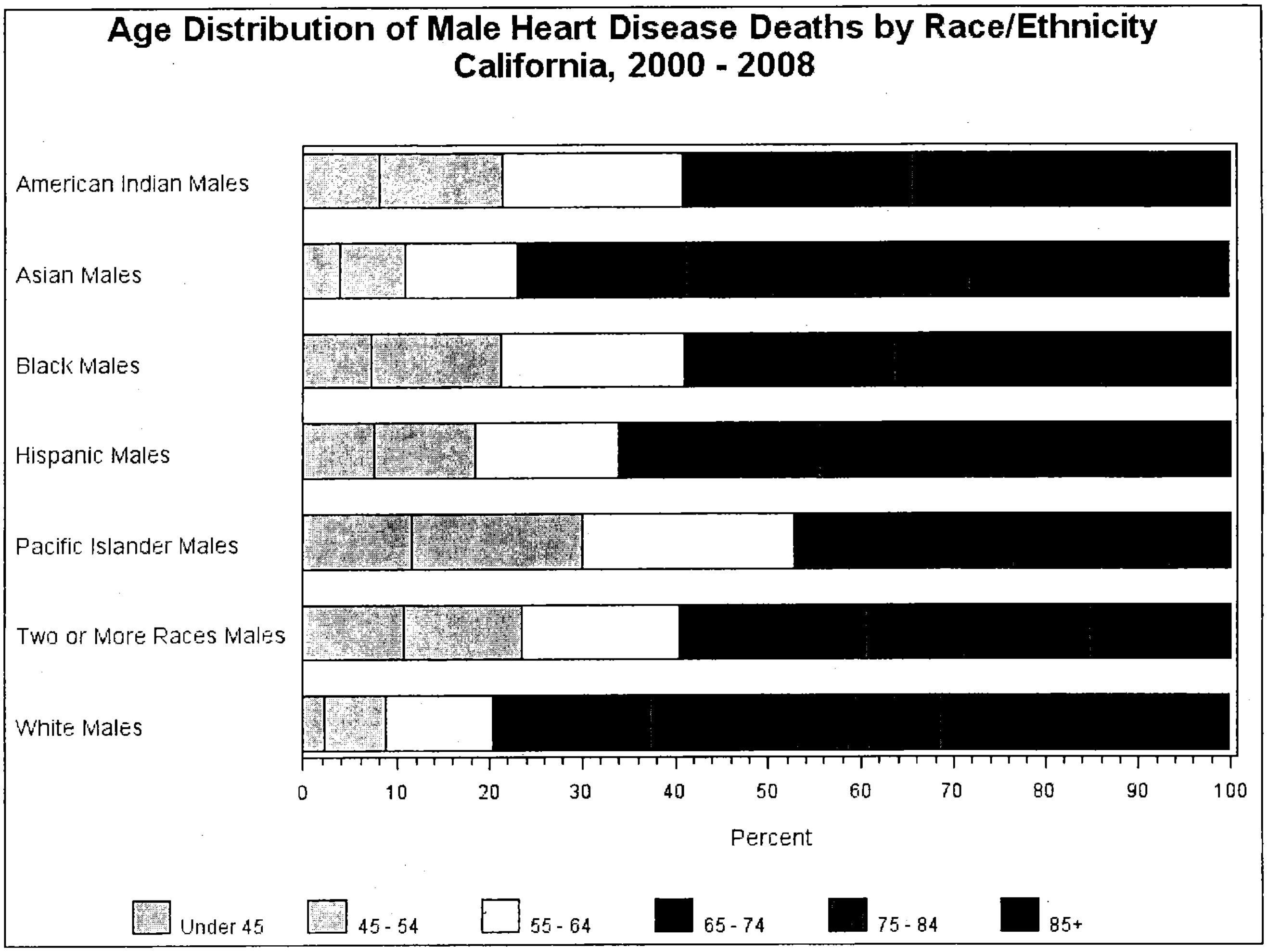
On average, men died earlier from heart disease than women in all race/ethnic groups. Pacific Islander males had the lowest average age of heart disease death and died an average of more than 20 years earlier than White women, the longest surviving group. The average ages of heart disease death by sex and race/ethnicity for 2000 through 2008 were as follows:

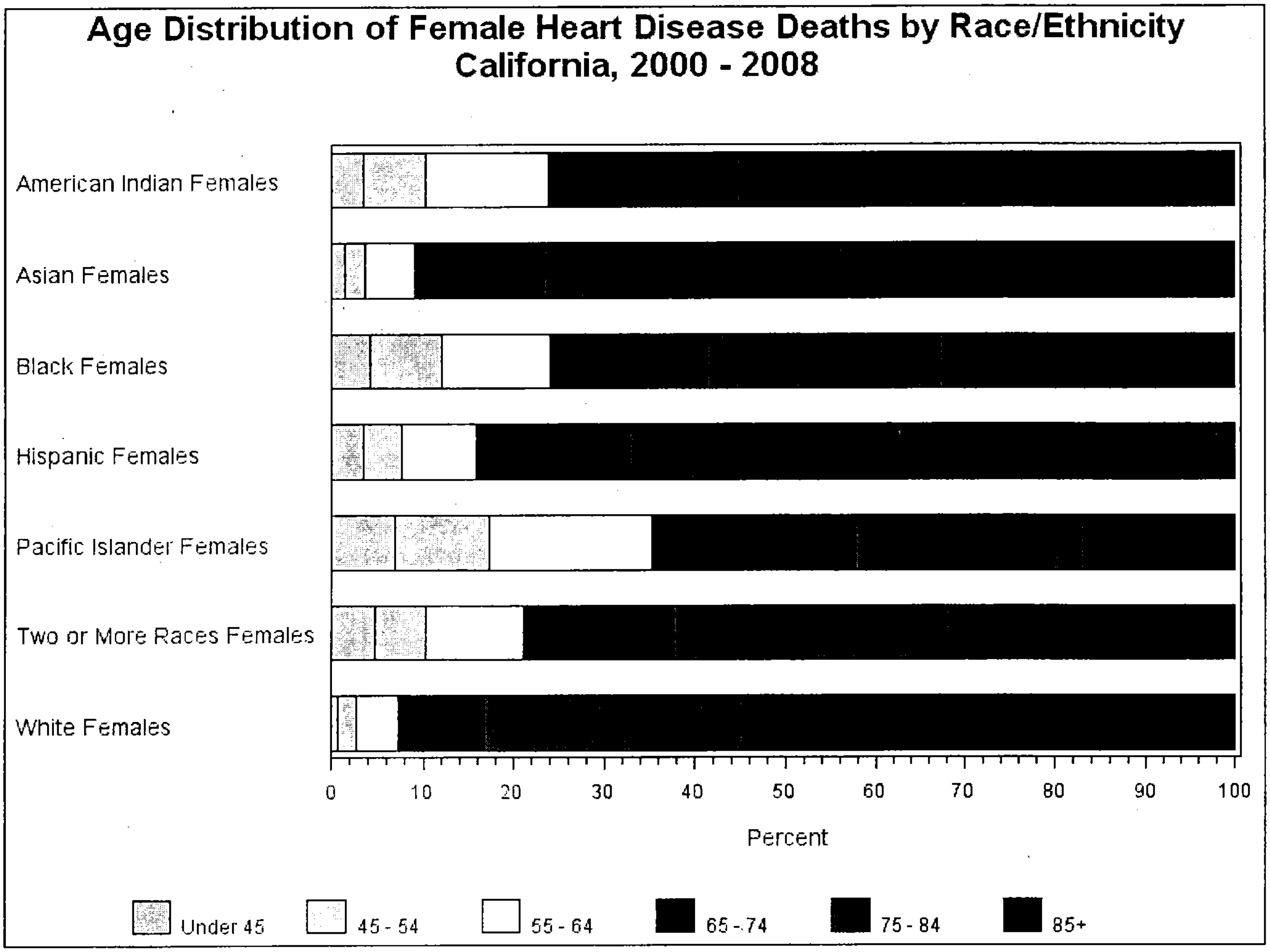
- American Indian: males 67.1 years, females 74.8 years.
- Asian: males 74.6 years, females 80.9 years.
- Black: males 67.5 years, females 75.1 years.
- Hispanic: males 69.6 years, females 77.8 years.
- Pacific Islander: males 62.6 years, females 69.2 years.
- Two or More Races: males 66.9 years, females 75.3 years.
- White: males 76.0 years, females 83.4 years.

The percentage of deaths that occurred to people under age 75 varied by sex and race/ethnicity, and some groups experienced more deaths at younger ages than other groups. Specifically, the proportion of heart disease deaths before age 75 was:

- More than 75 percent among Pacific Islander males.
- Between 50 and 75 percent among American Indian males, Black males, Hispanic males, males of Two or More Races, and Pacific Islander females.
- Between 25 and 50 percent among Asian males, White males, American Indian females, Black females, Hispanic females, and females of Two or More Races.
- Less than 25 percent among Asian females and White females.

The charts below show the age distribution of heart disease deaths by sex and race/ethnicity.





The risk of dying from heart disease increases with age. Age-specific death rates for all race/ethnic categories grouped by sex were generally higher in older age groups. Annual age specific heart disease death rates by sex and race/ethnic group are displayed in Table 2b (PDF) for males and Table 2c (PDF) for females.

Annual heart disease crude death rates by sex and race/ethnic group are also presented in Table 2b (PDF) for males and Table 2c (PDF) for females under the "All Ages" column.

See the Technical Notes for information about rate calculation and trend analysis.

County of Residence Populations

Fifty-four of California's fifty-eight counties had reliable age-adjusted heart disease death rates every year from 2000 through 2008. Kern County had the highest average age-adjusted death rate, and Marin County had the lowest average rate during the nine-year period.

Refer to Table 4 (PDF), Table 5 (PDF), and Table 6 (PDF) for detailed counts of deaths, age-adjusted rates, and 95 percent confidence intervals by county of residence. Trend charts showing age-adjusted heart disease death rates by county are accessible through the links provided below.

Statistically significant decreasing trends in heart disease death rates were seen in 40 counties. The largest numerical and percentage decreases occurred in Sutter County, which showed a drop of 46.1 percent from 2000 to 2008.

Alameda (PDF)	Contra Costa (PDF)	Del Norte (PDF)	El Dorado (PDF)
Fresno (PDF)	Imperial (PDF)	Kern (PDF)	Lake (PDF)
Lassen (PDF)	Los Angeles (PDF)	Madera (PDF)	Marin (PDF)
Monterey (PDF)	Napa (PDF)	Orange (PDF)	Placer (PDF)
Plumas (PDF)	Riverside (PDF)	Sacramento (PDF)	San Benito (PDF)
San Bernardino (PDF)	San Diego (PDF)	San Francisco (PDF)	San Joaquin (PDF)
San Luis Obispo (PDF)	San Mateo (PDF)	Santa Barbara (PDF)	Santa Clara (PDF)
Santa Cruz (PDF)	Siskiyou (PDF)	Solano (PDF)	Sonoma (PDF)

Stanislaus (PDF)	Sutter (PDF)	Tehama (PDF)	Tulare (PDF)
Tuolumne (PDF)	Ventura (PDF)	Yolo (PDF)	Yuba (PDF)

Fourteen counties exhibited rates that were reliable each year but did not show statistically significant trends.

Amador (PDF)	Butte (PDF)	Calaveras (PDF)	Colusa (PDF)
Glenn (PDF)	Humboldt (PDF)	Inyo (PDF)	Kings (PDF)
Mariposa (PDF)	Mendocino (PDF)	Merced (PDF)	Nevada (PDF)
Shasta (PDF)	Trinity (PDF)		

Four counties had rates that were unreliable or no events during one or more of the years studied. Graphs are provided for these counties, but no trend analysis was conducted. This information should be interpreted with caution.

Alpine (PDF)	Modoc (PDF)	Mono (PDF)	Sierra (PDF)

See the Technical Notes for information about rate calculation and trend analysis. A map of California is located here.

Technical Notes

Number of Events – The number of events provides a description of how a disease affects a population, but it is not useful for examining trends or comparison across groups because the number of events largely depends on population size.5

Crude Rates, Age-Specific Rates, and Age-Adjusted Rates – The crude death rate (number of deaths per population size) is a widely used mortality measure.5 This rate represents the average chance of dying during a specified period for persons in the entire population. However, crude death rates are influenced by the age distribution of the population. As such, crude death rate comparisons over time or between groups may be misleading if the populations being compared differ in age composition.

The age specific death rate is defined as the number of deaths occurring in a specified age group divided by the population for the specified age group, usually expressed per 100,000 population. Age-specific death rates allow one to compare mortality risks of a particular age group over time or between age groups at a particular point in time. Although effective in eliminating the effect of differences in age composition, age-specific comparisons can be cumbersome, because they require a relatively large number of comparisons, one for each age group.6

To control for the effect of age on death rates and provide a single measure, age-adjusted death rates are used.5 Age-adjusted rates are computed by separating deaths into their respective age groups based on the age of the decedent, and computing age-specific rates. These age-specific rates are then weighted according to the 2000 U.S. Standard Population, and are summed to produce the age-adjusted rate. Age-adjusted death rates are highly effective for making comparisons among population groups and among geographical areas because they remove the effects of dissimilar age distributions.

Three important caveats apply when using age-adjusted rates. First, the age-adjusted death rate does not reflect the mortality risk of a "real" population. The actual risk of mortality is represented by the crude death rate. The numerical value of an age-adjusted death rate depends on the standard used and, as a result, is not meaningful by itself. Age-adjusted death rates are appropriate only when comparing groups or examining trends across multiple time periods. A comparison of age-adjusted death rates among groups or periods over time will reflect differences in the average risk of mortality.

Second, age adjusting may mask important information if the age-specific rates between comparison groups do not have a consistent relationship. As an example, Anderson and Rosenberg (1998)5 demonstrate that the trend in the age-adjusted death rate for cancer does not reflect the complexities in the underlying age-specific rates. As averages, age-adjusted rates, like other averages, may be misleading, especially when age-specific rates reflect divergent trends over time. However, usually age-specific rates move roughly in parallel. Thus, age-adjusted death rates are a widely accepted and useful convention for analyzing trends.

Finally, because age-adjusted death rates are averages, they represent merely the beginning of an analytical strategy that should proceed to age-specific analyses, and then to an examination of additional sociodemographic, temporal, and geographic variables.

Data Sources – Numerator data are taken from California Department of Public Health death records, and denominator population data are obtained from the California Department of Finance "Race/Ethnic Population Estimates with Age and Sex Detail, July 2007." The 2000 U.S. Standard Population was used for calculating age-adjustments in accordance with statistical policy implemented by NCHS.5 Age-adjusted death rates are not comparable when rates are calculated with different population standards, e.g., the 1940 U.S. Standard Population.

Variability of Rates – Rates are sensitive to size variations in both the numerator (the number of vital events that occurred) and the denominator (the estimated population at risk). For example, in small counties a numerator variation of only a few cases might cause a relatively large shift in a rate, while in a large county could cause no difference in the rate. Likewise, a minor revision in a small county population estimate may cause a relatively major change in a county's vital event rate. Therefore, caution needs to be exercised when analyzing small numbers, including the rates derived from them.

Rates that are calculated from fewer than 20 deaths are considered unreliable (Tables 2a-2c). These rates are not shown, and are indicated with an asterisk (*). Unreliable age-adjusted rates by race/ethnicity and sex (Table 3) and county of residence (Table 5), are displayed with an asterisk (*) and are provided only as a point of information for further investigation. Rates based on no events are denoted with a dash (-).

Sampling Error and Vital Statistics – Vital events are essentially a complete count, because more than 99 percent of all vital events are registered. Although these numbers are not subject to sampling error, they may be affected by nonsampling errors in the registration process.

The number of vital events is subject to random variation and a probable range of values can be estimated from the actual figures, according to certain statistical assumptions. This is because the number of vital events that actually occurred can be thought of as one outcome in a large series of possible results that could have occurred under the same (or similar) circumstances.

A 95 percent confidence interval is the range of values for a measurement that would be expected in 95 out of 100 cases. The confidence intervals are the highest and lowest values of the range. Confidence intervals tell you how much a measurement could vary under the same (or similar) circumstances.

Confidence intervals based on 100 deaths or more – When there were 100 deaths or more, a normal approximation was used to calculate confidence intervals.

Confidence intervals based on fewer than 100 deaths – When there were fewer than 100 deaths, a gamma distribution was used to calculate confidence intervals.

Detailed procedures and examples for each type of calculation are given in Technical Notes of Deaths: Final Data for 2006; National Vital Statistics Reports; National Center for Health Statistics, 2009.7

Cause of Death – One of the most important uses for vital statistics data is the study of trends by cause of death. Vital statistics trend research yields valuable information about population health status, emerging public health problems, and at-risk populations, and can be used to develop strategies and allocate resources to improve public health.

Cause-of-death statistics are derived from the medical information reported on the death certificate by the certifying physician or coroner. The medical portion of the death certificate has fields for up to four causes of death (immediate, two intervening, and underlying) plus additional fields for recording contributing causes of death. Up to 20 causes can be entered onto a single death certificate. The cause-of-death field selected for coding and tabulation in this report is the "underlying cause of death." This is generally defined as the disease, injury, or complication that initiated the morbid events sequence leading directly to death.

Deaths by Place of Residence – Mortality data analysis in this report are based on records for all California resident deaths occurring in the fifty states, the District of Columbia, US territories, and Canada; all other worldwide resident deaths are excluded. Deaths to non -California residents were excluded from analysis.

Age Groups – The following age groups were used to compute age-specific and age-adjusted rates: under 1 year, 1-4 years, 5-14 years, 15-24 years, 25-34 years, 35-44 years, 45-54 years, 55-64 years, 65-74 years, 75-84 years, and 85 and older.

International Classification of Diseases, Tenth Revision (ICD-10) – Beginning in 1999, cause of death has been coded using ICD-10.8 For more information, see the National Center for Health Statistics ICD-10 page.

Race/Ethnicity – Beginning in 2000, the federal race/ethnicity reporting guidelines changed to allow more than one race to be recorded on death certificates. California initiated use of the new guidelines on January 1, 2000, and collects up to three races per certificate. To be consistent with population data, current reports tabulate race of decedent using all races identified on the certificate.

To meet the U.S. Office of Management and Budget minimum standards for race and ethnicity data collection and reporting, and to be consistent with the population data obtained from the California Department of Finance, this report presents Hispanic and the following non-Hispanic race/ethnic groups: American Indian, Asian, Black, Pacific Islander, White, and Two or More Races. Hispanic origin of decedents was determined first and includes decedents of any race group or groups. Non-Hispanic decedents who were reported with two or more races were subsequently placed in the Two or More Races group. Single non-Hispanic race groups are defined as follows: the "American Indian" race group includes Aleut, American Indian, and Eskimo; the "Asian" race group includes Asian Indian, Asian (specified/unspecified), Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Thai, and Vietnamese; the "Pacific Islander" race group includes Guamanian, Hawaiian, Samoan, and Other Pacific Islander; the "White" race group includes White, Other (specified), Not Stated, and Unknown.

Caution should be exercised in the interpretation of mortality data by race/ethnicity. Misclassification of race/ethnicity on death certificates may contribute to underreporting of deaths in American Indians, Asians, Hispanics, and Pacific Islanders.9 This would contribute to artificially low rates for these groups and the Two or More Races group. Multiple races identification experienced improved reporting of Two or More Races on the death certificate in 2000, which might have resulted in an increase in their death rates. Race groups' data that are not individually displayed on the tables or figures due to unreliable rates are collectively included the state data totals.

Trend Analysis – In this report, linear regression was performed to establish the presence of statistically significant trends over the period examined. The trends identified in the report as statistically significant are those for which an F test yielded a p-value less than or equal to 0.05 and had R-square values greater than 0.50 unless otherwise specified. Trend analyses were not performed in cases where rates for one or more years examined were unreliable.

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External Defibrillator Improvement Initiative

November 2010

Center for Devices and Radiological Health

U.S. Food and Drug Administration

External Defibrillator Improvement Initiative

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Executive Summary

External defibrillators are medical devices that diagnose life-threatening abnormal heart rhythms, or cardiac arrhythmia, and treat them by delivering electrical energy to the heart to restore its normal rhythm. They are used in emergency situations on patients who have collapsed due to sudden cardiac arrest. When used in the first few minutes following collapse, these devices often save lives.

External defibrillators are used in many settings by medical professionals, emergency responders, and by trained and untrained bystanders. The technology is based on decades of research and evolving knowledge of effective defibrillation therapies and rescue sequences.

There is risk associated with all medical devices, and external defibrillators can malfunction. The defibrillator industry has conducted dozens of recalls for external defibrillators, affecting hundreds of thousands of devices. Additionally, the Food and Drug Administration (FDA) has received thousands of reports of external defibrillator malfunctions, including some where the device failure occurred during a rescue attempt and may have contributed to patient harm or death. While the FDA continues to advocate use of these important life-saving devices and is not recommending any change to current clinical practices, we believe the devices can be improved in ways that materially improve patient safety.

Given the large number of recalls and medical device reports received for all types of external defibrillators and for all manufacturers of such devices, the FDA is beginning an initiative to foster the development of safer and more effective external defibrillators through improved design and manufacturing practices, and urge industry to address current practices for identifying, reporting, and acting on the device complaints. This initiative is part of the FDA's Center for Devices and Radiological Health's (CDRH) 2010 Strategic Priorities to proactively facilitate medical device innovation, making available to manufacturers CDRH's expertise and experience to improve the safety and effectiveness of marketed devices that have demonstrated safety problems and to facilitate the development of new devices to address unmet public health needs. It is representative of the agency's balanced public health approach to foster innovation for the next generation of medical devices while assuring that devices that enter the market are and remain safe and effective.

FDA's *External Defibrillator Improvement Initiative* will:

1 Promote innovation of next-generation external defibrillators to improve safety and effectiveness;
2 Enhance the ability of industry and the FDA to identify and resolve problems with devices currently on the market to address safety risks more quickly and effectively; and
3 Designate an appropriate premarket regulatory pathway for automated external defibrillators (AEDs) that promotes best practices for design and testing.

Background

External defibrillators (including automated external defibrillators, AEDs) are life-saving devices designed to restore normal heart rhythms following sudden cardiac arrest.

Each year, nearly 300,000 Americans collapse from sudden cardiac arrest. In sudden cardiac arrest, the heart unexpectedly stops pumping blood to the body. When normal heart rhythms are not restored quickly, sudden cardiac arrest can cause death.

Sudden cardiac arrest usually happens without warning, and the majority of people have no previously recognized symptoms of heart disease. Patient survival depends on a rapid sequence of rescue events that may include the successful delivery of a high-energy shock from an external defibrillator. Speed is critical -- first responders have only minutes before patients are beyond rescue. Each year, hundreds of patients in all kinds of settings are successfully rescued with the aid of external defibrillators.

1. Types of External Defibrillators

Defibrillators are devices that are designed to deliver electrical energy to the heart for the purposes of stopping a life-threatening cardiac arrhythmia and restoring the heart's normal rhythm. The term "external defibrillator" is generally used to refer to any device that operates outside the body and delivers energy through paddles or electrode pads for the purposes of restoring normal heart rhythm.

The types of external defibrillators that are the subject of this initiative are as follows:

Automated external defibrillators (AEDs) can be semi-automated or fully automated. Semi-automated defibrillators analyze the heart's rhythm, and if an abnormal rhythm is detected that requires a shock, then the device prompts the rescuer to press a button to deliver a defibrillation shock. Fully automated defibrillators deliver a defibrillation shock if commanded by the device software without user intervention. AEDs are used by trained users, first responders, and by untrained bystanders. They are used in homes and are increasingly found in public places such as airports, hotels, schools, and sports facilities.

Monitor Defibrillators are more complex devices that can include the ability to monitor different kinds of bodily functions such as blood oxygen level, pulse, and heart rhythm. These devices deliver external cardiac pacing and external defibrillation either manually or automatically. The monitor/defibrillators are used by medical professionals and are found mostly in hospitals and emergency medical systems.

Manual external defibrillators are used with (or have built-in) an electrocardiogram display to diagnose the rhythm of the heart. On the basis of the diagnosis, the clinician determines the energy level to be delivered to the patient. These devices are used predominantly in hospitals and on some ambulances.

2. Uses of External Defibrillators

External defibrillators are used in many settings, by people who have different levels of training. These training differences may play a role in external defibrillator performance.

- In the clinical setting, external defibrillators are used in emergency rooms, intensive care units (ICU) and throughout the hospital by trained professionals. Training is usually mandatory and refresher training is provided regularly. There are established systems for maintaining and assuring that the devices are ready to be used.
- Outside of hospitals, external defibrillators are used by emergency medical personnel and first responders such as police. The frequency and type of training required for first responders is set by employers and by state or local regulations.
- AEDs are found in airports, community centers, schools, government buildings, and other public locations. These devices are intended for use by the general public, but most require a prescription from a physician for purchase. Public Access to Defibrillation (PAD) programs make AEDs available in places where large numbers of people gather or where people who are at high risk for heart attacks live. PAD programs include training requirements. Currently, the American Heart Association provides training in basic life support (BLS) and advanced cardiac life support (ACLS) which includes the use of external defibrillators. Recertification in BLS and ACLS is required every two years. PAD programs must have a medical director who oversees the program and a program coordinator who is usually responsible for device maintenance.
- AEDs are also found in homes where they are intended to be used by minimally trained or untrained individuals.

3. Causes for Concern

External defibrillators are important, life-saving devices. However, over the past five years we have seen persistent safety problems with all types of external defibrillators, across all manufacturers of these devices. From Jan. 1, 2005 to July, 10, 2010, there were 68 recalls, exhibiting an increase from nine (in 2005) to 17 (in 2009, the last complete year for which data are available). During this period, the FDA received more than 28,000 medical device reports (MDRs), which also exhibited an increase from 4,210 (in 2005) to 7,807 (in 2009, the last complete year for which data are available). The FDA conducted multiple inspections of all external defibrillator manufacturers throughout this time period.

Many of the types of problems we have identified are preventable, correctable, and impact patient safety. As part of a comprehensive review the FDA identified several industry practices that have contributed to these persistent safety risks including industry practices for designing and manufacturing defibrillators, handling user complaints, conducting recalls and communicating with users. In some cases, these practices can contribute to device performance problems, place undue burden on users and put patients at risk.

To date, the FDA has addressed individual device problems on a case-by-case basis. However, our analysis of MDRs, recalls and inspections confirms that common problems persist across all types of external defibrillators and all manufacturers. Therefore, the FDA is taking steps to address these pervasive issues on an industry-wide basis.

The following are examples of industry practices contributing to continued safety concerns that the FDA identified during its review of external defibrillators:

Engineering Design Practices. Review of past recalls suggests that manufacturers of external defibrillators sometimes use design practices that lead to inconsistent device performance. In one example, a firm designed its voltage-monitoring circuit to draw power from the same power source it was intended to monitor. Because of this design, a momentary drop in the voltage caused a false signal to shut down the AED and the device was unable to deliver a shock, which may have caused a patient's death. In another case, a firm used the wrong kind of component in one of the circuits, causing the device to be susceptible to interference from noise coming from the device's power line. Good engineering design practices also require user interfaces (like dials, monitors, alarms, and connectors) meet users' needs. Recent surveys suggest that improvements in user interfaces may be warranted.

Manufacturing Practices. The FDA's analysis of recalls and inspections identified problems in how manufacturers test and incorporate components used in the manufacture of external defibrillators, as well as how they evaluate changes to the device before they are implemented to assure that device modifications do not adversely impact the safety and effectiveness of the technology. Between 2005 and 2010, the FDA issued nine warning letters to external defibrillator manufacturers, seven of which cited the firms for failing to appropriately control these aspects of their manufacturing process.

In several cases, manufacturers purchased components from suppliers who did not meet the manufacturers' required specifications. In some cases, the problem with the component was due to a change in how the component was manufactured by the supplier. However, it is the manufacturer's responsibility to assure that the components it receives meet its specifications.

Communicating Systemic Problems to Users. The FDA has observed cases where external defibrillator manufacturers have used a "fix-on-fail" strategy to deal with the problems they find. "Fix-on-fail" refers to the industry practice of identifying and trending problems on a case-by-case basis and repairing individual devices rather than communicating the problem to all users as part of the recall process.

In one example, a firm tracked hundreds of complaints tied to a known, trended defect. They serviced each device when it failed, but did not systematically notify other users of the problem so that these devices could be proactively evaluated and fixed if warranted. Companies must take appropriate actions when they identify known, trended defects by communicating to customers, conducting recalls when warranted, and reducing further device failures.

The FDA has also observed different industry practices for communicating the risk of device malfunctions to users. Some firms calculate these risks as the number of device failures out of the total number of months of device use, while others calculate the number of failures or deaths out of the number of products in distribution. These differences make it difficult for users to understand how common a problem is.

Adverse Event Reporting. From January 2005 through May 2010 the FDA received more than 28,000 adverse event reports for external defibrillators, including malfunctions, patient injuries and deaths. The FDA found the amount and quality of information in these reports to be highly variable across manufacturers. For some firms, a significant proportion of their malfunction reports failed to contain adequate information about the root cause of the problem, which limits the FDA's ability to identify, track, and address device safety problems and suggests that these manufacturers may not have conducted appropriate follow up in some cases.

Between 2005 and 2010, the FDA issued nine warning letters to external defibrillator manufacturers, four of which cited the firms for failing to appropriately report events.

External Defibrillator Improvement Initiative

The FDA is launching the *External Defibrillator Improvement Initiative* to foster the development of better-performing external defibrillators and to address current industry practices for designing and manufacturing devices and for identifying, reporting, and taking action to address device complaints they receive. The initiative will:

1. Promote innovation of next generation external defibrillators to improve safety and effectiveness.

To promote innovation and better understand patient outcomes, the FDA is collaborating with the University of Colorado's Department of Emergency Medicine to develop a multi-city AED registry. The registry will provide the infrastructure to foster the development of innovative AED features such as automated integration into local 9-1-1 systems. In July 2010, an initial meeting was held in Washington D.C., bringing together key stakeholder groups in discussions focused on the need for developing a comprehensive AED registry that can be used to track patient outcomes, optimize AED placement in communities and increase AED utilization by bystanders.

Continuing this effort, the FDA will work with multiple stakeholders to facilitate the development of next-generation defibrillators, enhance surveillance of defibrillators in community settings, and improve the rapid delivery of treatment for sudden cardiac arrest patients. The FDA will host a public workshop on Dec. 15 – 16, 2010, to further these efforts, bringing together government, industry, academia, and users, including clinicians and consumers, to share perspectives.

To assure that current and future devices are designed and manufactured appropriately, the FDA is also sending a letter to all manufacturers of external defibrillators encouraging them to meet with the agency early in the device development process to discuss ways in which they can avoid common problems in the design and manufacturing of these devices.

2. Enhance the ability of industry and the FDA to identify and respond to problems with devices currently on the market to address potential safety risks more quickly and effectively.

The FDA will be working with device manufacturers to improve current industry practices for handling user complaints, reporting adverse events, failure analysis of device malfunctions, conducting recalls, and communicating with users. The Dec. 15-16, 2010 public workshop will discuss the nature, scope, and impact of the defibrillator problems that have been observed and outline expectations for how industry should improve compliance with FDA regulations. In addition, the multi-city AED registry will enhance surveillance of defibrillators in community settings to more rapidly identify and address potential safety problems.

3. <u>Designate an appropriate premarket regulatory pathway for AEDs that promotes best practices for design and testing.</u>

The FDA classifies medical devices into one of three categories based on the level of control necessary to provide reasonable assurance of safety and effectiveness. The classification process is a risk-based process that allows the FDA to apply the appropriate level of regulatory oversight before devices are marketed. Class III devices are those requiring the greatest level of control due to their life-saving impact, their potential for injury, or lack of information about how to control the device's risks.

Automated external defibrillators (AEDs) were given a Class III designation when they were determined to be substantially equivalent to similar Class III devices that were on the market prior to the 1976 Medical Device Amendments. They have always been regulated through the 510(k) process, a premarket pathway that is typically reserved for Class I and Class II devices, but which has also been used for some Class III devices that were allowed to be reviewed under the 510(k) regulations until reclassified or determined to require a PMA.

According to a 1990 amendment to the 1976 legislation, the FDA must either down-classify AEDs to Class II or keep AEDs as Class III and require they go through the more stringent Premarket Approval (PMA) process. The FDA is now proceeding with the formal classification of AEDs. In January 2011, the FDA is convening an advisory panel meeting to discuss which of these regulatory pathways is more appropriate for AEDs to provide reasonable assurances of safety and effectiveness for these devices.

A final decision about the classification and regulatory pathway for AEDs is anticipated to be published in 2011.

Conclusion

External defibrillators are used in hospitals, public places, and homes worldwide to save the lives of patients in sudden cardiac arrest. External defibrillators have contributed to significant improvements in patient care. However, they may occasionally malfunction. Through the *External Defibrillator Improvement Initiative*, the FDA seeks to support the benefits of external defibrillators while reducing the associated risks by promoting innovation, enhancing problem identification and response, and designating an appropriate premarket regulatory pathway for these devices. Because of their proven public health benefit, FDA continues to strongly encourage the use of external defibrillators when appropriate during the resuscitation of cardiac arrest victims.

Medical & Radiation Emitting Device Recalls

New Search Back to Search Results

Class 2 Recall
Philips and Laerdal brands of HeartStart HS1 Defibrillator Family

See Related Information[20]

Date Posted	January 04, 2013
Recall Number	Z-0643-2013
Product	Philips and Laerdal brands of HeartStart HS1 Defibrillator Family Model number M5066A, M5067A, and M5068A Automated External Defibrillator Manufactured by Philips Medical Systems, Seattle, WA 98121 USA. The HS1 Defibrillator is intended to treat ventricular fibrillation, the most common cause of sudden cardiac arrest. Using voice prompts, light emitting diodes (LEDs) and buttons, the user is guided through the response. The HS1 uses a SMART biphasic, impedance compensating exponential waveform to deliver a nominal 150 J to adults and nominal 50 J to infants/children.
Code Information	HS1 product family all start with A in the serial number and break down into 3 catalog numbers - M5066A, M5067A and M5068A: 1) M5066A (referred to as Onsite or HS1), Philips brand, 510 (k) = K020715, sold nationally and internationally, serial numbers range from A021-00038 through A12E-03490, with 306,108 total devices. 2) M5067A, Philips brand 510(k) = K040904, sold nationally and internationally, serial numbers range from A05C-00727 through A12D-01406, with 978 total devices. 3) M5068A, Philips brand 510(k) = K020715, sold nationally and internationally, serial numbers range from A021J-00207 through A12E-01900, with 22,760 total devices 4) M5066A, Laerdal brand, 510 (k) = K020715, sold internationally, serial numbers range from A021-00036 through A12D-02148, with 60,433 total devices. 5) M5067A, Laerdal brand, sold as Home device-cleared for OTC on initial 510(k) = K040904, serial numbers range from A021-00133 through A11B-00970, with 8659 total devices. 6) M5068A, Laerdal brand, 510(k) = K020715, sold internationally, serial numbers range from A02K-00172 through A11H-00868, with 5217 total devices. Please note the serial number range represents first and last serial number for each model. Serial numbers are not continguous. Laerdal is a distribution partner in EU and Canada, sold internationally
Recalling Firm/ Manufacturer	Philips Medical Systems North America Co. Phillips 22100 Bothell Everett Hwy Bothell, Washington 98021-8431
For Additional Information Contact	AED Recall Support 800-263-3342 Ext. 6
Reason for Recall	Philips determined that it is important to clarify information in the Owner's Manual and keep customers informed about the maintenance of their FRx (models 861304 and 861305), OnSite (models M5066A and M5067A), or HeartStart Home (model M5068A) automated external defibrillators (AEDs) shipped between December 2005 and July 2012. Philips had determined there is a need to emphasize the importance o
Action	Philips Healthcare sent an Emergency Care and Resuscitation letter Customer Information Letter dated July 26, 2012, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to contact their Philip's representative to obtain the tools and information they need to ensure that their device is functioning properly. For questions regarding this recall, please call AED Recall Support at 1-800-263-3342 (Option 6).
Quantity in Commerce	Estimate 613,000 devices shipped
Distribution	Worldwide Distribution - USA (nationwide) and the countries of Japan and Malaysia.

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Links on this page:

Automated External Defibrillators (AEDs)

Approximately 890 deaths from coronary heart disease occur outside of the hospital or emergency room every day. Most of these deaths are due to the sudden loss of heart function or sudden cardiac death.[1] In 2001 and 2002, there were 6628 workplace fatalities reported to OSHA; 1216 from heart attack, 354 from electric shock, and 267 from asphyxia. A number of these victims, up to 60 percent, might have been saved if automated external defibrillators (AEDs) were immediately available. Chances of survival from sudden cardiac death diminish by 7 – 10 percent for each minute without immediate CPR or defibrillation. After 10 minutes, resuscitation rarely succeeds. An AED is an electronic device designed to deliver an electric shock to a victim of sudden cardiac arrest. Ventricular fibrillation may be restored to normal rhythm up to 60 percent of the time if treated promptly with an AED, a procedure called defibrillation.

This page is a product of the OSHA and the American Heart Association (AHA) and the former OSHA and American Association of Occupational Health Nurses, Inc. (AAOHN) Alliances.

OSHA does not have standards specific to automated external defibrillators (AEDs). However, exposures to first-aid hazards are addressed in specific standards for the general industry.

Contents

Page last reviewed: 04/23/2007

Highlights

- Cardiac Arrest and Automated External Defibrillators [18 KB PDF*, 4 pages]. OSHA Technical Information Bulletin (TIB), (2001, December 17).
- Saving Sudden Cardiac Arrest Victims in the Workplace: Automated External Defibrillators. OSHA Publication 3185-09N, (2003). Also available as a 384 KB PDF, 4 pages. Provides information on the importance of readily-available AEDs, and encourages the installation of the devices in workplaces. Also includes a list of resources for more detailed guidance on the use of AEDs as well as how to obtain qualified training.
- American Heart Association (AHA). OSHA Alliance.

OSHA Standards

This section highlights standards, Federal Registers (rules, proposed rules, and notices), directives (instructions for compliance officers), and standard interpretations (official letters of interpretation of the standards) related to AEDs.

Note: Twenty-five states, Puerto Rico and the Virgin Islands have OSHA-approved State Plans and have adopted their own standards and enforcement policies. For the most part, these States adopt standards that are identical to Federal OSHA. However, some States have adopted different standards applicable to this topic or may have different enforcement policies.

General Industry (29 CFR 1910)

- 1910 Subpart Z, Toxic and hazardous substances [related topic page]
  - 1910.1030, Bloodborne pathogens [related topic page]

Federal Registers

- Electric Power Generation, Transmission, and Distribution; Electrical Protective Equipment; Proposed Rule. Proposed Rules 70:34821-34980, (2005, June 15). Included as part of the proposed rule, OSHA requests information on costs, safety, and efficacy of and experience with AED devices.
- Survey of Automatic External Defibrillator Use in Occupational Settings; Proposed Information Collection Activity; Request for Comment. Notice 70:23234-23236, (2005, May 4). OSHA plans to supplement a statistical survey with extended case study interviews with selected respondents, as there is limited information about AED use in occupational settings.
- Search all available Federal Registers.

Directives

- Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens. CPL 02-02-069 [CPL 2-2.69], (2001, November 27). Employers will not be cited if they have not offered the hepatitis B vaccination series to an employee whose only exposure to blood would be responding to injuries resulting from workplace incidents as long as this was only a collateral duty of the employee and certain other requirements have been met. Members of an Automated External Defibrillator (AED) Team would also fall under this category if the same conditions exist.
- Search all available directives.

Standard Interpretations

- Emergency medical services on construction sites. (2005, March 2).
- Automated External Defibrillator training is not specifically required by the Permit-Required Confined Space standard; AEDs are not required first aid supplies. (2004, June 17).
- Hepatitis B vaccination requirements for employees providing first aid as a collateral duty. (2000, November 1). OSHA has provided an exception in its enforcement policy for members of automated external defibrillator (AED) teams that meet certain conditions.
- Search all available standard interpretations.

AEDs in the Workplace

Automated external defibrillators (AEDs) are an important lifesaving technology and may have a role to play in treating workplace cardiac arrest. Most sudden cardiac deaths occur outside of the hospital. It is estimated that 5 percent or less of victims of sudden cardiac deaths are successfully resuscitated and discharged alive from the hospital.[2] In a study of Public-Access Defibrillation (PAD), communities with volunteers trained in CPR and the use of AEDs had twice as many victims survive compared to communities with volunteers trained only in CPR.[3] To assist in addressing AED issues, information is provided below regarding occupational risk factors and the use of AEDs in the workplace.

- Automated External Defibrillators Can Save Lives During Cardiac Emergencies [1 MB PDF*, 2 pages]. OSHA Publication 3174, (2001). Stresses the need for AEDs in the workplace to save lives. States that AEDs are effective, easy to use, and relatively inexpensive.
- Saving Sudden Cardiac Arrest Victims in the Workplace: Automated External Defibrillators. OSHA Publication 3185-09N, (2003). Also available as a 376 KB PDF, 4 pages. Provides information on the importance of readily-available AEDs, and encourages the installation of the devices in workplaces. Also includes a list of resources for more detailed guidance on the use of AEDs as well as how to obtain qualified training.
- Cardiac Arrest and Automated External Defibrillators [18 KB PDF*, 4 pages]. OSHA Technical Information Bulletin (TIB), (2001, December 17).
- Best Practices Guide: Fundamentals of a Workplace First-Aid Program [163 KB PDF*, 28 pages]. OSHA Publication 3317-06N, (2006). Presents a summary of the basic elements for a first-aid program at the workplace and includes information on automated external defibrillators and programs.
- Automated External Defibrillation in the Occupational Setting [107 KB PDF, 7 pages]. American College of Occupational and Environmental Medicine (ACOEM) Position Statement, *J Occup Environ Med.* Volume 54, Number 9, (2012, September). Provides position statement of ACOEM written by Larry M. Starr, PhD, and guidance for the use of AEDs in occupational settings.
- Learn About Automated External Defibrillators. American Red Cross. Includes information on AED training programs, and the benefits of having an AED at your facility.
- Occupational Heart Disease. National Institute for Occupational Safety and Health (NIOSH) Workplace Safety and Health Topic. Addresses many of the hazards associated with occupational risks of coronary heart disease.

AED Programs

Public access defibrillation programs that place automated external defibrillators (AEDs) in areas where cardiac arrests may occur can reduce the response time up to three to five minutes. The following references provide information for establishing an effective AED program in the workplace.

- Public Access Defibrillation Guidelines: Guidelines for Public Access Defibrillation Programs in Federal Facilities. Federal Occupational Health (FOH) Notice 66.100, (2001, May 23). Provides a general framework for initiating a design process for public access defibrillation (PAD) programs in federal facilities.
- Automated External Defibrillator Program. Federal Occupational Health (FOH). Offers a variety of information on how to establish an AED program, existing programs, and answers to frequently asked questions about AEDs.
- Learn About Automated External Defibrillators. American Red Cross. Includes information on AED training programs, and the benefits of having an AED at your facility.
- How to Set Up an AED Program. Sudden Cardiac Arrest Association (SCAA). Provides an overview of sudden cardiac arrest with links to information on impact of AEDs, legal considerations, community program components, on-site AED programs, and examples of successful programs.
  - Educational Materials: Learn About Sudden Cardiac Arrest
- For additional information on safety and health programs, see OSHA's Injury and Illness Prevention Programs Safety and Health Topics Page.

Additional Information

Related Safety and Health Topics Pages

- Emergency Preparedness and Response
- Medical and First Aid

Training

Emergency medical service teams typically respond to cardiac arrest where early defibrillation improves survival. In order to respond more rapidly to cardiac arrest, automated external defibrillators (AEDs) have been developed which may be used by trained people. Training resources are provided below.

- Quiz - Save a Co-Worker's Life. American Red Cross.
- CPR. American Heart Association (AHA). Provides links to training topics including training courses, international programs, and instructor information.
- First Aid, CPR, and AED. American Red Cross. Offers first aid and CPR course programs for the community, workplace, and professional rescuers.
- First Aid Training Programs. National Safety Council (NSC). Serves as a tool for training employees or the general public on the latest skills, techniques, and expertise in life-saving procedures offering emergency care, standard first aid, CPR, and AED Instructor-led classroom courses.

Safety and Health Success Stories

The following is an account submitted to OSHA, or that was based on information obtained by OSHA from secondary sources, where the employer implemented programs or utilized best practices and reported successful results.

- Success with Automated External Defibrillators (AEDs). OSHA, (2004).

Other Resources

- Small Business. OSHA.
  - On-site Consultation
    - Program Information and Benefits

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2. Culley L., et al. "Public Access Defibrillation in Out-of-Hospital Cardiac Arrest: A Community-Based Study." *Circulation Online* (2004, March 15). Also available in Print, Circulation (2004, April): 1859-1863.

3. Hallstrom, A. and J. Ornato. "Public-Access-Defibrillation and Survival after Out-of-Hospital Cardiac Arrest." *New England Journal of Medicine* 351.7(2004, August 12): 637-646.

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JOURNAL OF THE AMERICAN HEART ASSOCIATION

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Public Locations of Cardiac Arrest : Implications for Public Access Defibrillation

Linda Becker, Mickey Eisenberg, Carol Fahrenbruch and Leonard Cobb

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Public Locations of Cardiac Arrest

Implications for Public Access Defibrillation

Linda Becker, MA; Mickey Eisenberg, MD, PhD; Carol Fahrenbruch, MSPH; Leonard Cobb, MD

Background—The purpose of this study was to describe the public locations of cardiac arrest and to estimate the annual incidence of cardiac arrest per site to determine optimal placement of automatic external defibrillators (AEDs). This was a retrospective cohort study.

Methods and Results—Locations of cardiac arrest were abstracted from data collected by emergency medical service programs in Seattle and King County, Washington, from January 1, 1990, through December 31, 1994. Types of commercial and civic establishments were tallied and grouped into 23 location categories consistent with Standard Industrial Codes, and the number of sites within each location category was determined. With the addition of "public outdoors" and "automobiles" as categories, there were 25 location categories. During the study period, 7185 arrests occurred, 1130 (16%) of which were in public locations. An annual incidence of cardiac arrest per site was calculated. Ten location categories with 172 sites were identified as having a higher incidence of cardiac arrest (≥.03 per year per site). Thirteen location categories had a lower incidence of arrest (≤.01 per year per site). There were ≈71 000 sites within these categories.

Conclusions—Placement of 276 AEDs in the 172 higher-incidence sites would have provided treatment for 134 cardiac arrest patients in a 5-year period, 60% of whom were in ventricular fibrillation. We estimate between 8 and 32 lives could be saved in 5 years. To cover the remaining 347 arrests occurring in public in a 5-year period, defibrillators would have to be placed in 71 000 sites, not including outdoors and automobiles. Placement of AEDs in public locations can be guided by the site-specific incidence of arrest. ***(Circulation*. 1998;97:2106-2109.)**

Key Words: heart arrest ■ defibrillation ■ survival ■ resuscitation

Placement of AEDs to provide for public access defibrillation holds the promise of shortening time from collapse to shock for VF, thereby improving survival. Even a small decrease in time from collapse to shock is a major factor in the VF survival rate. Because it is not realistic to place an AED in every public location, identification of those places in which cardiac arrest most frequently occurs should guide the location of public access defibrillators to maximize their usefulness.

In Seattle and King County, Washington, the first emergency personnel to arrive at the scene of a cardiac arrest are usually EMTs in a vehicle equipped with a defibrillator. Paramedics are simultaneously dispatched and arrive several minutes later. Faster defibrillation might be achieved by placing defibrillators in the community and training lay persons in their use. The purpose of the present study was to determine the location and incidence of cardiac arrest in public places to plan for the most efficient placement of AEDs.

Methods

We abstracted data from EMS registries of cardiac arrest in Seattle and King County, Washington (total population of 1.5 million in the 1990 census). Data were abstracted for the period January 1, 1990, through December 31, 1994, and included presumed cause, address, and location of arrest. A case was defined according to Utstein entry criteria.[1] In addition, the arrest had to have occurred in a public place before the arrival of EMS personnel, and resuscitation efforts had to have been undertaken by EMS personnel. All ages were included. Arrests due to trauma were excluded because defibrillation is not the first priority for most of these. A public place was defined as an indoor commercial or civic establishment or outdoors except immediately outside a patient's home. We excluded private residences, nursing homes, and fire stations. Also excluded were arrests in clinics or doctors' offices, on the grounds that an unknown number of them may have had defibrillators available. The majority of cases (89%) were due to presumed heart disease. The remainder (11%) included other causes such as respiratory problems, overdose, cancer, drowning, SIDS, neurological disorders, endocrine problems, and anaphylactic shock. Etiologic classification was based on field reports within the city and field reports, hospital records, and death certificates within the county.

The place of arrest was routinely recorded on the medical incident report. We classified the various places using SIC codes.[2] This is the classification standard that underlies all establishment-based federal economic statistics. There are unique SIC codes for every type of establishment, and the establishments are listed in approximately the same way they appear in the yellow pages of

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From the Emergency Medical Services Division (L.B., M.E.), Seattle-King County Department of Public Health, and the Department of Medicine (M.E., C.F., L.C.), University of Washington, Seattle.

Reprint requests to Linda J. Becker, MA, Emergency Medical Services Division, 999 3rd Ave, Suite 700, Seattle, WA 98104.

E-mail linda.becker@metrokc.gov

Selected Abbreviations and Acronyms

AED = automated external defibrillator
EMS = emergency medical services
EMT = emergency medical technician
SIC = Standard Industrial Classification
VF = ventricular fibrillation

the telephone directory. By grouping similar places, we compiled a list of 23 location categories. We added 2 categories, outdoors and automobiles, for a total of 25 location categories. We calculated an annual incidence of cardiac arrest for each location category; the number of arrests in each location category in 5 years was divided by 5 and then by the total number of sites in that category. Fire stations were excluded because they have defibrillators on site. We included 106 privately operated ambulances that did not have defibrillators on board. The denominator for vehicles was the ≈1 322 000 cars and trucks licensed in the city and county. For the location category "outdoors," there was, of course, no denominator.

Results

A total of 7185 nontraumatic cardiac arrests occurred before arrival of EMS personnel in Seattle and King County during the study period, and 1130 (16%) were in public places. Type of public place was missing for 96 cases. We determined there were ≈71 000 public sites in the 23 location categories, not including cars and trucks or public outdoor locations. Location categories with the most sites were nonretail businesses (33 662) and retail stores (17 390). Of arrests in public, most locations were outdoors (32%; 385/1130) or in cars (15%; 168/1130).

There were 10 location categories that each had a relatively high annual incidence of cardiac arrest, ≥.03 per site, or ≥1 arrest per 30 sites (1 arrest in 30 sites in 1 year is 1/30=.03). These are listed in Table 1. It would require ≥30 sites in these types of location categories to yield 1 arrest per year. We termed these the higher-incidence sites. Of these, the Seattle-Tacoma International Airport had the highest incidence, with 7 cardiac arrests per year. All these arrests took place in or near the terminal; none occurred in the air. The ferry/ferry terminal/train terminal category had an annual incidence of .1 per year. Stated differently, each ferry, ferry terminal, or train terminal had 1 cardiac arrest every 10 years, or a total of 10 ferries would have 1 passenger per year experience a cardiac arrest. These 10 location categories, numbers of arrests and sites, and annual incidence per site are summarized in Table 1.

The remaining categories had ≤1 arrest annually per 100 sites. These are termed the lower-incidence categories. The data are summarized in Table 2. For example, schools and churches had an incidence of .002 per year, or 1 arrest per year per 500 sites, and retail stores had an incidence of .0005 per year, or 1 in 2000 sites per year. The concept of higher-incidence sites and lower-incidence sites is reflected in a study from Dallas, Tex, that described the incidence of cardiac arrest as low in high-rise office buildings and high in the jail.[3]

The last 2 categories in Table 2 are arrests that occur in vehicles and outdoors. A very low incidence occurred in vehicles (1 arrest per year per 10 000 vehicles), although with 168 arrests, this category had the second-highest absolute number. The category "outdoors" had the highest absolute number of cardiac arrests. Obviously, there was no way to determine the number of sites in the outdoors category. We estimate that it would take 276 defibrillators to provide rapid defibrillation at the 172 sites with the higher incidence of cardiac arrest. The number of defibrillators needed per location category is shown in Table 1. Potentially, these defibrillators could be used to treat ≈27 cardiac arrests per year. An average of 10 AEDs would need to be placed in public settings to treat 1 cardiac arrest per year.

Discussion

Public access defibrillation has the potential to increase survival rates from cardiac arrest. As shown elsewhere,[4] survival is greater for individuals who experience cardiac

TABLE 1. Incidence of Cardiac Arrest per Site: Higher-Incidence Location Categories

Location Category	Arrests in 5 Years	Number of Sites	Annual Incidence Per Site, Average (Upper 95% CI)*	Number of Sites Required to Yield 1 Arrest per Year	Defibrillators Needed per Category
International airport	35	1	7 (12.5)	1	15
County jail	5	1	1 (2.4)	1	11
Large shopping mall	10	3	.6 (1.8)	2	27
Public sports venue	11	6	.4 (1.2)	3	24
Large industrial site	14	8	.4 (.8)	4	46
Golf course	23	47	.1 (.2)	5	47
Shelter	6	11	.1 (.3)	10	11
Ferries/train terminal	7	13	.1 (.3)	10	13
Health club/gym	18	47	.08 (.2)	12	47
Community/senior center	5	35	.03 (.07)	30	35
Total	134	172	N/A	78	276

*All lower 95% CIs are 0.

TABLE 2. Incidence of Cardiac Arrest per Site: Lower-Incidence Location Categories

Location Category	Arrests in 5 Years	Number of Sites	Annual Incidence per Site, Average (Upper 95% CI)*	Number of Sites Required to Yield 1 Arrest per Year
Entertainment place	68	1245	.01 (.02)	100
Hotel/motel	22	377	.01 (.03)	100
Private ambulance	3	106	.03 (.07)	167
Bus	31	1138	.005 (.01)	200
Bar/tavern	11	413	.005 (.01)	200
Civic/fraternal	7	316	.004 (.01)	250
Government office	6	448	.003 (.005)	333
Nonretail business	48	33 662	.003 (.004)	333
Industrial manufacturing	40	3304	.002 (.004)	500
School/church	21	1943	.002 (.004)	500
Restaurant	36	4109	.002 (.004)	500
Retail store	47	17 390	.0005 (.001)	2000
Construction site	7	12 606	.0001 (.0003)	10 000
Vehicles	168	1 322 040	.0001 (.00003)	10 000
Outdoors	385	N/A	N/A	N/A
Total	900	N/A	N/A	N/A

*All lower 95% CIs are 0.

arrest in public places. These individuals are younger, have fewer symptoms before arrest, are more likely to be in VF, and are more likely to have a witnessed arrest with bystander-initiated CPR. The survival rate of this group might be further enhanced by strategic placement of defibrillators in the community. Logically, the use of an AED located at or near the site of arrest would achieve defibrillation faster than if resuscitation efforts were delayed until the arrival of EMS personnel.

The distribution of defibrillators for the high-incidence categories could be accomplished in many different ways and would likely vary with each community. The following is a plan for placement of the 276 defibrillators in our 172 higher-incidence categories. At the international airport, there are 75 gates located in 15 clusters of 5 gates each. One defibrillator could be placed at each cluster. These 15 defibrillators would be used on 7 cardiac arrests per year. The county jail has 11 floors. Due to security restrictions regarding use of the elevators, efficient placement might consist of 1 defibrillator per floor. The 3 shopping malls have a total of 27 entrances to the outside; 1 defibrillator placed at each would provide coverage for 2 arrests per year. The 6 public sports arenas could have a total of 24 defibrillators, based on an average of 4 at each site, or 1 defibrillator per 15 000 spectators. They would be used in ≈2 arrests per year. The largest manufacturing company, whose plants account for 4 of the 14 sites in this category and >40 000 employees, already has 1 defibrillator per site. There are 23 EMT vehicles located throughout the plants. In the event of a medical emergency, an EMT is dispatched simultaneously with the fire truck that carries the defibrillator and usually arrives before the company fire truck. If each EMT vehicle were equipped with a defibrillator, time to defibrillation could be shortened. These 4 sites would require a total of 23 defibrillators, which is ≈1 per 1500 employees. At this rate, all the industrial sites would have a total of 46 defibrillators. Each of the 47 golf courses, 11 homeless shelters, 18 health clubs, and 35 community/senior centers could have a defibrillator, as well as each of the 10 ferries and 3 ferry and train terminals.

Our study suggests that certain location categories would benefit from public placement of AEDs. Our data do not address the issues of cost-effectiveness, training requirements, maintenance of AEDs, or likelihood that the devices would actually be used when needed. A further limitation to the study lies in a certain amount of imprecision in determining the number of sites per location category. For example, in the retail business category, we were not able to discern how many were mail-order or in-home businesses. Also, the construction site category contains an unknown number of sites that were in operation for only part of the study period.

Only ≈16% of arrests occur in public. We did not consider other factors that influence outcome, such as witnessed arrest, bystander CPR, or rhythm on arrival (60% were in VF on arrival of EMS personnel in the present study). On the basis of 80 VF arrests in the highest-incidence sites (60% of 134 cases) with a survival rate between 10% and 40%, we estimate that between 8 and 32 lives might be saved over a 5-year period with distribution of the 276 defibrillators proposed in Table 1.

Planning for placement of AEDs in public should be guided by the site-specific incidence of arrest. If we placed 276 defibrillators in the 172 sites with the highest incidence, we would have the potential for public access defibrillation for 134 arrests in a 5-year period, ≈80 of which would have an initial rhythm of VF. However, to cover the remaining 347 arrests in public, defibrillators would have to be placed in >71 000 sites, not including automobiles or outdoors. We conclude that placing defibrillators in public locations is a reasonable strategy, but probably only in locations with relatively high incidences of arrest. We suggest that each community identify those sites with high incidences of cardiac arrest to plan for rational placement of AEDs.

Acknowledgments

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The Automated External Defibrillator: Medical Marvel But Measurement Mystery

Lack of Data Gathering Impedes Broader and More Effective Use of a Life-Saving Device

By Hoag Levins... | ...May, 2012 ... | ... Comment Below

PHILADELPHIA -- Publicly-accessible automated external defibrillators (AEDs) can seem near-miraculous in their ability to pull sudden cardiac arrest victims back from sure death. Not surprisingly, stories of their successes have a strong emotional appeal in a country where more than 900 people die of cardiac arrest every day. But actually measuring and analyzing the national scope and impact of this "bystander" AED emergency response model remains an elusive goal for policy makers and the nation's health care research community.

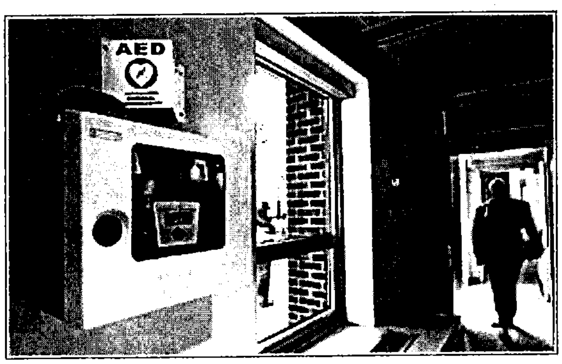

Photo: Hoag Levins

The nearly-miraculous medical capabilities of AEDs are well established but scientific data about their placement, use and outcomes is lacking.

Hardly larger than laptop computers, AEDs are smaller versions of the manually-operated devices long used in hospitals to shock a suddenly-stopped human heart back into a normal rhythm. AEDs are so fully automated that aside from flipping the power switch and placing their adhesive "paddles" on a person's bare chest, the user has only to press one or two buttons to complete the process. One 2006 *Journal of the American Medical Association* article hailed them for being so laymen-friendly "they may be used appropriately by individuals with as little as a sixth-grade education."

There are now an estimated 1 million of these devices in place across the U.S. and studies over the last two decades clearly show that when properly used by a bystander within minutes of a sudden cardiac arrest an AED can dramatically increase survival probability.

Lack of scientific data
But other facts about the deployment, use and efficiency of publicly-accessible AEDs are less well defined, even as governments, corporations and individuals purchase and install an estimated $500 million worth of additional machines each year. There is, for instance, a lack of central registries at the city, state and national level capable of routinely gathering data about AEDs' exact locations or battery power levels or overall operational status. Also largely unknown are the criteria used to place many of them in their current locations, or how many times they are used by members of the public, or what the outcomes of those emergency response events are, or how the bystander AED model's overall national benefits compare to its overall costs.

Dr. Michael Sayre, Vice Chairman of the American Heart Association's Emergency Cardiovascular Care Committee, says the lack of fundamental scientific data on AED resusciation trends reminds him of the famed adage from the eminent 19th-century scientist Sir William Thompson Kelvin that "If you can't measure it, you can't improve it."

Photo: OSUMC

Dr. Michael Sayre, Vice Chairman of the American Heart Association's Emergency Cardiovascular Care Committee finds the lack of AED data frustrating.

'Missed opportunities'
"There absolutely are a lot of missed opportunities because of our inability to really measure what's going on with AEDs," said Dr. Sayre, who is also an Associate Professor of Emergency Medicine at Ohio State University Medical Center. "This sort of data gathering has proven to be more difficult than many people initially imagined it would be."

Dr. Graham Nichol, medical director of the clinical trial centers of both the University of Washington and the national Resuscitation Outcomes Consortium, agrees. "The biggest challenge to expanding the public's use of AEDs is lack of knowledge about the location of the devices," he said. "There is no systematic data gathering about patterns of AED distribution, use or outcome. Nor is there systematic data gathering about out-of-hospital cardiac care process and outcome. A few years ago, some of us recommended designating cardiac arrest as a public health condition to facilitate this reporting but there has been little progress since then."

Bystander reticence
Despite the machines' proven life-saving potential, actual use of AEDs by members of the general public has remained relatively low. Multiple studies over the last decade indicate that sudden cardiac arrests in public spaces are often

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The Practical Difficulties of Implementing 'Choosing Wisely' Recommendations

Academics Debate Hospitals' Smoker Hiring Ban
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observed by large numbers of bystanders, almost all of whom do nothing beyond calling 911.

The widespread installation of the battery-powered, knapsack-sized devices in public locations ramped up dramatically after passage of the 2000 Cardiac Arrest Survival Act mandating their placement in federal buildings. At the time, Congressional testimony by the American Heart Association and announcements by President Bill Clinton predicted that the use of such bystander AEDs would save 20,000 more lives a year.

Ten years later, in 2010, extrapolating from its studies in eight U.S. and two Canadian cities, the Resuscitation Outcomes Consortium, a multi-center collaboration of U.S. and Canadian cardiac arrest investigators, estimated that bystander AEDs save a total of about 474 lives annually across both countries.

Photo: SCAA

Sudden Cardiac Arrest Association President Lisa Levine says U.S. culture has not yet embraced the AED.

Tiny percentage

That same year, the Cardiac Arrest Registry to Enhance Survival (CARES), set up in 2004 by the Centers for Disease Control and Emory University's School of Medicine, finalized a report of its first 63 months of monitoring out-of-hospital cardiac arrests (OHCA) in 36 communities in 20 states. A bystander AED was used in 1,172 of 31,689 incidents and a total of 275 of those victims survived.

Dr. Vincent Mosesso, Jr., Medical Director of both the University of Pittsburgh Medical Center's Prehospital Care Services and the national Sudden Cardiac Arrest Association (SCAA), said that nationally only two percent of sudden cardiac arrest victims get treated with a bystander AED and "there's a huge potential to save more." A patient-advocacy nonprofit headquartered in Washington, D.C. with 52 chapters across the country, the SCAA's 6,000 members are mostly cardiac arrest survivors, health care professionals and emergency responders.

Little impact

Overall, available evidence suggests that fifteen years of equipping American buildings with hundreds of thousands of bystander AED units has had little impact on national out-of-hospital cardiac arrest (OHCA) survival statistics. *Circulation,* the American Heart Association Journal, published a 2010 report on a systematic review of 79 studies of U.S. resuscitation trends. It concluded that "Survival from OHCA has not significantly improved in almost 3 decades, despite enormous efforts in research spending and the development of novel drugs and devices."

"What's both sad and frustrating is that the AED has not become ingrained in our culture yet," said SCAA President Lisa Levine. "We need to not only incorporate these devices into our buildings but into our community consciousness as well -- and that hasn't happened." To change that, the SCAA is lobbying to have AED orientation made a mandatory in America's high schools.

"If we did that," Levine said, "in just four years we'd have hundreds of thousands of AED-trained individuals out in their communities. But that's been an uphill battle because it's one thing to mandate training and quite another to fund it."

Beyond the lack of basic knowledge that impedes wider bystander-AED use is the even larger problem of knowing where to find one when you need it. In a 2010 article about AEDs in *Current Opinion in Critical Care,* University of Iowa Children's Hospital pediatrician Dr. Diane L. Atkins wrote "the author is aware of three instances in Iowa, Georgia and Washington where a student died despite the onsite availability of an AED. In each case, the AED was not used because its presence was unknown to those around the victim."

Photo: Hoag Levins

Emergency physician Raina Merchant is concerned about the public's inability to quickly find out where AEDs are located.

AED locations not known

On the other side of the country, this same issue has energized Dr. Raina Merchant, Assistant Professor of Emergency Medicine at the University of Pennsylvania's Perelman School of Medicine in Philadelphia. "If you're trying to increase the use of AEDs across any geographic area, the first step is to make sure that members of the general public, or the 911 centers they most often call, have some quick, easy way to find out exactly where local AEDs are, but that's exactly what you don't find in city after city," she said.

During the last decade, most states passed laws authorizing the use of AEDs; some statutes call for central registries but few jurisdictions have established such databases. And even those that have tried have encountered unexpected problems. For instance, Washington State is generally regarded as having the country's best-organized public AED program along with a law requiring registration of all public machines and locations. In King County, comprising Seattle and its suburbs, the AED registry is part of the computer system of the EMS dispatch centers. In a three-year study of those centers' daily operations from 2007 to 2009, researchers analyzed the role that AEDs played in local response to all the county's out-of-hospital cardiac arrests. One surprising finding was that more than half of the public AED units bystanders actually used to treat

OHCA victims were not in the county's highly-regarded EMS database or shown on its AED map.

Difficult challenge

"I think the example of King County is instructive," said Dr. Merchant. "Even in that Mecca for resuscitation science, they didn't have 50% of the devices in their database. It illustrates how difficult a challenge this is for any city or county."

In Philadelphia, Dr. Merchant is spearheading an innovative effort to create the country's first interactive city directory and map of crowd-sourced AED locations. A research fellow at both the Leonard Davis Institute of Health Economics and Penn Medicine's Center for Resuscitation Science, she has raised funds from organizations like the Robert Wood Johnson Foundation's Health and Society Scholar's program, and organized the creation of MyHeartMap.org. Over the last several months, the social media initiative recruited more than 300 smartphone-wielding AED documenters with a contest offering a cash prize to the person who found the most public AED locations. In early May when the contest ended, more than 1,500 AEDs had been located. Each of the two winners found and photographed more than 400 devices, and each won a $9,000 prize. The information generated by the contest has been entered into a database and will soon be the core of a GPS-connected interactive smart phone app that can be used to quickly locate the nearest AED anywhere in Philadelphia.

Lack of knowledge and inclination

In recent years, other researchers have looked at the general public's attitudes toward bystander AEDs and reported a significant lack of knowledge as well as inclination. Researchers in U.S., European and Japanese cities found that a high percentage of "bystander" AED responders in public places were actually off-duty professionals trained in emergency response procedures, including healthcare workers, police officers, firemen and EMS technicians.

A shopping mall study by investigators from Brown University and the University of Pittsburgh found that 57% of the public were not willing to use an AED for fear of operating it incorrectly and further harming the victim. Thirty eight percent were worried that using an AED on a dying person could potentially ensnare them in personal legal liabilities. The actual facts are that in most states, Good Samaritan laws specifically absolve public AED responders from any legal liability related to their resuscitation attempts and medical authorities say AEDs aren't dangerous to use.

"There's almost no chance of doing any harm to yourself or to the patient with an AED," said University of Pennsylvania emergency physician Zachary Meisel. "These units are fully automated; they read the downed person's cardiac rhythm and won't shock if the patient doesn't need it. So, when in doubt, use the AED along with manual chest

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compressions -- because that can prevent not only death but long term neurological injury."

Nevertheless, concerns about using AEDs appear to share a certain international consistency. When a five-member team from Amsterdam's VU University Medical Center surveyed more than 1,000 travelers from 38 nations passing through that city's central railway station, they found that 47% were not willing to use an AED and 53% did not know what an AED was when shown one. Forty nine percent believed only medical personnel were authorized to access the station's wall-mounted AEDs.

'Not yet sufficiently prepared'

The researchers' 2011 paper in the *Annals of Emergency Medicine* concluded that "Only a minority of individuals demonstrate sufficient knowledge and willingness to operate an AED, suggesting that the public is not yet sufficiently prepared for the role... Wide-scale public information campaigns are an important next step to exploit the lifesaving potential of public access defibrillation."

In Philadelphia, Dr. Merchant's social media AED mapping project is designed to be both an information gathering effort as well as a promotional campaign employing the culture's most popular digital communications technology to directly engage large numbers of local residents with the issue of sudden cardiac arrest and AED function. It has spawned waves of stories about AEDs in the local and national print, online and TV media.

"We used the fun of the chase and the gadget-enthusiasm of gamers and techies and geocachers to make this thing fly as an educational exercise," said Dr. Merchant. "It's collecting data we need and improving the participants' awareness of these devices and their life-saving importance."

The same kind of central AED database Merchant is working to establish in Philadelphia can also be useful in managing other aspects of citywide defibrillator programs, like device maintenance and operability. Because so few jurisdictional authorities have accurate central AED registries, it's impossible to generate the address lists that would enable local officials or journalists to systematically visit a region's AED sites to check the maintenance and battery-life date on the front of each machine; or ascertain if there is a maintenance program in effect for a given

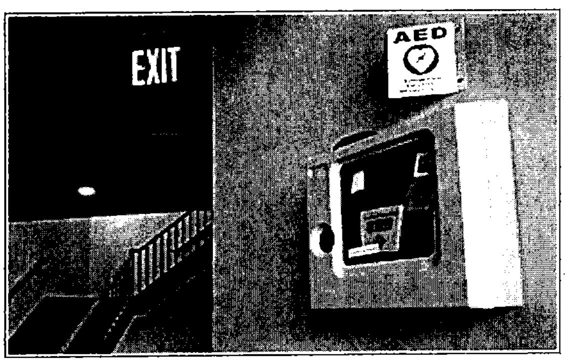

Photo: Hoag Levins

Once installed, AEDs remain in place for years and require routine maintenance and functionality testing. Their batteries slowly deplete and their chest pads also "age out" and can become dysfunctional.

group of AEDs that have hung on the same walls for years.

The same lack of ownership and location data can also inhibit the recall or repair of AED models that have been found to be defective. AEDs are curious in that they are a Class III medical device sold as consumer electronics products through mass-market outlets like Walmart and Amazon.com. Class III devices are the most strictly regulated by FDA and are typically only available via physicians and hospitals; AEDs are covered by the same rules that apply to defibrillators implanted in the body. But the two kinds of devices are subject to very different record-keeping protocols.

FDA advisories

For instance, surgically-implanted defibrillators must be documented in a central national registry run by the American College of Cardiology. When the FDA issues advisories about potential mechanical problems or dangers in various implantable models, it's relatively easy to know where the defective units are, as well as to communicate with the hospital and surgeons that put them in. But what happens when the FDA must issue advisories about potentially defective AEDs whose malfunction could directly result in a life not being saved?

In 2006 Dr. Jignesh Shah of Beth Isreal Deconess Medical Center and Harvard Medical School and Dr. William Maisel, now chief scientist of the FDA's Center for Devices and Radiological Health, completed a study of AED advisories and published their findings in the *Journal of the American Medical Association.* They found 52 FDA advisories affecting 385,922 AED units and noted that "current advisory notification schemes arguably do not adequately inform the public" because there were so few records of where the AEDs were located or exactly who owned or oversaw them.

'Impossible to know'

The authors went on to conclude "the inability to track devices and end users makes it impossible to know how many AED units were actually fixed or taken out of service during the study period because of these advisories... efforts should be directed at developing a reliable system to locate and repair potentially defective (AEDs) in a timely fashion."

That often-broken connection between AEDs installed in unknown locations and FDA safety advisories is only one part of the larger challenge of maintaining such devices in a fully-operation state over long periods of time.

What is believed to be the first academic study to assess the routine maintenance and long-term functionality of a typical cluster of public AEDs was published in the journal, *Resuscitation,* in 2009. University of Iowa investigators visited business, school and government building AED locations throughout Johnson County, Iowa. They wrote, "AEDS were frequently inaccessible and were noted to have depleted batteries and/or expired AED pads... Consistent maintenance protocols need to be implemented to insure that successful defibrillation is possible when a sudden cardiac arrest occurs."

AEDs malfunctioned, patients died

A few months ago a team of researchers led by Dr. Lawrence Deluca of the University of Arizona's Emergency Medicine Research Center published the result of their study of FDA AED adverse event reports in the *Annals of Emergency Medicine*. They analyzed 1,150 instances in which an AED failed to operate properly and the sudden cardiac arrest victim being treated died. The authors wrote that "data on device maintenance ...were frequently absent" and that "underreporting, inadequate tools for analysis, and lack of structured data collection" thwarted efforts to determine the cause of many AED failures in fatal adverse events.

In its latest *External Defibrillator Improvement Initiative Paper*, the FDA emphasizes the importance of enhancing the safety and effectiveness of AEDs as well as the manual defibrillators used by emergency response teams. It notes, "Over the past five years we have seen persistent safety problems with all types of external defibrillators, across all manufacturers of these devices. From Jan. 1, 2005 to July 10, 2010, there were 68 recalls, exhibiting an increase from nine in 2005 to 17 in 2009, the last complete year for which data are available. During this period, the FDA received more than 28,000 medical device reports (MDRs), which also exhibited an increase from 4,210 in 2005 to 7,807 in 2009."

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Hoag Levins is the Managing Editor of the LDI Health Economist. HoagL@wharton.upenn.edu

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Lay Rescuer Automated External Defibrillator ("Public Access Defibrillation") Programs: Lessons Learned From an International Multicenter Trial: Advisory Statement From the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology

Mary F. Hazinski, Ahamed H. Idris, Richard E. Kerber, Andrew Epstein, Dianne Atkins, Wanchun Tang and Keith Lurie

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Lay Rescuer Automated External Defibrillator ("Public Access Defibrillation") Programs

Lessons Learned From an International Multicenter Trial

Advisory Statement From the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology

Mary F. Hazinski, RN, MSN; Ahamed H. Idris, MD; Richard E. Kerber, MD; Andrew Epstein, MD; Dianne Atkins, MD; Wanchun Tang, MD; Keith Lurie, MD

Abstract—Lay rescuer automated external defibrillator (AED) programs may increase the number of people experiencing sudden cardiac arrest who receive bystander cardiopulmonary resuscitation (CPR), can reduce time to defibrillation, and may improve survival from sudden cardiac arrest. These programs require an organized and practiced response, with rescuers trained and equipped to recognize emergencies, activate the emergency medical services system, provide CPR, and provide defibrillation. To determine the effect of public access defibrillation (PAD) programs on survival and other outcomes after SCA, the National Heart, Lung, and Blood Institute, the American Heart Association (AHA), and others funded a large prospective randomized trial. The results of this study were recently published in *The New England Journal of Medicine* and support current AHA recommendations for lay rescuer AED programs and emphasis on planning, training, and practice of CPR and use of AEDs. The purpose of this statement is to highlight important findings of the Public Access Defibrillation Trial and summarize implications of these findings for healthcare providers, healthcare policy advocates, and the AHA training network. (***Circulation.* 2005;111:3336-3340.**)

Key Words: AHA Science Advisory ■ defibrillation ■ heart arrest ■ fibrillation ■ cardiopulmonary resuscitation

Since 1995, the American Heart Association (AHA) has promoted the development of lay rescuer automated external defibrillator (AED) programs to improve survival from out-of-hospital sudden cardiac arrest (SCA).[1–3] These programs are also known as "public access" defibrillation (PAD) programs. The AHA has emphasized the importance of organization, planning, and training to maximize effectiveness of these programs.[4]

To determine the effect of PAD programs on survival and other outcomes after SCA, the National Heart, Lung and Blood Institute (NHLBI), the AHA, and others funded a large prospective randomized trial. The results of this study were published recently in *The New England Journal of Medicine*.[5] The purpose of the present statement is to highlight important findings of the Public Access Defibrillation (PAD) trial and summarize implications of these findings for healthcare providers, healthcare policy advocates, and the AHA training network.

Background

Although estimates of the annual number of deaths caused by out-of-hospital SCA in the United States vary widely,[6–9] the AHA estimates that ≈250 000 people die in the United States each year from SCA outside the hospital setting.[10] At the time of first heart rhythm analysis, ≈40% of SCA victims demonstrate ventricular fibrillation (VF), an abnormal heart rhythm that causes the heart to quiver so that it is unable to pump blood effectively.[8] It is likely that an even higher proportion of people with SCA have VF at the time of collapse. Many people who experience sudden VF cardiac arrest can

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survive if bystanders act immediately. If VF is untreated, then cardiac standstill will develop, and successful resuscitation will be unlikely.[11]

The AHA has traditionally used 4 links in a chain to illustrate the important actions that can create a "chain of survival" for victims of VF SCA.[12] These links are as follows:

1. Early recognition of the emergency and activation of the emergency medical services (EMS) system ("9-1-1").
2. Early bystander cardiopulmonary resuscitation (CPR).
3. Early delivery of a shock with a defibrillator.
4. Early advanced life support.

Bystanders can now perform 3 of the links in this chain. Bystander recognition of the emergency and EMS activation are critical first steps in response to an SCA, ensuring that basic and advanced life support providers are dispatched to the site of the arrest. In most communities, the time interval from collapse to the arrival of EMS personnel is 7 to 8 minutes or longer. This means that the victim depends on the actions of bystanders and local rescuers to perform the first 2 or 3 links in the chain of survival during the first minutes after SCA.

Bystanders need to provide immediate CPR for victims of SCA. CPR provides blood flow to the heart and brain. In addition, CPR increases the likelihood that a shock delivered by a defibrillator will terminate the VF and that the heart will resume an effective rhythm after defibrillation. These effects of CPR appear to be particularly important if shock delivery does not occur for $\geq$4 minutes after collapse.[13] Defibrillation does not "restart" the heart; defibrillation stops VF and allows the heart to resume a normal rhythm. In the first few minutes after defibrillation, the heart rhythm may be slow and the heart may not pump blood effectively. CPR may be needed for several minutes after defibrillation until adequate heart function resumes.[14]

Lay rescuers can use computerized devices called AEDs to deliver a shock to victims of VF cardiac arrest. The rescuer attaches the AED to the victim with adhesive pads or electrodes. The AED records and analyzes the victim's ECG rhythm, informs the rescuer if a shock is needed, and provides voice and audio prompts to guide the rescuer through all steps of AED use. The AED computerized algorithms that are used to analyze the victim's heart rhythm are accurate. AEDs will deliver a shock only when VF or its precursor, rapid ventricular tachycardia, is present and will not deliver a shock to a person with a normal heart rhythm.[15]

The success of the actions of rescuers at the scene of an SCA is time critical. Several studies have documented the effects of time to defibrillation and the effects of bystander CPR on survival from SCA. For every minute that passes between collapse and defibrillation, survival from witnessed VF SCA falls 7% to 10% if no CPR is provided.[11] When bystander CPR is provided, the fall in survival is more gradual and averages 3% to 4% per minute from collapse to defibrillation.[11,16] CPR can double[11,16] or triple[17] survival from witnessed SCA at any interval to defibrillation.

Lay rescuer AED programs may increase the number of SCA victims who receive bystander CPR and can reduce time to defibrillation. These programs require an organized and practiced response with rescuers trained and equipped to recognize emergencies, activate the EMS system, provide CPR, and provide defibrillation. Small studies of lay rescuer AED programs in airports[18] and casinos[19,20] and with police officers[14,21–23] have demonstrated a 49% to 74% survival rate from out-of-hospital witnessed VF SCA when immediate bystander CPR is provided and defibrillation occurs within 3 to 5 minutes of collapse. These high survival rates, however, are attained only in programs that reduce time to defibrillation.[24]

The PAD Trial

The PAD trial involved 993 facilities in 24 urban and suburban regions in North America and reported outcomes from 239 episodes of out-of-hospital SCA with attempted resuscitation.[5] A facility was included if it had a history of at least 1 out-of-hospital cardiac arrest every 2 years or if at least 1 out-of-hospital cardiac arrest was predicted during the study period. Each study site was required to have clearly defined geographic boundaries and a typical EMS response interval of 3 to 15 minutes.

Methods

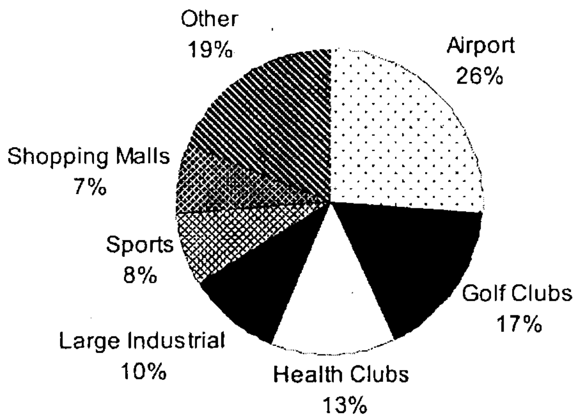
Participating sites were urban and suburban communities served by EMS systems that provide advanced life support. Each site identified distinct units within their service area (eg, buildings, public areas). These units were randomly allocated to train and equip volunteers to provide either CPR only or CPR plus AED response. All of the volunteer rescuers received rigorous, standard training to recognize SCA, phone 9-1-1, and perform CPR according to AHA recommendations. Volunteers at the sites offering CPR plus AED response also were trained and equipped to use AEDs. At CPR-plus-AED sites, AEDs were placed to enable volunteers to retrieve and deliver an AED to a victim of SCA within 3 minutes of collapse.

The trial was conducted from July 2000 through September 2003. Approximately 20 000 volunteers received training in programs that offered frequent retraining and refresher drills. More than 1600 AEDs were placed to conduct the trial. Most (84%) of the study facilities were in public locations such as recreational facilities and shopping centers. Additional details of the study design and methodology have been published.[25]

Results

In the units providing only bystander CPR, 15 of 107 persons experiencing definite cardiac arrest (ie, an arrest of cardiac origin with rhythm identification) survived to hospital discharge. In the units providing bystander CPR plus AED response, 30 of 128 victims of definite cardiac arrest survived to discharge. This increase in the number of survivors of definite cardiac arrest in units with CPR plus AED response compared with the number of survivors in the units providing CPR response alone was statistically significant ($P<0.05$).[26]

In this study, nearly two thirds of all victims of SCA in both groups received bystander CPR. Compared with sites with CPR-only response, sites with CPR plus AED response had a shorter interval from collapse to first rhythm assess-



Public locations with high incidence of SCA in Seattle and King County, Washington, 1990 to 1994 (n=134). Adapted with permission from Becker et al.[27] Copyright 1998 American Heart Association.

ment (6 versus 8.7 minutes) and a higher incidence of VF (57% versus 47%). These differences were statistically significant. No inappropriate shocks were delivered. Adverse events were rare and consisted chiefly of stolen AEDs and transient psychological stress among rescuers.

It is important to note that residential sites represented ≈16% of the study sites and accounted for 28% of the cardiac arrests but <5% of the survivors. The study lacked statistical power to detect whether lay rescuer AED programs increase survival from SCA in residential settings.

Implications for Public Policy

Estimates of the incidence of SCA in the United States vary widely because SCA is not a reportable disease or cause of death. In the PAD study, the observed number of cardiac arrests during the study period was substantially lower (<50%) than the number predicted. This correlates with recent data suggesting that the incidence of SCA may be 0.5 per 1000 adults >35 years old.[6,7] To quantify the problem and evaluate the effect of any interventions designed to reduce death from SCA, this cause of death must be reportable.

EMS databases may enable the identification of sites of cardiac arrests to better pinpoint priority sites for lay rescuer AED programs. Although the organization of information in state EMS databases varies widely, recent attempts to collect national EMS data have been encouraging.

The PAD trial[5] confirms the value of the elements of the chain of survival in improving the outcome of SCA. The trial supports current AHA recommendations for lay rescuer AED programs and the emphasis on planning, training, practice of CPR, and use of AEDs. Early recognition, early CPR, and early defibrillation all contribute to an increased chance of survival from out-of-hospital SCA. The authors note that if the increased number of survivors from the PAD trial is extrapolated to all episodes of out-of-hospital SCA that occur in public locations annually in the United States, then ≈2000 to 4000 additional lives can be saved every year with widespread implementation of lay rescuer community AED programs. This would require the placement of AEDs in those public locations with a high incidence or likelihood of SCA (see the Figure).[27]

In the PAD trial, survival with structured lay rescuer programs that included bystander CPR response was higher than previously reported by traditional EMS systems.[5] This implies that public sites that do not provide AED programs may still improve survival from SCA by training volunteers to recognize cardiac arrest, phone 9-1-1, and give bystander CPR before the arrival of EMS providers.

Lay rescuer AED programs will be most cost effective if they are present at sites where at least 1 witnessed SCA is likely to occur every few years. In the PAD trial, sites were enrolled if there were at least 250 adults >50 years old present at the site during waking hours (≈16 hours per day). Other criteria (eg, presence of high-risk persons) that can be used to select AED program sites are posted on the AED website (http://www.americanheart.org/ecc/PAD).

It is important to note that the PAD trial was not designed to evaluate home defibrillation or defibrillation provided by untrained rescuers. A national study is under way to evaluate home defibrillation, and the results of this study are expected to provide additional information about the potential benefits of home AED programs.

The AHA recommends critical elements for lay rescuer AED programs: healthcare provider oversight and planning, training of anticipated rescuers in CPR and use of the AED, link with the EMS system, and a plan for maintenance and quality improvement monitoring.[4] The AHA has particularly emphasized the importance of training rescuers and the development and practice of a structured response plan. Even in the PAD trial, with rescuers trained to respond to SCA, resuscitation was attempted for only half of the witnessed SCA victims, and the on-site AED was used for only about one third of SCA victims. These findings suggest that rescuers may need more training or practice than that offered in the study and document that the mere presence of an AED does not ensure that it will be used when SCA occurs.

The selection of sites for potential lay rescuer AED programs and the placement of the AEDs within the site are important in the planning for the program. Published data about the most likely sites of SCA in the community[27] can be used to identify potential sites for these lay rescuer AED programs (see the Figure). The AHA recommends that the AEDs be placed in the site so that they can be reached within a 1- to 1.5-minute brisk walk from any location.

Implications for Future AHA Activities

The promotion of PAD programs is an important component of the AHA's comprehensive strategy to prevent heart disease and stroke through risk factor prevention, identification and control, early identification and treatment of acute events, and prevention of recurrent events. The PAD trial results validate the importance of the AHA chain of survival in improving outcome from out-of-hospital witnessed SCA. The results document the importance of program planning, rescuer training, the link with the local EMS system, and a system of device maintenance and quality improvement monitoring in lay rescuer AED programs to improve outcome from SCA.

All states have passed legislation or regulations that allow lay rescuer AED programs, but the heterogeneity of the state laws has created confusion for lay rescuers and has complicated attempts to establish lay rescuer AED programs. An AHA scientific statement is being developed that will delineate critical state legislative components and implementation strategies for lay rescuer AED programs.

The PAD trial results are being carefully reviewed by AHA resuscitation experts to refine recommendations for resuscitation and lay rescuer AED programs. In addition, the researchers gained experience in obtaining community informed consent and institutional review board approval.[28] For further information about lay rescuer AED programs, see http://www.americanheart.org/ecc/PAD.

Writing Group Disclosures

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers Bureau/Honoraria	Ownership Interest	Consultant/ Advisory Board	Other
Mary F. Hazinski	Vanderbilt University	None	None	None	None	Paid AHA consultant/senior science editor	None
Ahamed H. Idris	University of Texas–Southwestern	Medtronic; Laerdal; Medcool; NASA; Department of Defense	None	None	None	Philips SAB member	Holds patent for mouth-to-mouth ventilation device
Richard E. Kerber	University of Iowa Hospital	Philips Medical Systems; Guidant	None	None	None	None	None
Andrew Epstein	University of Alabama–Birmingham	Boston Scientific; Irvine Biomedical; Biosense; Medtronic; Guidant; St. Jude Medical	None	Speakers bureau: AstraZeneca, Reliant, GlaxoSmithKline, Medtronic, Guidant, St. Jude Medical	None	None	None
Dianne Atkins	University of Iowa	Philips Medical Systems; Zoll Medical Corporation; Wyeth-Ayerst; Berlex Medical (latter 2 completed 2001)	None	None	None	None	None
Wanchun Tang	Institute of Critical Care Medicine	American Heart Association; Philips; Zoll Medical Corporation	None	None	None	None	None
Keith Lurie	University of Minnesota	None	None	None	Founder and Chief Medical Officer, Advanced Circulatory Systems (manufacturer of CPR devices and CPR device technology)	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit.

Reviewer Disclosures

Reviewer	Employment	Research Grant/Other Research Support	Speakers Bureau/Honoraria	Ownership Interest	Consultant/Advisory Board	Other
Dr Robert Berg	University of Arizona Health Sciences Center	Medtronic	None	None	None	None
Dr Mickey Eisenberg	University of Washington	Medtronic; Philips Medical Systems; Laerdal	None	None	None	None
Dr Terry Vanden Hoek	University of Chicago	None	None	None	None	None

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EDITOR'S CHOICE

Automated external defibrillator use at NCAA Division II and III universities

J A Drezner,[1] K J Rogers,[2] J G Horneff[3]

[1]Department of Family Medicine, University of Washington, Seattle, Washington, DC, USA
[2]Department of Orthopedics, Alfred I DuPont Hospital for Children, Wilmington, Delaware, USA
[3]University of Pennsylvania, Philadelphia, Pennsylvania, USA

Correspondence to
Dr Jonathan A Drezner, Department of Family Medicine, University of Washington, Box 354410, Seattle, Washington, DC 98195, USA; jdrezner@fammed.washington.edu

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ABSTRACT

Objective The placement of automated external defibrillators (AEDs) at collegiate sporting venues is a growing trend. The purpose of this study was to investigate the prevalence, location and past utilisation of AEDs at *National Collegiate Athletic Association (*NCAA) Division II and III universities.

Design Cross-sectional survey.

Setting NCAA Division II and III universities.

Participants Questionnaires were mailed to the head athletic trainer at NCAA Division II and III (N=711) colleges and universities in the fall of 2003. Findings were compared to previously published results at Division I institutions.

Main outcome measure Prevalence, location and past utilisation of AEDs.

Results Completed surveys were returned by 254 NCAA Division II and III institutions for a 35.7% response rate (254/711). 205 (81%) institutions had at least one AED in the university athletic setting, with a median of 2 AEDs per institution (range 1–9). Athletic training rooms (75%) were the most likely location to place an AED. Twelve cases of AED use for sudden cardiac arrest were reported with 67% (8/12) occurring in older non-students, 16% (2/12) in intercollegiate athletes and 16% (2/12) in students (non-intercollegiate athletes). The AED deployed a shock in eight cases. 8 of 12 (66%) victims were immediately resuscitated, but only 4 survived to hospital discharge (overall survival 33%). None of the intercollegiate athletes or students survived.

Conclusions Most NCAA Division II and III institutions that responded to the survey have implemented AEDs in their athletic programs, although they have a lower prevalence of AEDs than previously reported at Division I universities. Although no benefit was demonstrated in a small number of intercollegiate athletes, AEDs were successfully used in older individuals on campus with cardiac arrest.

The presence of automated external defibrillators (AEDs) has grown significantly in the collegiate athletic setting since the late 1990s.[1 2] The success of public access defibrillation programs combined with an increased awareness of sudden cardiac arrest (SCA) in the athletic population and the desire to prevent a catastrophic sudden cardiac death (SCD) has led to a greater emphasis on emergency preparedness and the prompt availability of AEDs.[3]

SCA is the leading cause of death in young athletes,[4] but identification of athletes with underlying cardiovascular disease is difficult as many of these athletes are asymptomatic and do not have abnormal findings on a physical exam. Four of five athletes who suffer a SCD have no premonitory symptoms before their SCA.[5] Thus, cardiac arrest is often the sentinel presentation of their cardiovascular disease, emphasising the need for appropriate emergency planning and secondary prevention of SCD.

In the treatment of SCA, prompt recognition of SCA combined with early cardiopulmonary resuscitation (CPR) and early defibrillation are critical. The time from cardiac arrest to defibrillation is the strongest determinate of survival, with survival rates declining approximately 7–10% with each minute defibrillation is delayed.[6] A target goal of <3–5 min from the time of collapse to the first shock in response to a cardiac arrest has been recommended by the American Heart Association and an Inter-Association Task Force.[3 7] Emergency preparedness for SCA requires a comprehensive and coordinated response plan, reviewed and practiced by targeted responders at least annually and has the potential to benefit student-athletes and other persons at athletic events such as spectators, coaches and other individuals on campus.[3 8]

The presence and utilisation of AEDs at *National Collegiate Athletic Association (*NCAA) Division I institutions has been previously reported.[1 2] The purpose of this study was to investigate AED prevalence and past utilisation at NCAA Division II and III institutions.

METHODS

Study design

The study was a retrospective survey with questionnaires mailed to the head athletic trainers at NCAA Division II and III (N=711) colleges and universities in the fall of 2003. The study design was similar to a previous study of NCAA Division I institutions completed by the authors[2] and used a similar questionnaire with minor modifications to gather more specific information about each AED use. A single follow-up letter or email request was sent over a 2-month period if a response was not received within 4 weeks of the initial mailing. Head athletic trainers were surveyed as a likely individual to have knowledge of AEDs and past utilisation within the college athletic setting.

The outcome measures analysed included: (1) prevalence and location of AEDs at Division II and III universities, (2) past AED utilisation and (3) obstacles to implementing AEDs. AED prevalence and location were also compared to our findings at NCAA Division I universities.[2]

The institutional review board of the University of Pennsylvania approved the study.

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Statistical analysis

Collected data were analysed by descriptive statistics using SPSS V.11.0 (SPSS, Chicago, *Illinois*, USA). Division II and III universities were subdivided based on their NCAA classification to measure and identify factors on university or athletic resources affecting AED usage. The immediate resuscitation rate and deployment of a shock were measured in the event of an SCA event and use of an AED. Demographic information was calculated based on the age range of the SCA victim and subsequently divided into groups based on their activity on campus: older non-student (such as spectators, coaches, officials or other attendees on campus), intercollegiate athlete or student non-intercollegiate athlete.

RESULTS

Completed surveys were returned by 254 NCAA Division II and III institutions for a response rate of 35.7% (254/711); 96/254 (37.8%) of Division II institutions and 158/254 (62.2%) of Division III institutions returned surveys. The head athletic trainer completing the survey was employed at the school for an average of 8 years (range of 1–43). The cost of each AED ranged from US$0 (ie, donated) to US$5000 with an average cost of US$2270 per AED.

Location and prevalence

Two hundred and five (81%) institutions of 254 respondents had an at least one AED in the university athletic setting (74/96 (77%) of Division II institutions; 128/158 (81%) of Division III institutions), with a median of 2 AEDs per institution (range 1–9). Institutions had AEDs for an average of 3.18 years (range of 1–7 years; 1998–2004). Schools were more likely to acquire their AED in recent years, with the greatest number of schools (50) acquiring their AED in 2003. Athletic training rooms were the most likely location to store an AED, with 75.6% of schools having at least one AED (range 1–4) located in their athletic training room. Locations for AEDs on other parts of campus are described in table 1.

Table 1 Location of AEDs at NCAA Division II and III institutions

Location	Percentage	Range
Athletic training room	75.6	0–4
Recreation centre	34.1	0–3
Campus police	33.7	0–15
Basketball facility	23.2	0–2
Other	22.4	0–3
Student health centre	10.7	0–1
Football facility	7.8	0–2
Swimming centre	8.8	0–1
Baseball facility	5.4	0–2
Ice hockey	5.4	0–1
Crew facility	0.5	0–1

AED, automated external defibrillator; NCAA, *National Collegiate Athletic Association.*

AED use and outcomes

Twelve AED uses to treat SCA were reported by 12 institutions (4.7% of all respondents). The details and outcomes of these cases are summarised in table 2. Athletic trainers provided the AED used in 5 of 12 (42%) cases, and campus police responded with the AED in 4 of 12 (33%) cases. The setting of the SCA was primarily at a recreation/fitness facility (5) or an intercollegiate athletic practice or competition (3); two events also occurred on campus and one event occurred each at an intramural competition and a swimming facility.

Eleven of 12 cases involved a witnessed collapse. In 7 of 11 cases with a witnessed collapse, it was reported that the SCA victim did not have a pulse or spontaneous respirations for any amount of time after collapse. CPR was initiated before the application of the AED in 11/12 cases. The average time from collapse to initiation of CPR was 80 s (range ≤30 s to 3–4 min), with CPR initiated in <30 s in five of the cases. The average time from full cardiopulmonary arrest to application of the AED was 3.27 min (range <30 s to 10 min) in the 11 cases that reported this information.

The AED deployed a shock in 10 cases. Four SCA victims received multiple shocks; three cases reported two shocks and one case had four shocks (average=1.75 shocks per case).

The SCA victims included three spectators (25%), two intercollegiate athletes (16.6%), two student non-intercollegiate athletes (16.6%), two attendees on campus (16.6%), one retired faculty (8.3%), one campus staff member (8.3%) and one senior athlete (8.3%). The age range of SCA victims was 20–80 years of age (mean=50). Students or student-athletes represented 33% (4/12) of SCA cases, and older non-students represented 67% (8/12) of SCA cases.

Eight of 12 (66%) victims were immediately resuscitated with return of spontaneous circulation at the site of the SCA, but only four survived to hospital discharge (overall survival 33%). None of the four students (two intercollegiate athletes

Table 2 Details and outcomes of SCA cases

Person		Age	Setting	AED source	Time to first shock	Cause of SCA	Outcome
1	Intercollegiate athlete	21	Practice	Firefighters	8–10 min	Hypertrophic cardiomyopathy	Died at the scene
2	Spectator	70	On campus	EMT	NA	Coronary artery disease	Died at the scene
3	Retired faculty	71	Rec centre	ATC	3 min	Previous cardiac history (likely CAD)	Survived to hospital discharge
4	Other attendee on campus	50	On campus	Police	NA	Unknown	Unknown
5	Spectator	62	Game	ATC	3 min	Unknown	Died in the emergency room
6	Intercollegiate athlete	27	Rec centre	Police	5–7 min	Massive myocardial infarction	Died in the emergency room
7	Campus staff member	60	Rec centre	Police	1–2 min	Previous cardiac history (likely CAD)	Died in the emergency room
8	Spectator	60	Game	ATC	1 min	Arrhythmia	Survived to hospital discharge
9	Student non-intercollegiate athlete	20	Rec centre	ATC	3–4 min	Ventricular fibrillation (autopsy negative)	Died in the emergency room
10	Senior athlete	80	Swimming pool	ATC	1.5 min	Previous cardiac history (likely CAD)	Survived to hospital discharge
11	Student non-intercollegiate athlete	20	Intramural	Police	5 min	Cardiomegaly	Died at the scene
12	Other attendee on campus	54	Rec centre	Public	45 s	Myocardial infarction	Survived to hospital discharge

AED, automated external defibrillator; ATC, certified athletic trainer; CAD, coronary artery disease; EMT, emergency medical technician; Rec, recreation; SCA, sudden cardiac arrest.

and two non-intercollegiate athletes) survived to hospital discharge. Of the older victims, four of eight (50%) survived to hospital discharge.

Arrival of an ambulance took between 2 and 20 min after initial activation of the emergency medical services (EMS) system (mean=7.9 min; 10 incidents reported). For the four cases of SCA that occurred during exercise, one occurred at rest after practice, two during moderate intensity exercise and one during heavy exercise. The cause, profile and outcome of SCA events are described in table 2.

Obstacles to implementing AEDs

Forty-six of 49 schools without AEDs provided information about their obstacles to acquiring and implementing AEDs. Eleven institutions responded that AEDs were purchased but not yet installed on campus, 22 were currently debating the need for AEDs, 7 had not addressed the need for AEDs and 6 addressed the issue and chose not to purchase AEDs. Twelve institutions stated that money and resources were the primary obstacle to implementing an AED, and one cited medical-legal concerns. Five respondents without AEDs wished they had an AED for a past situation when one was not available. These situations included one elderly fan collapsed during a match; one spectator died of a heart attack during a game; one fan had a heart attack and survived; one athlete suffered syncope and was later diagnosed with hypertrophic cardiomyopathy and one athlete suffered an arrhythmia during exercise.

Comparison to Division I

This study followed a similar survey by the authors on the prevalence, location and utilisation of AEDs at Division I athletic programs conducted in the same year (2003).[2] Ninety per cent of Division I institutions had at least one AED at selected athletic venues, compared to 77% of Division II and 81% of Division III institutions (fig 1). Division I universities had twice the median number of AEDs per institution compared to Division II and III including when adjusted for the number of intercollegiate athletes (fig 2 and 3). The athletic training room was the most common location to place an AED in all Divisions.

DISCUSSION

The single greatest factor affecting survival after SCA is the time interval from arrest to defibrillation.[9] Survival rates from out-of-hospital cardiac arrest using the traditional EMS system in the USA are <5%.[10–12] The placement of AEDs in public locations where cardiac arrest commonly occurs, such as airports, casinos, shopping malls and other highly trafficked areas, has proven to be an effective strategy to improve survival from SCA.[13–17] Jorgenson *et al*[18] found the rate of AED use was 11.6% per year in public places such as malls, residential buildings and recreational facilities and that lay responders could successfully use AEDs in an emergency situation without harm or injury to patients, bystanders or the operators. Recent advances in technology have further simplified operation of an AED, improved effectiveness and accuracy and reduced cost.

Lay rescuer and public access defibrillation programs are designed to shorten the time interval from SCA to shock delivery. These programs train lay rescuers and first responders in CPR and AED use and place AEDs in high-risk public locations for SCA. Studies of rapid defibrillation using AEDs with non-traditional first responders and trained or untrained laypersons have demonstrated survival rates from 41% to 74% if bystander CPR is provided and defibrillation occurs within 3–5 min of collapse.[2 14–17 19–23] Key elements to the success of these programs include training of motivated responders in CPR and AED use, a structured and practiced response and short response times.

In the collegiate athletic setting, AEDs provide a means of early defibrillation for young athletes and for other individuals on campus who may experience an unexpected cardiac arrest. At Division I universities, Drezner *et al* found that older non-students such as spectators, coaches and officials accounted for 77% of SCA cases at collegiate sporting venues and that treatment with an AED provided a survival benefit with a 54%

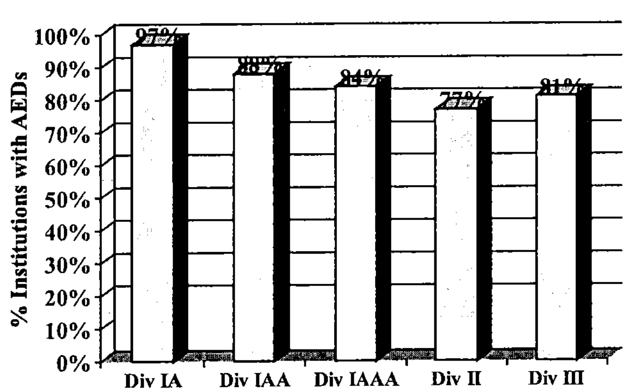

Figure 1 Prevalence of automated external defibrillators at *National Collegiate Athletic Association* Division I, II and III institutions.

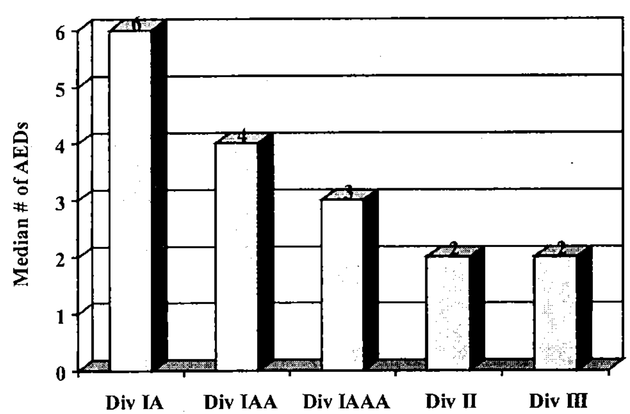

Figure 2 Median automated external defibrillators per institution.

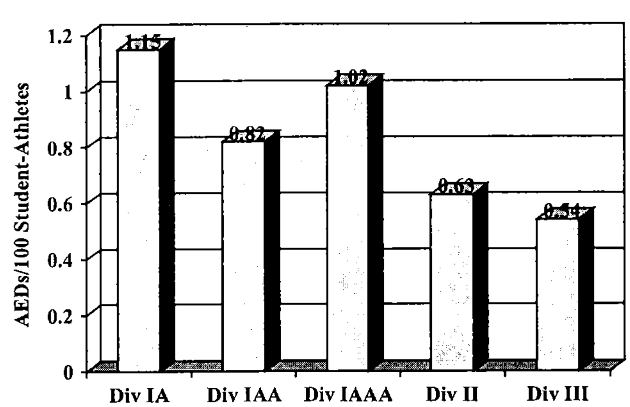

Figure 3 Automated external defibrillators per 100 student-athletes.

overall immediate resuscitation rate.[2] Coris *et al* also demonstrated that four of five AED uses on a Division I campus were used for treatment of SCA in spectators and athletic department staff rather than intercollegiate athletes, and the survival rate to hospital discharge was 61%.[24]

This is the first study to investigate AED utilisation at NCAA Division II and III athletic programs. This study was a retrospective survey and limited by a low response rate, the potential for recall bias and the potential under-reporting of SCA cases if unknown to the athletic trainers completing the questionnaire. The prevalence of AEDs found in this study also may have been influenced by responder bias, with those universities having AEDs being more likely to respond to the survey.

Similar to Division I,[2 24] this study demonstrated a 50% survival rate for older non-students who suffer SCA at Division II and III institutions if treated promptly with an AED. AED use for SCA also was more likely in an older non-student than in a student or student-athlete. None of the four intercollegiate athletes or students with SCA survived. This finding is similar to initial reports of AED utilisation in the college athletic setting that did not identify a survival benefit in a small number of intercollegiate athletes with SCA.[2 24 25] Drezner *et al*[26] also reported a poor overall survival rate of only 11% for exercise-related SCA in the youth from 2000 to 2006 in the USA.[26] The reasons for the lower survival rate in athletes is only speculative but could be due to delayed rescuer recognition of SCA or a higher prevalence of cardiomyopathy that may become more resistant to defibrillation.

More recently, preliminary findings from the National Registry for AED Use in Sports demonstrate improved survival for student-athletes with SCA in the high school athletic setting.[27] Upon review of 1710 nationwide high schools with on-site AED programs, 36 (2%) schools reported a case of AED utilisation within a 1-year period from July 2006 to June 2007. Twenty-two of the cases were in older non-students and 14 cases were in high school student-athletes. The overall survival rate to hospital discharge was 64% for both student-athletes and older non-students with SCA.[27] These findings strongly support the value of on-site AED programs for the treatment of SCA in young athletes.

A critical component to emergency planning for SCA in athletics is to individualise response plans to account for the geography of the area covered, location and distances between athletic venues, the likely first responders to an emergency and the number of AEDs available for distribution. Most Division II and III athletic programs responding to this study had only 1–2 AEDs. Placement of the AED in a central location accessible to many potential responders, such as the athletic training room, may provide the best strategy to achieve early defibrillation at multiple locations. In this study, the AED was brought to the scene of SCA by responding emergency personnel in 6 of 12 cases (campus police in four cases and emergency medical technicians or firefighters in two cases). Division II and III universities had a higher reliance on the EMS system to achieve early defibrillation than did Division I universities.[2] This is probably related to the presence of more AEDs distributed at a wider number of athletic facilities in Division I programs, a finding that could reflect disparities in financial resources.

All potential first responders to SCA—coaches, administrators, athletic trainers and campus security personnel—must know the locations of an AED on campus. In this study, the most common setting for AED use was exercising at a recreational facility (5 of 12 cases). A communication system also needs to be developed to activate both the EMS system and the local response team so the AED can be brought to the site of SCA as quickly as possible. Integration of the AED program with the local EMS system also has been shown to increase survival from SCA.[21 28]

In conclusion, most NCAA Division II and III institutions that responded to this survey have implemented AEDs in their athletic programs, although they have a lower prevalence of AEDs than previously reported at Division I institutions. AED programs should be part of a comprehensive emergency plan for SCA that includes an effective communication system, training of potential first responders in CPR and AED use, acquisition of appropriate emergency equipment and routine practice and review of the response plan. Early defibrillation and decreasing response times are critical to improving survival rates for SCA in the athletic setting.

What is already known on this topic

- The placement of automated external defibrillators (AEDs) in public locations shortens the time to defibrillation in the treatment of sudden cardiac arrest and is an effective strategy to improve survival.
- In the collegiate athletic setting, AEDs provide a means of early defibrillation for student-athletes and for other individuals on campus who may experience an unexpected cardiac arrest.

What this study adds

- AED use for sudden cardiac arrest (SCA) at collegiate athletic venues is more likely in an older non-student than in a student or student-athlete.
- Prompt utilisation of an AED provides a high survival rate for older non-students who suffer SCA at *National Collegiate Athletic Association* Division II and III universities.

Competing interests None.

Ethics approval This study was conducted with the approval of the University of Pennsylvania.

Provenance and peer review Not commissioned; externally peer reviewed.

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Automated external defibrillator use at NCAA Division II and III universities

J A Drezner, K J Rogers and J G Horneff

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Automated External Defibrillation in the Occupational Setting

Larry M. Starr, PhD

On November 13, 2000, President Clinton signed into law H.R. 2498, the Cardiac Arrest Survival Act, designed to expand the availability of automated external defibrillators (AEDs) in public settings and that required the Secretary of the Department of Health and Human Services to establish guidelines for the placement of AEDs in buildings owned or leased by the federal government. In May 2002, President Bush signed into law the Community Access to Emergency Devices Act within H.R. 3448 (sections 159, 312, and 313) of the Public Health Security and Bioterrorism Response Act, and on June 12, 2002, he finalized this as Public Law 107-188. The provisions authorized the availability of grants to states and localities for the purchase and placement of AEDs in public places where cardiac arrests are likely to occur and encouraged private companies to purchase AEDs and to train employees in cardiopulmonary resuscitation (CPR) and emergency defibrillation.

To support AED federal legislation, to increase awareness and value, and to offer recommendations about AEDs in the occupational setting, the American College of Occupational and Environmental Medicine (ACOEM) has included the *AEDs in the Workplace* Web site, containing survey data, case studies, reference database, and other academic and practice resources, in their Health and Productivity Management Center.[1] ACOEM also issued in 2001, and reaffirmed in 2006, a position statement on AEDs in the workplace.[2] This document updates that statement by addressing the following topics: (1) history and overview of AEDs; (2) epidemiology, morbidity, mortality, and incident locations; (3) sudden cardiac arrest (SCA) and the "chain of survival" paradigm; (4) AED technologies; (5) public-access defibrillation; and (6) guidance for the use of AEDs in occupational settings.

HISTORY AND OVERVIEW OF AEDS

Making its debut in 1979, the term "AED" commonly refers to any device that analyzes cardiac rhythm and enables the delivery of an electric shock when necessary.[3] Utilizing solid-state circuitry and microcomputer technologies, AEDs identify ventricular fibrillation (VF) and ventricular tachycardia (VT) then voice prompts a user to prepare for delivery of a shock. Two modes of AED are available. An "automated" AED analyzes then prompts a user to press a button to deliver a shock. Some AEDs are multifunctional and can be set to operate in "automatic" mode, which analyses and delivers a shock without a user prompt.

Annual sales and the total number of AEDs in the United States are difficult to confirm. One study published in 2006 estimated that more than 200,000 are sold annually for public use in the United States.[4] A 2011 industry report estimated that total US sales in 1996 were approximately 18,645 devices, and by 2006 total sales had reached more than 775,000, an increase of 30% per year over the decade.[5] Annual revenue forecasts for the defibrillator market by 2015 are estimated to be $1.7 billion in the United States,[4] and when implantable cardioverter defibrillators are included, in excess of $11 billion globally.[6]

Submitting key words, "automated external defibrillator," to the National Library of Medicine's pubmed.gov search site produces more than 11,000 scholarly papers written about AEDs including clinical and field reports. Although some devices have had safety alerts and recalls commonly attributed to manufacturer quality control,[4,7] most research has demonstrated that overall, devices are safe, effective, accurate, and increasingly cost-effective.[8–12] As AEDs are easy to transport due to reduced size and weight (less than 7 pounds),[13] and because federal and state legislation enables and provides liability protection to acquirers and users,[14] AEDs are a standard of care device for health and allied health providers and are commonly available within medical institutions and for emergency medical services and fire departments, and police officers.[15,16] More than 30 years of evidence has also shown that little or no training or education is required for proper use,[17–20] because devices have easy-to-follow audio and visual prompt instructions,[21–23] or operate automatically without user decision making after pads are placed on the chest of the patient. For these reasons, AEDs are commonly available for voluntary emergency first aid responders and untrained bystanders who may be present at the scene of a cardiac arrest. This open access is promoted in part because the *2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations* published by the International Liaison Committee on Resuscitation (ILCOR), which represents principal resuscitation organizations worldwide including the American Heart Association (AHA), European Resuscitation Council, and the Heart and Stroke Foundation of Canada has recommended that "AED use should not be restricted to trained personnel. Allowing the use of AEDs by persons without prior formal training can be beneficial and may be lifesaving. Because (however) even brief training improves performance (eg, speed of use, correct pad placement), it is recommended that training in the use of AEDs be provided."[24]

As rapid use saves lives, AEDs are available for lay citizens across a broad spectrum of private and public locations including airports, casinos, community centers, educational institutions, and sports and shopping centers, and in tens of thousands of occupational settings where they are provided for use by health care and nonmedical first aid responders. Indeed, data collected from May 1, 2006, to April 30, 2007, from the Resuscitation Outcomes Consortium, an observational study involving 13,769 out-of-hospital cardiac arrests from 10 North American sites (8 US and 2 Canadian), showed that overall survival to hospital discharge was 7%, survival with bystander CPR but no AED was 9%, and when an AED was used and shock delivered survival was 38%.[25]

EPIDEMIOLOGY, MORBIDITY, MORTALITY, AND INCIDENT LOCATIONS

Cardiovascular diseases (CVD), including coronary heart disease and SCA, remain significant concerns to general public health and the occupational setting in particular. According to the 2011 statistical

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Address correspondence to: Larry M. Starr, PhD, Organizational Dynamics Graduate Studies, University of Pennsylvania, 3440 Market Street, Suite 100, Philadelphia, PA 19104-3335 (lstarr@sas.upenn.edu).

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update provided by the AHA an estimated 82,600,000 American adults have one or more types of CVD.[26] Of these, 40,400,000 are estimated to be younger than 60 years. Total CVD includes 76,400,000 people with high blood pressure, 16,300,000 with coronary heart disease, 7,900,000 who experienced myocardial infarction, 9,000,000 with angina pectoris, 5,700,000 with heart failure, and 7,000,000 who experienced a stroke.

The AHA noted that CVD accounted for 33.6% (813,804) of all 2,243,712 deaths in 2007 (the most recent data available), an average of one death every 39 seconds.[25] Data have also indicated that approximately one of every six or 406,351 deaths in the United States resulted from coronary heart disease. The AHA estimate for 2011 is that 785,000 Americans will have a new coronary attack, approximately 470,000 will have a recurrent attack, and an additional 195,000 silent first myocardial infarctions will be identified.

A significant number of cardiac arrests occur in out-of-hospital locations. Out-of-hospital cardiac arrests data collected by emergency medical service programs in Seattle and King County, Washington, from January 1, 1990, through December 31, 1994,[27] revealed that public sites represented 16% of incidents. The Resuscitation Outcomes Consortium examined the period 2005–2007 for seven US sites (Alabama, Dallas, Iowa, Milwaukee, Pittsburgh, Portland [Oregon], and Seattle and King County) and three Canadian sites (Ottawa, Toronto, and Vancouver) and reported 12,930 out-of-hospital cardiac arrests, of which 15.8% occurred in public locations.[28] In a 2007 report of the Save Hearts in Arizona Registry and Education program, which reviewed emergency medical services (EMS) first-care reports submitted voluntarily by 30 municipal fire departments responsible for approximately 67% of Arizona's population, the total number of out-of-hospital adult arrests of presumed cardiac etiology reported statewide was 1097.[29] Of these, 15% occurred in public locations.

There are several electrical abnormalities that result in SCA, but the majority of deaths begin with an initial rhythm of VF.[30–32] If VF is not treated quickly, nearly all patients degenerate to asystole,[33] which is fatal.[34] In patients known to have ischemic heart disease, the out-of-hospital cardiac arrests incidence of VF and VT is 80% to 90%.[35]

Over the past three decades, the recorded incidence of VF or pulseless VT as the initial rhythm encountered by EMS in out-of-hospital cardiac arrests has decreased significantly,[36,37] from approximately 70% to 23%,[25,38] with an overall incidence of 26%.[27] Ventricular fibrillation or VT is higher for bystander-witnessed events in public and occupational settings, because bystanders arrive sooner than EMS; thus, survival to hospital discharge is nearly three times higher when an AED is applied by a lay responder after a cardiac arrest in a public location than in a private home where the initial assessment and responses are primarily made by EMS (34% vs 12% for arrests at home).[39] The consensus of science to correct VF and pulseless VT is immediate chest compression followed by a single electric shock with a controlled dose and duration of energy followed by resumption of chest compressions. If circulation does not return, this is followed by a sequence of compression and electric shock with the same or with increasing energy levels.[40]

Cardiopulmonary resuscitation without electric therapy may sustain a patient in VF for a short time but only rarely restores an organized rhythm. Indeed, performing CPR in the period of 1.5 to 3 minutes before defibrillation does not necessarily improve survival for patients with out-of-hospital VF or pulseless VT.[41,42] And delaying CPR even for AED rhythm assessment is associated with decreased probability of conversion of VF to another rhythm.[42,43] As return of an adequate perfusing rhythm requires immediate application of the combination of CPR, defibrillation, and pharmacotherapy as soon as possible after arrest, establishing controls to support these enhances the probability of survival.

SUDDEN CARDIAC ARREST AND THE CHAIN-OF-SURVIVAL PARADIGM

Factors contributing to out-of-hospital survival following SCA have been described primarily in terms of a time-related, linear chain-of-survival paradigm.[44,45] The sequential interventions (links) leading to survival are (1) early recognition and call for EMS; (2) early initiation of basic life support CPR; (3) early defibrillation (AED); and (4) early advanced (cardiac) life support (ALS) primarily involving drug intervention protocols. Following the release of the *2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*, a fifth link, integrated post–cardiac arrest care, was added.[46]

Sudden cardiac arrest survival has been described as dependent on the sequential availability of the links although more advanced applications may jump ahead of lesser ones. For example, if workplace allied health personnel or the arriving community EMS responders are not qualified or prepared to deliver ALS, this link may not be available until the patient arrives at a medical center. If CPR-trained first aid responders initiate chest compressions in conjunction with an AED, and this is quickly followed by intervention by ALS-level responses, then timing between these links will likely be shorter.

In a systematic review of literature through 2008, the factors most correlated with survival to hospital discharge following out-of-hospital cardiac arrest were witnessed by a bystander, witnessed by EMS, applying bystander CPR, being found in VF or VT, and achieving return of spontaneous circulation.[47] Without intervention, survival following SCA decreases rapidly to zero. Several studies have reported that for each minute of untreated cardiac arrest, the probability of successful rhythm conversion decreases by up to 10%, producing an equivalent per-minute-death rate.[48,49] Conversely, survival rates as high as 90% have been reported when the collapse-to-defibrillation ("drop-to-shock") time is within 1 minute.[50–52]

To empirically define the contribution of each link in the chain of survival, data from the Seattle experience were examined between 1976 and 1991.[49] A best-fit model demonstrated the following equation:

Survival rate = 67% at collapse − 2.3% per minute to CPR − 1.1% per minute to defibrillation − 2.1% per minute to ACLS

As noted by the authors,

> The regression constant, 67%, represents the probability of survival in the hypothetical situation in which all treatments are delivered immediately after collapse to patients with prehospital cardiac arrest.... With delays in CPR, defibrillatory shock, and definitive care, the magnitude of the decline in survival rate per minute is the sum of the three coefficients (−2.2%, −1.1%, −2.1%), or −5.5%.[49]

Although the chain-of-survival paradigm is an established metaphor, some argue that it is too simple because the forces that affect survival are complex.[53] For example, when the four survival categories are examined in more detail, at least 50 "known or speculative" and additional "yet to be identified" factors not included in the chain can be acknowledged as influencing SCA survival.[54] In addition, only approximately 7.9% of victims survive out-of-hospital cardiac arrest in the United States (a number that has not changed significantly in almost 30 years[47]) and there is a fivefold difference in survival rate among US communities.[38] Thus, some commentators have called for a rethinking of the approach to cardiac arrest in terms of relevant links,[55] and the use of a chain metaphor.[56]

AED TECHNOLOGIES

AED Analysis of Rhythms, Waveforms, Energy Levels, and Application

Automated external defibrillators utilize microprocessors to analyze several characteristics of the surface electrocardiogram signal. Wave frequency, amplitude, and some integrated features such as slope or morphology are identified and compared with preset values. In an unresponsive, nonbreathing, pulseless patient, an AED will advise shocks for monomorphic and polymorphic VT, supraventricular tachycardia, or VF.

Early AED models offered monophasic or biphasic waveforms. Monophasic waveforms provide current flows in a single direction (polarity). When the rate at which the pulse falls to zero is gradual, they are referred to as monophasic damped sinusoidal. When the rate is instantaneous, they are called monophasic truncated exponential. Biphasic waveform defibrillators deliver a sequence of two pulses in which the second is of opposite polarity to the first. Although biphasic damped sinusoidal and biphasic truncated exponential are both technically possible, almost all AEDs currently provided are biphasic truncated exponential devices.

Reviewing all levels of evidence, ILCOR and AHA recommended that for a biphasic truncated exponential waveform for defibrillation of pulseless VT/VF cardiac arrest, it is reasonable to start with an energy level of 150 to 200 J.[40] Although they note that there is insufficient evidence to determine the initial energy level for any other biphasic waveform, initial and subsequent shocks using this waveform should be at 360 J. Although there is lower total shock success for monophasic defibrillation,[57] in the absence of a biphasic defibrillator, a monophasic defibrillator is acceptable and use of a high initial energy (360 J) seems preferable.[40]

Shock success is usually defined as termination of VF 5 seconds after the shock. When defibrillation is required, a single shock should be provided with resumption of chest compressions/CPR immediately after the shock. Chest compressions should not be delayed for rhythm reanalysis or a pulse check immediately after a shock. For second and subsequent biphasic shocks, the same initial energy level is acceptable.

Device "Errors"

With the increase in size and competition of the AED manufacturing and distribution market over the past decade, the defibrillator industry has recalled hundreds of thousands of devices and has notified the US Food and Drug Administration (FDA) about thousands of adverse incident reports including device failure during a rescue attempt that may have contributed to patient harm or death.[58] In response, the FDA's Circulatory System Devices advisory committee has discussed whether additional regulatory controls may be needed to ensure safe and reliable performance and long-term monitoring of devices.[59,60] Despite these reviews, the remarkable lifesaving benefits continue to outweigh the number or nature of reports so federal agencies including FDA and the Occupational Safety and Health Administration continue to advocate use of these important lifesaving devices. Indeed, there is no recommendation from any federal, state, or medical agency to make any change to current AED clinical practice.

PUBLIC ACCESS DEFIBRILLATION

The public access defibrillation (PAD) concept gained momentum in 1992 when the AHA Task Force on the Future of CPR challenged the medical device industry to create AEDs that would make early defibrillation accessible to the public.[61] Public access defibrillation applies to all US organizations including the federal government,[62] and is defined as out-of-hospital cardiac arrest treated with an AED by persons other than the community-designated personnel. For example, the state of Maryland PAD exempts from PAD policy "all healthcare facilities, physician's offices, dentist's offices, federal government agencies, jurisdictional EMS operational programs, and commercial ambulance services."[63]

The rationale for PAD was based on the concern that in many densely populated areas, traditional EMS responders cannot respond in sufficiently short time to perform resuscitation and maximize survival. It was determined that training and equipping lay responders to use AEDs and provide resuscitation until arrival of EMS was a practical and appropriate solution to that problem.

All US states have passed a version of PAD legislation describing the process of acquisition, control, and use of an AED by lay responders. Elements commonly addressed in state legislation include immunity for rescuers, acquirers, and enablers; training requirements for users; medical supervision or involvement; and EMS notification. A summary of the details of state PAD legislation is available in AED-information databases such as the National Conference of State Legislatures,[64] and the National Center for Early Defibrillation.[65]

Although survival from PAD has been shown to be increasing and effective,[66] and although PAD legislation requires AED sales to be state-registered, registry compliance and governance continue to show challenges. For example, a 2004 review of PAD in North Carolina indicated that the state EMS database contained only 18% of PAD locations, suggesting that there are a large number of AEDs placed in communities that are not registered within the community PAD system.[67] Arlington, Texas, with a population of more than 365,000, provides a list and map of only 32 AEDs available for "all businesses."[68] In Philadelphia, researchers from the University of Pennsylvania have designed a contest to find AEDs in the city to "enable us to build a comprehensive map and registry of Philadelphia AEDs that can be used in emergency situations by the 911 center and the public."[69]

GUIDANCE FOR THE USE OF AEDS IN OCCUPATIONAL SETTINGS

Federal and state government agencies and dozens of professional, safety, and medical societies have issued AED position statements over the past decade.[70] Occupational Safety and Health Administration has established partnerships with the American Association of Occupational Health Nurses[71] and ACOEM,[72] in which resources are offered to occupational sites including reference to the ACOEM AED guidance[73] and by citing that "volunteers trained in CPR and the use of AEDs had twice as many victims survive compared to ... volunteers trained only in CPR."[74] The following are updated ACOEM guidance for the use of AEDs in the occupational setting.

Establishment of a Management System for the AED Program

A management system should be established within each organization to have clearly defined lines of responsibility for those who oversee and monitor the program.

Medical Direction and Administrative Control of the AED Program

A qualified medical director should be assigned to manage all medical aspects of the AED program. Medical direction responsibilities include but are not limited to providing the required written authorization to acquire the AED and performing a case-by-case review each time the AED is used in the occupational setting.

An administratively qualified person should be responsible for the program's overall administration and coordination activities. Responsibilities include but are not limited to establishing or integrating the AED program with an ongoing quality assurance system, ensuring compliance with industry-related and other regulatory requirements, ensuring proper interface with local EMS, and ensuring proper education, training, or support for AED users prior to and following use.

Awareness of and Compliance With Federal and State Regulations, and Policies

An occupational AED program must comply with appropriate federal guidelines such as the Cardiac Arrest Survival Act and federal and state PAD legislation. As the details of state PAD legislation vary, a single corporate policy for a geographically separated organization may be insufficient unless it addresses all elements where the AEDs are placed. An occupational AED program should address and be in compliance with relevant medical practice insurance requirements and insurance programs for the organization, and for occupational physicians and nurses, and any programs affecting lay responders.

Development of a Written AED Program Description for Each Location

A written summary of the AED program should be prepared, distributed, and discussed with all relevant (eg, administrative, safety, security, health care) personnel at an occupational facility. As state PAD legislation requires registration of AEDs and EMS notification, and may require additional communication to ensure smooth application of medical protocols, all information associated with PAD state requirements and compliance should be included in the written program.

Integration With an Overall Occupational Emergency Response Plan and Coordination with Local Emergency Medical Services

The AED program should be a component of the more general plan describing emergency responses at the occupational setting. Topics addressed by the AED component should include but not be limited to the awareness and placement of AEDs to ensure easy and timely access; procedure for notification of suspected cardiac emergency to occupational medical, trained first aid responders, and bystanders; assessment of scene and patient; proper body substance isolation procedures; CPR and AED response protocols; clinically appropriate patient transport to a medical facility including how continuation of care will be ensured; occupational responder and bystander debriefing; equipment review, service, and replacement; and methods to review follow-up care.

Coordination with local EMS should be part of an integrated plan. This includes but is not limited to review and coordination between EMS protocols and occupational response protocols; communication and logistic support to ensure rapid EMS access to the occupational site and to patient location; collaboration between EMS and occupational responders about on-site patient treatment and supervision; transition from the occupational site to the local medical center; and integration of occupational follow-up protocols with those at the medical center.

Selection and Training of Responders

Although an AED should be used by the first available bystander, trained or not, all designated occupational first aid responders and all occupational health care users should receive training that is recognized and standardized. Topics should include adult (and child, if appropriate) CPR and use of the specific AED expected to be available and used at the occupational site. Short video/computer self-instruction (with minimal or no instructor coaching) that includes synchronous hands-on practice ("practice-while-you-watch") in basic life support can be considered as an effective alternative or retention method to instructor-led courses. Occupational medical and administrative leaders are encouraged to identify individuals at the workplace who would be regularly trained in CPR/AED and first aid or ALS procedures, if appropriate to the work environment. Such people would be more likely to recognize, respond, and support the responses of bystanders when SCA or another medical emergency occurs.

Selection of AEDs

All AEDs must meet federal FDA medical device and federal and state PAD legislation criteria. Automated external defibrillator devices should also meet the most current recommendations of ILCOR and AHA. When an older, previously acquired device is available, training of responders should address any aspects of the device that vary from current recommendations.

Selection of and Placement of AED and Ancillary Supplies

Ancillary supplies should be available for use when managing an occupational SCA involving an AED. Examples include but are not limited to bloodborne pathogens responder and cleanup kits to ensure compliance with body substance isolation procedures,[75] CPR barrier masks with one-way valve, AED responder kits to support application of self-adhesive defibrillation pads (razor to shave chest hair and towel to dry the chest after removal of a transdermal patch),[76] and a CPR audio prompting device to guide action and timing sequences of CPR ventilations and compressions.[77,78]

As dyspnea, hypoxemia, or signs of heart failure or shock are indications for oxygen administration and as use of 100% oxygen during adult cardiac arrest continues to be part of the recommended treatment algorithm according to ILCOR and AHA,[24] a CPR resuscitation mask with an oxygen port to permit delivery of supplemental oxygen for the breathing or nonbreathing patient and a portable emergency oxygen device should be available. To support this, the 2011 training guidelines issued by the American Red Cross[79] and the National Safety Council[80] include administration of oxygen as part of AED and CPR responding. Also, FDA medical device and drug policies continue to recognize emergency oxygen as appropriate for use without prescription by properly trained personnel.[81] Precautions to minimize sparking from the paddles/pads and avoidance of use when high-flow oxygen is directed across the chest should be taken.[58]

When practical, AEDs and ancillary supplies should be placed to allow initiation of resuscitation and use of the AED ("drop-to-shock" interval) within as brief a period of time as possible following suspected cardiac arrest. As probability of survival reportedly can decrease by 7% to 10% per minute until defibrillation,[49] a 5-minute response time is a goal. Estimating the time needed for transport and set up of the AED in various work areas can help determine whether a proposed location is appropriate.

Schedules for Training/Retraining

As life support knowledge and skills, both basic and advanced, can deteriorate in as little as 3 to 6 months, frequent assessments and, when needed, refresher training are recommended to maintain knowledge and skills.[79]

Scheduled Equipment Maintenance and Replacement

A preventive and postresponse service procedure should be established. Records should be maintained for the AED and all ancillary supplies.

Establishment of an AED Quality Assurance Program

The AED program should be incorporated into or have its own quality assurance program. Elements should include but are not limited to medical review by a qualified physician after every AED use; record keeping of all AED-related training, locations, servicing; and records of all medical reviews following AED use. In addition, a method to evaluate the efficacy of the program against its objectives (educational and administrative), and a method to improve or sustain critical elements should be provided.

Cost of Start-up and Continued Management

Administrators and health care practitioners should be aware that *acquiring* an AED is one element of a comprehensive and ongoing program. Costs must be identified to initiate (eg, acquisition of the device, training, and materials; administration, coordination) and to sustain the continued operation of a program. These ongoing costs should be monitored.

CONCLUSION

Development of a program to acquire and utilize AEDs is a reasonable, appropriate, and increasingly common aspect of managing SCA in the occupational setting. However, acquiring the AED is but one of the elements necessary for such a program. To comprehensively address the prevention of SCA morbidity and mortality among working age adults, a complete AED program is recommended.

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OUTCOMES OF RAPID DEFIBRILLATION BY SECURITY OFFICERS AFTER CARDIAC ARREST IN CASINOS

TERENCE D. VALENZUELA, M.D., M.P.H., DENISE J. ROE, DR.P.H., GRAHAM NICHOL, M.D., M.P.H., LANI L. CLARK, B.S., DANIEL W. SPAITE, M.D., AND RICHARD G. HARDMAN, B.S.

ABSTRACT

Background The use of automated external defibrillators by persons other than paramedics and emergency medical technicians is advocated by the American Heart Association and other organizations. However, there are few data on the outcomes when the devices are used by nonmedical personnel for out-of-hospital cardiac arrest.

Methods We studied a prospective series of cases of sudden cardiac arrest in casinos. Casino security officers were instructed in the use of automated external defibrillators. The locations where the defibrillators were stored in the casinos were chosen to make possible a target interval of three minutes or less from collapse to the first defibrillation. Our protocol called for a defibrillation first (if feasible), followed by manual cardiopulmonary resuscitation. The primary outcome was survival to discharge from the hospital.

Results Automated external defibrillators were used in 105 patients whose initial cardiac rhythm was ventricular fibrillation. Fifty-six of the patients (53 percent) survived to discharge from the hospital. Among the 90 patients whose collapse was witnessed (86 percent), the clinically relevant time intervals were a mean (±SD) of 3.5±2.9 minutes from collapse to attachment of the defibrillator, 4.4±2.9 minutes from collapse to the delivery of the first defibrillation shock, and 9.8±4.3 minutes from collapse to the arrival of the paramedics. The survival rate was 74 percent for those who received their first defibrillation no later than three minutes after a witnessed collapse and 49 percent for those who received their first defibrillation after more than three minutes.

Conclusions Rapid defibrillation by nonmedical personnel using an automated external defibrillator can improve survival after out-of-hospital cardiac arrest due to ventricular fibrillation. Intervals of no more than three minutes from collapse to defibrillation are necessary to achieve the highest survival rates. (N Engl J Med 2000;343:1206-9.)

OUT-OF-HOSPITAL cardiac arrest is a major cause of death in the United States.[1,2] Studies of cardiac arrest in the nation's largest cities have shown dismal rates of survival to hospital discharge (less than 5 percent for cases of ventricular fibrillation in which the collapse is witnessed).[3,4] By contrast, some mid-sized urban areas with excellent emergency medical systems have achieved survival rates of 15 to 35 percent.[5,6] The majority of cases of out-of-hospital cardiac arrest arise from ventricular fibrillation.[7,8] Survival after out-of-hospital cardiac arrest due to ventricular fibrillation is determined primarily by the length of time from the onset of ventricular fibrillation to electrical defibrillation.[9] Therefore, early in the 1990s, the American Heart Association initiated a program to ensure public access to defibrillation and reduce the delay between collapse and electrical defibrillation.[10] The keys to reducing the interval from collapse to defibrillation are increasing the availability of automated external defibrillators and increasing the number of people trained to use them. We conducted a prospective, observational study of cardiac arrest in casinos to determine whether training casino security officers in electrical defibrillation and manual cardiopulmonary resuscitation would increase the rate of survival to discharge from the hospital after cardiac arrest.

METHODS

Subjects

We identified persons who had had cardiac arrest in casinos in Clark County, Nevada (in which Las Vegas, Henderson, and Laughlin are located); Lake Tahoe, Nevada; Philadelphia, Mississippi; and

From the Department of Emergency Medicine, College of Medicine (T.D.V., L.L.C., D.W.S.), and the Division of Epidemiology and Biostatistics, College of Public Health (D.J.R.), University of Arizona, Tucson; the Clinical Epidemiology Unit, Ottawa Civic Hospital, University of Ontario, Ottawa, Ont., Canada (G.N.); and the Clark County Fire Department, Las Vegas (R.G.H.). Address reprint requests to Dr. Valenzuela at the Department of Emergency Medicine, 1501 N. Campbell Ave., P.O.B. 245057, Tucson, AZ 85724-5057, or at terry.aemrc.arizona.edu.

Tunica, Mississippi. The subjects had cardiac arrest within the property of the casinos, including the common areas where gambling occurred and the hotel rooms. Subjects who met the inclusion criteria had been unconscious and unresponsive, had no palpable carotid pulse, and had no spontaneous respiration. Subjects less than nine years of age or weighing 36 kg or less were excluded, according to the specifications of the defibrillator manufacturers. Age and weight were estimated visually by security officers. Data on cases of cardiac arrest were collected consecutively from participating casinos.

Training and Equipment of Responders

The security officers were required to have current American Heart Association basic-cardiopulmonary-resuscitation certification before training. Training was conducted by two of the investigators and lasted five to six hours. The curriculum consisted of the following: introduction to cardiac arrest and objectives of defibrillation training, basic anatomy and physiology of cardiac arrest, assessment of the patient, orientation to the automated external defibrillator, protocol for automated external defibrillation, small-group practice with the defibrillator, skills testing, written examination, and review. Two to three hours of the course consisted of hands-on practice and scenarios. The passing score for the written test was set at 75 percent.

An initial group of approximately 1350 security officers from 10 casinos was trained and equipped by March 1, 1997. Thereafter, security officers at casinos that requested participation in the program were trained as the time of the investigators allowed. All officers received the same course and testing. A prospectively set threshold for data analysis (100 cases of ventricular fibrillation) was reached on October 12, 1999. Data were collected from a total of 32 casinos over approximately 32 months.

The casinos were encouraged to place a sufficient number of defibrillators on their premises to meet a goal of no more than three minutes of elapsed time from collapse to defibrillation. Implementation of these recommendations was left to the management of the individual casinos. Casino security officers staged mock cardiac arrests at various locations to determine the length of time required to bring defibrillators to those locations from their storage places. The casinos were free to purchase any current-generation automated external defibrillator; several brands were in use by the end of the study.

Protocol

Security officers remain in designated areas of the casinos at all times. An officer is always visible from any point in the public area of the casino. In addition, security cameras mounted in the ceiling randomly scan the public areas, and security personnel can focus on unusual events. In our study, when the officers were notified by radio of the presence of a "sick person," the nearest officer proceeded to the patient and assessed him or her for responsiveness, spontaneous respiration, and palpable carotid pulse. This officer initiated manual cardiopulmonary resuscitation if indicated. A second officer, who had also been informed by radio of the patient's location and who had prior knowledge of where the defibrillators were stored, brought the nearest defibrillator to the patient. The defibrillator was immediately attached and activated, and audible prompts (by a recorded voice) from the various devices were followed. Resuscitative efforts by the security officers continued until the patient regained pulse and spontaneous respiration or until the paramedics arrived.

Collection of Data

Data from the participating casinos were provided to the study investigators by the Clark County Fire Department. The casinos outside Nevada are owned by corporations with headquarters in Las Vegas and also reported through the Clark County Fire Department. The following data were collected: the subject's name, address, Social Security number (for collection of follow-up data from survivors), and date of birth; the location of the arrest in the casino; whether the subject was receiving cardiopulmonary resuscitation from either the first-responding security officer or from a bystander when the security officer equipped with a defibrillator arrived; and the presence or absence of a pulse, the subject's respiratory effort, and any change in level of consciousness at the time the subject left the casino with the paramedics. In addition, the security officers completed a one-page data form and an incident report specific to the casino.

The time of collapse and the time of initiation of manual cardiopulmonary resuscitation for witnessed arrests were obtained from security videos if the subject collapsed in a common area. If the cardiac arrest was witnessed in a hotel room, the security officer asked the witness or witnesses about the interval between the collapse and the call for help. The time of the call for help was documented on the officer's incident report.

The defibrillation times were recorded automatically by the defibrillator devices. Two types of devices were used. In the case of one type, each device's internal clock is synchronized when contact with the main computer is made to transmit data after an event or each month if the automated electrical defibrillator is not used. The computer's clock is synchronized daily with an atomic clock in Boulder, Colorado. For the other type of device, whose internal clock could not be synchronized remotely, the machine was reset every day to match the casino's security-center clock.

The defibrillators recorded a detailed sequence of events during resuscitation that provided tracings of the cardiac wave form with real clock times and, if the device had audio recording, an audio recording of the resuscitation effort. The time of arrival of the paramedics at the arrest scene was obtained from audio recordings, dispatch records, reports from the emergency medical service, and security videotapes. Data on the subjects' outcomes and their hospital course were obtained by the paramedics of the Clark County Fire Department from the hospitals to which the subjects were transported. Study data forms and electronic data from the defibrillators were collected from all participating casinos by the Clark County Fire Department and forwarded to investigators at the University of Arizona for review and analysis.

Outcome Variables

The time of collapse, time of initiation of manual cardiopulmonary resuscitation, and time of first electrical defibrillation were used to calculate the predictor intervals from collapse to cardiopulmonary resuscitation and from collapse to defibrillation. The primary outcome variable was survival to discharge from the hospital. Consent for review of hospital records was obtained from surviving subjects and from family members of those who did not survive. The study was approved by the institutional review board of the University of Arizona.

Statistical Analysis

Descriptive statistics such as proportions, means, and standard deviations were used to summarize the results. A sample size of 100 subjects with cardiac arrest due to ventricular fibrillation was prospectively established to ensure that the accuracy of the model of survival after cardiac arrest could be estimated with a standard error of no more than 5 percent. The rate of survival among subjects undergoing defibrillation no more than three minutes after collapse was compared with that among subjects undergoing defibrillation more than three minutes after collapse by a chi-square test, and the 95 percent confidence interval was computed for the difference between the rates of survival. Differences between the results for the subjects in our study and previously reported results for patients in Tucson, Arizona, and King County, Washington,[9] were examined with use of chi-square tests for categorical variables and Kruskal–Wallis tests for continuous variables. All P values are two-sided.

RESULTS

The demographic characteristics of the subjects and the intervals from collapse to various interventions are shown in Table 1. The sample contained 148 subjects

TABLE 1. CHARACTERISTICS OF SUBJECTS WITH CARDIAC ARREST IN CASINOS.*

CHARACTERISTIC	ALL CARDIAC ARRESTS (N=148)	WITNESSED ARRESTS WITH AN INITIAL RHYTHM OF VENTRICULAR FIBRILLATION (N=90)
Age — yr	64±12	65±11
Male sex — %	80	84
CPR administered before arrival of defibrillator — no. (%)	63 (43)	49 (54)
Interval from collapse to CPR — min	—†	2.9±2.8
Initial rhythm of ventricular fibrillation — no. (%)	105 (71)	90 (100)
Interval from collapse to attachment of defibrillator — min	—†	3.5±2.9
Interval from collapse to first defibrillation — min	—†	4.4±2.9
Interval from collapse to arrival of paramedics — min	—†	9.8±4.3
Survival to discharge from hospital — no. (%)	56 (38)	53 (59)

*Plus–minus values are means ±SD. CPR denotes cardiopulmonary resuscitation.

†Intervals from collapse to intervention could not be calculated for unwitnessed arrests.

with confirmed cardiac arrest. None of them were children, and therefore no cases were excluded because of the age and weight criteria. One hundred five subjects had an initial cardiac rhythm of ventricular fibrillation, 17 had pulseless electrical activity, and 26 had asystole. No subjects whose initial cardiac rhythm was not ventricular fibrillation survived to discharge from the hospital. Of the 148 subjects in the total group, 17 (11 percent) were pronounced dead at the scene, 60 (41 percent) were pronounced dead in the hospital emergency department, 15 (10 percent) were admitted to the hospital and died before discharge, and 56 (38 percent) survived to discharge from the hospital.

Ventricular fibrillation accounted for 105 of the 148 cases (71 percent). Fifteen subjects who had ventricular fibrillation collapsed unobserved; three of them survived to hospital discharge (20 percent). Of the 105 patients with ventricular fibrillation, 4 (4 percent) were pronounced dead at the scene, 35 (33 percent) were pronounced dead in the hospital emergency department, 10 (10 percent) were admitted to the hospital and died before discharge, and 56 (53 percent) survived to discharge from the hospital.

We performed subgroup analysis on data from the 90 subjects with witnessed cardiac arrest due to ventricular fibrillation. They were predominantly male (84 percent), with a mean (±SD) age of 65±11 years. The demographic characteristics of this subgroup did not differ significantly from those of the entire group of subjects. Fifty-four percent of the subjects with witnessed arrests received cardiopulmonary resuscitation before the arrival of the guard with the defibrillator: 61 percent of them from security officers, 16 percent from strangers, 14 percent from family members, and 8 percent from friends or coworkers. The mean intervals from collapse to various interventions were 2.9±2.8 minutes for cardiopulmonary resuscitation, 3.5±2.9 minutes for attachment of the defibrillator, 4.4±2.9 minutes for the first defibrillation shock, and 9.8±4.3 minutes for arrival of the paramedics. Fifty-three of those with witnessed cardiac arrest due to ventricular fibrillation (59 percent) survived to discharge from the hospital; those who did not survive died at the casino (2 percent), in the emergency department of the hospital (29 percent), or after hospital admission (10 percent). Among subjects whose collapse was witnessed, the survival rate was 74 percent (26 of 35) for those who received their first defibrillation no later than three minutes after collapse and 49 percent (27 of 55) for those who received their first defibrillation more than three minutes after collapse. This difference (25 percentage points) was statistically significant ($P=0.02$), with a 95 percent confidence interval of 5.6 to 44.8 percentage points.

DISCUSSION

The work of White and others demonstrated that people without other medical training could successfully resuscitate victims of out-of-hospital cardiac arrest due to ventricular fibrillation.[11,12] Investigators subsequently advocated strategies to shorten the delay from collapse to electrical defibrillation by training and equipping for defibrillation new classes of responders with a variety of backgrounds.[13] Device manufacturers responded to the American Heart Association's public-access defibrillation initiative by producing automated external defibrillators that are simpler and less expensive and that require less maintenance than previous portable defibrillators.

The challenge for the future is to decide where defibrillators should be available, place them there, and train appropriate groups of people to use them. Some airlines have already placed defibrillators on their aircraft and trained their attendants to use them.[14-16]

On the basis of their experience with cardiac arrests in casinos, officers of the Clark County Fire Department reasoned that casino security officers, whose job involves rapid response to emergencies but who have not previously received medical training other than basic cardiopulmonary resuscitation, would be ideal candidates for training in a rapid-defibrillation program. Our objective was to determine whether these officers could successfully resuscitate victims of cardiac arrest due to ventricular fibrillation through the use of automated external defibrillators. The survival rates achieved in this project were very high for persons with out-of-hospital cardiac arrest due to ventricular fibrillation.

What accounts for the apparent success of this project, and what are the implications for so-called public-access defibrillation? First, the majority of all arrests in this study occurred in the public areas of the casinos, not in the guests' rooms, and therefore were visible to security officers and video cameras. Studies of traditional emergency-medical-services systems indicate that less than 20 percent of cardiac arrests occur in public places.[17] The arrests in the casinos were therefore more frequently witnessed and recognized than those in other studies, and treatment was initiated sooner. Cardiac arrests are not likely to be detected as quickly in sites such as apartment buildings or gated communities, where residents do not spend extended periods in public areas. Second, the response intervals in the casinos were shorter than those reported with traditional emergency-response systems. The intervals from collapse to cardiopulmonary resuscitation were significantly shorter for the arrests that occurred in casinos (2.9 minutes) than for those that occurred in Tucson, Arizona (4.7 minutes), and King County, Washington (3.4 minutes), as were the intervals from collapse to defibrillation (4.4 minutes in the casinos, 5.1 minutes in King County, and 9.5 minutes in Tucson).[9]

These results have implications for the Public Access Defibrillation Study funded by the National Heart, Lung, and Blood Institute, a prospective, randomized study of rapid defibrillation by nonmedical providers. Survival rates in study sites where collapse-to-defibrillation intervals are not consistently in the range of three to four minutes may not be much higher than those with the best traditional emergency-medical-services systems; still, the results from these sites may be an improvement over those of emergency-medical-services systems with prolonged response times. Casinos also have an unusually high density of cardiac arrests in their public areas, in comparison with other types of public places.[18]

The limitations of this study include the lack of access to data on cardiac arrests that occurred in casinos other than the participating casinos during the study period. At the time the study was undertaken, uncertainty about potential legal liability limited the group of casinos willing to risk participation. A rolling implementation strategy, such as we used, was the only feasible option. In addition, there was no formal neurologic testing in survivors. However, the disposition of the subjects sheds light on their neurologic function at discharge. At the end of the study, no survivor was dependent on others for daily support. Therefore, it is unlikely that any survivor could be classified in cerebral-performance categories higher than 1 (good cerebral performance) or 2 (moderate cerebral disability) on the widely used Cerebral Performance scale.[19]

Our study has shown that rapid defibrillation by casino security officers is both feasible and effective; it also demonstrates that, to increase the survival rates over those obtained with standard emergency-services systems, the interval between collapse and the first defibrillation must be short.

We are indebted to the Clark County Fire Department, whose officers conceived the project; to the participating casinos, which had the courage to implement this program when their potential liability was unclear; to the medical directors of the casinos who, without financial compensation, provided the local medical oversight necessary for the project; and to Medtronic-PhysioControl for supplying the study computers.

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ORIGINAL ARTICLE

Ventricular Tachyarrhythmias after Cardiac Arrest in Public versus at Home

Myron L. Weisfeldt, M.D., Siobhan Everson-Stewart, Ph.D., Colleen Sitlani, M.S., Thomas Rea, M.D., Tom P. Aufderheide, M.D., Dianne L. Atkins, M.D., Blair Bigham, M.Sc., Steven C. Brooks, M.D., M.H.Sc., Christopher Foerster, M.Sc., Randal Gray, M.A.Ed., Joseph P. Ornato, M.D., Judy Powell, B.S.N., Peter J. Kudenchuk, M.D., and Laurie J. Morrison, M.D., for the Resuscitation Outcomes Consortium (ROC) Investigators

ABSTRACT

BACKGROUND

The incidence of ventricular fibrillation or pulseless ventricular tachycardia as the first recorded rhythm after out-of-hospital cardiac arrest has unexpectedly declined. The success of bystander-deployed automated external defibrillators (AEDs) in public settings suggests that this may be the more common initial rhythm when out-of-hospital cardiac arrest occurs in public. We conducted a study to determine whether the location of the arrest, the type of arrhythmia, and the probability of survival are associated.

METHODS

Between 2005 and 2007, we conducted a prospective cohort study of out-of-hospital cardiac arrest in adults in 10 North American communities. We assessed the frequencies of ventricular fibrillation or pulseless ventricular tachycardia and of survival to hospital discharge for arrests at home as compared with arrests in public.

RESULTS

Of 12,930 evaluated out-of-hospital cardiac arrests, 2042 occurred in public and 9564 at home. For cardiac arrests at home, the incidence of ventricular fibrillation or pulseless ventricular tachycardia was 25% when the arrest was witnessed by emergency-medical-services (EMS) personnel, 35% when it was witnessed by a bystander, and 36% when a bystander applied an AED. For cardiac arrests in public, the corresponding rates were 38%, 60%, and 79%. The adjusted odds ratio for initial ventricular fibrillation or pulseless ventricular tachycardia in public versus at home was 2.28 (95% confidence interval [CI], 1.96 to 2.66; $P<0.001$) for bystander-witnessed arrests and 4.48 (95% CI, 2.23 to 8.97; $P<0.001$) for arrests in which bystanders applied AEDs. The rate of survival to hospital discharge was 34% for arrests in public settings with AEDs applied by bystanders versus 12% for arrests at home (adjusted odds ratio, 2.49; 95% CI, 1.03 to 5.99; $P=0.04$).

CONCLUSIONS

Regardless of whether out-of-hospital cardiac arrests are witnessed by EMS personnel or bystanders and whether AEDs are applied by bystanders, the proportion of arrests with initial ventricular fibrillation or pulseless ventricular tachycardia is much greater in public settings than at home. The incremental value of resuscitation strategies, such as the ready availability of an AED, may be related to the place where the arrest occurs. (Funded by the National Heart, Lung, and Blood Institute and others.)

From Johns Hopkins University, Baltimore (M.L.W.); University of Washington, Seattle (S.E.-S., C.S., T.R., J.P., P.J.K.); Medical College of Wisconsin, Milwaukee (T.P.A.); University of Iowa, Iowa City (D.L.A.); University of Toronto, Toronto (B.B., S.C.B., C.F., L.J.M.); University of Alabama, Birmingham (R.G.); and Virginia Commonwealth University, Richmond (J.P.O.). Address reprint requests to Dr. Weisfeldt at Johns Hopkins University, 1830 E. Monument St., Suite 9026, Baltimore, MD 21287, or at mlw5@jhmi.edu.

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The incidence of ventricular fibrillation or pulseless ventricular tachycardia as the first recorded rhythm in out-of-hospital cardiac arrest has declined dramatically in the past several decades.[1,2] Thirty years ago, 70% of such arrests were characterized by initial ventricular fibrillation or pulseless ventricular tachycardia; today, the incidence is 23%.[3,4] This decline is of substantial importance for public health, since more than 300,000 Americans have an out-of-hospital arrest each year, with an estimated survival rate of 7.9% nationally,[5] and the majority of survivors are in the subgroup of persons whose initial rhythm is ventricular fibrillation or pulseless ventricular tachycardia.[3]

Controlled clinical trials have shown that "public access defibrillation" — that is, the use of automated external defibrillators (AEDs) in public settings by trained laypersons — improves survival after an out-of-hospital cardiac arrest.[6] In contrast, layperson use of AEDs in residential settings has not proved to be of benefit, possibly owing in part to a lower prevalence of ventricular fibrillation or pulseless ventricular tachycardia as the initial rhythm.[7] These observations suggest that the incremental value of certain resuscitation strategies, such as the ready availability of an AED, may be related to the setting in which the arrest occurs.

The purpose of this study was to assess the frequency of initially identified ventricular fibrillation or pulseless ventricular tachycardia and survival among patients whose cardiac arrest was witnessed in a public setting or at home and, in particular, when an AED was applied by a bystander.

METHODS

STUDY DESIGN AND PATIENTS

The Epidemiologic Cardiac Arrest Registry of the Resuscitation Outcomes Consortium (ROC Epistry–Cardiac Arrest) is a population-based emergency-medical-services (EMS) registry of out-of-hospital cardiac arrest.[3] We carried out a prospective, multicenter, population-based cohort study involving patients who were assessed or treated by one or more of 208 ROC EMS agencies and their receiving institutions at seven U.S. sites (Alabama, Dallas, Iowa, Milwaukee, Pittsburgh, Portland [OR], and Seattle–King County) and at three Canadian sites (Ottawa, Toronto, and British Columbia). The study sites provided data for cardiac arrests that occurred between December 1, 2005, and March 31, 2007.[8]

Study patients included all persons 19 years of age or older with nontraumatic out-of-hospital cardiac arrest for whom external defibrillation was attempted (by lay bystanders or EMS personnel) or who were treated with chest compressions (by EMS personnel). The study was approved by the institutional review boards of the University of Washington (data coordinating center) and the participating U.S. and Canadian study sites. The requirement for informed consent was waived because the study was considered to meet the criteria for minimal risk.

DATA COLLECTION

Information about each subject was collected with the use of uniform definitions developed by the ROC investigators and included Utstein data elements.[9] The data elements included demographic characteristics of the patients, circumstances of the arrests, characteristics of care, and survival status. Data were collected by trained personnel who followed uniform procedures to ensure the validity and reproducibility of the data. All data recorded at study entry were subject to error, logic, and cross-form checks, which maximized the accuracy of the data. Routine, random, centralized review confirmed the initial rhythm as a stable, reproducible variable. Data were deidentified in compliance with the Health Insurance Portability and Accountability Act.

STUDY DEFINITIONS

A public location was defined as a street or highway, public building, place of recreation, industrial place, or other public property, excluding health care facilities (hospitals, medical clinics, and other health care institutions). A private location was defined as a home (the principal focus of this study), a residential institution (typically a nursing home), or some other nonpublic setting (usually a rural farmland location). Bystander-witnessed cardiac arrest was defined as an arrest observed by a person who was not part of the EMS system. AED application by a bystander was defined as AED placement (with or without delivery of a shock) by a person (or more than one person) outside the EMS system, including police on the scene before the arrival of EMS personnel. Bystander-administered AED shock was defined as a shock that was delivered by non-EMS personnel before the arrival of EMS personnel. An EMS-witnessed arrest was defined as a cardiac arrest that occurred in the presence of a member of the EMS response team. In the few instances in which it could not be determined whether a bystander had witnessed the arrest or had applied an AED or administered a shock, we assumed that the event was not witnessed or that an AED was not applied. Survival to hospital discharge was determined from available records (hospital or EMS records in most cases and public or media sources in rare cases).

FIRST RECORDED RHYTHM

Ventricular fibrillation or pulseless ventricular tachycardia was presumed to be the initial cardiac-arrest rhythm if the shock was delivered by a bystander-applied AED. The initial rhythm as assessed by EMS personnel was determined from the electronic electrocardiographic (ECG) recordings (in 25% of cases) or paper rhythm tracings (in 24%) derived from defibrillators or from descriptions of the initial rhythm in the EMS record (in 51%).

To confirm the accuracy of the reported initial rhythm, 30 arrests were randomly selected from each of four strata, defined by the location of the arrest (home vs. public location) and the first recorded rhythm (shockable [ventricular fibrillation or pulseless ventricular tachycardia] vs. nonshockable), and these 120 arrests were independently reevaluated by three of the authors on the basis of the EMS record, defibrillator ECG recordings, or both. The 13 arrests for which source documents could not be obtained were excluded from the reevaluation study. Rhythm diagnoses were completely concordant among the reviewers, who disagreed with a site interpretation of the reported rhythm in only 3 of 107 cases, for an estimated error rate of 3.1% (95% confidence interval [CI], 0.0 to 7.8) (taking into account the sampling rates for the four strata).

STATISTICAL ANALYSIS

Statistical analyses were conducted with the use of R software, version 2.1.1 (R Foundation for Statistical Computing). All statistical tests were two-sided, with a significance level of 0.05.

The frequencies of ventricular fibrillation or pulseless ventricular tachycardia and of survival to hospital discharge were calculated as simple proportions. Multiple logistic-regression analyses were used to assess the independent association between location and initially recorded ventricular fibrillation or pulseless ventricular tachycardia or survival to hospital discharge after adjustment for age, sex, bystander-witnessed cardiac arrest, the delivery of bystander-initiated cardiopulmonary resuscitation (CPR), and EMS response time from the 911 call until the arrival of the EMS vehicle, as appropriate.

RESULTS

STUDY POPULATION

Between December 2005 and April 2007, a total of 14,420 adult patients were treated by EMS personnel for a cardiac arrest occurring outside a health care facility (Fig. 1); complete data were available for 14,059 of these patients. The initial cardiac-arrest rhythm was known or was deemed shockable (i.e., ventricular fibrillation or pulseless ventricular tachycardia) as indicated by receipt of a bystander-administered AED shock in 12,930 patients (92%). Of this group, 5034 patients (39%) had cardiac arrests that were witnessed by a bystander in a home or public location, 273 (2%) had an AED applied by a bystander before the arrival of EMS personnel, and 1115 (9%) had arrests that were witnessed by EMS personnel.

Table 1 shows the key demographic characteristics and resuscitation status of the patients, including the frequency of ventricular fibrillation or pulseless ventricular tachycardia as the initial recorded rhythm and of survival, according to the location of the arrest. When cardiac arrest occurred in a nonpublic location, it was further characterized as taking place at home, in a residential facility (e.g., nursing home), or in some other private (nonhome) setting. Of 1324 patients in whom the cardiac arrest occurred in a residential institution or other private (nonhome) location, only 41 (3%) survived. This group was excluded from further analysis, so that the principal focus of our study was a comparison of cardiac arrests that occurred in public locations with those that occurred at home. For cardiac arrests that were witnessed by bystanders in public locations, the median time from the 911 call to the arrival of the EMS vehicle at the scene was 5.0 minutes (interquartile range, 3.8 to 6.6);

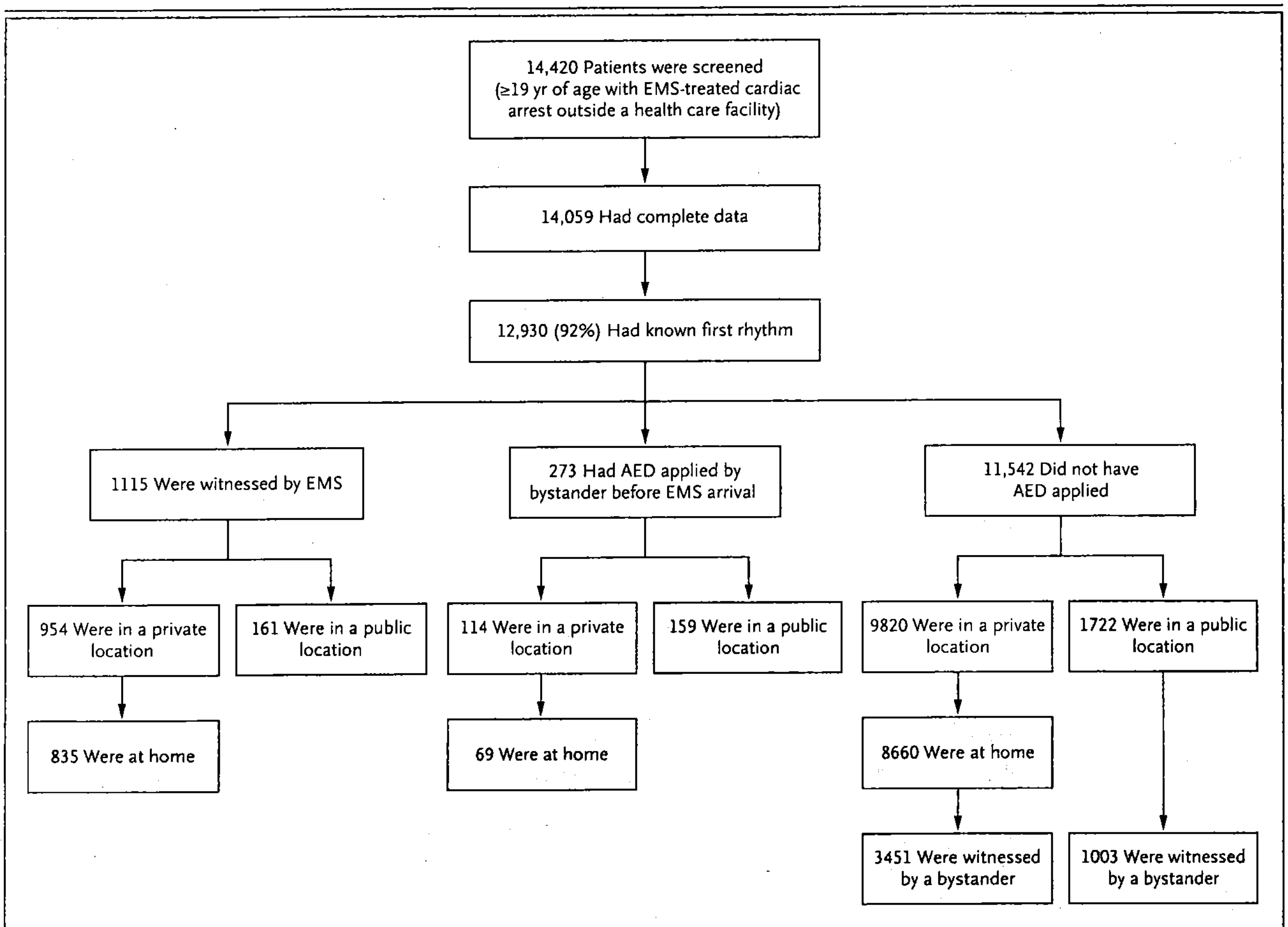

Figure 1. **Number of Patients with Cardiac Arrest in Subgroups and According to the Location Where the Arrest Occurred.**
AED denotes automatic external defibrillator, and EMS emergency medical services.

for bystander-witnessed arrests in the home, the median time was 5.6 minutes (interquartile range, 4.3 to 7.1).

INITIAL RHYTHM

The initial ascertainable rhythm was ventricular fibrillation or pulseless ventricular tachycardia (and, in rare cases, a hypotensive supraventricular tachycardia) in 3336 of the 12,930 arrests, for an overall frequency of 26% (Table 1). Of the 3451 patients with bystander-witnessed cardiac arrest that occurred in the home, 1193 (35%) had initial ventricular fibrillation or pulseless ventricular tachycardia on the arrival of EMS personnel, as compared with 600 of 1003 patients (60%) in whom cardiac arrest occurred in a public location (Table 2 and Fig. 2). The multivariable odds ratio for initial ventricular fibrillation or pulseless ventricular tachycardia after a bystander-witnessed arrest in a public location versus an arrest at home (adjusted for age, sex, bystander-administered CPR, and time from the 911 call to the arrival of EMS personnel at the scene) was 2.28 (95% CI, 1.96 to 2.66; P<0.001) (Table 3).

An AED was applied by a bystander before EMS arrival in 69 patients with cardiac arrests that occurred at home (Table 2 and Fig. 1). Of these patients, 25 (36%) had an initial shockable rhythm, as compared with 125 of 159 patients (79%) in whom an AED was applied by a bystander in a public location. The multivariate odds ratio for shockable rhythm in public versus at home (adjusted for sex, age, bystander-witnessed arrest, bystander-administered CPR, and time from the 911 call to EMS arrival) was 4.48 (95% CI, 2.23 to 8.97; P<0.001) (Table 3). Among the 835 cardiac arrests in the home that were witnessed by

Table 1. **Demographic Characteristics, Resuscitation Status, and Outcomes for Patients with Cardiac Arrest, According to the Location of the Arrest.***

Variable	Total Arrests (N=12,930)	Arrests in Private Location		Arrests in Public Location (N=2042)
		Home (N=9564)	Residential or Other Private Facility (N=1324)	
Mean age — yr	66.3±16.8	66.3±16.6	75.5±14.9	60.2±15.7
Male sex — no. (%)†	8227 (64)	5946 (62)	617 (47)	1664 (81)
Bystander witnessed arrest — no. (%)‡	5034 (39)	3485 (36)	424 (32)	1125 (55)
Bystander performed CPR — no. (%)§	4077 (32)	2463 (26)	689 (52)	925 (45)
Bystander applied AED — no. (%)¶	273 (2)	69 (1)	45 (3)	159 (8)
Bystander delivered AED shock — no. (%)	163 (1)	25 (<1)	14 (1)	124 (6)
EMS witnessed arrest — no. (%)	1115 (9)	835 (9)	119 (9)	161 (8)
Initial VF or pulseless VT — no. (%)‖	3336 (26)	2134 (22)	167 (13)	1035 (51)
Survival to hospital discharge — no. (%)	946 (7)	549 (6)	41 (3)	356 (17)

* Plus–minus values are means ±SD. AED denotes automated external defibrillator, CPR cardiopulmonary resuscitation, EMS emergency medical services, VF ventricular fibrillation, and VT ventricular tachycardia.
† Data were missing in 0.1% of cases.
‡ Data were missing and the arrest was presumed not to have been witnessed in 15.8% of cases.
§ Data were missing and CPR was presumed not to have been given in 8.5% of cases.
¶ Data were missing and the AED was presumed not to have been applied in 8.5% of cases.
‖ The initial cardiac-arrest rhythm (as determined by EMS personnel) was not known in 8% of cases, and these patients were therefore excluded from the analysis.

EMS personnel, the initial rhythm was ventricular fibrillation or pulseless ventricular tachycardia in 207 cases (25%), as compared with 61 of 161 EMS-witnessed cardiac arrests (38%) that occurred in a public location (Table 2 and Fig. 2). For EMS-witnessed cardiac arrests, the odds ratio for initial ventricular fibrillation or pulseless ventricular tachycardia in public versus at home (adjusted for age and sex) was 1.63 (95% CI, 1.13 to 2.35; P=0.009) (Table 3).

SURVIVAL TO HOSPITAL DISCHARGE

Survival outcomes are shown in Tables 1 and 2. Overall survival among the 12,930 patients whose initial cardiac-arrest rhythm was known was 7%. Survival rates after a cardiac arrest at home were 2% among the 5209 patients whose arrests were not witnessed by a bystander or EMS personnel or who did not have an AED applied by a bystander, 8% among the 3451 patients whose arrests were witnessed by a bystander, and 10% among the 1219 patients who were then given CPR by a bystander.

Among patients who had a cardiac arrest at home before the arrival of EMS personnel and for whom an AED was not applied by a bystander, the likelihood of survival to discharge was significantly increased if the arrest was witnessed by a bystander (odds ratio, 3.76; 95% CI, 3.01 to 4.70; P=0.004) and if the bystander administered CPR (odds ratio, 1.37; 95% CI, 1.10 to 1.70; P=0.004).

The survival rate among 1003 patients with bystander-witnessed cardiac arrests that occurred in a public setting was 20%; in 159 instances in which an AED was applied by a bystander, the survival rate was 34%, and in 124 instances in which an AED shock was administered by a bystander, the rate was 42%. The adjusted odds ratio for survival when an AED was applied by a bystander after a cardiac arrest in a public location versus an arrest at home was 2.49 (95% CI, 1.03 to 5.99; P=0.04). Among those who received a shock from an AED applied by a bystander, survival rates did not differ significantly according to the place where the cardiac arrest occurred (odds ratio for survival after an arrest in a public location vs. an arrest at home, 1.68; 95% CI, 0.58 to 4.88; P=0.34).

Table 2. **Demographic Characteristics, Resuscitation Status, and Outcomes of Patients with Cardiac Arrest at Home or in Public, According to Circumstances of the Event.***

Variable	Bystander Witnessed Cardiac Arrest		EMS Witnessed Cardiac Arrest		Bystander Applied AED	
	Home (N=3451)	Public (N=1003)	Home (N=835)	Public (N=161)	Home (N=69)†	Public (N=159)‡
Mean age — yr	67.8±15.5	61.7±15.7	67.7±15.7	59.6±17.6	61.8±16.5	60.0±14.2
Male sex — no. (%)	2257 (65)	805 (80)	491 (59)	112 (70)	43 (62)	138 (87)
Bystander carried out CPR — no. (%)	1219 (35)	555 (55)	9 (1)	0	61 (88)	150 (94)
Bystander delivered AED shock — no. (%)	—	—	—	—	25 (36)	124 (78)
Initial VF or pulseless VT — no. (%)	1193 (35)	600 (60)	207 (25)	61 (38)	25 (36)	125 (79)
Time from 911 call to EMS arrival — min						
Median	5.6	5.0				
Interquartile range	4.3–7.1	3.8–6.6				
Survival to hospital discharge — no. (%)	276 (8)	202 (20)	138 (17)	44 (27)	8 (12)	54 (34)

* Plus–minus values are means ±SD. AED denotes automated external defibrillator, CPR cardiopulmonary resuscitation, EMS emergency medical services, VF ventricular fibrillation, and VT ventricular tachycardia.
† Of the 69 arrests that occurred at home, 34 (49%) were witnessed by a bystander.
‡ Of the 159 arrests that occurred in public, 122 (77%) were witnessed by a bystander.

DISCUSSION

This study shows that shockable arrhythmias (ventricular fibrillation or pulseless ventricular tachycardia) are a relatively infrequent presentation of out-of-hospital cardiac arrest (with an overall incidence of 26%) and account for a remarkably low proportion of both EMS-witnessed arrests (25%) and bystander-witnessed arrests (35%) in the home. The frequency of shockable arrhythmias was higher for bystander-witnessed cardiac arrests in a public location (60%), particularly those in which an AED was applied by a bystander in a public location (79%) (Fig. 2). Therefore, as might be expected, the rate of survival to hospital discharge was significantly higher when an AED was applied by a bystander after a cardiac arrest in a public location (34%, vs. 12% for arrests at home; adjusted model P=0.04).

The limitations of this study should be acknowledged before we consider its implications and possible explanations for the findings. First, we did not have access to the ECG recordings from bystander-applied AED and cannot confirm independently that all shocked rhythms were ventricular fibrillation or pulseless ventricular tachycardia. However, AED rhythm-detection algorithms are considered to be highly sensitive and specific for a shockable arrhythmia, since a shock advisory is strongly correlated with its presence and a no-shock advisory with its absence.[10,11]

Second, it is possible that delays in calling for EMS help were responsible for the low frequency of ventricular fibrillation or pulseless ventricular tachycardia as the initial rhythm among cardiac arrests at home, including those witnessed by a bystander and those for which a bystander applied an AED. Ascertaining the delay between the time of the witnessed collapse and the call to EMS can be challenging in both the public setting and the home setting, since one must rely on accurate recollections by witnesses. Nevertheless, it is unlikely that such a delay would be greater today than it was in an earlier era, when ventricular fibrillation or pulseless ventricular tachycardia was the initial rhythm in 70% of all cardiac arrests.[1,2]

With respect to EMS delays, although the median time from the 911 call to EMS arrival was modestly longer for bystander-witnessed cardiac arrests at home than for those in public

(Table 2), the EMS response times were less than 7 minutes for more than 75% of the patients in both locations.

A spline-fit analysis (data not shown) relating the incidence of initial ventricular fibrillation or pulseless ventricular tachycardia to EMS response time in the case of bystander-witnessed cardiac arrests in public indicated that the frequency of this arrhythmia diminished from 60% to no less than 50% as the EMS response time increased from zero to 7 minutes. Therefore, it does not seem likely that the much lower frequency of ventricular fibrillation or pulseless ventricular tachycardia observed after cardiac arrest in the home would be accounted for by differences in EMS response time or other delays in the case of home-witnessed arrests. EMS response time was also not significantly related to the incidence of initial ventricular fibrillation or pulseless ventricular tachycardia in the multivariate analysis (Table 3). Furthermore, the frequency of these arrhythmias was similar (25%) for cardiac arrests in the home that were witnessed by EMS personnel, and in such cases, one would expect that the first rhythm was documented promptly after the event.

Survival data reported for the population groups in this study are consistent with previous reports on successful bystander-applied AED shocks and witnessed cardiac arrests in both public and nonpublic locations.[12-14] Among the patients in our study who received AED shocks from bystanders in public locations, the survival rate was 42%. This compares favorably with results from a study of cardiac arrests in casinos in which the approximate survival rate was 53% among patients who received AED shocks after the arrests were promptly recognized by means of video cameras on the gaming floor.[12] Similarly, in a study of cardiac arrests that occurred in Chicago airports, the survival rate was 60% among patients who received AED shocks delivered by bystanders.[14]

Studies in Osaka, Japan,[15] and in Copenhagen[16] came to similar conclusions regarding the incidence of ventricular fibrillation or pulseless ventricular tachycardia in public or workplace settings versus nonpublic ones. However, these studies did not specifically address arrests involving bystander-applied AEDs, nor did they exclude unwitnessed cardiac arrests, for which the interval between the arrest and the initial ECG is likely to be prolonged.

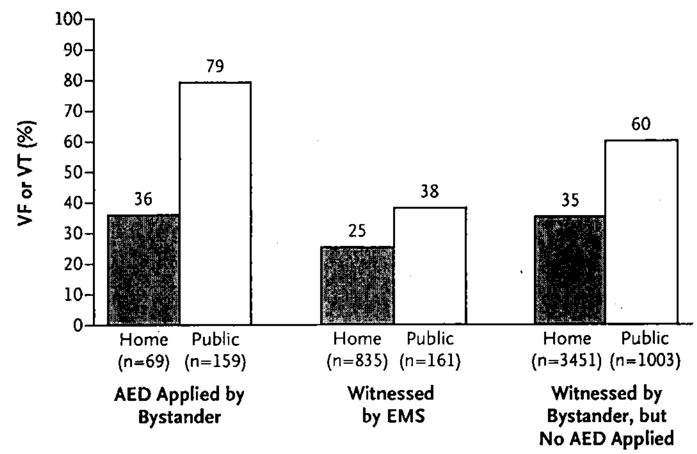

Figure 2. Ventricular Fibrillation (VF) or Pulseless Ventricular Tachycardia (VT) in Subgroup, According to the Location Where the Arrest Occurred.
The percentages shown are for the presence of shockable rhythms in cases of cardiac arrest in which a bystander applied an automated external defibrillator (AED) and for cases of cardiac arrest witnessed by emergency-medical-services (EMS) personnel and those witnessed by bystanders who did not apply an AED.

The results of this study have a number of important implications for public health and community strategies to improve survival after cardiac arrest. First, because only 20 to 30% of cardiac arrests in the United States and Canada occur in public settings, our findings suggest that AED programs and education in AED use by lay responders should be focused on these sites.[17,18]

Second, our findings suggest that the incremental benefit in survival from the use of AEDs in the home, as compared with a strategy that increases the frequency and quality of CPR by bystanders in the home, is likely to be small. The rate of survival after cardiac arrest in the home for the 1219 cases in which a bystander witnessed the event and performed CPR was 10%, which is similar to the 12% survival rate associated with use of a bystander-applied AED in the home. Increasing the rate of CPR by bystanders in the home, perhaps with dispatch assistance, might yield a benefit similar to that achieved with the use of home AEDs.[19-21]

Another strategy to improve survival is initial continuous chest compression without rescue breathing, which may also be more effective in cardiac arrest with ventricular fibrillation or pulseless ventricular tachycardia than in arrest with other initial rhythms. In experimental stud-

Table 3. Odds Ratios for Initial Ventricular Fibrillation or Pulseless Ventricular Tachycardia (or Shockable Rhythm) in Cardiac Arrests Occurring in Public versus Arrests at Home, According to Circumstances of the Event.*

Variable	Bystander Witnessed Arrest			EMS Witnessed Arrest			Bystander Applied AED		
	VF or VT	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio (95% CI)	VF or VT	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio (95% CI)	VF or VT	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio (95% CI)
	no./total no. of arrests (%)			*no./total no. of arrests (%)*			*no./total no. of arrests (%)*		
Location of arrest									
Home	1193/3451 (35)			207/835 (25)			25/69 (36)		
Public	600/1003 (60)	2.82 (2.44–3.26)	2.28 (1.96–2.66)†	61/161 (38)	1.85 (1.30–2.64)	1.63 (1.13–2.35)‡	125/159 (79)	6.47 (3.48–12.03)	4.48 (2.23–8.97)†
Male sex		2.15 (1.87–2.46)	1.88 (1.63–2.17)†		1.95 (1.44–2.64)	1.83 (1.34–2.48)†		3.07 (1.59–5.94)	2.08 (0.94–4.58)
Age (per 5-yr increase)		0.92 (0.90–0.93)	0.94 (0.92–0.96)†		0.93 (0.90–0.98)	0.99 (0.98–1.00)		1.00 (0.91–1.10)	1.02 (0.91–1.13)
Bystander witnessed arrest								4.67 (2.56–8.49)	3.50 (1.76–6.97)†
Bystander performed CPR		1.98 (1.75–2.24)	1.76 (1.55–2.01)†					1.96 (1.79–2.15)	2.09 (0.64–6.84)
Time from 911 call to EMS arrival		1.00 (1.00–1.00)	1.00 (1.00–1.00)					1.00 (0.99–1.02)	1.00 (0.98–1.03)

* AED denotes automated external defibrillator, CPR cardiopulmonary resuscitation, EMS emergency medical services, VF ventricular fibrillation, and VT pulseless ventricular tachycardia.
† P<0.001.
‡ P=0.009.

ies that propose continuous compression, ventricular fibrillation or pulseless ventricular tachycardia models of cardiac arrest are used.[22] Two recently published studies in humans showed no significant difference in survival between patients who were randomly assigned, on the basis of dispatchers' instructions to bystanders, to receive continuous compression without rescue breathing and those assigned to receive standard CPR with rescue breathing.[20,21] In one of the two studies, continuous compression without rescue breathing was associated with increased survival among patients with arrests due to cardiac causes[20]; in the other study, there was a trend toward increased survival with continuous compression and no rescue breathing among patients with arrests characterized by ventricular fibrillation or pulseless ventricular tachycardia.[21] If arrests characterized by ventricular fibrillation or pulseless ventricular tachycardia have better outcomes with continuous compression alone, this could be the more effective resuscitation strategy in the public setting, whereas rescue breathing along with compression might be of greater importance in the home, where the frequency of ventricular fibrillation or pulseless ventricular tachycardia is lower.[23]

Why is the initial recorded cardiac-arrest rhythm different when cardiac arrest occurs in a public location rather than in the home? One explanation is that the person who has a cardiac arrest in the home is typically older and more likely to have one or more chronic diseases that limit or preclude participation in activities outside the home. Thus, the location of an out-of-hospital cardiac arrest may be a surrogate variable for underlying disease or disease severity and the corresponding risk of ventricular fibrillation or pulseless ventricular tachycardia. For example, treatment with an implanted defibrillator is known to have a smaller effect on survival among patients with more severe heart failure than among those with less severe heart failure, suggesting that the incidence of shockable arrhythmias (ventricular fibrillation or pulseless ventricular tachycardia) differs between these two groups.[24]

In conclusion, our study shows that the frequency of ventricular fibrillation or pulseless ventricular tachycardia as the initial recorded rhythm is lower among patients with witnessed cardiac arrests in the home than among those with witnessed arrests in a public setting. This finding adds strength to the argument for putting AEDs in public locations. Although the role of AEDs in cardiac arrests that occur in the home will probably continue to evolve, the relatively low incidence of shockable arrhythmias in this setting suggests that a treatment strategy that emphasizes prompt, bystander-delivered CPR of high quality (e.g., with the assistance of a dispatcher) should be as effective in saving lives as the widespread deployment of AEDs in homes.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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Predictors of Survival From Out-of-Hospital Cardiac Arrest : A Systematic Review and Meta-Analysis

Comilla Sasson, Mary A.M. Rogers, Jason Dahl and Arthur L. Kellermann

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Predictors of Survival From Out-of-Hospital Cardiac Arrest

A Systematic Review and Meta-Analysis

Comilla Sasson, MD, MS; Mary A.M. Rogers, MS, PhD;
Jason Dahl, MD; Arthur L. Kellermann, MD, MPH

***Background*—**Prior studies have identified key predictors of out-of-hospital cardiac arrest (OHCA), but differences exist in the magnitude of these findings. In this meta-analysis, we evaluated the strength of associations between OHCA and key factors (event witnessed by a bystander or emergency medical services [EMS], provision of bystander cardiopulmonary resuscitation [CPR], initial cardiac rhythm, or the return of spontaneous circulation). We also examined trends in OHCA survival over time.

***Methods and Results*—**An electronic search of PubMed, EMBASE, Web of Science, CINAHL, Cochrane DSR, DARE, ACP Journal Club, and CCTR was conducted (January 1, 1950 to August 21, 2008) for studies reporting OHCA of presumed cardiac etiology in adults. Data were extracted from 79 studies involving 142 740 patients. The pooled survival rate to hospital admission was 23.8% (95% CI, 21.1 to 26.6) and to hospital discharge was 7.6% (95% CI, 6.7 to 8.4). Stratified by baseline rates, survival to hospital discharge was more likely among those: witnessed by a bystander (6.4% to 13.5%), witnessed by EMS (4.9% to 18.2%), who received bystander CPR (3.9% to 16.1%), were found in ventricular fibrillation/ventricular tachycardia (14.8% to 23.0%), or achieved return of spontaneous circulation (15.5% to 33.6%). Although 53% (95% CI, 45.0% to 59.9%) of events were witnessed by a bystander, only 32% (95% CI, 26.7% to 37.8%) received bystander CPR. The number needed to treat to save 1 life ranged from 16 to 23 for EMS-witnessed arrests, 17 to 71 for bystander-witnessed, and 24 to 36 for those receiving bystander CPR, depending on baseline survival rates. The aggregate survival rate of OHCA (7.6%) has not significantly changed in almost 3 decades.

***Conclusions*—**Overall survival from OHCA has been stable for almost 30 years, as have the strong associations between key predictors and survival. Because most OHCA events are witnessed, efforts to improve survival should focus on prompt delivery of interventions of known effectiveness by those who witness the event. ***(Circ Cardiovasc Qual Outcomes.* 2010;3:63-81.)**

Key Words: heart arrest ■ death, sudden ■ emergency medical services

In the United States, more than 166 000 patients experience an out-of-hospital cardiac arrest (OHCA) annually.[1] Approximately 60% are treated by emergency medical services.[1] Published rates of OHCA survival to hospital discharge range from 0.3% in Detroit[2] to 20.4% in Slovenia.[3] Among cities reporting data, the median rate of survival to hospital discharge is 6.4%.[4]

Previous meta-analyses of cardiac arrest research have focused on the use of new or emerging therapies (ie, impedance threshold device,[5] active compression-decompression cardiopulmonary resuscitation,[6] hypothermia,[7] emergency intubation[8]), new medications (ie, vasopressin,[9–11] epinephrine,[11,12] time to first medication administration[13]), and the use of automated external defibrillators by bystanders[14–16] and emergency medical technicians.[4,17] However, no group has conducted a systematic review to assess, with precision, the associations between key clinical factors and survival, and examine temporal trends in OHCA survival through the decades.

Two resuscitation rules[18,19] for emergency medical services (EMS) personnel have recently been shown to accurately predict which OHCA patients warrant rapid transport to the hospital for further care. These rules use 5 clinical criteria to predict survival from OHCA: arrest witnessed by a bystander, arrest witnessed by EMS, provision of bystander CPR, shockable cardiac rhythm, and return of spontaneous circulation (ROSC) in the field. Recently, 3 independent teams of researchers have validated these decision rules with a misclassification rate of 0.1%.[20–22] Despite these findings, the variability of survival by each clinical criterion has not been systematically evaluated across populations. Accordingly, we analyzed 30 years of data on OHCA in a systematic review and meta-analysis, taking into account potential sources of variation such as type of EMS system, baseline survival rates in the region, and location. We also analyzed temporal trends

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From the Departments of Emergency Medicine (C.S.) and Internal Medicine (M.A.M.R.), University of Michigan, Ann Arbor; the University of Rochester (J.D.), NY; and the Department of Emergency Medicine (A.L.K.), Emory University, Atlanta, Ga.

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Correspondence to Comilla Sasson, MD, MS, Robert Wood Johnson Clinical Scholars Program, 1150 W Medical Center Dr, 6312 Medical Science Building 1, Campus Box 5604. Ann Arbor, MI 48109. E-mail comilla@umich.edu

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in OHCA survival over this time frame to determine whether knowledge of OHCA pathophysiology and treatment is being effectively translated into improvements in outcome.

WHAT IS KNOWN

- Two resuscitation rules for emergency medical services (EMS) personnel have recently been shown to accurately predict which out-of-hospital cardiac arrest (OHCA) patients warrant rapid transport to the hospital for further care. These rules use 5 clinical criteria to predict survival from OHCA-arrest witnessed by a bystander, arrest witnessed by EMS, provision of bystander cardiopulmonary resuscitation (CPR), shockable cardiac rhythm, and return of spontaneous circulation (ROSC) in the field. Recently, 3 independent teams of researchers validated these decision rules with a misclassification rate of 0.1%.
- However, no group has conducted a systematic review to assess, with precision, the associations between these 5 key clinical factors and survival, and examine temporal trends in OHCA survival through the decades.

WHAT THE STUDY ADDS

- This meta-analysis brings together 30 years of research, involving more than 142 000 patients. Our findings conclusively affirm the value of bystander CPR, the critical importance of "shockable" rhythms, and the predictive value of ROSC in the prehospital setting.
- Forty percent of patients with OHCA are found with ventricular fibrillation/ventricular tachycardia, yet only 22% achieve ROSC. This group may be a priority population for future efforts to improve ROSC and survival to hospital discharge.
- The magnitude of effect sizes for the 5 clinical factors, such as provision of bystander CPR and an initial rhythm of ventricular fibrillation/ventricular tachycardia, are higher in communities that have low baseline survival rates. This suggests that efforts such as targeted CPR training to increase bystander CPR rates will have their greatest effect in communities with low baseline rates of survival.
- Survival from OHCA has not significantly improved in almost 3 decades, despite enormous efforts in research spending and the development of novel drugs and devices. The aggregate survival rate, recorded across various populations, is between 6.7% and 8.4%.

Methods

Data Sources and Searches

A systematic review of the literature was conducted to identify studies that evaluated 5 key factors known to be associated with survival: (1) arrest witnessed by a bystander, (2) arrest witnessed by an EMS provider, (3) provision of bystander cardiopulmonary resuscitation (CPR) before EMS arrival, (4) presenting rhythm (determined by EMS personnel to be ventricular fibrillation/ventricular tachycardia [VF/VT] or asystole), and (5) patient response to prehospital emergency cardiac care with ROSC in the field.

All studies published between January 1, 1950 through August 21, 2008 were considered. The following electronic databases were searched with the assistance of an experienced health services librarian, using a Boolean Search Strategy: PubMed, EMBASE, Web of Science, CINAHL, and all EBM Reviews (includes Cochrane DSR, DARE, ACP Journal Club, and CCTR). The root search was "Heart Arrest"[MeSH] AND ("Cardiopulmonary Resuscitation" [MeSH] OR "Resuscitation Orders"[MeSH]) AND (English[lang] AND ("adolescent"[MeSH Terms] OR "adult"[MeSH Terms:noexp] OR ("middle aged"[MeSH Terms] OR "aged"[MeSH Terms]))). We then added the keywords "Witnessed or Bystander" to the root search with "AND ((witness* OR unwitnessed OR bystander* OR observer* OR observed)) AND (("Survival"[MeSH] OR "Mortality"[MeSH] OR "mortality"[Subheading] OR "Survival Rate"[MeSH]))" or "Defibrillator or ROSC" with "AND (("Survival"[MeSH] OR "Mortality"[MeSH] OR "mortality"[Subheading] OR "Survival Rate"[MeSH])) AND (("Electric Countershock"[MeSH] OR ROSC OR defibrillation OR "Arrhythmias, Cardiac"[MeSH]))." The majority of articles we reviewed were retrieved from PubMed (353 of 909 articles). Only reports published in English were included.

In addition to these automated searchers, we conducted a hand search of bibliographies of key articles[4,23–26] and abstracts presented at major scientific conferences in 2006 to 2008. We also contacted 2 national cardiac arrest experts to identify any relevant but unpublished studies.

Study Selection

Two reviewers (C.S. and J.D.) evaluated each full text article and determined exclusions based on a priori criteria. This excluded any study which contained greater than 20% pediatric patients (age <18 years), a majority of events caused by a noncardiac etiology (trauma, drowning, electrocution, respiratory), cases of in-hospital arrest, survival through hospital discharge not reported, use of investigational interventions that were outside the standard of care at the time the study was conducted (eg, hypothermia), use of investigational devices (eg, abdominal compression device), and those that did not report any of the 5 variables of interest.

Using these criteria, the kappa for interrater reliability to be included in the study was 0.71. Disagreements were resolved by discussion. Three authors were contacted to clarify the dates of their study to ensure that we did not inadvertently double-count some patients,[27,28] to obtain specific data on a sole survivor of OHCA,[2] to clarify certain aspects of a field termination protocol,[29] and to obtain more information on survivors.[30]

Data Extraction and Quality Assessment

The 204 studies that met our preliminary selection criteria were further evaluated using the Newcastle Ottawa Scale for cohort studies. The Newcastle Ottawa Scale has been shown to be useful in rating the quality of observational studies in a standardized format.[31] Ultimately, 79 of these 204 studies met an a priori aggregate measure of quality, based on clearly defined patient selection, assessment of exposures and outcome, comparability of groups, and adequacy of follow-up to hospital discharge. Reasons for exclusion included: failure to comparably report outcome data for survivors versus nonsurvivors for at least 1 of the 5 clinical factors of interest (n=84); reporting of duplicate cohorts from the same study (n=18), majority of patients with noncardiac etiologies (n=14), and in-hospital cardiac arrests (n=9).

The following variables were extracted from the 79 studies: number of arrests in the study, total survivors followed to hospital discharge, case attributable to a presumed cardiac etiology, mean age, arrest witnessed by bystander or EMS, provision of bystander CPR, initial rhythm (VF/VT or asystole), achievement of ROSC, and outcome to hospital discharge. Bystander CPR was defined as any attempt at CPR initiated by someone other than the EMS/first responder team regardless of whether the event was witnessed or not. The presenting rhythm was based on the paramedic's assessment on scene. ROSC was recorded in any study that

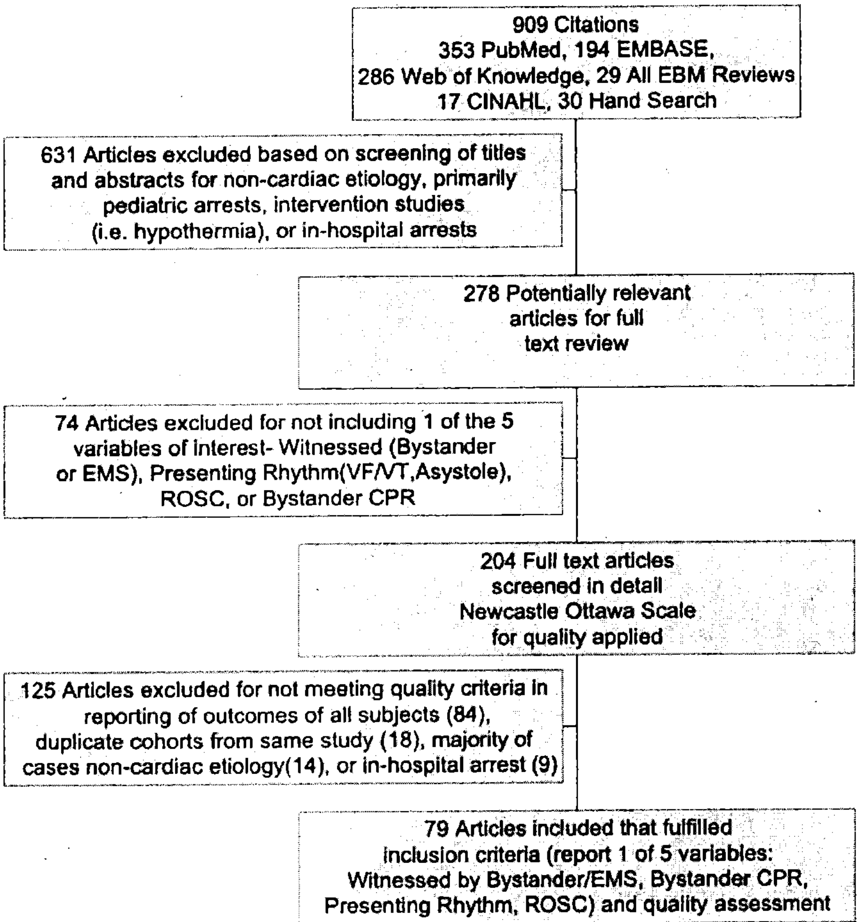

Figure 1. Flowchart of meta-analysis.

examined it as a predictor variable for survival to hospital discharge. Studies that used ROSC as an intermediate outcome were not included.

Data Synthesis and Analysis

The denominator for calculating rates of survival to hospital discharge in this meta-analysis was the number of adult patients with OHCA of presumed cardiac etiology for whom resuscitation was attempted in the prehospital setting. Crude (ie, unweighted) survival rates to hospital admission and to hospital discharge were calculated, as were pooled (ie, weighted) survival rates using the DerSimonian and Laird random-effects method.[32] In addition, pooled odds ratios for survival to discharge were determined for each clinical criterion (eg, witnessed by bystander, witnessed by EMS, etc) using the random-effects model. Studies that were duplicates of the same patient cohort or involved only public-access defibrillation were not included. To evaluate heterogeneity, Cochran's Q test and I^2, the degree of inconsistency among studies, were calculated. Begg's test and a visual inspection of the funnel plot were conducted to evaluate publication bias. The number needed to treat was calculated for witnessed events and bystander CPR, based on pooled survival rates to hospital discharge. This represents the number of persons with OHCA in whom an intervention (eg, bystander CPR) would have to be used to save 1 life.

Meta-regression was used to explore the heterogeneity in odds ratios (dependent variable) across studies. A random-effects model was used with estimation of the between-study variance by the restricted maximum likelihood method. Independent variables considered for inclusion were type of EMS system, study design (retrospective versus prospective cohort), mean response interval, mean age, time of follow-up, inclusion of <20% pediatric patients, inclusion of any events of noncardiac etiology, dates of patient inclusion, year of publication, physicians as part of the EMS out-of-hospital team, and baseline survival rates calculated as the survival rate of those OHCA patients without the variable of interest (eg, in the VF/VT meta-analysis, the survival rate for the patients in the sample who did not have a VF/VT arrest). Study location (international versus United States) was also evaluated, as many international EMS systems employ physicians in the prehospital setting and centralize operations.[33]

Temporal trends in OHCA survival were anticipated because of emerging technologies[7,34,35] and refinement of clinical guidelines.[25,36,37] Therefore, a meta-regression was conducted by regressing time as the independent variable (ie, final year of patient enrollment in the study) on OHCA survival rates (dependent variable) with a random-effects model with adjustment for location (international versus United States), mean age of the patients, mean response time interval (minutes), and type of EMS service.

As a secondary analysis, the association between baseline survival and differences in survival rates were further evaluated. Weighted multivariate linear regression was performed using 2 outcomes: (1) survival difference between bystander witnessed and bystander unwitnessed events; and (2) survival difference between EMS witnessed and EMS unwitnessed events ($n=25$ studies). In addition, weighted linear regression was conducted using survival difference for patients in VF/VT versus asystole as the dependent variable ($n=40$ studies). Weights were generated using the DerSimonian and Laird random-effects model. If there were no survivors in a given study, the LaPlace estimate was used to calculate the weights.[38,39]

All statistical tests were 2-sided, with α set at 0.05. STATA version 10.0 was used to conduct all analyses.

Table 1. Articles Included in the Meta-Analysis

Author	Year	Location	Meta-Analysis Variable Reported	Study Design	EMS System	Age Mean, y	Response Time Mean, min
Wilson	1984	Durham, NC	CPR, VF/VT, Asys	Prospective cohort	BLS	*	6.5
Smith	1985	Sacremento, CA	VF/VT, Asys	Retrospective cohort	BLS+ALS	*	*
Aprahamanian	1986	Milwaukee, WI	CPR, VF/VT, Asys	Retrospective cohort	BLS+ALS	65	6
Bachman	1986	Arrowhead Cty, MN	CPR	Prospective cohort	BLS+BLS-D+ALS	65.2	6.5
Bonnin	1989	Oakland County, MI	ROSC	Retrospective cohort	BLS+ALS	71	4.7
Becker	1991	Chicago, IL	Wit Bys, Wit EMS	Prospective cohort	ALS	67	8
Brison	1992	Canada	Wit Bys, Wit EMS, CPR	Prospective cohort	BLS+BLS-D	68.1	7.7
Bonnin	1993	Houston, TX	CPR, ROSC	Prospective cohort	BLS+ALS	64.7	10.1
Kellermann	1993	Memphis, TN	Wit Bys, VF/VT, CPR, ROSC	Retrospective cohort	BLS+ALS	64	3.4
Pepe	1993	Houston, TX	Wit Bys, Wit EMS, VF/VT, Asys	Prospective cohort	BLS+ALS	65	5
Richless	1993	Allegheny, PA	VF/VT	Retrospective cohort	BLS+ALS	67.3	7.2
Tresch	1993	Milwaukee, WI	VF/VT	Retrospective cohort	BLS+ALS	78.5	*
Van der Hoeven	1993	Leiden, Netherlands	CPR, VF/VT, Asys	Retrospective cohort	BLS+ALS	61.7	4.89
Kass	1994	York/Adams, PA	Wit Bys, Wit EMS, VF/VT, Asys	Retrospective cohort	BLS+ALS	*	*
Lombardi	1994	NYC, NY	Wit Bys, Wit EMS, CPR	Prospective cohort	BLS-D+ALS	70†	9.9
Schneider	1994	Mainz, Germany	VF/VT, Asys	Prospective cohort	BLS+ALS-P	63.2	5†
Crone	1995	Auckland, New Zealand	Wit EMS, CPR, VF/VT, Asys	Prospective cohort	ALS	65	7
Hodgetts	1995	Salford, Australia	ROSC	Retrospective cohort	BLS-D+ALS	63	8†
Rainer	1995	Glasgow/Edinburgh, Scotland	VF/VT, Asys	Prospective cohort	BLS-D+ALS+ALS-P	63.5	6.5†
Giraud	1996	France	Wit Bys, Wit EMS, VF/VT, Asys	Prospective cohort	BLS-D+ALS-P	20% <14	14†
Killien	1996	San Juan Islands, WA	VF/VT, Asys	Retrospective cohort	BLS+ALS	66	4.5
Kuisma	1996	Helsinki, Finland	Wit Bystander	Prospective cohort	BLS-D+ALS+ALS-P	*	7
Adams	1997	Scotland	Wit Bys, Wit EMS	Retrospective cohort	BLS-D	*	*
Fischer	1997	Bonn, Germany	Wit Bys, Wit EMS, VF/VT, Asys	Retrospective cohort	BLS+ALS-P	54% >65	5.5
Kuisma	1997	Helsinki, Finland	VF/VT, Asystole, CPR	Prospective cohort	BLS-D+ALS+ALS-P	56.7	8.4
Mitchell	1997	Edinburgh, Scotland	Wit EMS	Prospective cohort	BLS-D+ALS	67	7.7
Stapczynski	1997	Kentucky	VF/VT, CPR	Retrospective cohort	BLS-D	66	7.38
Valenzuela	1997	King County, WA	VF/VT	Retrospective cohort	BLS+ALS	64	5.1
Valenzuela	1997	Tucson, AZ	VF/VT	Retrospective cohort	BLS+ALS	66	9.5
De Vreede	1998	Maastricht, Netherlands	VF/VT, CPR	Prospective cohort	ALS	60.3	5.9
Joyce	1998	Salt lake City, UT	VF/VT, Asys	Retrospective cohort	BLS-D+ALS	66.9	4.4
Kette	1998	Fruilli, Italy	Wit Bys, Wit EMS	Prospective cohort	BLS+ALS+ALS-P	*	*
Lindholm	1998	Kansas City, MO	CPR, VF/VT, Asys, ROSC	Retrospective cohort	ALS	67	6.5
Tadel	1998	Slovenia	Wit Bys, Wit EMS, VF/VT, Asys	Retrospective cohort	BLS+ALS-P	*	10†
Waalewijn	1998	Amsterdam, Netherlands	Wit Bys, Wit EMS, CPR, VF/VT, Asys	Prospective cohort	ALS	64	10†
Absalom	1999	Norfolk, United Kingdom	Wit EMS, CPR, ROSC	Retrospective cohort	ALS	68	*
Bottinger	1999	Heidelberg, Germany	Wit Bys, Wit EMS, CPR, VF/VT, Asys	Prospective cohort	BLS+ALS+ALS-P	67	8

(*Continued*)

Table 1. Continued

Author	Year	Location	Meta-Analysis Variable Reported	Study Design	EMS System	Age Mean, y	Response Time Mean, min
Kuilman	1999	Rotterdam, Netherlands	VF/VT, Asys	Retrospective cohort	ALS-P	64.8	*
Lui	1999	Hong Kong	Wit Bys, Wit EMS, CPR, VF/VT, Asys	Retrospective cohort	BLS-D	68.7	6.42
Stiell	1999	Canada-OPALS 1	CPR, VF/VT, Asys	Prospective cohort	BLS-D	68	6.7
Sunde	1999	Oslo, Norway	Wit Bys, Wit EMS	Prospective cohort	ALS+ALS-P	69.5	7†
Swor	2000	Oakland County, MI	Wit EMS, VF/VT, CPR	Prospective cohort	BLS+ALS	66.5	6.1
Valenzuela	2000	casinos	VF/VT, Asys	Prospective cohort	D at public sites	64	9.8
Finn	2001	Perth, Australia	Wit Bys, Wit EMS	Prospective cohort	BLS-D+ALS	65.1	*
Groh	2001	Indiana	VF/VT, CPR	Prospective cohort	BLS-D+ALS	65.9	6.3
Jennings	2001	Victoria, Australia	VF/VT, Asys	Retrospective cohort	BLS+ALS	68.2	8
Rea	2001	Kings County, WA	CPR	Prospective cohort	BLS-D+ALS	68.7	5.2
Citerio	2002	Lombardia, Italy	VF/VT, Asys	Prospective cohort	BLS+ALS+ALS-P	70.1	8.5
Fan	2002	Hong Kong	VF/VT	Prospective cohort	BLS-D	73†	9†
Lim	2002	Singapore	VF/VT, Asys, ROSC	Retrospective cohort	BLS-D	65.1	11.9
Myerberg	2002	Miami, FL	Wit Bys, VF/VT	Prospective cohort	BLS-D+ALS	68.5	4.88
Smith	2002	Melbourne, Australia	Wit Bys, Wit EMS	Prospective cohort	BLS+BLS-D+ALS	*	8.75
Goto	2003	Akita, Japan	Wit Bys, Wit EMS, VF/VT, Asys	Prospective cohort	BLS-D	63.7	*
Grmec	2003	Slovenia	Wit Bys, VF/VT, Asys	Prospective cohort	BLS-D+ALS	63.9	10.6
Haukoos	2003	Los Angeles, CA	VF/VT, Asys	Retrospective cohort	BLS-D+ALS	70†	*
Nishiuchi	2003	Osaka, Japan	VF/VT	Prospective cohort	BLS-D	67.5	5.9
Ong	2003	Singapore	Wit Bys, Wit EMS, CPR	Prospective cohort	BLS-D	62.2	10.2
Horsted	2004	Copenhagen, Denmark	Wit Bys, Wit EMS, VF/VT, Asys	Prospective cohort	BLS-D+ALS-P	68	5
Rudner	2004	Katowice, Poland	Wit Bys, Wit EMS, CPR, VF/VT, Asys	Prospective cohort	BLS+ALS	63	7
Davies	2005	London, England	VF/VT, Asys	Prospective cohort	D at public sites	63.1	9.1
Handel	2005	Reading, OH	CPR, VF/VT, Asys, ROSC	Retrospective cohort	BLS+ALS	65.3	*
Hayashi	2005	Okayama, Japan	Wit Bys, Wit EMS, VF/VT, Asys	Prospective cohort	BLS-D	67.1	11
White	2005	Rochester, MN	Wit Bys, VF/VT	Prospective cohort	BLS-D+ALS	64.3	6.2
Drezner	2006	Multicenter	VF/VT	Retrospective cohort	D at public sites	21	*
Kellum	2006	Wisconsin	Wit Bys, VF/VT	Prospective cohort	BLS-D+ALS	*	6
Pleskot	2006	East Bohemia, Czech Republic	Wit Bys, CPR, VF/VT, Asys	Prospective cohort	BLS+ALS-P	67	7.4
Davis	2007	San Diego, CA	VF/VT, Asys, ROSC	Prospective cohort	BLS+ALS	66.3	7
Daya	2007	Resuscitation Outcomes Consortium	ROSC	Prospective cohort	BLS-D+ALS	*	*
Dunne	2007	Detroit, MI	Wit Bys, Wit EMS, VF/VT, Asys, ROSC	Retrospective cohort	ALS	63.3	8.36
Estner	2007	Dachau, Germany	Wit Bys, Wit EMS, CPR, VF/VT, Asys	Prospective cohort	BLS+ALS-P	63.9	7.74
Fairbanks	2007	Rochester, NY	Wit Bys, CPR, VF/VT, Asys	Retrospective cohort	BLS-D+ALS	67	5
Herlitz	2007	Sweden	Wit Bys, Wit EMS, VF/VT, CPR	Prospective cohort	BLS-D+ALS	67	6
Hostler	2007	Resuscitation Outcomes Consortium	Wit Bys, Wit EMS, CPR	Prospective cohort	BLS-D+ALS	*	*

(Continued)

Table 1. Continued

Author	Year	Location	Meta-Analysis Variable Reported	Study Design	EMS System	Age Mean, y	Response Time Mean, min
Iwami	2007	Osaka, Japan	Wit Bys	Prospective cohort	BLS+BLS-D	69.5	9.2
Jasinskas	2007	Lithuania	VF/VT, Asys	Prospective cohort	ALS-P	67	6
Ma	2007	Taipei, Taiwan	CPR, VF/VT, Asys	Prospective cohort	BLS-D+ALS	68.6	4†
Morrison	2007	Canada-OPALS 3	Wit Bys, Wit EMS, VF/VT, CPR	Prospective cohort	BLS-D+ALS	*	*
Vadeboncoeur	2007	Arizona	CPR	Prospective cohort	BLS+BLS-D+ALS	*	*
Fleischhackl	2008	Austria	VF/VT	Prospective cohort	D at public sites	62.5	*

BLS indicates basic life support; ALS, advanced life support; D, defibrillator capable; D at public sites, publicly available defibrillator studies; P, physicians onboard EMS; Wit Bys, witnessed by bystander; Wit EMS, witnessed by EMS; CPR, cardiopulmonary resuscitation; VF/VT, ventricular fibrillation/ventricular tachycardia; Asys, asystole; ROSC, return of spontaneous circulation.

*Not reported in study.

†Median value (age or response time).

Results

Search Results

There were 909 citations retrieved from the original search, 631 of which were excluded based on a priori exclusion criteria (Figure 1). Of the 278 articles chosen for full text review, 204 articles met inclusion criteria and were evaluated in detail. Studies were included if they had reported at least one of the five variables that are included in this meta-analysis.[2,3,19,27–30,40–109] One article by Valenzuela et al[67] contrasted OHCA cases that occurred in Washington State from those that occurred in Arizona, so it was analyzed as 2 separate studies. One study did not specify the total number of survivors, so it was only included in the sensitivity analysis of bystander CPR.[30]

Study Characteristics

Tables 1 and 2 display the study characteristics and variables used in the meta-analysis. All 79 articles were cohort studies. All documented the presence of at least 1 of the 5 variables in both survivors and nonsurvivors, with the primary outcome being survival to hospital discharge. The year of publication ranged from 1984 to 2008. Forty-six studies were conducted outside the United States. Twenty studies had less than 20% of their patients who were below the age of 18 years, whereas the remaining studies included adult patients only. Collectively, the 79 studies reported the outcomes of 142 740 patients.

The overall crude survival rate to hospital discharge in all the studies was 7.1% (10 017 survivors of 141 581 cases of OHCA). One study was not included because the total number of survivors was not reported.[30] The pooled rate of survival to hospital discharge in these studies was 7.6% (95% CI, 6.7 to 8.4). Of those studies that reported survival to hospital admission (n=49), the overall crude rate was 17.6%. The pooled survival to hospital admission rate was 23.4% (95% CI, 20.7 to 26.1).

Survival rates to hospital discharge, over 5-year time periods, are illustrated in Figure 2. There was no significant difference in survival rates over time (P=0.152) after adjustment for location (international versus United States), mean age of the patients, mean response interval, and type of EMS.

The results for each of the 5 clinical criteria are presented in the same manner (Figures 3 through 8). The studies were stratified into quintiles (tertiles for ROSC) based on the baseline survival rate. The vertical line marks the aggregate measure of the odds ratios across all studies.

Witnessed by Bystander

Thirty-six studies contained sufficient data to assess the association of an OHCA witnessed by a bystander (Figure 3). Collectively, these studies reported the outcomes of 95 539 cases. In these studies, the crude rate of survival to hospital discharge was 7.6% (7214 survivors). The pooled odds ratio for surviving to hospital discharge if a bystander witnessed the arrest (compared to unwitnessed events) ranged from 0.34 (95% CI, 0.07 to 1.66) among those with the highest baseline survival rates to 4.42 (95% CI, 1.81 to 10.80) in studies with the lowest baseline rates.

Witnessed by EMS

Thirty articles reported sufficient data to assess the association between OHCA being witnessed by EMS personnel and survival (Figure 4). In total, these studies reported on the outcomes of 83 229 cases, with a crude overall survival rate to hospital discharge rate of 6.1% (5056 survivors). The pooled odds ratio for survival among OHCA patients witnessed by EMS compared to all other arrests, ranged from 1.65 (95% CI, 0.63 to 4.34) in those with the highest baseline rates to 6.04 (95% CI, 4.12 to 8.85) in the studies with the lowest baseline rates of survival.

Bystander CPR

Odds ratios for the association between bystander CPR and survival are given in Figure 5 (n=32 studies). Collectively, these studies reported on the outcomes of 76 485 cases. In studies reporting overall rates of survival to hospital discharge, the crude rate was 6.7% (5094 survivors out of 75 388 patients). The pooled odds ratio for survival among patients receiving bystander CPR compared with those who did not ranged from 1.23 (95% CI, 0.71 to 2.11) in the studies with the highest baseline survival rates to 5.01 (95% CI, 2.57 to 9.78) in the studies with the lowest baseline rates. One study[30] was not included in the overall pooled odds ratio for by-

Table 2. Determination of Study Survival Rates

Author	Year	Total Adult Cardiac Arrests With Resuscitation Attempted	Resuscitation Not Attempted (Includes DNR, Obvious Death)	Survive to Admission	Survive to Discharge	Survival Rate to Hospital Discharge, %
Wilson	1984	126	0	28	11	8.7
Smith	1985	893	0	79	29	3.2
Aprahamanian	1986	319	126	94	42	13.2
Bachman	1986	512	*	24	14	2.7
Bonnin	1989	232	7	56	22	9.5
Becker	1991	3221	*	241	55	1.7
Brison	1992	1510	*	143	38	2.5
Bonnin	1993	1461	0	*	92	6.3†
Kellermann	1993	1068	0	267	85	8.0
Pepe	1993	2404	0	*	193	8.0
Richless	1993	96	0	14	3	3.1
Tresch	1993	196	0	37	10	5.1
Van der Hoeven	1993	257	0	39	6	2.3
Kass	1994	599	0	113	24	4.0§
Lombardi	1994	2329	*	*	52	2.2
Schneider	1994	211	125	50	19	9.0
Crone	1995	1069	0	240	135	12.6
Hodgetts	1995	100	82	*	2	2.0
Rainer	1995	455	0	105	52	11.4
Giraud	1996	113	146	22	8	7.1
Killien	1996	78	2	31	17	21.8
Kuisma	1996	255	68	98	44	17.3
Adams	1997	8651	*	*	612	7.1
Fischer	1997	464	82	185	74	15.9
Kuisma	1997	162	43	45	8	4.9
Mitchell	1997	275	*	*	27	9.8
Stapczynski	1997	311	0	46	19	6.1
Valenzuela	1997	7635	0	*	1086	14.2
Valenzuela	1997	665	0	*	46	6.9
De Vreede	1998	288	350	*	47	16.3
Joyce	1998	322	0	83	26	8.1
Kette	1998	344	*	60	23	6.7
Lindholm	1998	832	0	*	67	8.1
Tadel	1998	337	511	78	19	5.6
Waalewijn	1998	1046	400	165	134	12.8
Absalom	1999	260	0	59	26	10.0
Bottinger	1999	338	243	129	48	14.2
Kuilman	1999	898	0	441	276	30.7
Lui	1999	744	0	89	12	1.6
Stiell	1999	5335	0	366	197	3.7
Sunde	1999	326	573	96	30	9.2
Swor	2000	2608	108	538	189	7.2
Valenzuela	2000	148	0	71	56	37.8†
Finn	2001	1293	*	*	85	6.6‡
Groh	2001	388	0	61	21	5.4
Jennings	2001	115	96	22	6	5.2
Rea	2001	7265	*	*	1112	15.3

(*Continued*)

Table 2. Continued

Author	Year	Total Adult Cardiac Arrests With Resuscitation Attempted	Resuscitation Not Attempted (Includes DNR, Obvious Death)	Survive to Admission	Survive to Discharge	Survival Rate to Hospital Discharge, %
Citerio	2002	178	0	*	10	5.6‡
Fan	2002	320	82	*	4	1.3
Lim	2002	93	0	15	1	1.1
Myerberg	2002	738	0	*	51	6.9
Smith	2002	436	778	82	35	8.0
Goto	2003	203	227	*	20	9.9
Grmec	2003	216	*	128	44	20.4
Haukoos	2003	575	0	*	25	4.3
Nishiuchi	2003	974	176	236	50	5.1‡
Ong	2003	351	*	30	7	2.0
Horsted	2004	219	233	82	25	11.4
Rudner	2004	147	150	43	15	10.2
Davies	2005	172	4	*	39	22.7
Handel	2005	84	79	26	12	14.3‡
Hayashi	2005	179	0	*	2	1.1
White	2005	326	0	158	85	26.1
Drezner	2006	9	0	*	1	11.1†
Kellum	2006	358	169	*	39	10.9
Pleskot	2006	560	144	149	53	9.5
Davis	2007	1095	46	197	47	4.3
Daya	2007	7478	6052	*	568	7.6†
Dunne	2007	471	51	28	1	0.2‡
Estner	2007	412	277	180	47	11.4
Fairbanks	2007	539	277	*	27	5.0§
Herlitz	2007	38 413	*	*	2114	5.5‡
Hostler	2007	9886	*	*	727	7.4
Iwami	2007	12 437	*	*	433	3.5§
Jasinskas	2007	62	10	11	*	*
Ma	2007	1423	86	242	80	5.6
Morrison	2007	4673	40	671	239	5.1
Vadeboncoeur	2007	1097	*	*	*	*
Fleischhackl	2008	62	*	*	17	27†

Survival Rate to hospital admission and discharge is for all presenting rhythms.
*Not reported in study.
†Not included in overall survival rate.
‡Survival at 1-month reported.
§Survival at 1-year reported.

stander CPR because no information was provided on the community's baseline survival percentage.

The reporting of bystander CPR differed among studies. Because a patient who arrested in the presence of EMS personnel was never "eligible" to receive bystander CPR, we stratified studies by whether the arrest was witnessed by EMS. For the 19 studies that did not include EMS witnessed arrests in the total, the odds ratio for bystander CPR was 2.44 (95% CI, 1.69 to 3.19). This compared with an odds ratio of 1.69 (95% CI, 1.10 to 2.28) for studies in which all arrests, including EMS witnessed arrests, were included.

Ventricular Fibrillation/Ventricular Tachycardia

Fifty-eight studies contained sufficient data to assess the association between VF/VT as the presenting cardiac rhythm and OHCA survival (Figure 6). Outcomes were reported in 82 854 cases, with an overall crude survival rate to hospital discharge in these studies of 7.2% (5972 survivors). The pooled odds ratio for survival to hospital discharge among patients found in VF/VT compared to those found in all other rhythms ranged from 2.91 (95% CI, 1.10 to 7.66) in the studies with the highest baseline rates of survival to 20.62 (95% CI, 12.61 to 33.72) in the studies with the lowest baseline survival.

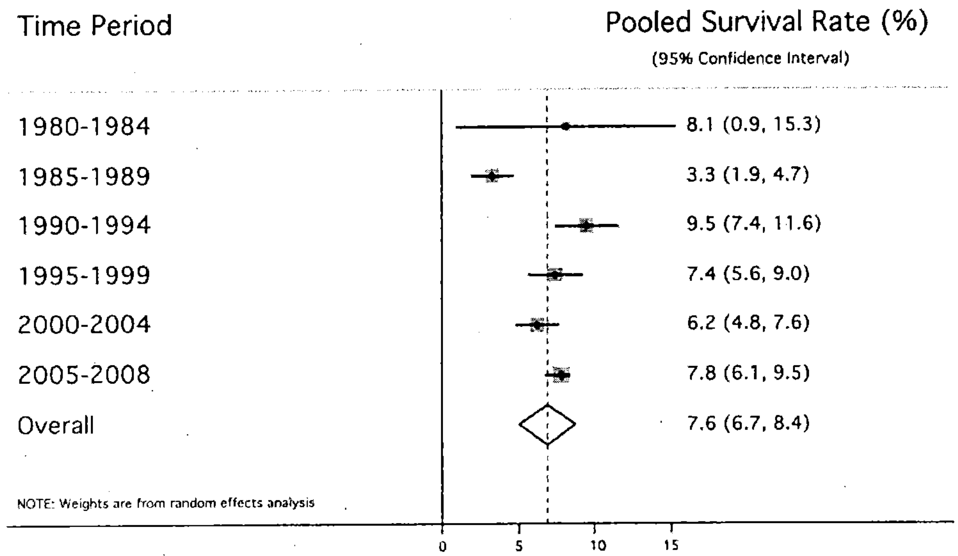

Figure 2. OHCA survival to hospital discharge by 5-year time periods (based upon final year of patient enrollment into study).

Asystole

Odds ratios for the relationship between asystole as the presenting cardiac rhythm and OHCA survival are shown in Figure 7 (n=40 studies). In total, outcomes were reported on 23 202 cases, with an overall crude survival rate in these studies of 8.1% (1870 survivors). The pooled odds ratio for survival to hospital discharge among those patients found in asystole compared with those patients found in all other cardiac rhythms ranged from 0.10 (95% CI, 0.03 to 0.31) in the studies with the lowest baseline rates of survival to 0.15 (95% CI, 0.09 to 0.25) in studies with the highest baseline rates.

Return of Spontaneous Circulation

Twelve studies reported data on the relationship between achieving prehospital ROSC and survival to hospital discharge (Figure 8). These studies reported the outcomes of 17 697 patients. Overall, the crude rate of survival to hospital discharge in these studies was 6.6% (1,162 survivors). The pooled odds ratio for survival to hospital discharge among patients who achieved ROSC in the field (compared to those who did not) ranged from 20.96 (95% CI, 7.43 to 59.13) in those with the highest baseline survival rates to 99.84 (95% CI, 14.30 to 696.89) in the studies with the lowest baseline rates of survival.

Study-specific odds ratios for ROSC were considerably elevated above the null in all strata; no point estimate was less than 8.49. Three of the 12 studies required ROSC to be "sustained" (patient had a pulse on leaving the scene of the OHCA). The other 9 considered any restoration of a palpable pulse, no matter how transient, to represent ROSC. One study did not document whether ROSC occurred in the prehospital setting versus in the emergency department.[20] The others defined ROSC as occurring before transport from the scene.

Excluding the one study[20] that did not limit ROSC to the prehospital setting reduced the subgroup OR (lowest baseline survival) from 99.84 (95% CI 14.30 to 696.89) to 35.29 (95% CI, 5.54 to 224.94). The overall pooled survival rate (absolute risk) of all subjects included in this analysis decreased from 15.5% (95% CI 0.0 to 33.3) to 5.1% (95% CI, 0.0 to 12.9) following exclusion of this study.

Number Needed to Treat to Save One Life

Survival rates to hospital discharge are listed by each of the 5 main clinical criteria in Table 3. The results indicate that 53% of all OHCA cases were witnessed by a bystander, 10% were witnessed by EMS, and 36% were unwitnessed. In addition, 32% of patients received bystander CPR, 40% were found in VF/VT arrest, 42% were found in asystole, and 22% achieved ROSC in the prehospital setting. Reported rates of survival to hospital discharge ranged from 0.1% to 33.6% across these groups, depending on the baseline survival rate (Table 3). The strongest predictor of survival to hospital discharge was ROSC in the field. In this group as many as 1 in 3 survived.

The number needed to treat (NNT) to save one life is also shown in Table 3. The data indicate that 17 persons experiencing OHCA would need to be witnessed by a bystander to save the life of one person in those areas where baseline survival rates were low. The corresponding NNT for areas with high baseline survival was 71. For regions in which baseline survival rates were high, 16 persons with OHCA would need to be witnessed by EMS to save the life of one person and in locations where baseline survival rates are low,

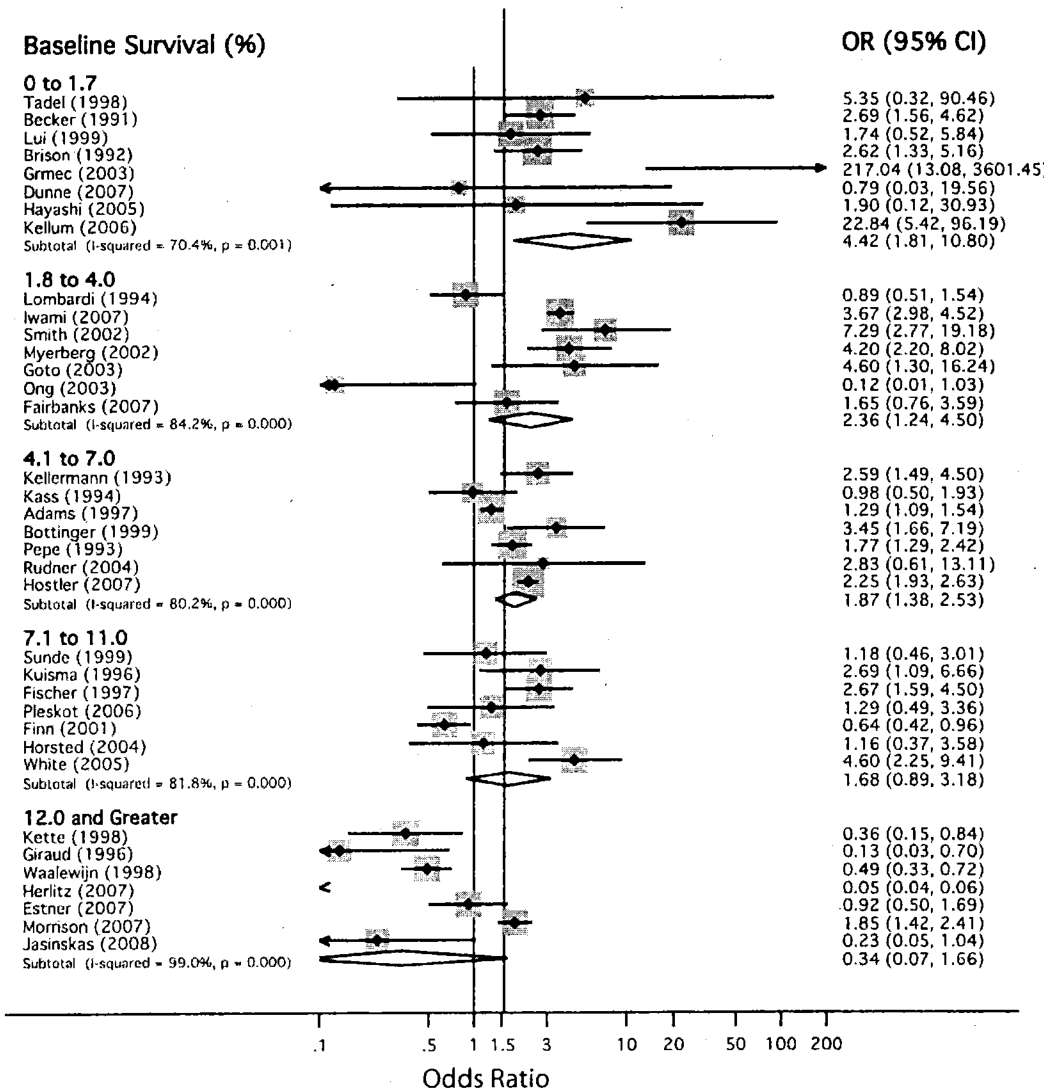

Figure 3. Forest plot of studies reporting witnessed by bystander stratified by baseline survival.

23 persons with OHCA would require an EMS witnessed event to save the life of one person. For bystander CPR, the NNT was 24 in areas with high baseline survival rates and 36 in areas with low rates.

Regression Analyses

Meta-regression analyses were conducted to assess predictors of heterogeneity among odds ratios. The only factor that significantly explained the heterogeneity in odds ratios for all 5 clinical criteria was baseline survival rate and therefore, analyses were stratified by this variable. In addition, the results of the weighted multivariate linear regression indicated that baseline survival significantly explained differences in survival rates. For example, as the baseline survival rate increased, the difference in survival between bystander-witnessed and unwitnessed arrests decreased (β coefficient=−0.7617; P=0.023).

The type of EMS system significantly explained heterogeneity in the odds ratio for VF/VT ($P<0.05$); the largest pooled OR was evident at those locations in which a defibrillator was available at public sites (OR=12.5) and the smallest pooled OR was at sites in which both basic and advanced life support were available (OR=5.1). The type of EMS system also significantly explained the heterogeneity in odds ratio for asystole; locations with basic life support only and locations with public access defibrillation yielded the greatest reduction in the odds ratios ($P<0.05$). Variation in the odds ratios could also be significantly explained by differences in case mix (ie, some studies included arrests of all etiologies) and length of follow-up (ie, some studies reported survival 1 month postevent). Mean response interval was a significant predictor of heterogeneity for arrests that were witnessed by EMS ($P<0.05$); for those locations in which the mean response time interval was less than 8 minutes, the pooled OR was 5.9, it was 2.4 in locations with a mean response time interval of 8 minutes or longer.

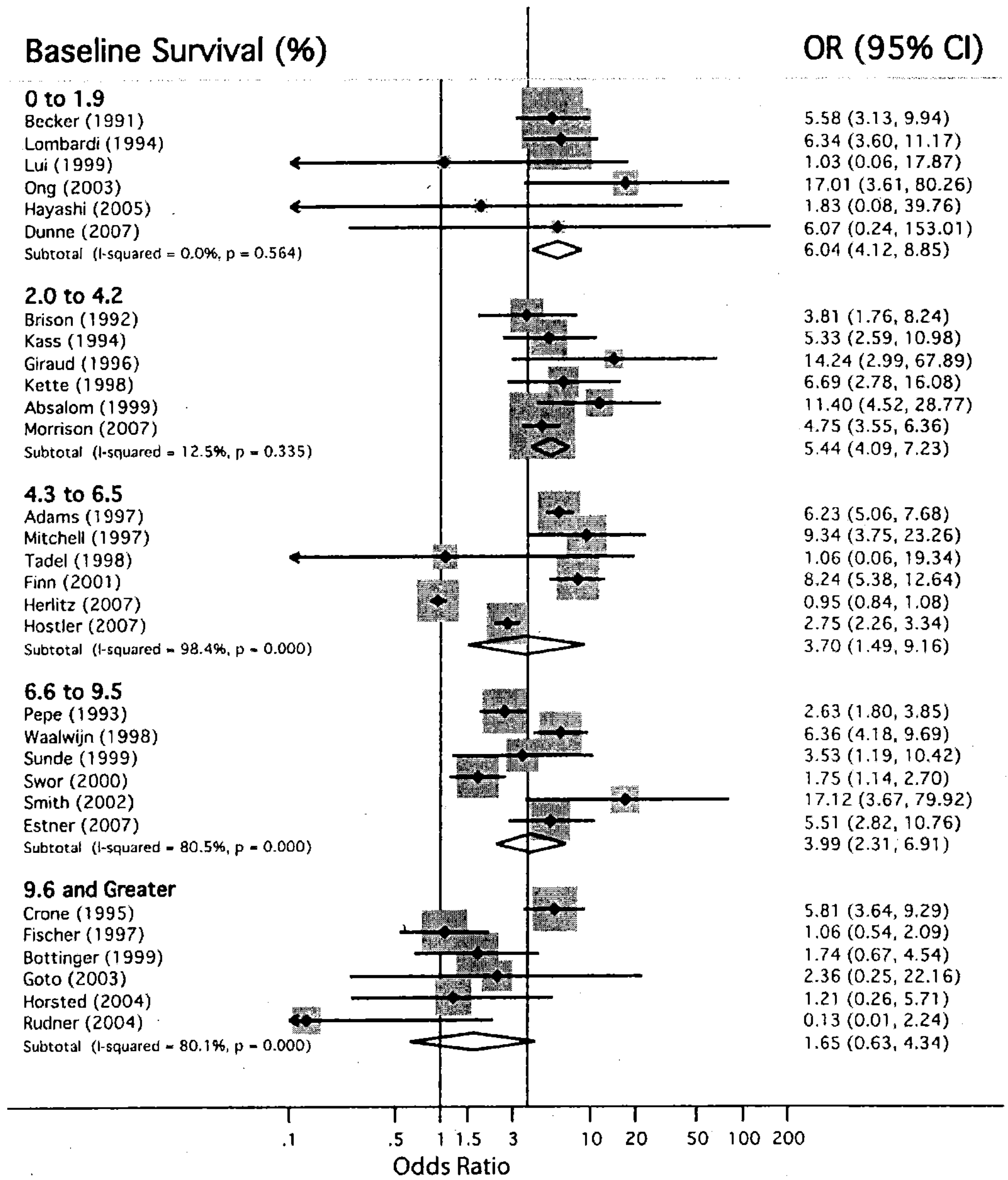

Figure 4. Forest plot of studies reporting witnessed by EMS stratified by baseline survival.

Sensitivity Analyses

We limited our analyses to adult cardiac arrest patients for whom resuscitation was attempted in the prehospital setting. Because having a consistent denominator (ie, total number of resuscitations attempted in the prehospital setting) was important, we conducted a sensitivity analysis that excluded four studies that described patients who sustained OHCA but failed to include information on patients who were treated but not transported to the emergency department.[29,51,57,86] Excluding these articles did not appreciably change our results. For example, the pooled odds ratio for VF/VT changed from 20.62 (95% CI, 12.61 to 33.72) to 22.69 (95% CI, 13.54 to 38.87) in the lowest baseline survival group, and from 2.91 (95% CI, 1.10 to 7.66) to 2.91 (95% CI, 1.10 to 7.67) in the highest baseline survival group.

In further sensitivity analyses, studies that contained elements which deviated from other studies were excluded. Four studies limited their analysis to OHCA cases that were not witnessed by EMS providers[78,97,99,103]; 6 studies reported survival at 1 month rather than at hospital discharge[2,81,85,90,95,108]; 3 studies reported survival 1 year post OHCA[52,103,105]; and 2 studies grouped pulseless electric activity and asystole together.[55,95] Excluding these studies did not appreciably alter our final pooled results.

Publication Bias

The Begg's test for publication bias was conducted. For all 5 criteria of interest, the Begg test was not significant (P>0.05). Visual inspection of funnel plots did not suggest publication bias.

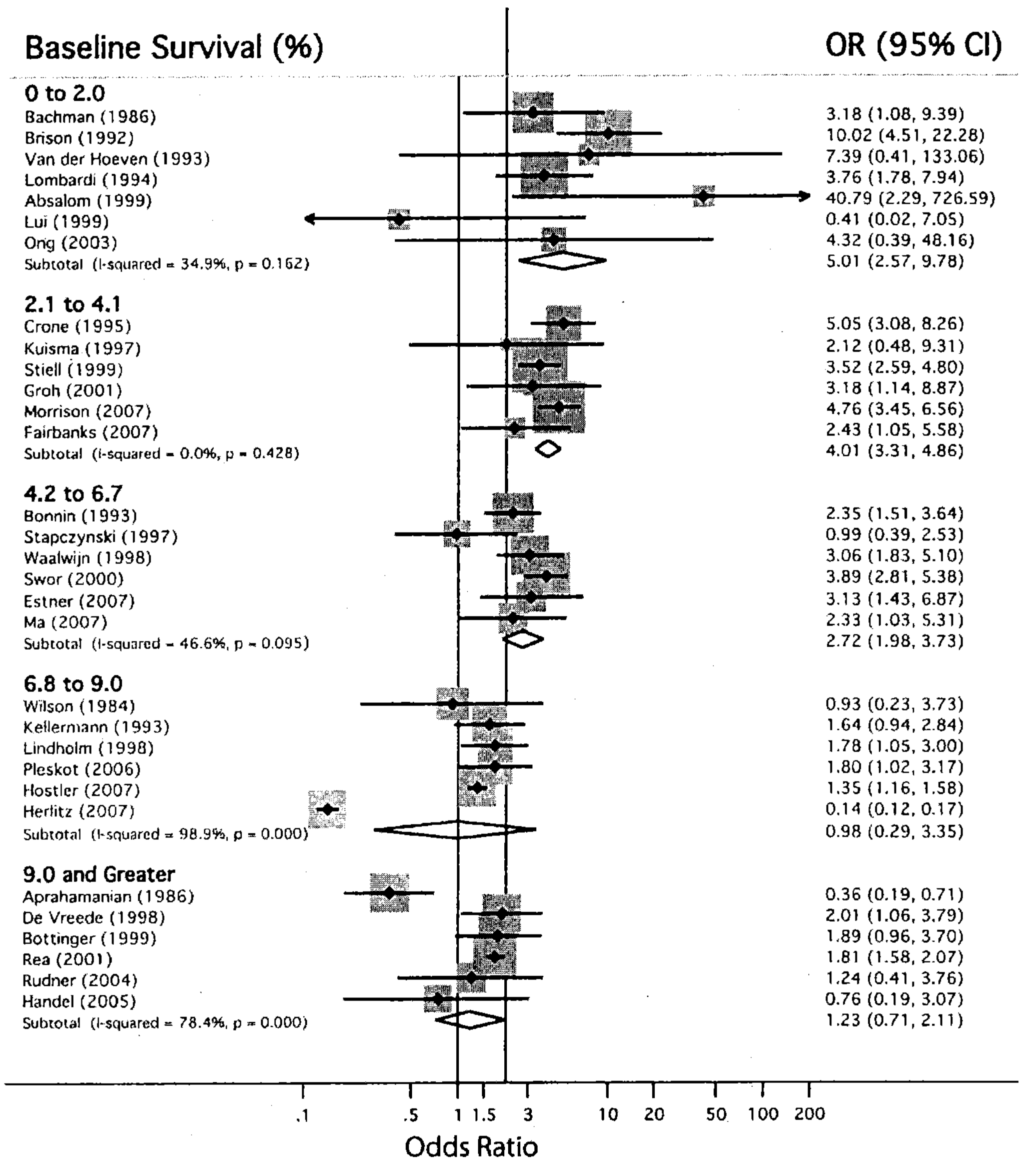

Figure 5. Forest plot of studies reporting bystander CPR stratified by baseline survival.

Discussion

Survival from OHCA has not significantly improved in almost 30 years. The aggregate survival rate, recorded across various populations, is between 6.7% and 8.4%. This lack of progress, despite enormous efforts in research spending, the introduction of novel drugs and devices, and periodic evidence-based revisions to clinical guidelines may be attributable, in part, to the offsetting influence of declining incidence of ventricular fibrillation arrests,[110–112] increasing age of the population,[113] and longer EMS response time intervals attributable to urbanization and population growth.[114] Breaking this barrier to achieve decisive improvements in OHCA survival represents a challenging and worthwhile goal for emergency cardiac care.

Recognizing the importance of several clinical predictors of OHCA survival may help communities and research scientists focus their efforts to achieve this goal. We found that OHCA victims who receive CPR from a bystander or an EMS provider, and those who are found in VF or VT, are much more likely to survive than those who do not. Moreover, we found that the strength of association between VF/VT and survival was greatest in locations in which a defibrillator is available at public sites. To put these observations in context, approximately 1 of every 4 to 7 patients with a presenting rhythm of VF/VT survive to hospital discharge, compared to only 1 of every 21 to 500 patients found in asystole. Because prompt provision of CPR delays the degradation of tachyarrythmias to asystole, this may explain why bystander CPR and prehospital defibrillation have such a positive impact on survival.[115]

By far the most powerful criterion associated with survival from OHCA is ROSC in the field. The odds of sur-

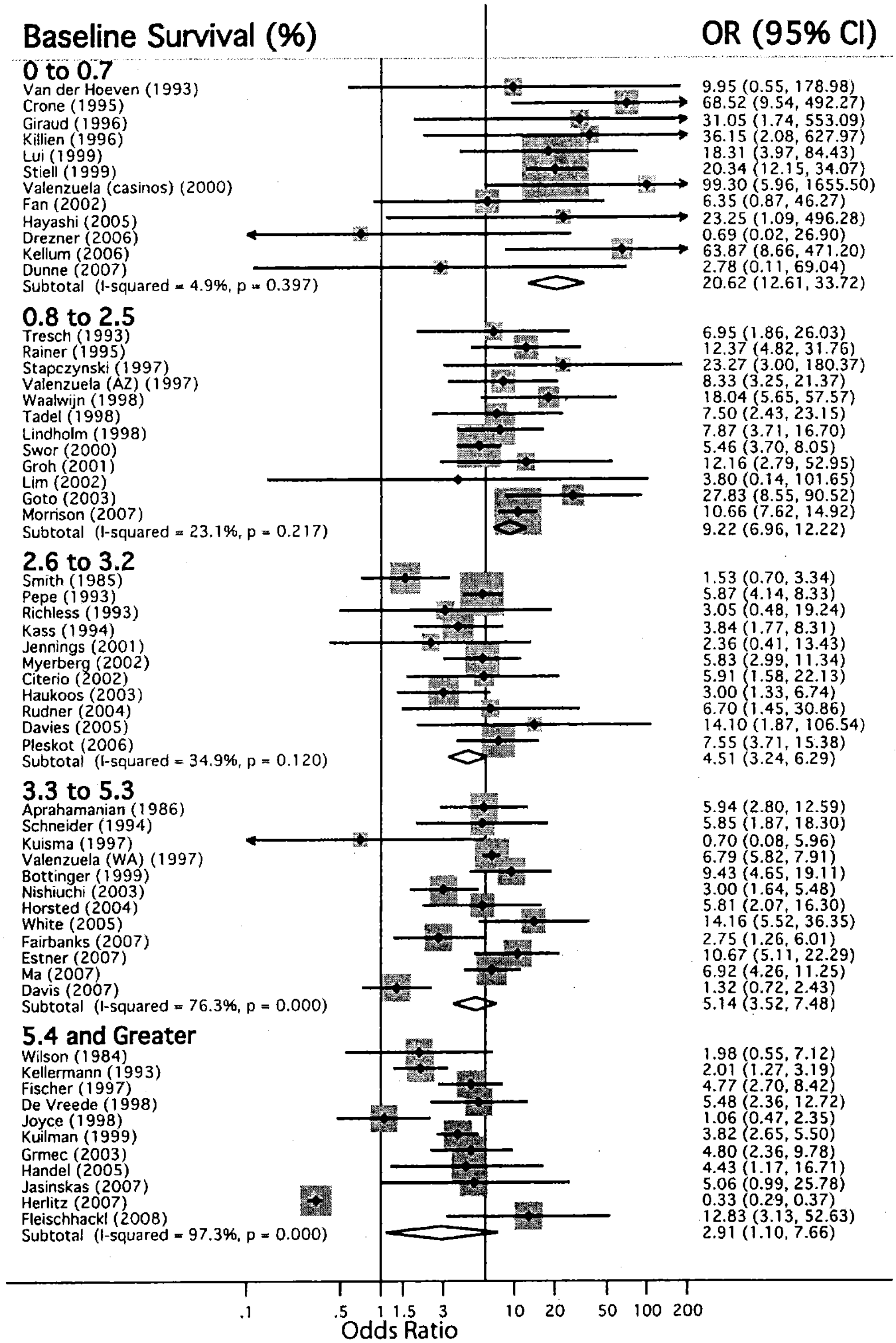

Figure 6. Forest plot of studies reporting ventricular fibrillation/tachycardia stratified by baseline survival.

vival ranged from 50% in communities where baseline survival rates are high to 20% (1 in 5) in areas were baseline survival is low. Failure to restore a pulse on scene indicates that the patient will not likely survive to hospital discharge, irrespective of the subsequent sophistication of in-hospital care. This finding strongly suggests that future efforts to boost OHCA survival should focus on optimizing provision of prehospital emergency cardiac care.[116,117] It is noteworthy

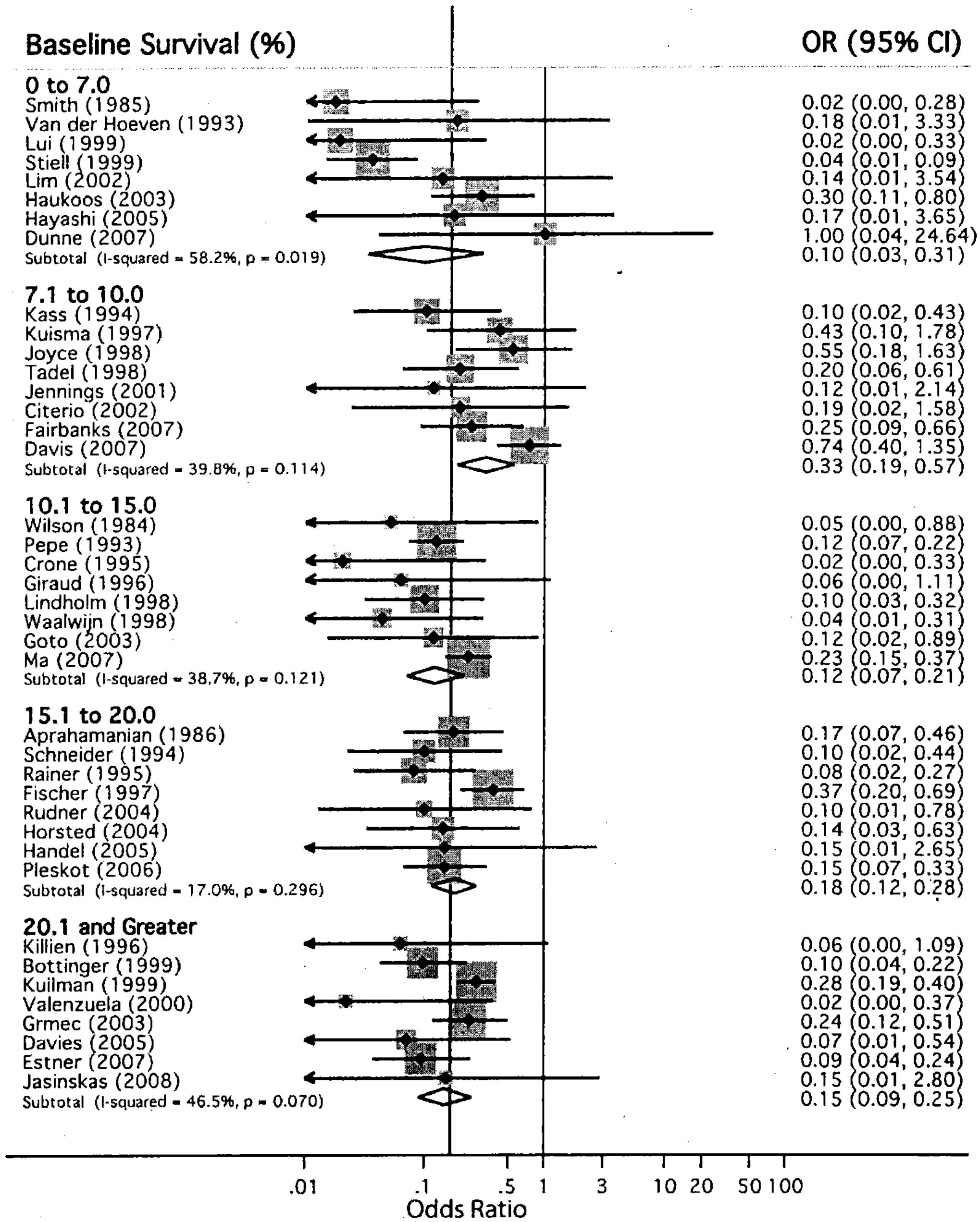

Figure 7. Forest plot of studies reporting asystole stratified by baseline survival.

that 40% of patients with OHCA were found with VF/VT, yet only 22% achieved ROSC. This group may be a priority population for future efforts to improve ROSC and survival to hospital discharge.

Although our analysis focused on 5 key variables, we examined several potentially confounding factors (eg, type of EMS system, United States versus international study, mean response time interval) to determine whether they introduced an unacceptable degree of heterogeneity to the main estimates of effect. The only external factor that was consistently significant across the 5 clinical factors was the baseline performance of the community's EMS system. In systems with lower baseline survival rates, the magnitude of effect sizes for the 5 clinical factors such as provision of bystander CPR and an initial rhythm of VF/VT, were higher than in communities that had high baseline survival rates. This suggests that efforts such as targeted CPR training to increase bystander CPR rates will have their greatest effect in communities with low baseline rates of survival. A corollary hypothesis is that the return on investment for focusing on these characteristics may diminish as the overall performance of a community's EMS system improves. It is important to note, however, that certain factors, most notably VF/VT arrest and ROSC,

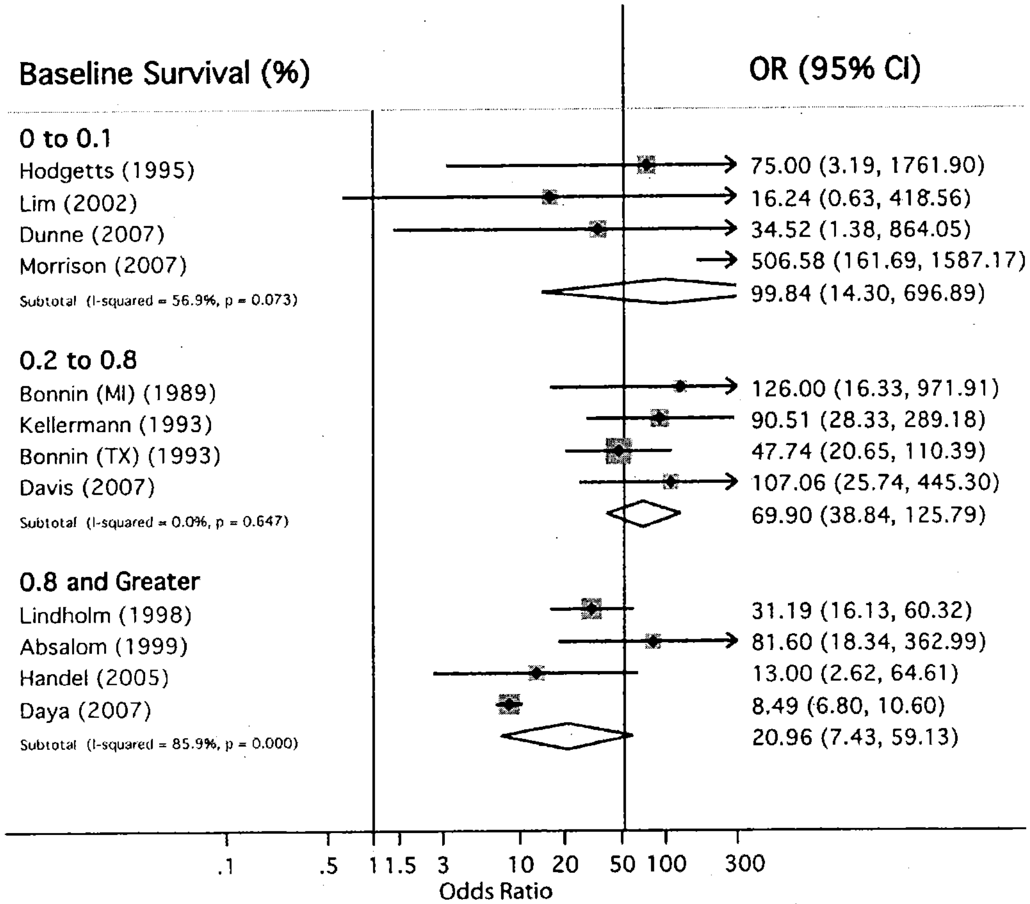

Figure 8. Forest plot of studies reporting return of spontaneous circulation stratified by baseline survival.

were significantly associated with OHCA survival in even the highest-performing EMS systems.

Some of the remaining heterogeneity between studies may be attributable to the highly variable nature of EMS systems in the United States and worldwide.[118] For example, many EMS agencies use locally-created protocols to determine whether and when to cease efforts if an OHCA patient does not respond to prehospital advanced cardiac life support.[119] Some communities provide their first responders with Basic Life Support training and an automated external defibrillator,

Table 3. Survival Rates and Number Needed to Treat by Clinical Criteria

Variable	Pooled Percentage of Cardiac Arrests With Attribute	Low Baseline Survival		High Baseline Survival	
		Pooled Survival Rate, %	NNT	Pooled Survival Rate, %	NNT
Witnessed by bystander	53% (45.0–59.9)	6.4 (3.5–9.3)	17	13.5 (5.6–21.5)	71
Witnessed by EMS	10% (8.0–11.3)	4.9 (1.3–8.4)	23	18.2 (3.7–32.8)	16
Not witnessed	36% (30.4–40.8)	0.5 (0.2–0.9)		12.1 (7.5–16.7)	
Bystander CPR	32% (26.7–37.8)	3.9 (1.8–6.0)	36	16.1 (11.5–20.7)	24
No bystander CPR	68% (62.6–74.8)	1.1 (0.5–1.8)		12.0 (10.0–14.0)	
Ventricular fibrillation/tachycardia	40% (36.6–43.3)	14.8 (9.4–20.2)		23.0 (13.8–32.2)	
No ventricular fibrillation/tachycardia	60% (56.2–62.9)	0.4 (0.2–0.6)		7.4 (6.1–8.7)	
Asystole	42% (36.0–46.8)	0.2 (0–0.3)		4.7 (1.0–8.4)	
No asystole	58% (52.9–63.8)	4.4 (2.1–6.6)		30.1 (23.8–36.4)	
Return of spontaneous circulation	22% (17.7–25.5)	15.5 (0.0–33.3)		33.6 (24.9–42.2)	
No return of spontaneous circulation	78% (74.5–82.3)	0.1 (0.0–0.2)		1.8 (1.5–2.1)	

NNT indicates number needed to treat to save 1 life.

whereas others rely on paramedics trained to provide Advanced Life Support. A few U.S. systems and many foreign countries routinely employ nurses or physicians in prehospital settings.[120] It is not clear whether different approaches to provider training affect survival rates from OHCA.[4,121]

Our study is limited in certain respects. Because individual-level patient data were not reported for each study, we could not adequately assess all patient characteristics and potential confounding factors which may influence survival. The studies in our meta-analysis did not contain enough data to simultaneously evaluate the effect of all 5 key criterion, so combined effects could not be assessed.

Despite our effort to apply quality criteria, it is possible that the reporting of predictor and outcome variables was inconsistent in some studies. The Utstein guidelines, designed by EMS leaders in 1991 and subsequently revised in 1996 and 2002, created a standardized approach to data collection.[120,122,123] Research has shown that even in the era of Utstein-guided reporting of OHCA care and outcomes, marked variations in survival from one community to the next persist.[124] This variability probably reflects persistent differences in approach. For example, although 57 of the 79 studies included in our meta-analysis were published after 1996, some articles did not consistently report the length of prehospital resuscitation intervals (ie, call to ambulance response time and first defibrillation), the range of pharmaceutical interventions, the training level of EMS providers, the duration of resuscitation efforts, or policies permitting termination of unsuccessful resuscitations in the field. We chose not to report our findings using the Utstein definition of survival (witnessed VF arrest surviving to hospital discharge), as this has been summarized in previous studies.[72,124,125]

We did not include studies that assessed investigational devices or emerging therapies that were outside the standard of care at the time these studies were conducted. Pulseless electric activity (or idioventricular rhythm) was not included in the meta-analysis, because the definitions applied to this type of rhythm were highly nonuniform across studies. And, although the articles included in our meta-analysis were limited to English publications, the information was gathered from 26 countries and represents a variety of populations and EMS systems. Finally, our analysis was restricted to studies with primarily adult patients. Cardiac arrest in pediatric populations differs in fundamental ways from OHCA in adults.

Although the overall rate of OHCA survival has not improved, the field of cardiac and cerebral resuscitation is rapidly evolving. Most of the studies incorporated in our meta-analysis were conducted before the advent of therapeutic hypothermia. This treatment has been shown to benefit resuscitated patients.[7,34,35] Patients treated under the recently revised AHA guidelines for CPR, which emphasize rapid compressions and deemphasize ventilation, could not be distinguished from earlier studies included in the meta-analysis.[36] However, there is hope that these recent changes in technique and emphasis will improve outcomes.[126–129] Future studies will need to take such changes into account to assess their impact on survival.

This meta-analysis brings together almost 30 years of research, involving more than 142 000 patients. Our findings conclusively affirm the value of bystander CPR, the critical importance of "shockable" rhythms, and the predictive value of ROSC in the field. Focused strategies designed to boost rates of bystander CPR, deliver earlier defibrillation, and achieve ROSC before transport are likely to do more to improve aggregate rates of OHCA survival than interventions applied later in a patient's treatment. Currently, 92% of individuals who experience OHCA each year do not survive to hospital discharge. This dismal statistic can be improved.

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Disclosures

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In the article by Sasson et al, "Predictors of Survival From Out-of-Hospital Cardiac Arrest: A Systematic Review and Meta-Analysis," which appeared online November 10, 2009 (*Circ Cardiovasc Qual Outcomes.* DOI: 10.1161/CIRCOUTCOMES.109.889576), an error occurred in Table 3.

Table 3 in the original article showed the number of patients with the characteristic in whom 1 person survived (ie, 1/pooled survival rate). The corrected Table 3 corresponds with the text and shows the Number Needed to Treat (NNT) using the formula 1/absolute risk reduction to determine the number of people needed to treat to save 1 life with 1 of the 3 conditions in which an intervention is possible (witnessed by bystander, witnessed by EMS, provision of bystander CPR).

This correction has been made to the print and current online versions of the article. The authors regret the error.

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Part 10: First Aid

Introduction

In 2004 the American Heart Association (AHA) and the American Red Cross (ARC) cofounded the National First Aid Science Advisory Board (Table) to review and evaluate the scientific literature on first aid. The goals of the National First Aid Science Advisory Board are to reduce morbidity and mortality due to emergency events and to analyze the scientific evidence that answers the following questions:

- What are the most common emergency conditions that lead to significant morbidity and mortality?
- In which of these emergency conditions can morbidity or mortality be reduced by the intervention of a first aid provider?
- How strong is the scientific evidence that interventions performed by a first aid provider are safe, effective, and feasible?

Members of the National First Aid Science Advisory Board reviewed morbidity data from the US Centers for Disease Control and Prevention and first aid texts to identify common causes of injury and injury fatalities and selected the topics for evidence evaluation that are included in this section. The conflict of interest statements of the Board can be assessed through the website *http://www.C2005.org*. For further information about the evidence evaluation process, see Part 1: "Introduction." The information presented here represents a consensus summary of the scientific evidence relevant to common first aid interventions with consensus treatment recommendations.

Definition of First Aid

The National First Aid Science Advisory Board defined first aid as assessments and interventions that can be performed by a bystander (or by the patient/victim) with minimal or no medical equipment. The board defined a first aid provider as someone with formal training in first aid, emergency care, or medicine who provides first aid.

The board agreed that recommended assessments and interventions should be medically sound and based on scientific evidence or, in the absence of such evidence, on scientific consensus. Administration of first aid must not delay activation of the emergency medical services (EMS) system or other medical assistance when such assistance is required. It is recognized that certain conditions that can be treated with first aid may not require EMS involvement or assistance by other medical professionals. The National First Aid Science Advisory Board strongly believes that education in first aid should be universal: everyone can and should learn first aid.

The National First Aid Science Advisory Board recognized that the scope of first aid is not a purely scientific one and is related to both training and regulatory issues. The definition of scope is therefore variable, and it should be defined according to circumstances, need, and local regulatory requirements.

Future Directions

The evidence review by the National First Aid Science Advisory Board confirmed the paucity of scientific evidence on first aid subjects. Many of the following recommendations have been made by extrapolation from the experience of healthcare professionals or evidence derived from healthcare settings. Research is needed to ensure that future guidelines are based on a larger body of scientific evidence.

Overview

This document summarizes current evidence for evaluation and first aid interventions for medical, injury, and environmental emergencies. The broad range and number of topics reviewed and limitations of journal space require succinctness and brevity in science statements and treatment recommendations. This is not intended as a comprehensive review of every aspect of first aid. Rather, it is intended to evaluate the evidence available to support management of common problems.

Medical Emergencies

The experts reviewed published evidence to support the first aid use of oxygen and to support assistance with the use of asthma inhalers and epinephrine autoinjectors. Although there was no published information on the first aid application of any of these common adjuncts, some recommendations could be made to support assistance with asthma inhalers and epinephrine autoinjectors based on extrapolated evidence from use by laypersons.

Oxygen Administration[W264]

Consensus on Science

Although oxygen administration is a basic healthcare provider procedure, the reviewers found no studies that evaluated emergency oxygen administration by first aid providers. Many studies included oxygen as a professional treatment modality, but all identified studies were confounded by the heterogeneity of subject disease states and condition, diverse equipment needs, and multiple adjunctive treatments. These

From the 2005 First Aid Science Advisory Board Evidence Evaluation Conference, hosted by the American Heart Association and the American Red Cross in Dallas, Texas, January 23–24, 2005.

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Organizations Represented on the National First Aid Science Advisory Board

- Academy of Orthopaedic Surgeons
- American Academy of Pediatrics
- American Association of Poison Control Centers
- American Burn Association
- American College of Emergency Physicians
- American College of Occupational and Environmental Medicine
- American College of Surgeons
- American Heart Association
- Army Medical Command
- The American Pediatric Surgical Association
- American Red Cross
- American Safety and Health Institute
- Australian Resuscitation Council
- Canadian Red Cross
- International Association of Fire Chiefs
- International Association of Fire Fighters
- Medic First Aid International
- Military Training Network
- National Association of EMS Educators
- National Association of EMS Physicians
- National Association of EMTs
- National Safety Council
- Occupational Safety and Health Administration
- Save a Life Foundation

variables prevent extrapolation of the results of any of the reviewed studies to first aid applications.

Treatment Recommendation
There is insufficient evidence to recommend for or against the use of oxygen by the first aid provider.

Assistance With Use of Inhalers[W253]

Consensus on Science
Severe asthma and deaths from asthma are increasing,[1] so it is likely that first aid responders will be asked to help victims with respiratory distress caused by asthma. Patients with asthma often use prescribed bronchodilator inhalers, but the reviewers found no studies evaluating the efficacy of first aid providers assisting patients in the use of these inhalers for breathing difficulty. Nonrandomized studies documented the ability of adults to appropriately self-administer bronchodilator medications (LOE 4)[2–4] and the ability of parents to correctly administer metered-dose inhalers to their children (LOE 4).[5] An important difference in the first aid situation, however, is that the first aid provider may not know the victim, the victim's medical history, or what medications the victim takes. Thus the studies regarding parents constitute LOE 7 (extrapolated) information applied to first aid.

Treatment Recommendation
Because the frequency and mortality from severe asthma is increasing[1] and bronchodilator therapy is safe and can be effective during episodes of severe asthma, the first aid rescuer should assist with administration of bronchodilator therapy.

Epinephrine Autoinjector[W199,W252]

Consensus on Science
A severe allergic reaction (anaphylaxis) can cause life-threatening airway edema and obstruction, vasodilation, and cardiovascular collapse. Although administration of epinephrine is a cornerstone of emergency management of severe allergic reactions, the reviewers found no studies of the safety, efficacy, or feasibility of first aid providers assisting with administration of epinephrine autoinjectors. Many adults and children with a history of anaphylaxis carry a prescribed epinephrine autoinjector.

Evidence from one small retrospective study (LOE 7)[6] reported that parents who administer epinephrine to their children via an autoinjector can do so safely and effectively. Evidence from other studies (LOE 7)[7–9] highlighted the need for additional education and retraining of parents and healthcare providers in the use of epinephrine autoinjectors.

Treatment Recommendation
Given the widespread use of epinephrine autoinjectors and their documented efficacy in the rapid delivery of epinephrine,[10] first aid providers may be trained to assist in the use of an epinephrine autoinjector for a victim of anaphylaxis when the victim has a prescribed autoinjector and the victim is unable to use it.

Recovery Position[W146A,W146B,W155,W274]

Consensus on Science
Although the recovery position is widely used in healthcare settings, the reviewers found no studies evaluating the safety, effectiveness, or feasibility of this position in unresponsive, breathing victims in the out-of-hospital setting. All identified studies of specific recovery positions used healthy, responsive adult volunteers (LOE 3–5), so results are at best extrapolated (LOE 7) to unresponsive victims.

Any recovery position used for the patient with known or suspected spinal injury should maintain a patent airway, stabilize the spine, and minimize movement of the victim. Two human prospective cohort studies in healthy adult volunteers (extrapolated from LOE 3)[11,12] suggest that the modified HAINES position results in more neutral position of the cervical spine than the traditional lateral recovery position. HAINES is an acronym for **H**igh **A**rm **IN** **E**ndangered **S**pine: the rescuer extends the victim's arm above the head and rolls the victim to the side, onto that arm, and then bends the victim's knees. The subjects in these studies were responsive (with presumably normal muscle tone), however, and had no head, neck, or cervical spine injury. In addition, the study of the HAINES position did not include study of the movement of patients to that position.

The recovery position was also reviewed by the Basic Life Support Task Force. For additional information see Part 2: "Adult Basic Life Support" and the associated worksheets.[W146A,W146B,W155]

Treatment Recommendation
The use of the recovery position with the victim lying on his or her side with the dependent hand placed in front of the

body is recommended for the unconscious victim with an intact airway, spontaneous respiration, and signs of circulation. This position is easy to teach, but conscious volunteers who were placed in the position developed some vessel and nerve compression (LOE 3).[13,14] Nerve and vessel injury can develop, particularly if the victim remains in the position for a long period of time.

The preferred position for the victim with known or suspected spinal injury is to stabilize the spine in the supine position and minimize movement of the victim. Use of the recovery position may be necessary if it is difficult to maintain a patent airway in the supine position, if the victim has secretions or emesis, or if the rescuer must leave the victim and there is no provider trained in spinal stabilization. If use of the recovery position is absolutely necessary, use the HAINES recovery position: extend the victim's arm above the head and roll the victim to the side so that the victim's head rests on that arm. Bend both legs to stabilize the victim.

Injury Emergencies

There was little published evidence about common first aid maneuvers to stabilize the cervical spine; control bleeding; and treat wounds, abrasions, burns, and musculoskeletal injuries. Because the consequences of spinal cord injury are severe, the experts developed consensus treatment recommendations for stabilization of the cervical spine based on extrapolation from healthcare provider experiences. Treatment of bleeding in the battlefield provided evidence regarding the use of pressure and tourniquets by trained lay rescuers and healthcare providers. But these results must be applied with caution to the first aid setting when medical assistance may be available within minutes.

The experts found that many "common sense" treatments for wounds, burns, musculoskeletal injuries, and dental and environmental injuries are supported by only low levels of evidence.

Cervical Spine Injuries

Cervical Spine Stabilization[W256,W257,W268,W269,W150A,W150B]

Consensus on Science

Approximately 2% of adult victims of blunt trauma evaluated in the emergency department suffer a spine injury (LOE 3),[15,16] and this risk is tripled in patients with craniofacial injury (LOE 4)[17] or a Glasgow Coma Scale score of <8 (LOE 4).[18]

EMS and emergency department personnel can correctly identify injury mechanisms that may produce spinal injury in adults (LOE 3[15,19,20]; LOE 4[21]) and in children.[22] EMS personnel can properly apply spinal immobilization devices in such circumstances (LOE 3),[23–25] although they may not accurately detect signs and symptoms of actual spinal injury (LOE 3[26–28]; LOE 4[29,30]). Results of these healthcare provider studies constitute only extrapolated evidence (LOE 7) for first aid actions. There are no studies showing that first aid providers can recognize potential or actual spinal injury.

There is no evidence that first aid rescuers can correctly use spinal immobilization devices. Although the failure to detect and immobilize cervical spine injury in hospitalized patients is associated with a 7-fold to 10-fold risk of secondary neurologic injury (LOE 3[31]; LOE 4[32]), it is not clear if the secondary injuries occur in the prehospital setting and can be prevented by spinal immobilization devices. A 5-year retrospective chart review (LOE 4)[33] with a multivariate analysis compared all patients with blunt traumatic spine or spinal cord injuries admitted to a trauma hospital in Malaysia with patients with similar injuries admitted to a US trauma hospital. Physicians blinded to hospital origin found less evidence of neurologic disability in the Malaysian patients, who were transported without spinal immobilization, than in the US patients, who were transported with spinal immobilization devices in place.

There is some evidence that spinal immobilization devices can be harmful. A retrospective chart review (LOE 4)[34] found that spinal immobilization devices masked life-threatening injuries. In addition, immobilization on a spine board restricted pulmonary function in healthy adults (LOE 3)[35] and children (LOE 3).[36] Application of a cervical collar increased intracranial pressure in healthy patients (LOE 3)[37] and patients with traumatic brain injury.[38]

Spine immobilization was also reviewed by the Basic Life Support Task Force. For additional information see Part 2: "Adult Basic Life Support" and the associated worksheets.[W150A,W150B]

Treatment Recommendation

Considering the serious consequences of spinal cord injury, most experts agree that spinal motion restriction should be the goal of early treatment of all patients at risk for spinal injury. The first aid provider should restrict spinal motion by manual spinal stabilization if there is any possibility of spinal injury.

In the absence of any evidence supporting the first aid use of immobilization devices and with some evidence suggesting potential harm even when these devices are used by healthcare providers, the first aid provider should refrain from use of spinal immobilization devices.

Severe Bleeding

Application of Pressure and Tourniquets[W254,W255]

Consensus on Science

Direct pressure. Although bleeding is a common first aid emergency and control of hemorrhage can be lifesaving, only 2 studies reported the efficacy of direct pressure to control hemorrhage in the prehospital or field hospital settings, and in both studies the pressure was applied by trained medical personnel. One retrospective case series (LOE 5)[39] described the technique of hemorrhage control by highly trained ambulance workers. Hemorrhage control was achieved by wrapping an adhesive elastic bandage applied directly over a collection of 4 × 4-inch gauze pads placed on the wound surface. The roll was wrapped around the body surface over the bleeding site until ongoing hemorrhage ceased. The pressure was effective in stopping bleeding in all cases with no complications. A second nonrandomized observational case series from a field hospital (LOE 4)[40] compared the efficacy of direct pressure applied by trained providers with an elastic bandage to control hemorrhage in 50 successive victims of traumatic amputations to the effectiveness of tourniquets used for 18 previous victims with traumatic amputations from mine explosions. Less ongoing bleeding, higher survival rates, and higher admission hemoglobin were observed in the 50 victims for whom bleeding was controlled with direct pressure compared with the 18 earlier victims who had bleeding controlled with a tourniquet. Four studies from cardiac catheterization experience (LOE 7, extrapolated from LOE 1 and 2),[41–44] one animal study (LOE 6),[45] and clinical experience document that direct pressure is an effective and safe method of controlling bleeding. The efficacy, feasibility, and safety of use of pressure points to control bleeding have never been subjected to any reported study, and there have been no published studies to determine if elevation of a bleeding extremity helps to control bleeding or causes harm.

Tourniquets. The use of tourniquets by a first aid provider to control bleeding is controversial. Tourniquets are routinely and safely used to obtain extremity ischemia for orthopedic and vascular surgical procedures in operating rooms where applied pressure and occlusion time are strictly measured and controlled and on the battlefield when occlusion time is carefully documented. But these results cannot be extrapolated to the first aid setting. Two studies illustrate the contradictory evidence reported about the effectiveness and safety of tourniquet use in the first aid setting. In a retrospective military field case series (LOE 5),[46] 110 tourniquets were applied to 91 soldiers by medical (47%) or nonmedical (53%) personnel. The tourniquets controlled bleeding in most (78%) of the victims, typically within 15 minutes. Penetrating trauma was the most common mechanism of injury, and ischemic time was 83 ± 52 minutes (range of 1 to 305 minutes). The rate of success was higher for medical staff compared with soldiers and for upper limbs (94%) compared with lower limbs (71%, $P<.01$). Neurologic complications of the tourniquet were reported in 7 limbs of 5 patients (5.5%) who had an ischemic time of 109 to 187 minutes. Complications included bilateral peroneal and radial nerve paralysis, 3 cases of forearm peripheral nerve damage, and 1 case of paresthesia and weakness of the distal foot.In the nonrandomized report (LOE 5)[40] of victims of traumatic amputation from mine explosions cited in the previous section, tourniquet use resulted in more bleeding, lower survival rates, and lower admission hemoglobin than direct pressure with an elastic bandage. Complications following tourniquet use in the operating room are well documented. Tourniquet use during surgical procedures has produced temporary (LOE 5)[47] or permanent (LOE 7)[48] injury to the underlying nerves and muscles (LOE 5)[49] and limb ischemia with resulting systemic complications, including acidemia and hyperkalemia (LOE 2).[50] Complications can include reperfusion injury (LOE 2)[51] and limb loss. These complications are related to the pressure applied (LOE 5)[52] and occlusion time (LOE 2).[50]

Treatment Recommendation

The first aid provider should try to control external bleeding by applying direct pressure.

There is insufficient evidence to recommend for or against the first aid use of pressure points or extremity elevation to control bleeding.

Tourniquets may be useful under some unique conditions (eg, battlefield conditions when rapid evacuation is required and ischemic time is carefully monitored). Additional studies are needed to identify those conditions and the indications and procedures for use. The method of application and best design of tourniquets is still under investigation.[53] There is insufficient evidence about the effectiveness, feasibility, and safety of tourniquets to recommend for or against their use by first aid providers to control bleeding.

Wounds and Abrasions

Wound Irrigation[W259,W266]

Consensus on Science

Wound irrigation is often used in the prehospital and hospital setting to clean wounds. There is strong evidence from human and animal studies that wound irrigation using clean running tap water is at least as effective as wound irrigation with normal saline. In 1 Cochrane meta-analysis (LOE 1),[54] 1 small randomized human study (LOE 2),[55] and 1 human case series (LOE 5),[56] irrigation with running tap water was more effective than irrigation with saline in improving wound healing and lowering infection rates. In 1 small randomized human study (LOE 2),[57] irrigation with tap water produced wound infection rates equivalent to that observed after irrigation with normal saline. Although many of these studies were performed in healthcare settings, running tap water is readily available to lay rescuers in the out-of-hospital setting.

Treatment Recommendation

Superficial wounds and abrasions should be irrigated with clean tap water.

Use of Antibiotic Ointment[W265]

Consensus on Science

Two prospective, randomized controlled studies compared the effectiveness of triple antibiotic ointment with single antibiotic ointment or no ointment in conditions comparable to first aid situations. In one human volunteer study (LOE 1)[58] of the effects of applied ointment to intradermal chemical blisters inoculated with a single organism (*Staphylococcus aureus*), contaminated blisters treated with triple antibiotic ointment healed significantly faster and with a lower infection rate than blisters treated with either single antibiotic ointment or no ointment. Both triple and single antibiotic ointments were superior to no treatment in promoting healing of the contaminated blisters. In a study (LOE 1)[59] of 59 children in a rural day care center, application of triple antibiotic ointment to minor skin trauma (eg, mosquito bites, abrasions) resulted in lower rates of one skin infection, streptococcal pyoderma, than the rates of that infection observed in children who received applications of placebo ointment (15% versus 47%).

Extrapolation of results from studies of surgically created wounds supports the use of antibiotic ointments. In 2 studies involving human volunteers with wounds that were created under sterile conditions (ie, dermabrasion or split-thickness skin graft donor sites), triple antibiotic ointment was superior to no ointment in minimizing pigment changes[60] and scarring.[61] These reports may not be relevant to the treatment of nonsurgical and probably nonsterile wounds in the first aid setting. Triple antibiotic ointment can eliminate coagulase-negative staphylococci underlying the skin surface (LOE 7),[62] but its impact on wound contamination and healing cannot be extrapolated from these studies.

Treatment Recommendation
Lay rescuers should apply antibiotic ointment or cream to cutaneous abrasions and wounds to promote faster healing with less risk of infection. The use of triple antibiotic ointment may be preferable to double- or single-agent antibiotic ointment or cream.

Thermal Burns

Cooling With Water[W247]

Consensus on Science
Immediate cooling of thermal burns with cold tap water is supported by a large number of observational clinical studies and controlled experiments in animals. Cooling may provide pain relief and reduce formation of edema, infection rates, depth of injury, and need for grafting and may promote more rapid healing. One small, controlled human volunteer study (LOE 3),[63] several large retrospective human studies (LOE 4[64]; LOE 5[65–67]), and multiple animal studies (LOE 6)[68–72] document consistent improvement in wound healing and reduced pain when burns are cooled with cold water (10°C to 25°C [50°F to 77°F). Several studies (LOE 6)[69,73] indicate that cooling of burns should begin as early as possible and continue at least until pain is relieved (LOE 5).[74]

There is limited (LOE 5) evidence that brief application of ice or ice water may be safe and effective for small burns in adults,[64,68,74,75] but prolonged application of ice or ice water may result in additional tissue injury (necrosis)[67] (LOE 5[76]; LOE 6[77]). Evidence from animal studies (LOE 6)[78] suggests that cooling of large burns ($\geq$20% of total body surface area) with ice or ice water for $\geq$10 minutes can result in hypothermia.

Treatment Recommendation
Cooling of burns with cold water as soon as possible is safe, feasible, and effective as a first aid treatment. First aid providers should avoid cooling burns with ice or ice water for $>$10 minutes, especially if burns are large ($>$20% total body surface area).

First Aid for Burn Blisters[W248]

Consensus on Science
There is no clear, evidence-based consensus on the treatment of burn blisters. Many treatment recommendations are based on level 5 or lower studies and common practice. Although many first aid guidelines recommend that burn blisters be left intact, some researchers suggest that burn blister fluid may retard healing, particularly when blisters are large ($>$2.5 cm) and thin-walled. One case control study (LOE 4)[79] looked at wound healing rates for intact blisters versus those in which fluid was drained and found that removal of burn blister fluid enhanced healing. In contrast, most animal data (LOE 6)[80–82] documents faster healing rates, significantly lower infection rates, and less scar tissue formation in animals with burn blisters left intact compared with those with debrided burn blisters.

Treatment Recommendation
Because the need for blister debridement is controversial and requires equipment and skills that are not consistent with first aid training, first aid providers should leave burn blisters intact and cover them loosely.

Musculoskeletal Injuries (Fractures, Sprains, and Contusions)

Stabilization[W260,W273]

Consensus on Science
There are numerous reports of the benefits of stabilization of extremities by trained providers, but it is impossible to extrapolate this data to the first aid provider. There is no evidence to support the hypothesis that realignment of a fractured extremity bone by a lay first aid provider is safe, effective, or feasible.

Treatment Recommendation
The first aid provider should assume that any injury to an extremity can include a potential bone fracture. The first aid provider may manually stabilize the injured extremity but should not attempt to straighten it.

Compression[W261]

Consensus on Science
The reviewers found no data to support the hypothesis that compression of an injured extremity is safe, effective, and feasible when performed by a first aid provider. Although it is widely accepted (LOE 7)[83] that compression of an injured extremity decreases edema, this concept has not been subjected to randomized trials. One small study (LOE 7)[84] with Doppler evaluation of blood flow to the toes of 10 healthy female volunteers suggests that moderate circumferential compression may compromise distal (toe) blood flow, but this information must be extrapolated to the first aid arena.

Treatment Recommendation
There is inadequate evidence to recommend for or against the use of a circumferential bandage to compress a closed soft-tissue injury and reduce formation of edema (Class Indeterminate).

Application of Cold[W262]

Consensus on Science
The basic principle in first aid for soft-tissue injuries is to decrease hemorrhage, edema, and pain. Cold therapy has been shown to reduce edema in animal[85,86] and human[87,88] studies. Cold therapy has been shown experimentally to reduce the temperature of various tissues, including muscles and joints in healthy[89–92] and postoperative[93] subjects. Ice therapy also contributes to reductions in arterial and soft-tissue blood flow along with bone metabolism as shown in nuclear medicine imaging studies.[94] It appears to be time dependent.[95]

The application of ice is effective for reducing pain, swelling, and duration of disability[87,96] after soft-tissue injury. There is good evidence to suggest that cold therapy reduces edema.[86,87,97] One postoperative study evaluating anterior cruciate ligament reconstruction suggested that cold therapy contributed to no objective benefit in the postoperative period related to length of hospital stay, range of motion, use of pain medication, and drain output.[93] However, there was a trend for a decrease in oral pain medication in the group of patients treated with ice bags. Other types of cold therapy, including cold gel,[98] frozen pea bags,[89] and other cold therapy delivery systems,[85,91] may also be beneficial. Some studies[85,89,99] showed that refreezable gel packs are inefficient. Cold therapy modalities that undergo a phase change seem to be more efficient in decreasing tissue temperature.[91]

Treatment Recommendation

Cooling is generally safe, effective, and feasible in first aid for a sprained joint and soft-tissue injury. Cold applied for >20 minutes may be detrimental, although there are several reports that suggest that longer application may continue to cool the joint without additional complications.[91]

There is insufficient information to make recommendations on optimal frequency, duration, and initial timing of cryotherapy after an acute injury.[100,101] Many textbooks are not consistent in their recommendations related to duration, frequency, and length of ice treatment.[100]

To prevent cold injury to the skin and superficial nerves, it is best to limit ice to periods ≤20 minutes at a time with a protective barrier.[102,103] A damp cloth or plastic bag barrier may be ideal, whereas cold is not conducted as well through padded elastic bandages.[100] Caution should be exercised when applying ice to an injury in a person with little subcutaneous fat, especially over areas of superficial peripheral nerves.[102,104]

Dental Injuries

Tooth Avulsion[W275]

Consensus on Science

The evidence reviewed included an expert opinion review article (LOE 7)[105] and extrapolated evidence from a study of survival of lip fibroblasts in various media (LOE 7).[106] Expert opinion and a study of tissue survival in mild versus salt solutions or other storage media supported placement of avulsed teeth in milk until reimplantation or other definitive care can be provided.

Treatment Recommendation

The consensus of the experts is that the potential harm from attempted reimplantation of an avulsed tooth outweighs the potential benefit, and that avulsed teeth should be stored in milk and transported with the injured victim to a dentist as quickly as possible.

Environmental Injuries

Relatively good animal data is available to evaluate the treatment of snakebite, but little evidence is available on which to base specific treatment recommendations for cold injuries.

Snakebite[W270,W271]

Consensus on Science

Although some first aid texts recommend that rescuers must remove venom from a snakebite, a controlled animal study (LOE 6)[107] showed no clinical benefit and earlier death in animals with snakebites that were treated with suction compared with animals with snakebites treated without suction. Two subsequent studies (LOE 5[108]; LOE 6[109]) showed that the application of suction resulted in the removal of some injected venom, but these reports did not examine clinical outcome. The use of a suction device on rattlesnake envenomation in a porcine model (LOE 6)[110] showed no benefit and suggested injury may occur with suction. A simulated snakebite study in human volunteers (LOE 5)[111] determined that a suction device recovered virtually no mock venom.

If a snakebite is from an elapid (eg, coral) snake, first aid treatment includes application of pressure immobilization. The landmark article by Sutherland (LOE 6)[112] showed that pressure immobilization after elapid snakebites retarded venom uptake in monkeys. In a human study Howarth (LOE 3)[113] showed that lymphatic flow and mock venom uptake can be safely reduced by proper application of pressure (40 to 70 mm Hg for upper limbs, 55 to 70 mm Hg for lower limbs) and immobilization and that either alone is insufficient. Pressure bandages should not be applied too tightly because they will restrict blood flow. A recent study in pigs (LOE 6)[114] documented improved survival rates with application of moderate pressure and immobilization.

Treatment Recommendation

First aid providers should not apply suction to snakebite envenomation sites.

Properly performed pressure immobilization is recommended for first aid treatment of elapid snakebites. The first aid provider creates this pressure by applying a snug bandage that allows a finger to slip under the bandage.

Cold Injuries

Hypothermia[W267]

Consensus on Science

The goals of care for the victim of hypothermia are to stop the fall in core temperature, establish a steady, safe rewarming rate, and support cardiorespiratory function.[115] Although there is a general belief that hypothermic patients should be rewarmed, there is very little data to support any specific method or timing of rewarming in the out-of-hospital setting.

One small in-hospital study[116] of adult patients with hypothermia randomized to warming with forced-air convective covers plus warmed IV fluids versus cotton blankets plus warmed IV fluids documented that forced-air rewarming (using an air-filled blanket) raised the core temperature faster than passive rewarming and produced no additional complications. In a prospective randomized study[117] of 8 healthy volunteers who were anesthetized and cooled to 33°C (91.4°F) (shivering was prevented with administration of meperidine) core temperature increased more rapidly with active rewarming using a resistive heating blanket than with passive rewarming using reflective foil. It is difficult to extrapolate these results to all victims of hypothermia in the first aid setting. The need for lay rescuers to institute fast or active rewarming in the prehospital setting has not been established.

In a retrospective chart review (LOE 4),[118] prehospital rewarming strategies did not affect outcome of hypothermic patients admitted through the emergency department. Active prehospital rewarming may lead to increased complications such as the "afterdrop phenomenon," in which vasodilation results in increased perfusion of cold extremities and delivery of acidotic blood to the central circulation.[119]

This topic was also reviewed by the Basic Life Support Task Force. For additional information see Part 2: "Adult Basic Life Support," and the related worksheet.[W162A]

Treatment Recommendation
The first aid provider should provide passive warming (using blankets) as feasible for victims of hypothermia. Victims should be transported to a facility where active rewarming can be initiated. If the victim is in a remote location far from medical help, the first aid rescuer may initiate active rewarming.

Frostbite[W267]

Consensus on Science
There is little published evidence about the first aid treatment of frostbite. One opinion review with a case report[120] suggests that the frostbitten body part should be rewarmed in the prehospital setting only if there is no chance of refreezing. Other consensus opinion reviews[121] suggest that the frostbitten part should not be rubbed or massaged because this can increase tissue damage.

Treatment Recommendation
The first aid provider should rewarm a frostbitten body part unless there is a possibility that it might refreeze.

Poisoning

Poisoning can be caused by solids, liquids, gases, and vapors. Solids and liquids are ingested or absorbed through the skin, whereas gases and vapors are typically inhaled (vapors can also be absorbed through the skin). This evidence evaluation process did not review the evidence surrounding first aid for inhaled toxins.

Water irrigation was shown to be effective for topical chemical or caustic burns. Some common first aid treatments for ingested poisons, such as drinking water or administration of syrup of ipecac, are not supported by evidence and may be harmful, so they are not recommended. There was inadequate evidence to recommend for or against the use of activated charcoal in the first aid setting.

Toxic Exposure and Chemical Burns

Water Irrigation[W258,W259]

Consensus on Science
Irrigation of the skin and eye after exposure to caustic agents can reduce the severity of tissue damage. Evidence from multiple studies examining alkali and acid exposure to both the eye (LOE 1–8)[122–127] and the skin (LOE 4–6)[128–134] document improved outcome when water irrigation is rapidly administered in first aid treatment. One nonrandom case series (LOE 5)[134] of immediate (first aid) versus delayed (healthcare provider) skin irrigation documented a lower incidence of full-thickness burns and 50% reduction in length of hospital stay with immediate and copious irrigation of skin chemical burns. Animal evidence (LOE 6) also supports water irrigation to reduce toxic exposure from acid burns to the skin[124,130] and eye.[122,123] In a study of rats with acid skin burns,[130] water irrigation within 1 minute of the burn prevented any drop in tissue pH, whereas delayed irrigation allowed a progressively more significant fall in tissue pH.

Treatment Recommendation
To treat skin or eye exposure to acid or alkali, the first aid provider should immediately irrigate the skin or eye with copious amounts of tap water.

Ingested Poisons

Water and Gastrointestinal Decontamination[W249,W250,W251]

Consensus on Science
As noted in the *ECC Guidelines 2000,*[135] there is no human evidence to support the administration of water or milk after the ingestion of a poison. Although animal studies of caustic (acid or alkali) ingestions have documented reduced esophageal tissue injury following lavage with or ingestion of saline, cola, orange juice, water or milk, outcome data was limited to tissue pH studies or tissue injury and did not evaluate survival rates. In addition, these studies did not address ingestion of noncaustic substances. Because the poisoned patient may have an altered level of consciousness that compromises airway protective reflexes, expert opinion suggests that administration of anything by mouth may be harmful.

Three randomized clinical trials (LOE 2) in children[136] and adults[137,138] have shown no benefit and possible harm from the administration of syrup of ipecac after toxic ingestion. In 2 studies[136,138] administration of ipecac delayed the use of activated charcoal and in 1 trial[138] increased charcoal emesis and length of stay. One prospective, randomized clinical trial (LOE 2)[139] of 200 adults treated for ingestion in the emergency department with either ipecac plus activated charcoal or ipecac alone documented higher complication rates and higher incidence of aspiration pneumonia among adults who received ipecac alone. A large retrospective study of 752 602 children in the American Association of Poison Control Center Toxic Exposure Surveillance System Database (LOE 4)[140] was unable to document improvement in outcome or reduction in healthcare use related to administration of syrup of ipecac for potentially toxic ingestions. Administration of syrup of ipecac has been associated with harm in case reports (LOE 5)[141–144] and clinical studies (LOE 2).[139]

Administration of activated charcoal to animals immediately after drug ingestion can reduce the amount of drug absorbed, but effectiveness varies and decreases over time.[145,146] The published experience pertaining to first aid administration of activated charcoal is limited. Although 1 prospective uncontrolled study (LOE 4)[147] and 2 retrospective case series(LOE 5)[148,149] suggest that activated charcoal may be safely administered to children at home and can reduce the time to activated charcoal administration, activated charcoal was rarely recommended for childhood poisonings and was successfully administered to only two thirds of the victims.[147] Studies in healthy children document that children will not take the recommended dose of activated charcoal.[150] Although a retrospective chart review (LOE 5)[151] of 878 patients who received multiple doses of activated charcoal in the hospital documented a low incidence of complications, aspiration did occur in this study, and the results are likely to be worse in the prehospital setting with no healthcare providers in attendance. Some reports of aspiration of activated charcoal were identified,[151–153] but the precise incidence of this complication is unknown.

Treatment Recommendation

The administration of water or milk to the victim of ingested poison is not recommended.

Based on lack of evidence of benefit and documentation of potential harm, syrup of ipecac is not recommended for toxic ingestions.

There is insufficient evidence to recommend for or against the use of activated charcoal in first aid.

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Part 3: Defibrillation

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Part 3: Defibrillation

The 2005 Consensus Conference considered questions related to the sequence of shock delivery and the use and effectiveness of various waveforms and energies. These questions have been grouped into the following categories: (1) strategies before defibrillation, (2) use of automated external defibrillators (AEDs), (3) electrode-patient interface, (4) use of the electrocardiographic (ECG) waveform to alter management, (5) waveform and energy levels for the initial shock, (6) sequence after failure of the initial shock (ie, second and subsequent shocks), and (7) other related topics.

The *ECC Guidelines 2000*[1] state that defibrillation should be attempted as soon as ventricular fibrillation (VF) is detected, regardless of the response interval (ie, time between collapse and arrival of the AED). If the response interval is >4 to 5 minutes, however, there is evidence that 1½ to 3 minutes of CPR before attempted defibrillation may improve the victim's chance of survival. The data in support of out-of-hospital AED programs continues to accumulate, and there is some evidence supporting the use of AEDs in the hospital. Analysis of the VF waveform enables prediction of the likelihood of defibrillation success; with this information the rescuer can be instructed to give CPR or attempt defibrillation. This technology was developed by analysis of downloads from AEDs; it has yet to be applied prospectively to improve defibrillation success and is not available outside research programs.

All new defibrillators deliver a shock with a biphasic waveform. There are several varieties of biphasic waveform, but the best variant and the optimal energy level and shock strategy (fixed versus escalating) have yet to be determined. Biphasic devices achieve higher first-shock success rates than monophasic defibrillators. This fact, combined with the knowledge that interruptions to chest compressions are harmful, suggests that a 1-shock strategy (1 shock followed immediately by CPR) may be preferable to the traditional 3-shock sequence for VF and pulseless ventricular tachycardia (VT).

Strategies Before Defibrillation

Precordial Thump[W59,W166B]

Consensus on Science

No prospective studies have evaluated the use of the precordial (chest) thump. In 3 case series (LOE 5)[2–4] VF or pulseless VT was converted to a perfusing rhythm by a precordial thump. The likelihood of conversion of VF decreased rapidly with time (LOE 5).[4] The conversion rate was higher for unstable or pulseless VT than for VF (LOE 5).[2–6]

Several observational studies indicated that an effective thump was delivered by a closed fist from a height of 5 to 40 cm (LOE 5).[3,4,6–8] Other observational studies indicated that additional tachyarrhythmias, such as unstable supraventricular tachycardia (SVT), were terminated by precordial thump (LOE 5).[9,10] Potential complications of the precordial thump include rhythm deteriorations, such as rate acceleration of VT, conversion of VT into VF, complete heart block, and asystole (LOE 5[3,5,6,8,11,12]; LOE 6[13]). Existing data does not allow an accurate estimate of the likelihood of these complications.

Treatment Recommendation

One immediate precordial thump may be considered after a monitored cardiac arrest if an electrical defibrillator is not immediately available.

CPR Before Defibrillation[W68,W177]

Consensus on Science

In a before–after study (LOE 4)[14] and a randomized trial (LOE 2),[15] 1½ to 3 minutes of CPR by paramedics or EMS physicians before attempted defibrillation improved return of spontaneous circulation (ROSC) and survival rates for adults with out-of-hospital VF or VT when the response interval (ambulance dispatch to arrival) and time to defibrillation was ≥4 to 5 minutes. This contrasts with the results of another trial in adults with out-of-hospital VF or VT, in which 1½ minutes of paramedic CPR before defibrillation did not improve ROSC or survival to hospital discharge (LOE 2).[16] In animal studies of VF lasting ≥5 minutes, CPR (often with administration of epinephrine) before defibrillation improved hemodynamics and survival rates (LOE 6).[17–21]

Treatment Recommendation

A 1½- to 3-minute period of CPR before attempting defibrillation may be considered in adults with out-of-hospital VF or pulseless VT and EMS response (call to arrival) intervals >4 to 5 minutes. There is no evidence to support or refute the use of CPR before defibrillation for in-hospital cardiac arrest.

Use of AEDS

AED Programs[W174,W175]

Consensus on Science

A randomized trial of trained lay responders in public settings (LOE 2)[22] and observational studies of CPR and defibrillation

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performed by trained professional responders in casinos (LOE 5)[23] and lay responders in airports (LOE 5)[24] and on commercial passenger airplanes (LOE 5)[25,26] showed that AED programs are safe and feasible and significantly increase survival from out-of-hospital VF cardiac arrest if the emergency response plan is effectively implemented and sustained. In some studies defibrillation by trained first responders (eg, firefighters or police officers) has improved survival rates from witnessed out-of-hospital VF sudden cardiac arrest (LOE 2[27]; LOE 3[28,29]; LOE 4[30,31]; LOE 5[32]). In other studies AED defibrillation by trained first responders has not improved survival.[14,33]

Approximately 80% of out-of-hospital cardiac arrests occur in a private or residential setting (LOE 4).[34] However, there is insufficient data to support or refute the effectiveness of home AED programs.

Treatment Recommendation
Use of AEDs by trained lay and professional responders is recommended to increase survival rates in patients with cardiac arrest. Use of AEDs in public settings (airports, casinos, sports facilities, etc) where witnessed cardiac arrest is likely to occur can be useful if an effective response plan is in place. The response plan should include equipment maintenance, training of likely responders, coordination with local EMS systems, and program monitoring. No recommendation can be made for or against personal or home AED deployment.

AED Program Quality Assurance and Maintenance[W178]

Consensus on Science
No published trials specifically evaluated the effectiveness of AED program quality improvement efforts to further improve survival rates. Case series and reports suggest that potential improvements can be made by reviewing AED function (rhythm analysis and shock), battery and pad readiness, operator performance, and system performance (eg, mock codes, time to shock, outcomes) (LOE 5).[35–42]

Treatment Recommendation
AED programs should optimize AED function (rhythm analysis and shock), battery and pad readiness, operator performance, and system performance (eg, mock codes, time to shock, outcomes).

AED Use in Hospitals[W62A]

Consensus on Science
No published randomized trials have compared AEDs with manual defibrillators in hospitals. One study of adults with in-hospital cardiac arrest with shockable rhythms showed higher survival-to–hospital discharge rates when defibrillation was provided through an AED program than with manual defibrillation alone (LOE 4).[43] In an animal model, use of an AED substantially interrupted and delayed chest compressions compared with manual defibrillation (LOE 6).[44] A manikin study showed that use of an AED significantly increased the likelihood of delivering 3 shocks but increased the time to deliver the shocks when compared with manual defibrillators (LOE 6).[45] In contrast, a study of mock arrests in simulated patients showed that use of monitoring leads and fully automated defibrillators reduced time to defibrillation when compared with manual defibrillators (LOE 7).[46]

Treatment Recommendation
Use of AEDs is reasonable to facilitate early defibrillation in hospitals.

Electrode-Patient Interface

Electrode Pad/Paddle Position and Size[W63A,W63B,W173A,W173B]

Consensus on Science

Position. No studies of cardiac arrest in humans have evaluated the effect of pad/paddle position on defibrillation success or survival rates. Most studies evaluated cardioversion (eg, atrial fibrillation [AF]) or secondary end points (eg, transthoracic impedance [TTI]).Placement of paddles or electrode pads on the superior-anterior right chest and the inferior-lateral left chest were effective (paddles studied in AF, LOE 2[47]; pads studied in AF, LOE 3[48]; effect of pad position on TTI, LOE 3[49]). Alternative paddle or pad positions that were reported to be effective were apex-posterior (pads studied in VF and AF, LOE 4[50]; effect of pad position on TTI, LOE 3[49]), and anteroposterior (paddles studied in AF, LOE 2[51]; pads studied in AF, LOE 2[52], LOE 3[53]; effect of pad position on TTI, LOE 3[49]). One study showed lower TTI with longitudinal placement of the apical paddle (LOE 3).[54] Placement of the pad on the female breast increased impedance and may decrease efficacy of defibrillation (LOE 5).[55] High-voltage alternating current (eg, from high power lines) interfered with AED analysis (LOE 6).[56]

Size. One human study (LOE 3)[57] and one animal study (LOE 6)[58] documented higher defibrillation success rates with larger paddles: 12.8-cm paddles were superior to 8-cm paddles. Eight studies (LOE 3[53,57,59,60]; LOE 5[61]; LOE 6[55,62,63]) demonstrated that increased pad size decreased TTI. In one canine study, significantly increased myocardial damage was reported after defibrillation with small (4.3 cm) electrodes compared with larger (8 and 12 cm) electrodes (LOE 6).[64]

Treatment Recommendation
Paddles and electrode pads should be placed on the exposed chest in an anterolateral position. Acceptable alternative positions are anteroposterior (paddles and pads) and apex-posterior (pads). In large-breasted patients it is reasonable to place the left electrode pad (or paddle) lateral to or underneath the left breast. Defibrillation success may be higher with 12-cm electrodes than with 8-cm electrodes. Small electrodes (4.3 cm) may be harmful; myocardial injury can occur.

Self-Adhesive Defibrillation Pads Versus Paddles[W71]

Consensus on Science
One randomized trial (LOE 2)[65] and 2 retrospective comparisons (LOE 4)[50,66] showed that TTI is similar when either pads or paddles are used. One prospective comparison of pads and paddles (LOE 3)[67] showed lower TTI when paddles were applied at an optimal force of 8 kg compared with pads. One randomized study of chronic AF showed similar effectiveness for self-adhesive pads and manual paddles when monophasic

damped sinusoidal or BTE waveforms were evaluated separately (LOE 7).[68] Several studies (LOE 5[69–71]; LOE 6[72]) showed the practical benefits of pads over paddles for routine monitoring and defibrillation, prehospital defibrillation, and perioperative defibrillation.

Treatment Recommendation
Self-adhesive defibrillation pads are safe and effective and are an acceptable alternative to standard defibrillation paddles.

Waveform Analysis

VF waveform analysis has the potential to improve the timing and effectiveness of defibrillation attempts; this should minimize interruptions in precordial compressions and reduce the number of unsuccessful high-energy shocks, which cause postresuscitation myocardial injury. The technology is advancing rapidly but is not yet available to assist rescuers.

Prediction of Shock Success From VF Waveform[W64A,W64B,W64C,W65A]

Consensus on Science
Retrospective analyses of the VF waveform in clinical and animal studies and theoretical models (LOE 4[73–82]; LOE 6[83–93]) suggest that it is possible to predict with varying reliability the success of defibrillation from the fibrillation waveform. No studies specifically evaluated whether treatment can be altered by the prediction of defibrillation success to improve survival from cardiac arrest.

Initial Shock Waveform and Energy Levels

Several related questions were reviewed. Outcome after defibrillation has been studied by many investigators. When evaluating these studies the reviewer must consider the setting (eg, out-of-hospital versus in-hospital), the initial rhythm (eg, VF/pulseless VT), the duration of arrests (eg, out-of-hospital with typical EMS response interval versus electrophysiology study with 15-second arrest interval), and the specific outcome measured (eg, termination of VF at 5 seconds).

Biphasic Versus Monophasic Waveforms for Ventricular Defibrillation[W61A,W61B,W172]

Consensus on Science
In 3 randomized cardiac arrest studies (LOE 2),[94-96] a reanalysis of one of these studies (LOE 2),[93] 2 observational cardiac arrest studies (LOE 4),[98,99] a meta-analysis of 7 randomized trials in the electrophysiology laboratory (LOE 1),[100] and multiple animal studies, defibrillation with a biphasic waveform, using equal or lower energy levels, was at least as effective for termination of VF as monophasic waveforms. No specific waveform (either monophasic or biphasic) was consistently associated with a greater incidence of ROSC or higher hospital discharge rates from cardiac arrest than any other specific waveform. One retrospective study (LOE 4)[99] showed a lower survival-to-hospital-discharge rate after defibrillation with a biphasic truncated exponential (BTE) waveform when compared with a monophasic truncated exponential (MTE) device (20% versus 39.7%, $P=0.01$), but survival was a secondary end point. This study had multiple potential confounders, including the fact that CPR was provided to more subjects in the MTE group.

No direct comparison of the different biphasic waveforms has been reported as of 2005.

Treatment Recommendation
Biphasic waveform shocks are safe and effective for termination of VF when compared with monophasic waveform shocks.

Energy Level for Defibrillation[W60A,W60B]

Consensus on Science
Eight human clinical studies (LOE 2[94]; LOE 3[101]; LOE 5[95,96,98,99,102,103]) described initial biphasic selected shock energy levels ranging from 100 J to 200 J with different devices but without clearly demonstrating an optimal energy level. These human clinical studies also described use of subsequent selected shock energy levels with different devices for shock-refractory VF/VT ranging from 150 J to 360 J but without clearly demonstrating an optimal energy level.

Seven more laboratory studies (LOE 7)[104–110] in stable patients evaluated termination of induced VF with energy levels of 115 J to 200 J.

Neither human clinical nor laboratory studies demonstrated evidence of significantly greater benefit or harm from any energy level used currently. One human study in the out-of-hospital setting showed an increased incidence of transient heart block following 2 or more 320-J monophasic damped sine wave (MDS) shocks when compared with an equal number of 175-J MDS shocks, but there was no difference in long-term clinical outcome (LOE 2).[111]

Only 1 of the reviewed animal studies showed harm caused by attempted defibrillation with doses in the range of 120 J to 360 J in adult animals; this study indicated that myocardial damage was caused by higher-energy shocks (LOE 6).[112]

One in-hospital study of 100 patients in VF compared MDS shocks of low (200 J to 240 J), intermediate (300 J to 320 J), and high (400 J to 440 J) energy (LOE 2).[113] First-shock efficacy (termination of VF for ≥5 seconds) was 39% for the low-energy group, 58% for the intermediate-energy group, and 56% for the high-energy dose group. These differences did not achieve statistical significance. A study of electrical cardioversion for AF indicated that 360-J MDS shocks were more effective than 100-J or 200-J MDS shocks (LOE 7).[114] Cardioversion of a well-perfused myocardium, however, is not the same as defibrillation attempted during VF cardiac arrest, and any extrapolation should be interpreted cautiously.

Treatment Recommendation
There is insufficient evidence for or against specific selected energy levels for the first or subsequent biphasic shocks. With a biphasic defibrillator it is reasonable to use 150 J to 200 J with BTE waveforms or 120 J with the rectilinear biphasic waveform for the initial shock. With a monophasic waveform defibrillator, an initial shock of 360 J is reasonable.

Second and Subsequent Shocks

Fixed Versus Escalating Energy[W171]

Consensus on Science
Only one small human clinical study (LOE 3)[101] compared fixed energy with escalating energies using biphasic defibrillators. The study did not identify a clear benefit for either strategy.

Treatment Recommendation
Nonescalating- and escalating-energy biphasic waveform defibrillation can be used safely and effectively to terminate VF of both short and long duration.

1-Shock Protocol Versus 3-Shock Sequence[W69A,W69B,W69C]

Consensus on Science
No published human or animal studies compared a 1-shock protocol with a 3-stacked shock sequence for any outcome. The magnitude of success of initial or subsequent shocks depended on the specific group of patients, the initial rhythm, and the outcome considered. Shock success was defined as termination of VF for ≥5 seconds after the shock. Resuscitation success can include ROSC and survival to hospital discharge. Only shock success is cited below.

First-shock success. Six studies of defibrillation in out-of-hospital cardiac arrest reported first-shock success in patients whose initial rhythm was shockable (VF/pulseless VT):

- In studies that used a 200-J MDS waveform, the first-shock success rate was 77% to 91% (LOE 2[94,97]; LOE 5[95,99]). In studies that used a 200-J MTE waveform, the first-shock success rate was 54% to 63% (LOE 4).[97,99]
- In studies that used a 150-J BTE waveform[97,99,115,116] and 1 study that used a 200-J BTE waveform,[95] the first-shock success rate was 86% to 98%.[95,97,99,115,116]
- The first-shock success rate with a 120-J rectilinear biphasic waveform was 85% (according to L.J. Morrison, MD, in oral discussion at the 2005 Consensus Conference).[94]

Although the first-shock success rate was relatively high in patients with out-of-hospital cardiac arrest and an initial rhythm of VF, the average rate of ROSC with the first shock (for MDS, MTE, and BTE waveforms) was 21% (range 13% to 23%) (LOE 5).[99]

Second- and third-shock success rates. Six studies of defibrillation in out-of-hospital cardiac arrest reported the shock success (defined above) rate of the first shock and subsequent 2 shocks (if the initial shock was unsuccessful) for patients with an initial rhythm of VF/pulseless VT. The figures below refer to only those patients who remained in VF after the first shock, and they represent the proportion of these cases successfully defibrillated by either the second or third shock.

- In 2 studies that used the MDS waveform with increasing energy levels (200 J to 200/300 J to 360 J), the combined shock success of the second and/or third shocks when the first shock failed was 68% to 72% (LOE 5).[94,99] In 2 studies that used the MTE waveform with increasing energy levels (200 J to 200 to 360 J), the combined shock success of the second and third shocks when the first shock failed was 27% to 60% (LOE 5).[97,99]
- In 4 studies that used the fixed-energy 150-J BTE waveform, the combined shock success of the second and third shocks when the first shock failed was 50% to 90% (LOE 5).[97,99,115,116]
- In the 1 study that used a rectilinear waveform with increasing energy levels (120 J to 150 J to 200 J), the combined success rate of the second and third shocks when the first shock failed was 85% (LOE 5).[94]

One study of defibrillation for out-of-hospital cardiac arrest in which the initial rhythm was VF reported a 26% rate of ROSC with the initial series of up to 3 shocks (for BTE waveforms) combined with preshock or postshock CPR or both (LOE 5).[116]

Treatment Recommendation
Priorities in resuscitation should include early assessment of the need for defibrillation (Part 2: "Adult Basic Life Support"), provision of CPR until a defibrillator is available, and minimization of interruptions in chest compressions. Rescuers can optimize the likelihood of defibrillation success by optimizing the performance of CPR, timing of shock delivery with respect to CPR, and the combination of waveform and energy levels. A 1-shock strategy may improve outcome by reducing interruption of chest compressions. A 3-stacked shock sequence can be optimized by immediate resumption of effective chest compressions after each shock (irrespective of the rhythm) and by minimizing the hands-off time for rhythm analysis.

Related Defibrillation Topics

Defibrillator Data Collection[W66]

Consensus on Science
Collection of data from defibrillators enables a comparison of actual performance during cardiac arrests and training events. The results of 3 observational studies (LOE 5)[117–119] suggest that the rate and depth of external cardiac compressions and ventilation rate were at variance with current guidelines.

Treatment Recommendation
Monitor/defibrillators modified to enable collection of data on compression rate and depth and ventilation rate may be useful for monitoring and improving process and outcomes after cardiac arrest.

Oxygen and Fire Risk During Defibrillation[W70A,W70B]

Consensus on Science
Several case reports (LOE 5)[120–125] described instances of fires ignited by sparks from poorly attached defibrillator paddles in the presence of an oxygen-enriched atmosphere. The oxygen-enriched atmosphere rarely extends >0.5 m (1.5 ft) in any direction from the oxygen outflow point, and the oxygen concentration returns quickly to ambient when the source of enrichment is removed (LOE 5[122]; LOE 6[126]). The most severe fires were caused when ventilator tubing was disconnected from the tracheal tube and then left adjacent to

the patient's head during attempted defibrillation (LOE 5).[121,123,125] In at least one case a spark generated during defibrillation ignited oxygen delivered by a simple transparent face mask that was left in place (LOE 5).[120]

In a manikin study (LOE 6)[126] there was no increase in oxygen concentration anywhere around the manikin when the ventilation device was left attached to the tracheal tube, even with an oxygen flow of 15 L/min.

Treatment Recommendation

Rescuers should take precautions to minimize sparking (by paying attention to pad/paddle placement, contact, etc) during attempted defibrillation. Rescuers should try to ensure that defibrillation is not attempted in an oxygen-enriched atmosphere.

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Predicting Survival From Out-of-Hospital Cardiac Arrest: A Graphic Model

From the Center for Evaluation of Emergency Medical Services, Emergency Medical Services Division, Seattle, King County Department of Public Health; and Department of Medicine and Biostatistics, University of Washington,† Seattle.*

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Mary P Larsen, MS*
Mickey S Eisenberg, MD, PhD*†
Richard O Cummins, MD, MPH, MSc*†
Alfred P Hallstrom, PhD†

Study objective: To develop a graphic model that describes survival from sudden out-of-hospital cardiac arrest as a function of time intervals to critical prehospital interventions.

Participants: From a cardiac arrest surveillance system in place since 1976 in King County, Washington, we selected 1,667 cardiac arrest patients with a high likelihood of survival: they had underlying heart disease, were in ventricular fibrillation, and had arrested before arrival of emergency medical services (EMS) personnel.

Methods: For each patient, we obtained the time intervals from collapse to CPR, to first defibrillatory shock, and to initiation of advanced cardiac life support (ACLS).

Results: A multiple linear regression model fitting the data gave the following equation: survival rate = 67% – 2.3% per minute to CPR – 1.1% per minute to defibrillation – 2.1% per minute to ACLS, which was significant at $P < .001$. The first term, 67%, represents the survival rate if all three interventions were to occur immediately on collapse. Without treatment (CPR, defibrillatory shock, or definitive care), the decline in survival rate is the sum of the three coefficients, or 5.5% per minute. Survival rates predicted by the model for given EMS response times approximated published observed rates for EMS systems in which paramedics respond with or without emergency medical technicians.

Conclusion: The model is useful in planning community EMS programs, comparing EMS systems, and showing how different arrival times within a system affect survival rate.

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INTRODUCTION

Survival to hospital discharge from out-of-hospital sudden cardiac arrest depends in part on the time to three critical prehospital interventions: CPR, defibrillation, and advanced care (eg, intubation, medication).[1-3] The shorter that the time interval is between collapse and these three interventions, the higher is the probability of survival.[1-5] From the moment of collapse, the likelihood of survival decreases rapidly with each minute that elapses without initiation of life-saving procedures. Prehospital interventions typically occur in a sequence: CPR is started by bystanders or emergency medical services (EMS) personnel followed by defibrillatory shocks administered by emergency medical technicians (EMTs) authorized to defibrillate or by paramedics and then followed by advanced care administered by paramedics. The average time to performance of these critical interventions determines a community's overall survival rate from sudden cardiac arrest.

We developed a model that describes the relationship between a community's average time intervals to these three critical interventions and its overall survival rate. The model is easy to apply, and its lessons are readily interpretable.

MATERIALS AND METHODS

Since 1976, we have collected information on all patients with out-of-hospital cardiac arrests in King County, Washington, for whom emergency personnel attempted resuscitation (9,245). Data were obtained from multiple sources, including EMS run reports, hospital records, death certificates, and interviews with bystanders. Detailed methods of data collection are described elsewhere.[3-5] For all cases, we determined retrospectively the etiology of the cardiac arrest, whether the collapse was witnessed, and the cardiac rhythm associated with the arrest. For all witnessed cardiac arrests, we determined the time intervals to the three critical interventions: from collapse to CPR, from collapse to first defibrillatory shock, and from collapse to advanced care. Time of collapse may be biased by inaccurate recall of exact times surrounding a stressful event, such as a sudden cardiac arrest. In our data, however, time of collapse is gathered consistently from dispatcher recordings and paramedic on-scene reports. We expect neither the nature of this potential bias nor the method of estimating time of collapse to change in the future. Thus, the timing guidelines proposed by the model should be no different for future cases than they would be for the cases on which the model is based.

We estimated time intervals to actual treatment as follows: the time interval to bystander-initiated CPR was taken from interviews with the bystander or from the incident report prepared by EMS personnel; the time interval to EMS-initiated CPR was estimated from the EMS response time plus one minute (the time needed for EMTs or paramedics to arrive at the scene, reach the patient's side, and position the patient); and the time interval needed for EMTs or paramedics to attach the defibrillator and clear the patient for defibrillation once CPR was in progress was estimated to be two minutes past EMT arrival or one minute past time of initiation of CPR by EMTs. In our data, the time interval from arrival of paramedics to the initiation of advanced care was estimated to be two minutes past paramedic arrival if defibrillation had taken place before paramedic arrival, three minutes past paramedic arrival if defibrillation had not yet taken place, and four minutes past paramedic arrival if the paramedics were the only EMS providers on the scene. These intervals to interventions are the best estimates of EMTs, paramedics, and EMS medical directors.[1,2]

We recognize that "advanced care" by paramedics includes multiple interventions delivered over time (intubation, initiation of IV access, administration of multiple medications, rhythm assessment, hyperventilation). For simplicity of analysis, however, we focused on a single time interval, from collapse to the moment when paramedics were ready to perform advanced interventions.

To determine the effect of these three time intervals on survival, we selected a somewhat uniform group with a higher likelihood of survival: patients who had a witnessed cardiac arrest due to underlying heart disease, who were in ventricular fibrillation, and whose arrest occurred before arrival of EMS personnel (1,667). Survival was defined as discharge alive from the hospital.

We estimated the relative strength of influence of each time interval on survival using a multiple linear regression model with survival (discharge from the hospital) as the outcome and time interval from collapse to CPR (I_{CPR}), time interval from collapse to first shock (I_{DEFIB}), and time interval from collapse to advanced care (I_{ACLS}) as predictors. Age, sex, underlying morbidity, and time to various hospital procedures, although certainly relevant to the survival rate, were not included in the model because they were not considered to be under EMS control. The model is expressed as the following equation:

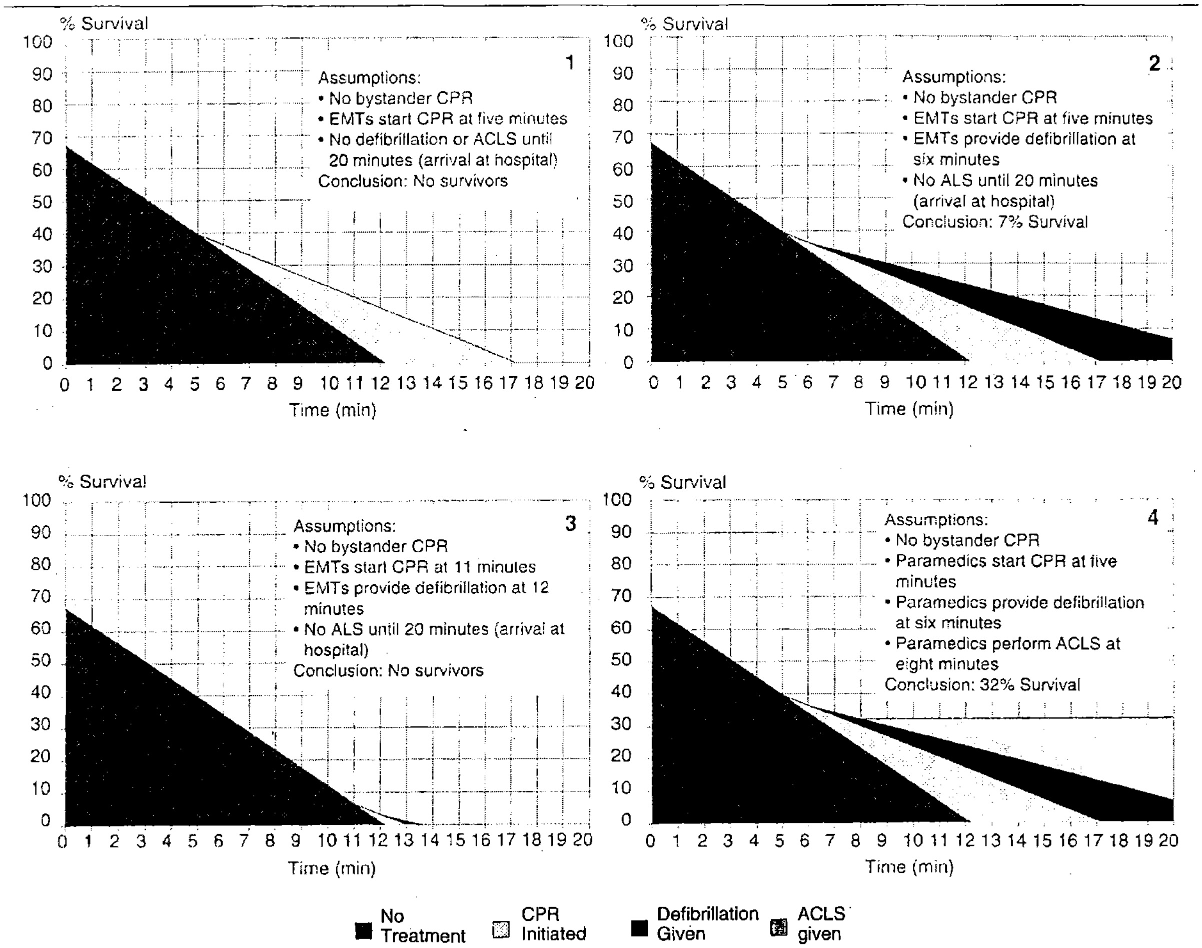
$$\text{Survival rate} = C_{COLLAPSE} + C_{CPR}I_{CPR} + C_{DEFIB}I_{DEFIB} + C_{ACLS}I_{ACLS} \quad (1)$$

where C_{CPR}, C_{DEFIB}, and C_{ACLS} are the regression coefficients (relative strength of the effect) for the designated time intervals (I) and $C_{COLLAPSE}$ is the regression constant, which represents the survival rate expected when treatment is available immediately on collapse, ie, the hypothetical situation in which a patient went into cardiac arrest at the exact moment when an endotracheal tube was inserted, an IV catheter entered a vein, and defibrillator paddles were placed on the chest. Although a term to account for random measurement error generally is included in regression models, for simplicity we have omitted this term.

To test for the effects of interactions between terms or squared effects of any one term (a term multiplied by itself, such as $I_{DEFIB} \times I_{DEFIB}$), we also performed a stepwise linear regression using all possible products and squares of terms using a significance level of $P = .1$. None of these factors contributed significantly to the model, indicating that a simple, additive model was the most efficient.

All three time intervals, I_{CPR}, I_{DEFIB}, and I_{ACLS}, were limited to 20 minutes; cases with EMS arrival times in excess of 20 minutes were not included in the model. The survival rate is between 0% and 100% by definition. Within these limits, the model consists of a curve, the slope of which becomes more shallow with each intervention. Because the individual outcome measure is discharge alive from the hospital and we are assessing the effect of prehospital treatments only, the decline in survival is considered to be zero after the delivery of advanced care.

Figures 1-4.
Survival from cardiac arrest for 1) EMT system with response time of four minutes; 2) EMT-D system with a response time of four minutes; 3) EMT-D system with a response time of ten minutes; 4) paramedic system with a response time of four minutes.

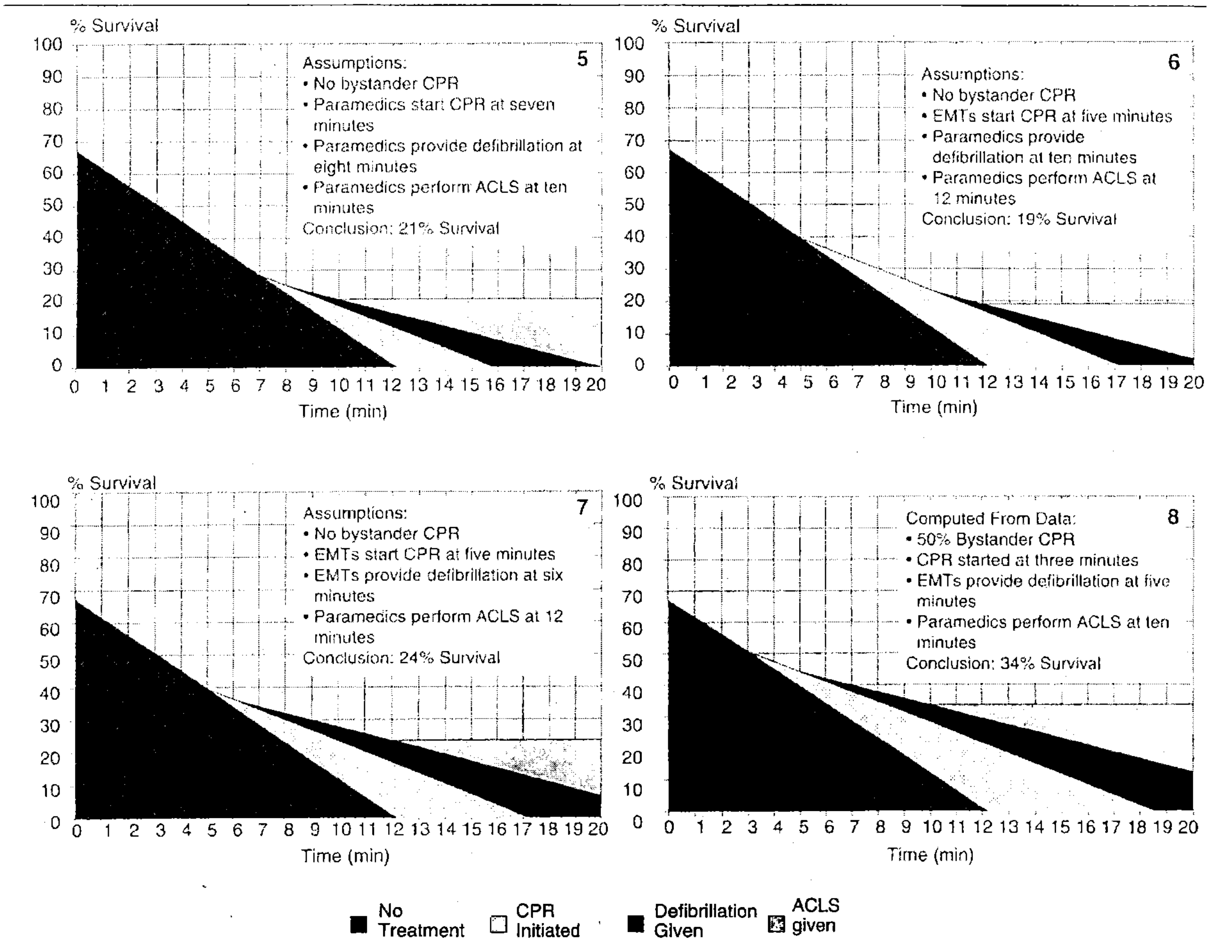


The final step in the development of the model was the elimination of outliers, atypical observations that have undue influence on the fit of the model. We eliminated all observations with residuals (difference between the observed survival rate and the rate predicted by the model) that exceeded the 98th percentile (ie, observations with residuals in the top 2%). After elimination of the outliers, the model was fit again, and the resulting coefficients were used to predict the rate of survival.

To assess the performance of our model, predicted survival rates obtained from the model were compared with rates reported for communities representative of different types of EMS systems: basic EMT, EMT-D (EMTs trained and authorized to defibrillate), paramedic, basic EMT/paramedic, and EMT-D/paramedic. For this comparison, we used data that contained EMS response times and survival rates for cardiac arrest cases in ventricular fibrillation.[4-18] From the EMS response times available from these studies, time intervals to CPR, defibrillation, and ACLS were estimated as described above.

For EMT and EMT-D systems, we assumed that both defibrillation and advanced care occurred on arrival at the hospital 20 minutes after collapse. Although 20 minutes is an estimate, we know this is close to the reported times for systems with EMT-level care.[3]

Figures 5-8.
Survival from cardiac arrest for 5) paramedic system with a response time of six minutes; 6) EMT/paramedic system with response times of four and nine minutes, respectively; 7) EMT-D/paramedic system with response times of four and nine minutes, respectively; 8) King County with an EMT-D/paramedic system with response times of four and nine minutes, respectively, and 50% bystander CPR.



RESULTS

Plotting the rate of survival as the resuscitation process unfolds demonstrates changes in the survival rate with each procedure (Figures 1 through 8). If nothing is done, the survival rate declines to zero rapidly. Any single point on this curve represents the predicted survival for the hypothetical situation in which CPR, defibrillation, intubation, IV medications, and so on occur simultaneously; that is, nothing is done until a particular point in time, and then all interventions occur simultaneously. With the earlier performance of each critical procedure (CPR, defibrillation, ACLS), this decline becomes slower. The regression model gives the following coefficients (standard errors in parentheses) for the three time intervals: time to CPR, –2.3% per minute (0.7%, $P = .001$); time to first shock (DEFIB), – 1.1% per minute (0.7%, $P = .09$); time to paramedic arrival (advanced care [ACLS]), – 2.1% per minute (0.3%, $P < .001$); and a regression constant of 67% (3%, $P < .001$). The F test for the regression model, 45.8 (3,1663 degrees of freedom),[6] was significant at $P < .001$. Substituting these coefficients into the equation gives the following:

$$\text{Survival rate} = 67\% - 2.3\% \times I_{CPR} - 1.1\% \times I_{DEFIB} - 2.1\% \times I_{ACLS} \quad (2)$$

which can be read as the following:

Survival rate =
67% at collapse – 2.3% per minute to CPR – 1.1% per minute to defibrillation – 2.1% per minute to ACLS

The regression constant, 67%, represents the probability of survival in the hypothetical situation in which all treatments are delivered immediately on collapse to patients with prehospital cardiac arrest. This probability is hypothetical because there are no actual patients in our data base for whom time intervals to all three treatments is zero. The shortest time interval to CPR and defibrillation in our model is one minute, and the shortest time interval to ACLS is two minutes. Among 26 patients with prehospital arrest and CPR, defibrillation, and ACLS delivered within three minutes, however, the average survival rate was 50%. With delays in CPR, defibrillatory shock, and definitive care, the magnitude of the decline in survival rate per minute is the sum of the three coefficients (–2.3%, –1.1% , –2.1%), or –5.5%. For each minute to first shock after the start of CPR, survival declines by 3.2% (–5.5% + 2.3%); and for each minute to advanced care once CPR has been started and the first shock has been given, survival declines by 2.1% (–5.5% + 2.3% + 1.1%).

The figure shows a model representation of five types of community EMS services: EMT, EMT-D, paramedic only, EMT/paramedic, and EMT-D/paramedic. These plots demonstrate the change in survival rate as EMS arrival times vary for each system. When comparing survival rates predicted by the model and those observed in the literature (Table), the largest differences between the observed survival rates and those predicted by the model occurred at the lower end of the survival scale. The model predicted no patient survival to 20 minutes when EMTs provide CPR only, whereas observed survival rates for EMT-only systems in three different communities varied from 3% to 12%. For EMT-D systems with an arrival time of four minutes, a 7% survival rate was predicted, and a 26% survival rate was observed. Observed and predicted survival rates agreed more closely for paramedics, EMT/paramedics, and EMT-D/paramedics—systems in which all of these critical procedures were performed before hospital arrival.

Table.
Reported and predicted survival rates for different types of EMS systems

EMS Agency Type	EMT Response Time (min)	Paramedic Response Time (min)	Estimated Time to (min): CPR	Defibrillation	ACLS	Reported Survival Rate (%)	Predicted Survival Rate From Model (%)
EMT only	4		5	20	20	12[4,5]	0
	7		8	20	20	3-20[8-10]	0
EMT-D	4		5	6	20	26[9]	7
	10		11	12	20	12[11]	0
Paramedic	4		5	6	8	14-30[12,13]	30
	6		7	8	10	15[14,15]	21
EMT/paramedic	3	7	4	8	10	25[16]	28
	4	9	5	10	12	33[17]	19
EMT-D/paramedic	4	9	5	6	12	34[18]	24
King County (EMT-D/ paramedic)	4	9	3	5	10	34	34

To verify the stability of the model we split the sample, using patient identification numbers ending in 0 through 4 as the first sample and those ending in 5 through 9 as the second sample. The coefficients of both split models were within two standard deviations of each other. Also, predicted values of both models were within 7% of each other and within 7% of the predicted value for the entire model.

DISCUSSION

The model demonstrates the critical role that time plays in the success of resuscitation from sudden cardiac arrest. The shorter the time to critical interventions, the higher the survival rate. Although this is intuitive, the model demonstrates the quantitative contribution of each intervention to the survival rate. Each intervention used alone slows the rate of dying, and the model clearly shows how placing each treatment earlier in the protocol improves the likelihood of survival. For instance, when a EMT-D/paramedic system is in place with average arrival times of four and nine minutes, respectively, a community bystander CPR program could decrease the average time to CPR by two minutes. Notice in comparing 7 with 8 in the figure that the effect of beginning CPR two minutes earlier enhances the contributions of the other procedures, making the total contribution to survival 10%, much more than the 2.1% per minute, or 4.2%, for the two minutes' earlier CPR. Putting defibrillators in the hands of EMTs makes a difference of 5% in the survival rate given EMT and paramedic arrival times of four and nine minutes, respectively.

Even though the EMS systems of different communities vary in their ability to provide CPR, defibrillatory shocks, and advanced care rapidly, the model can predict expected changes in survival rate for any of these systems given a hypothetical change in protocol. The model does not distinguish effects on survival rate due to factors not under EMS control, such as age, sex, underlying morbidity, and quality of hospital care. Customization of the model by computing coefficients from a community's data may be necessary when demographics, rate of bystander CPR, and hospital care standards differ from those in King County.

Of particular interest is a direct comparison between an EMT/paramedic system and a EMT-D/paramedic system showing the effect of shifting the responsibility for defibrillation from paramedics to EMTs. Fortunately, observed times were available for both systems where the EMTs arrive in four minutes and the paramedics arrive in nine minutes. An EMT/paramedic system that gave an expected survival rate of 19% had an observed rate of 33%. An EMT-D/paramedic system with the same arrival times gave a predicted rate of survival of 24% and an observed rate of 34%, showing a strong improvement in predicted survival rates when both CPR and defibrillation are provided early by EMTs. The current survival rate for King County, which has an EMT-D/paramedic system with an average EMT arrival time of four minutes, an average paramedic arrival time of nine minutes, and a bystander CPR rate of 50%, is 34%, representing the payoff of the aggressive public education campaign on bystander CPR and the policy of training and authorizing EMTs to defibrillate.

In addition, recent research shows that an EMT-D program can improve the probability of survival in ways other than simply providing earlier defibrillation. Because it transfers the task of defibrillation out of the hands of paramedics, it allows paramedics to move more quickly to intubation and IV medication. This means that the specific elements of advanced care occur earlier in such systems.[19] Furthermore, moving defibrillation earlier in an EMT-D system means that personnel will treat an absolutely greater number of persons in ventricular fibrillation because they arrive before the ventricular fibrillation has deteriorated to asystole.[20]

Several assumptions weaken the model. First, we did not have exact times to CPR and defibrillation for all cases. We were forced to estimate these time intervals by adding constants to the EMS response times. These estimates, while consistently applied, are less accurate than measuring exact time intervals. Second, the model assumes that the start of delivery of ACLS is the last procedure that defines the survival rate. We know that this is not true but is merely a representation of the fact that no further information on treatment and response is provided until hospital discharge. Of course, additional interventions occur in the hospital, but the major prehospital interventions end with the performance of ACLS. Third, because the three time intervals are not independent (the same agency often provides at least two procedures), the model best describes situations where CPR, first defibrillatory shock, and advanced care follow each other in the order listed.

As the table shows, the model does not agree with published data for EMT-only and EMT-D communities. One of the following factors may explain this. The published data were from many different sources, making it difficult to assess consistency of reporting among them. Average time intervals to first shock and advanced care were not available for EMT and EMT-D systems. The 20 minutes assumed to be the time interval for advanced care reflects the average hospital arrival time for these systems.[3] The greater-than-expected number of survivors for the actual systems may reflect intervals of less than 20 minutes. Data for these systems tended to be much older and were obtained for communities with smaller populations, which would have allowed faster transport of patients to the hospital. The more advanced lifesaving procedures were not provided, saving time for transport (as the model shows, however, this option does not result in more lives saved). Sample sizes for these studies were smaller, making the effect of random noise greater. A high bystander CPR rate (rates as high as 35% were given[9]) could account for the positive survival times seen for these communities.

CONCLUSION

Knowledge of the relationship between EMS time intervals and survival rate can guide an EMS system to improvements that should increase the survival rate. The model is useful for planning EMS in any community and for comparing the different types of EMS systems. In addition, this model can reflect the variation in survival rates when response times differ within a single system. The model can be customized easily to describe any community. However, a linear least-squares regression on a binary outcome variable may not be valid on small sample sizes. Also, because the predictors (time intervals to CPR, first defibrillatory shock, and advanced care) are highly correlated, the model performs best when applied to systems where all three treatments are given before hospital arrival and the average times to treatment can be computed from the data rather than assumed.

An individual case of cardiac arrest has two possible outcomes: the individual lives or dies. However, this model shows each individual's probability of survival based on a community's ability to deliver CPR, defibrillation, and advanced care.

The model is a graphic representation of the "chain of survival"[21] concept describing the linkage among access, CPR, defibrillation, and ACLS. Between survival and the time intervals by which these interventions are provided, life ebbs rapidly and the slope of death is steep, but the downward fall need not be an inevitable plummet into the jaws of death.

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Address for reprints:

Mary P Larsen, MS
Center for Evaluation of Emergency Medical Services
Emergency Medical Services Division
900 4th Avenue, Suite 850
Seattle, Washington 98164

CPR Statistics

Updated:Apr 24,2013

CPR & Sudden Cardiac Arrest (SCA)
Fact Sheet

Anyone can learn CPR – and everyone should! Sadly, 70 percent of Americans may feel helpless to act during a cardiac emergency because they either do not know how to administer CPR or their training has significantly lapsed. This alarming statistic could hit close to home, because home is exactly where 88 percent of cardiac arrests occur. **Put very simply: The life you save with CPR is mostly likely to be someone you love.**

This June, in honor of National CPR Week, the American Heart Association is calling on all Americans to learn how to give Hands-Only® CPR by watching a simple one-minute video at heart.org/cpr. Once you have learned CPR, give 5 people you care about the power to save lives by equipping them to act quickly in a crisis.

Don't be afraid; your actions can only help. **If you see an unresponsive adult who is not breathing or not breathing normally, *call 911 and push hard and fast on the center of the chest.***

WHY LEARN CPR?
Cardiac arrests are more common than you think, and they can happen to anyone at any time.

- Nearly 383,000 out-of-hospital sudden cardiac arrests occur annually, and 88 percent of cardiac arrests occur at home.
- Many victims appear healthy with no known heart disease or other risk factors.
- Sudden cardiac arrest is not the same as a heart attack.
  - Sudden cardiac arrest occurs when electrical impulses in the heart become rapid or chaotic, which causes the heart to suddenly stop beating.
  - A heart attack occurs when the blood supply to part of the heart muscle is blocked. A heart attack may cause cardiac arrest.

WHO CAN YOU SAVE WITH CPR?
The life you save with CPR is mostly likely to be a loved one.

- Four out of five cardiac arrests happen at home.
- Statistically speaking, if called on to administer CPR in an emergency, the life you save is likely to be someone at home: a child, a spouse, a parent or a friend.
- African-Americans are almost twice as likely to experience cardiac arrest at home, work or in another public location than Caucasians, and their survival rates are twice as poor as for Caucasians.

WHY TAKE ACTION?

- Failure to act in a cardiac emergency can lead to unnecessary deaths.
- Effective bystander CPR provided immediately after sudden cardiac arrest can double or triple a victim's chance of survival, but only 32 percent of cardiac arrest victims get CPR from a bystander.
- Sadly, less than eight percent of people who suffer cardiac arrest outside the hospital survive.
- The American Heart Association trains more than 12 million people in CPR annually, to equip Americans with the skills they need to perform bystander CPR.

SEE A VIDEO, SAVE A LIFE
You can prepare yourself to act in an emergency by simply viewing the Hands-Only® CPR instructional video.

- A study published in the March 8 issue of *Circulation: Cardiovascular Quality and Outcomes* showed that people who view a CPR instructional video are significantly more likely to attempt life-saving resuscitation.
- Hands-Only CPR (CPR with just chest compressions) has been proven to be as effective as CPR with breaths in treating adult cardiac arrest victims.
- The American Heart Association has recommended Hands-Only CPR for adults since 2008.

As of June, 2011

Popular Articles

1 Understanding Blood Pressure Readings
2 Heart Attack Symptoms in Women
3 What are the Symptoms of High Blood Pressure?
4 Low Blood Pressure
5 What Your Cholesterol Levels Mean
6 Warning Signs of a Heart Attack
7 Target Heart Rates
8 Good vs. Bad Cholesterol
9 Types of Blood Pressure Medications
10 BLS for Healthcare Providers - Classroom

| CEO Nancy Brown

I, Kristine Neale, declare as follows:

I am a resident of the State of California and over the age of eighteen years, and not a party to the within action; my business address is: Two Palo Alto Square, Suite 300, 3000 El Camino Real, Palo Alto, California 94306-2112. On August 9, 2013, I served the foregoing document(s) described as:

RESPONDENT'S REQUEST FOR JUDICIAL NOTICE

☐	By transmitting via facsimile the document(s) listed above to the fax number(s) set forth below on this date before 5:00 p.m.
☐	By placing the document(s) listed above in a sealed envelope with postage prepaid, via First Class Mail, in the United States mail at Palo Alto, California addressed as set forth below.
☐	By causing the document(s) listed above to be personally served on the person(s) at the address(es) set forth below.
☒	By placing the document(s) listed above in a sealed overnight service envelope and affixing a pre-paid air bill, and causing the envelope, addressed as set forth below, to be delivered to an overnight service agent for delivery.

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Ryan M. Craig
TRACHTMAN & TRACHTMAN
27401 Los Altos, Suite 300
Mission Viejo, CA 92691

David G. Eisenstein
LAW OFFICES OF
DAVID G. EISENSTEIN
4027 Aidan Circle
Carlsbad, CA 92008

Robert A. Roth
TARKINGTON, O'NEILL,
BARRACK & CHONG
2711 Alcatraz Avenue, Suite 3
Berkeley, CA 94705

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I am readily familiar with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business.

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I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 9, 2013, at Palo Alto, California.

Kristine Neale

Kristine Neale