The National EMS Research Agenda Executive Summary

Michael R. Sayre, MD Lynn J. White, MS Lawrence H. Brown, EMT-P Susan D. McHenry, MS For the National EMS Research Agenda Writing Team

From the Department of Medicine, Section of Emergency Medicine, University of Chicago, Chicago, IL (Sayre); the Department of Emergency Medicine, Northeastern Ohio Universities College of Medicine and Akron General Medical Center, Akron, OH (White); the Department of Emergency Medicine, Upstate Medical University, Syracuse, New York (Brown); and the National Highway Traffic Safety Administration, US Department of Transportation, Washington, DC (McHenry).

Copyright © 2002 by the American

College of Emergency Physicians.

0196-0644/2002/\$35.00 + 0 **47/1/129241**

doi:10.1067/mem.2002.129241

[Ann Emerg Med. 2002;40:636-643.]

Imagine if you will, the public outcry that would ensue if a jumbo jet filled with passengers crashed every day in the United States. Regrettably, Americans no longer need to imagine disasters that result in the tragic loss of lives. However, each day, more people die of sudden cardiac arrest than would fill a Boeing 747. The most effective way to improve the odds of survival for sudden cardiac arrest is rapid defibrillation in the prehospital setting. As high quality emergency medical services (EMS) developed during the 1970s, cardiac arrest survival rates increased from near nothing to about 20% in a few progressive cities. However, essentially no additional progress in survival from cardiac arrest has occurred since 1980. For children, the odds of survival remain abysmal. Less than 2% of children with prehospital cardiac arrest survive to leave the hospital.

Trauma systems developed during the 1970s to address the inadequacy of care for victims of traffic crashes. EMS began to transport patients directly to regional trauma centers, often bypassing closer community hospitals. With the establishment of these regional trauma centers the odds of survival from motor vehicle crashes improved. This reduction in mortality from injury illustrates the value of having EMS professionals who understand how to use the emergency care resources available in each community.

The vast majority of patients cared for by EMS, however, are not victims of cardiac arrest or major injury. They have illnesses or injuries that are not life threatening yet require access to medical care. EMS spends about five billion dollars each year, most of which is used for the provision of care to patients without life threatening conditions. Essentially no research has been performed to evaluate the effectiveness of EMS care for this group of patients.

Progress in prehospital emergency patient care is needed. There is not enough high quality EMS-related research to drive improvements in patient outcome, and vast amounts of money are being spent for patient care with little rigorous evaluation of the effectiveness of that care. Methodologically sound research must be incorporated into all facets of the EMS system. This document, The National EMS Research Agenda, discusses the reasons why EMS research is important and emphasizes that the responsibility for examining EMS practice lies with all stakeholders in EMS.

Performance of high quality EMS research is hindered by five impediments:

- 1. A paucity of highly skilled researchers;
- 2. Inadequate funding;
- 3. Failure of EMS professionals to understand the importance of conducting EMS research and translating the findings into clinical practice;
- 4. A lack of integrated information systems that provide for meaningful linkage with patient outcomes;
- 5. Logistical problems in obtaining informed consent. However, these barriers can be overcome.

DEVELOP RESEARCHERS

High quality research will not occur unless there are individuals with the training and experience to accurately answer important questions. Currently, there are few expert researchers with an interest in EMS-related problems who have an understanding of the special challenges of conducting research in the EMS setting. Researchers with a wide variety of backgrounds including physicians, nurses, EMS professionals, public health experts, and scientists from other disciplines need to be encouraged to perform EMS research.

Recommendation 1

A large cadre of career EMS investigators should be developed and supported in the initial stages of their careers. Highly structured training programs with content directed toward EMS research methodologies should be developed.

• Fellowship training programs capable of producing at least five EMS researchers per year are needed. Federal agencies are potential funding sources for these fellowships. Ideally, fellowship programs should be at least two years in length and should produce individuals with training and expertise in both research methods and funding acquisition. A doctoral degree (PhD, MD, etc.) should be a prerequisite for entry into the training programs. Program funding that includes institutional overhead and provides funds to ensure that research projects can be accomplished during the fellowship is essential. Individual training grants specifically tar-

geted to EMS specific topics and system evaluation should be available.

FACILITATE COLLABORATION

Effective EMS research necessitates creating working relationships between EMS researchers and social scientists, economists, health services researchers, epidemiologists, operations experts, clinical scientists, basic scientists, and researchers from other disciplines. Building these relationships requires a dedicated and committed core research group with access to reliable funding sources.

Recommendation 2

Centers of Excellence should be created to facilitate EMS research. These Centers will bring together experienced investigators, institutional expertise, and resources such as budgetary and information systems support. Centers will develop and maintain strong working relationships with local and regional EMS providers. As the focal point of these resources, Centers of Excellence will be the catalyst for collaboration between EMS systems and investigators. Such an environment will enable quality research to flourish.

- One or more federal agencies should encourage the submission of proposals to develop at least five EMS Centers of Excellence. Each successful applicant should be funded for five years and be evaluated for renewal in a competitive application process. At least \$1 million should be devoted to development of research programs and infrastructure at each Center every year. Each Center should be located within an academic institution with ties to fellowship programs, career faculty researchers, multidisciplinary expertise, training programs, and other resources necessary to create research infrastructure.
- One or more federal agencies should issue requests for proposals for at least two regional EMS research centers. The centers will organize and manage multi-system studies. The centers will form a network to facilitate access to data. Each center should operate on a five-year funding cycle with a competitive renewal process at the end of each five-year phase.

ESTABLISH A RELIABLE FUNDING STREAM

The absence of funding for major EMS research represents a huge obstacle to improving the health of the public. Researchers cannot perform research without financial support. Most research accomplished to date within EMS has been conducted on shoestring budgets using volunteer labor, surplus supplies, and in kind contributions from hospitals, medical schools, and EMS agencies.

Researchers also need dedicated time to perform EMS research. Since investigators frequently have competing roles in their work, they are pressured by their institutions to spend time on projects with the best reimbursement. Institutions will release investigators from other responsibilities to concentrate on EMS research if there are incentives and advantages for the organization. Despite the lack of a concerted and focused effort, the advances in EMS that have occurred historically are remarkable. However, failing to intentionally plan for and fund EMS research will likely delay discoveries that have the potential to save untold numbers of lives.

Additional annual funding in an amount equal to 1% of the annual expenditures on EMS systems should be allocated for research into the effectiveness of those systems. This would mean approximately \$50 million would be available for research each year.

Recommendation 3

Federal agencies that sponsor research should acknowledge their commitment to EMS research.

- The federal government should increase its commitment and support of EMS research.
- A joint announcement, similar to that issued for EMS Research concerning children (PS-01-044), should be issued to provide opportunities for conducting EMS research under the sponsorship of a group of Federal agencies and to broadly describe the areas in which research is warranted. Each sponsoring agency should delineate and prioritize specific areas of interest and provide detailed information regarding application upon request.

• The number of fully federally funded controlled clinical trials conducted in the EMS setting should increase by 25% each year for five years beginning in the 2003 fiscal year.

ESTABLISH ALTERNATIVE FUNDING SOURCES

The federal government should not be the only organization funding EMS research. Charitable foundations often offer unique and flexible funding, some of which should be dedicated to EMS research. State EMS lead agencies traditionally have not performed EMS research, but they should develop a serious commitment to improve patient care based upon evidence generated by high quality research. Ideally, state agencies should collaborate with at least one academic institution with expertise in EMS research. This collaboration will give state regulators, provider agencies, and EMS professionals access to individuals with expertise regarding grant applications and local research related issues. This academic collaborator should also offer guidance to the state lead agency on EMS research policies.

Recommendation 4

States, corporations, and charitable foundations should be encouraged to support EMS research.

- State lead EMS agencies should promote prehospital research and facilitate the development of relationships and resources necessary for such studies.
- Corporations and charitable foundations should provide funds for EMS related research.

RECOGNIZE THE NEED FOR EMS RESEARCH

In most fields of human endeavor, there is a significant time delay from a new discovery until the new methods are integrated into practice. EMS has a similar delay in implementation of research results. This delay can negatively impact patient care by perpetuating erroneous or ineffective practices and by inhibiting timely implementation of new effective treatments.

The problem of translating research into practice is especially difficult in EMS. Most EMS professionals are not trained to critically evaluate new treatments and so they do not possess the skills to decide whether evidence truly supports their use. Therefore, EMS agencies should employ physicians with the expertise to evaluate new treatments and with the ability to develop and improve patient care protocols based on scientific findings. These physicians should work to educate EMS providers about the scientific process of linking research findings to clinical care. This relationship will provide an environment in which EMS personnel will be able to adopt new protocols with an understanding of how decisions were made. The culture within EMS needs to change to promote research and demand evidence before implementing new system modifications, medications, or drug therapies.

Recommendation 5

The efforts of EMS professionals, delivery systems, academic centers, and public policy makers should be organized to support and apply the results of research.

- The National Highway Traffic Safety Administration (NHTSA) should adopt a curriculum for EMS educators that teaches critical review of the scientific literature.
- The National Fire Academy should continue to offer courses that convey the importance of EMS research and detail specific strategies by which fire services can facilitate EMS research.
- Federal agencies should adopt or develop a curriculum for EMS administrative officers that will instill the importance of evidence-based decision-making, reduction of medical errors, and introspection into the culture of EMS organizations.
- Appropriate research principles should be included in the core content of EMS education of first responders, EMT-Basics, EMT-Intermediates, and EMT-Paramedics.
- National and state accrediting agencies for EMS educational programs should require that familiarity with the scientific literature be an essential component of EMS education programs.

- Academic institutions should develop training pathways for EMS professionals interested in pursuing a research career.
- EMS agencies should contribute to the research process by agreeing to collaborate with academic institutions. Collaboration should include assistance with field data collection and patient enrollment in research studies.

VIEW RESEARCH AS NECESSARY FOR THE IMPROVEMENT OF PATIENT CARE

EMS organizations and agencies of the federal government have an obligation to promote the development of a culture within EMS organizations that values and supports research.

Recommendation 6

EMS professionals of all levels should hold themselves to higher standards of requiring evidence before implementing new procedures, devices, or drugs.

CREATE RELIABLE INFORMATION SYSTEMS

EMS care delivery is unusual in that the patients are only under EMS care for a short time and may not be known by name. The lack of accurate patient identification presents a major challenge for the investigator wishing to measure outcomes. In addition because of the fragmented nature of the EMS delivery system, a given EMS agency may care for only a limited number of critically ill patients annually. Thus, the use of standardized data collection, data linkage, and reporting mechanisms are critical to allow patient outcomes to be compiled and meaningfully evaluated.

Recommendation 7

There should be standardized data collection methods at local, regional, state, and national levels. These data must be devoid of information that allows individual patient identification. All EMS provider agencies should adopt the Uniform Prehospital Data Elements for data collection.

- NHTSA should sponsor a process to revise the Uniform Prehospital Data Elements at least every ten years.
- State lead EMS agencies should require all EMS organizations in their jurisdictions to collect and submit to the state the Uniform Prehospital Data Elements at a minimum, and states should report that information to a national EMS data repository.
- Federal agencies should promote the development and maintenance of a national EMS data repository to facilitate comparison of EMS system designs on the effectiveness of care delivery and improving patient safety.

ENHANCE ETHICAL APPROACHES TO RESEARCH

In many emergency situations, time is inadequate to allow a critically ill patient or a surrogate decision maker to appropriately consider the risks and benefits of participating in a research study. There are two sets of regulations (Department of Health and Human Services and US Food and Drug Administration [FDA]) concerning the waiver of informed consent for medical research. These two sets of regulations have created some confusion among EMS researchers. Their implementation has exposed a fundamental problem associated with conducting research with subjects who cannot provide consent: There is a direct and irrevocable tension between protecting the rights of research subjects and the ability to investigate and improve the care rendered to future patients. The current federal regulations on research in emergency situations may have the unintended consequence of ensuring that EMS professionals will provide care that has not been scientifically validated. New interventions to treat critical illness will continue to be introduced into the EMS environment, but difficulty in complying with the requirements of the consent regulations may impede the ability of EMS researchers to ensure that they have been studied appropriately first.

Recommendation 8

The FDA and the Office for Human Research Protections (OHRP) should work with EMS research stake-

holders to evaluate the current requirements for exception from informed consent in emergency situations and to identify those requirements that are serious impediments to conducting EMS research. The FDA, OHRP, and EMS research stakeholders should work together to develop and propose EMS-specific consent strategies as well as appropriate revisions to the existing regulations to reduce the impediments to research while continuing to adequately protect research subjects.

- There should be a national conference that brings together a large variety of EMS research stakeholders and regulators to recommend improvements to the emergency exception to informed consent procedures.
- Based on the recommendations of the FDA and OHRP, Congress should amend the laws governing exception from informed consent for emergency research to reduce the regulatory burden and facilitate research while continuing to protect the rights of research subjects.
- There should be educational programs that explain the consent process and recommend strategies by which EMS researchers can fulfill the requirements.
- Educational programs that describe the difficulties in obtaining consent in the EMS environment, explain the emergency exception from consent process, and promote acceptance by and consistency among Institutional Review Board (IRBs) should be made available to IRB members and administrators.

CONCLUSION

A national investment in EMS research infrastructure is necessary to overcome the obstacles currently impeding EMS research. Funding is needed to train new researchers and to establish their careers. Increased financial support is necessary to develop effective prehospital treatment for the diseases that drive the design of the EMS system, including injury and sudden cardiac arrest. Innovative strategies to make EMS research easier to accomplish in emergency situations must be legitimized and implemented. Researchers must have access to patient outcome information so that the impact of prehospital patient care can be evaluated and improved.

Incorporating standard scientific methodology into the evaluation of biomedical and technical advances in prehospital care is crucial. Research is the key to maintaining an appropriate focus on improving the overall health of the community in a competitive and cost conscious health care market. Most importantly, research is essential to ensure that the best possible patient care is provided in the prehospital setting.

SUMMARY

The National EMS Research Agenda makes the following recommendations:

- 1. A large cadre of career EMS investigators should be developed and supported in the initial stages of their careers. Highly structured training programs with content directed toward EMS research methodologies should be developed.
- 2. Centers of Excellence should be created to facilitate EMS research. These Centers will bring together experienced investigators, institutional expertise and resources such as budgetary and information systems support. Centers will develop and maintain strong working relationships with local and regional EMS providers. As the focal point of these resources, Centers of Excellence will be the catalyst for collaboration between EMS systems and investigators. Such an environment will enable collaborative research to flourish.
- 3. Federal agencies that sponsor research should acknowledge their commitment to EMS research.
- 4. States, corporations, and charitable foundations should be encouraged to support EMS research.
- 5. The efforts of EMS professionals, delivery systems, academic centers, and public policy makers should be organized to support and apply the results of research.
- 6. EMS professionals of all levels should hold themselves to higher standards of requiring evidence before implementing new procedures, devices, or drugs.
- 7. There should be standardized data collection methods at local, regional, state, and national levels. These data must be devoid of information that allows individual patient identification. All EMS provider

agencies should adopt the Uniform Prehospital Data Elements for data collection.

8. The Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) should work with EMS research stakeholders to evaluate the current requirements for exception from informed consent in emergency situations and to identify those requirements that are serious impediments to conducting EMS research. The FDA, OHRP, and EMS research stakeholders should work together to develop and propose EMS-specific consent strategies as well as appropriate revisions to the existing regulations to reduce the impediments to research while continuing to adequately protect research subjects.

An investment in EMS research infrastructure is necessary to overcome the obstacles currently impeding EMS research. Funding is needed to train new researchers and to establish their careers. Increased financial support is necessary to develop effective prehospital treatment for the diseases that drive the design of the EMS system, including injury and sudden cardiac arrest. Innovative strategies to make EMS research easier to accomplish in emergency situations must be legitimized and implemented. Researchers must have access to patient outcome information so that the impact of prehospital patient care can be evaluated and improved. Incorporating standard scientific methodology into the evaluation of biomedical and technical advances in prehospital care is crucial. Research is the key to maintaining an appropriate focus on improving the overall health of the community in a competitive and cost conscious health care market. Most importantly, research is essential to ensure that the best possible patient care is provided in the prehospital setting.

The full agenda report is published as a supplement to the July/September 2002 issue of *Prehospital Emergency Care*.

The full National EMS Research Agenda is available at www.ResearchAgenda.org.

Supported by the National Highway Traffic Safety Administration, US Department of Transportation and the Maternal and Child Health Bureau, Health Resources Services Administration, Department of Health and Human Services (Grant No. DTN 22-99-H-05100).

Sayre et al

Address for reprints: Michael R. Sayre, MD, Department of Emergency Medicine, Bethesda North Hospital, 1527 Vancross Court, Cincinnati, OH 45230-5141; 513-231-7537, fax 513-231-7428; E-mail SayreMR@one.net.

REFERENCES

- 1. Murphy S. Deaths: final data for 1998. Vol. 48, No. 11 ed. Hyattsville, MD: Public Health Service; 2000.
- 2. Eisenberg MS, Bergner L, Hallstrom A. Out-of-hospital cardiac arrest: improved survival with paramedic services. *Lancet*. 1980;1:812-815.
- 3. Becker LB, Smith DW, Rhodes KV. Incidence of cardiac arrest: a neglected factor in evaluating survival rates. *Ann Emerg Med.* 1993;22:86-91.
- 4. Young KD, Seidel JS. Pediatric cardiopulmonary resuscitation: a collective review. *Ann Emerg Med.* 1999;33:195-205.
- 5. Mullins RJ, Mann NC. Population-based research assessing the effectiveness of trauma systems. *J Trauma*. 1999;47(3 Suppl):S59-S66.

APPENDIX A.

The National EMS Research Agenda Writing Team.

Role	Name	Affiliation
Principal investigator	Michael R. Sayre, MD	University of Chicago
Co-investigators	Lynn J. White, MS	Akron General Medical Center
	Lawrence H. Brown, EMT-P	Upstate Medical University
Writing team members	Michael Armacost, MA, NREMT-P	Colorado Department of Health
	J. Michael Dean, MD, MBA	University of Utah
	Scott B. Frame, MD, FACS (deceased)	University of Cincinnati
	Baxter Larmon, PhD, MICP	UCLA School of Medicine
	Susan MacLean, RN, PhD	Emergency Nurses Association
	N. Clay Mann, PhD, MS	University of Utah
	Gregg Margolis, MS, NREMT-P	George Washington University
	Isabelle Melese-d'Hospital, PhD	Emergency Medical Services for Children National Resource Center
	Keith Neely, MPA, EMT-P (deceased)	Oregon Health Sciences University
	Michael O'Keefe	Vermont Department of Health
	Daniel W. Spaite, MD	University of Arizona
Contracting office technical representative	Susan D. McHenry, MS	National Highway Traffic Safety Administration
Federal partners	Timothy B. Davis, MD	National Center for Injury Prevention and Control (Centers for Disease Control and Prevention)
	Elinor Walker	Agency for Healthcare Research and Quality
Ex-Officio	Jon R. Krohmer, MD	NAEMSP
Administrative staff	Dede Gish Panjada, MBA	NAEMSP
	Jennifer Kimzey	NAEMSP
NAEMSP, National Association of EMS	Physicians.	

APPENDIX B.

Organizations invited to participate in the national review team.

Organization	Representative	Web Site
Air Medical Physicians Association (AMPA)	Kenneth Williams, MD, FACEP	www.ampa.org
American Academy of Family Physicians (AAFP)	Jeffrey Susman, MD	www.aafp.org
American Academy of Orthopaedic Surgeons (AAOS)	Andrew Pollak, MD, FAAOS	www.aaos.org
American Academy of Pediatrics (AAP)	Nate Kuppermann, MD, MPH	www.aap.org
American Ambulance Association (AAA)	Kurt Krumperman, EMT-P	www.the-aaa.org
American College of Emergency Physicians (ACEP)	Alan Katz, MD, FACEP	www.acep.org
American College of Osteopathic Emergency Physicians (ACOEP)	John W. Becher, DO, FACOEP	www.acoep.org
American College of Surgeons/Committee on Trauma (ACS/COT)	Scott Frame, MD, FACS (dec.)	www.facs.org
American Public Health Association (APHA)	Richard Levinson, MD, DrPH	www.apha.org
Association of Air Medical Services (AAMS)	Jeff Plant, MD, FRCP	www.aams.org
Committee on Accreditation of Educational Programs for the EMS Professions (CoAEMSP, formerly the JRCEMT-P)	James M. Atkins, MD	www.coaemsp.org
Emergency Nurses Association (ENA) Health Resources and Services Administration/	Kathy Robinson, RN	www.ena.org
Maternal and Child Health Bureau/Emergency Medical Services for Children (HRSA/MCHB/EMSC)	Cindy Doyle, RN, MA	www.mchb.hrsa.gov www.ems-c.org
International Association of Fire Chiefs (IAFC)	Chief John Sinclair, EMT-P	www.iafc.org
International Association of Fire Fighters (IAFF)	Lori Moore, MPH, EMT-P	www.iaff.org
National Association of EMS Educators (NAEMSE)	Judith A. Ruple, PhD, RN, NREMT-P	www.naemse.org
National Association of EMS Physicians (NAEMSP)	Richard Hunt, MD, FACEP	www.naemsp.org
National Association of EMS Quality Professionals (NAEMSQP)	Todd Hatley, MBA, MHA, REMT-P	www.naemsqp.org
National Association of Emergency Medical Technicians (NAEMT)	Jay Scott, BS, NREMT-P	www.naemt.org
National Association of State EMS Directors (NASEMSD)	Kevin McGinnis	www.nasemsd.org
National Council of State EMS Training Coordinators (NCSEMSTC)	Don Wood	www.ncsemstc.org
National Registry of Emergency Medical Technicians (NREMT)	Howard Werman, MD	www.nremt.org
National Volunteer Fire Council (NVFC)	Kenneth R. Knipper, EMT-B	www.nvfc.org
Prehospital Care Research Forum (PCRF)	Elizabeth Criss, RN, CEN, MAEd	www.pcrf.mednet.ucla.edu
Society for Academic Emergency Medicine (SAEM)	Robert O'Connor, MD	www.saem.org