

## SPECIAL CONTRIBUTIONS

# National EMS Research Agenda: Proceedings of the Implementation Symposium

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### Abstract

The National EMS Research Agenda identified eight recommendations for improving the conduct of emergency medical services (EMS) research in the United States. EMS leaders from across the country attended a two-day symposium to discuss implementation of the Research Agenda recommendations. The participants suggested specific methods to move the recommendations forward. These included improving training opportunities for EMS researchers, stimulating increases in available funding sources, facilitating the integration of research into practice,

and crafting alterations within the regulatory environment. Participants felt that EMS must be more broadly integrated into the public health continuum. Federal agencies, states, local governments, charitable foundations, and corporations are asked to examine their practices to increase opportunities for participation in EMS research programs at all stages of the process. **Key words:** emergency medical services; research methods; national EMS research agenda. *ACADEMIC EMERGENCY MEDICINE* 2003; 10:1100–1108.

The EMS Research Agenda describes the evolution of emergency medical services (EMS) research with regard to academic, political, and financial influences over the past three decades.<sup>1</sup> The document articulates the need to improve both the quality and quantity of research within the field of EMS and emphasizes why academic researchers, public policy makers, EMS professionals, and agency stakeholders must put forth a collaborative investment in the EMS research infrastructure. Because such an effort will provide the impetus for the development of researchers who can perpetuate and expand EMS research, the Agenda asserts that this process should begin immediately. The EMS Research Agenda document is intended to serve as a comprehensive resource promoting this endeavor and identifies a course of action necessary to begin the process.

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### IMPLEMENTATION SYMPOSIUM

In June 2002, a National EMS Research Agenda implementation symposium was convened in Alexandria, Virginia. The purpose of this meeting was to disseminate the message of the EMS Research Agenda, to encourage a collaborative vision that provides direction to EMS research, and to initiate the process of building a foundation and infrastructure for future EMS research. Specific approaches for putting into action the eight major recommendations set forth in the EMS Research Agenda were sought.

**Process.** Following a plenary session providing an overview of the National EMS Research Agenda, strategies for implementing each of the eight recommendations of the Agenda were presented in a small group setting by professionals with expertise related to the recommendation. Each small group then evaluated strategies that appeared most likely to bring about the successful implementation of that particular recommendation. Participants rotated through small group sessions and at the end of the day reconvened in a plenary session to discuss the proposed strategies and their viability.

**Participants.** Members of the symposium executive committee selected individuals to lead discussions for each recommendation. These speakers were chosen for their interest and involvement in EMS or for their particular expertise in the recommendation topic. Table 1 lists these speakers and their representative affiliations. General audience participation was encouraged.

**TABLE 1. List of Conference Speakers and Facilitators**

Representative	Organization
James M. Atkins, MD	University of Texas Southwestern Medical Center, Dallas, TX
Lance B. Becker, MD	University of Chicago, Chicago, IL
Marti Benedict, RN, BSN, CIP	SUNY Upstate Medical University, Syracuse, NY
Michelle Biros, MS, MD	Hennepin County Medical Center, Minneapolis, MN
Judith Brooks	Office for Human Research Protections, Department of Health and Human Services, Rockville, MD
Lawrence H. Brown, EMT-P	SUNY Upstate Medical University, Syracuse, NY
Cindy Doyle, RN, MA	Health Resources and Services Administration/Maternal and Child Health Bureau/ Emergency Medical Services for Children (HRSA/MCHB/EMSC), Rockville, MD
Henry Halperin, MD	Johns Hopkins University, Baltimore, MD
Dan Kavanaugh, MSW	HRSA/MCHB EMSC Program, Rockville, MD
Marge Keyes	Agency for Health Care Research and Quality, Washington, DC
Baxter Larmon, PhD, MICP	University of California at Los Angeles, Los Angeles, CA
Bonnie M. Lee	Office for Good Clinical Practice, Food and Drug Administration, Rockville, MD
E. Brooke Lerner, PhD	State University of New York at Buffalo, Buffalo, NY
Ronald F. Maio, DO	Injury Research Center, Ann Arbor, MI
Gregg S. Margolis, MS, NREMT-P	The George Washington University, Washington, DC
Susan D. McHenry, MS	National Highway Traffic Safety Administration, Washington, DC
Greg Mears, MD	University of North Carolina—Chapel Hill, Chapel Hill, NC
Joan Mellor	Medtronic Foundation, Minneapolis, MN
Robert E. O'Connor, MD, MPH	Christiana Care Health System, Newark, DE
Michael R. Sayre, MD	Good Samaritan Hospital, Cincinnati, OH
Jane Scott, SCD, MSN	R. Adams Cowley Shock Trauma Center, University of Maryland, Baltimore, MD
Vernon K. Sondak, MD	University of Michigan, Ann Arbor, MI
George Sopko, MD, MPH	National Heart, Lung, and Blood Institute, Bethesda, MD
Daniel Spalte, MD	University of Arizona, Tucson, AZ
Lynn J. White, MS	Akron General Medical Center, Akron, OH

## RECOMMENDATIONS OF THE NATIONAL EMS RESEARCH AGENDA

The following suggestions for implementing each of the recommendations of the National EMS Research Agenda were generated by discussions held during the implementation symposium meeting. They are presented as individually attainable activities that can be completed independently, through collaboration by members of the EMS community, to further the development of 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."<sup>1</sup>

**Background and Discussion.** Because EMS researchers are in short supply, creative methods are needed to encourage development of additional EMS researchers. Rather than create a new infrastructure designed specifically for developing EMS investigators, existing programs and funding mechanisms can be used. An excellent model program is the Robert Wood Johnson Foundation Clinical Scholars program. The Clinical Scholars program is a two-year training experience open to physicians from any medical or surgical specialty who have completed residency training.

Several excellent EMS researchers have been Robert Wood Johnson (RWJ) clinical scholars such as Mickey Eisenberg,<sup>2</sup> Arthur Kellermann,<sup>3</sup> Herb Garrison,<sup>4</sup> and Richard Cummins.<sup>5</sup> Clinical scholars are given a stipend and administrative support during the training program. Most obtain a research-oriented advanced degree such as a masters in public health, and skilled mentorship from experienced investigators is a key part of the curriculum. Physicians with an interest in EMS research are encouraged to apply to become a RWJ clinical scholar now without waiting for the development of additional, EMS-specific training programs.

A similar program for nonphysician EMS researchers is a priority need. There are already a number of EMS-oriented nonphysician investigators producing high-quality research such as James Menegazzi, PhD, the current editor of *Prehospital Emergency Care*<sup>6</sup>; Ellen MacKenzie, PhD, director of the Injury Control Center at Johns Hopkins University<sup>7</sup>; N. Clay Mann, PhD, with the National EMS-C Data Analysis Resource Center<sup>8</sup>; and Al Hallstrom, PhD, principal investigator for the Public Access Defibrillation trial.<sup>9</sup> Additional doctoral-level nonphysician investigators with an interest in EMS are in training or have recently completed schooling, and they can be expected to produce high-quality research in the near future. However, additional training opportunities would allow more EMS researchers within the specialty to compete successfully for funding. Prospective EMS researchers should be encouraged to obtain a research-

oriented graduate-level education, with a minimum of two years of postbaccalaureate training, preferably leading to a master-level degree. A number of research training awards are available from various agencies of the federal government for which EMS researchers could apply. There are different awards for non-clinicians and clinicians, as well as applicants without doctoral degrees. The NIH has a comprehensive description of these opportunities on its Web site at <http://grants.nih.gov/training/careerdev/intro.html>. These awards include the "K" series for individuals and the "T" series for institutions. An applicant is more likely to be successful with careful coaching from an experienced mentor and should maintain regular contact with the contracting officer at the federal agency during the application process.

Prospective EMS researchers can benefit from existing expertise at schools of public health. Many EMS researchers have made use of the synergy between the public health experts and EMS to accomplish interesting projects.<sup>10-12</sup> A school of public health often houses a number of experienced researchers who are experts in health services research and who would be good mentors for investigators interested in EMS systems research. The faculty at a school of public health often includes nonclinicians who may be interested in creating a partnership with a researcher who has clinical experience. In addition, these programs provide a mechanism for interested EMS professionals to obtain a doctoral degree.

#### *Immediate Actions.*

- Prospective EMS researchers can apply for existing research training awards to gain experience and to enhance their ability to compete for future grant awards.
- A "career development" conference should be planned in which successful EMS researchers describe strategies for success and include federal agency representatives and others who can describe funding opportunities. The conference should be targeted toward EMS professionals considering a research career or actively pursuing research training, as well as emergency medicine residents and junior faculty interested in EMS research.
- Leading EMS researchers should create a list of important EMS research questions and hold a consensus conference to establish research priorities. The purpose of this process is to engage funding agencies to target grants for work on those priorities. Items on the list should be "important" questions answerable with current technology.
- A centralized list of Web sites with value to EMS researchers including grant application materials and basic information about the process of applying for funding from both federal and non-federal sources should be developed.

#### *Long-term Goals.*

- The educational objectives in national EMS curricula should be changed to further promote understanding of importance of research.
- An educational module for distribution to EMS training programs that can be used by educators to teach research methods and critical literature review to their students should be created.
- EMS research organizations should develop formal relationships with schools of public health to provide a career pathway for EMS professionals to obtain research-oriented doctoral degrees.
- Interested academic and professional societies need to develop political partnerships to build support for increased funding for training new EMS researchers.

**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."<sup>1</sup>

**Background and Discussion.** The diffuse nature of EMS clinical care has inhibited the development of research. Unlike many other parts of medicine, EMS patient care occurs in a wide variety of locations and then continues into the hospital, where the EMS no longer has any contact with the patient. Strong links are needed among all stakeholders in the care of EMS patients, including state and local health departments; fire departments; EMS agencies; medical schools; hospitals; municipal, county, and state government; labor unions; and patient advocacy groups. Such links are needed to facilitate EMS-related research. As noted by others, the lack of a clear clinical location such as a hospital makes obtaining patient outcome information quite challenging.<sup>4,13</sup> A Center of Excellence provides a well-developed research infrastructure to promote the successful completion of complex clinical and basic investigations while providing an organized system of links between organizations. The National Center for Research Resources, which resides within the National Institutes of Health (NIH), makes specialized resources available to researchers. One such resource is the General Clinical Research Center (GCRC), of which there are currently 75 in place across the United States. These GCRCs could potentially be used to facilitate EMS-related research, because much of the infrastructure is already maintained with funding from the NIH. The GCRCs are also sources of training opportunities, and information about the

program is available on the Internet at <http://www.nccr.nih.gov/clinical/crfact.pdf>.

One problem faced by prospective EMS centers of excellence is that federal "Center of Excellence" awards go to organizations that are already *de facto* centers of excellence because those organizations have the expertise to compete successfully for grants. The process of developing a center of excellence in the NIH system is a multiyear effort and begins with "K" training awards, then "R" investigator initiated awards, and finally "P" program awards. It is a challenge to maintain that effort solely through extramural support. A significant financial commitment is needed from a primary sponsoring organization to ensure that future grant funding and its attendant overhead money will make the investment pay off. The program project grants, or "P" awards, are multiyear awards that typically support three to six linked projects. Each institute within the NIH has different policies on awarding "P" grants. For example, the guidelines for the National Institute of Child Health and Human Development (NICHD) for P01 awards can be read on the Internet at [http://www.nichd.nih.gov/funding/dsr\\_p01\\_guide.htm](http://www.nichd.nih.gov/funding/dsr_p01_guide.htm).

Despite the challenges, opportunities are available in newly developing areas of interest to EMS researchers such as patient safety and bioterrorism. Because relatively little research infrastructure currently exists in those areas, nascent EMS researchers are well positioned for obtaining funding for these issues. While it is important to remain focused on specific research goals, a certain degree of flexibility and creativity will allow the researcher to adapt the research program to fit the needs of the funding agencies.

#### *Immediate Actions.*

- EMS agencies and academic centers such as colleges of medicine and schools of public health should create formal written linkages to establish the framework for a collaborative center of excellence.
- The resulting collaborative groups should apply for K and T awards from the NIH in relevant areas of concentration for EMS.

#### *Long-term Goals.*

- Leading EMS researchers should develop programs that are competitive for federally funded program project grants (P01).
- One or more EMS research groups should develop a model to be used by the National Center for Research Resources to encourage one or more GCRCs to incorporate EMS-related research into its area of expertise.

**Recommendation 3.** "Federal agencies that sponsor research should acknowledge their commitment to EMS research."<sup>1</sup>

**Background and Discussion.** Because of the diffuse nature of the EMS clinical care system and the wide variety of illnesses and injuries cared for by EMS, existing federal funding initiatives often unintentionally exclude many EMS research initiatives, because they frequently do not fit into existing clinical research models. Therefore, multiagency solutions are needed to provide structure for additional EMS research projects. Federal agencies need to change what they are looking for to include the EMS perspective. They also will need to include people who understand how EMS works when reviewing grants. Multiagency initiatives are needed because parts of EMS research fall into different domains, across different agencies, or different medical specialties.

Several agencies have worked toward these goals. Some fund EMS research by offering grants that build research infrastructure or that support clinical research projects. Among these, the Emergency Medical Services for Children (EMS-C) program supported a data analysis center to support EMS-C data analysis and research. The Pediatric Emergency Care Research Network is supported through a partnership between the EMS-C Program and the Division of Research, Training, and Education within the Maternal and Child Health Bureau of the Health Resources and Services Administration. This \$1.8 million initiative has created infrastructure to conduct research to improve the emergency medical care for children both inside and outside the hospital. The National Highway Traffic Safety Administration has sponsored several projects, including the EMS Outcomes Project<sup>4</sup> and the National EMS Research Agenda.<sup>1</sup> The PULSE Initiative sponsored by the National Heart, Lung, and Blood Institute seeks to improve survival from sudden cardiac arrest and will offer EMS clinical researchers opportunities for obtaining funding.<sup>14</sup> The Agency for Healthcare Research and Quality has supported EMS research efforts by Keith Neely<sup>15</sup> and Craig Newgard.<sup>16</sup>

#### *Immediate Actions.*

- Federal agencies that sponsor research should incorporate EMS into their mission statements.
- Federal grant review committees should include scientists with knowledge of EMS systems.
- EMS trade and professional organizations should provide written materials to local, state, and federal research funding agencies that succinctly explain the key role of EMS in strengthening the public health and accessing the acute health care system.
- EMS professional organizations should develop mechanisms for reviewing federal requests for proposals, identifying those who would benefit from the participation of EMS, and informing the responsible funding agency. This process should be designed to educate federal partners of the integration of EMS into the health care research continuum.

*Long-term Goals.*

- EMS trade and professional organizations should cooperate in hiring a lobbyist who will explain the value of EMS to federal agencies and elected representatives.
- EMS professional and trade organizations should collaborate to advocate to the public about the necessity for including EMS research in federal initiatives. This will be accomplished using a variety of means including encouraging the media to portray EMS accurately, obtaining the services of a famous spokesperson, and developing written materials for public consumption.
- EMS trade and professional organizations should recruit advocacy organizations such as the American Association of Retired Persons, the American Heart Association, and the American Red Cross, as well as spinal cord injury victims, traffic accident victims, and family voices to serve as political partners who will be champions of the EMS cause with political and community leaders.

**Recommendation 4.** “States, corporations, and charitable foundations should be encouraged to support EMS research.”<sup>1</sup>

*Background and Discussion.* In some states, EMS regulatory agencies tightly control the medical care that is provided by EMS agencies, whereas in other states, medical decisions are left up to local medical directors. In most states, new research findings are adopted very slowly as a result of cost concerns and the challenges inherent in re-education of EMS professionals. Statewide uniformity of care should not be the primary priority of state EMS regulatory agencies; rather, EMS provider agencies that are ready and able to implement new research findings should be actively encouraged by state regulators to do so. Through research, the best practices of EMS organizations should be detected by the state EMS regulatory apparatus and those practices promoted to other provider agencies.

Some states regulate research in the prehospital setting, erecting a barrier to the process that may serve to hinder research, which already is regulated by the federal government and local Institutional Review boards (IRBs). These structures should be evaluated to ensure that they offer significant incremental benefit over the existing federal regulatory process.

Corporations and charitable foundations have mission statements governing their work. It may be possible to work with these agencies to enhance their ability to support EMS research by modifying their missions to include EMS-related activities.

*Immediate Actions.*

- State EMS lead agencies should help to stimulate research activity within their state and ensure that

their existing rules and regulations do not obstruct the conduct of EMS research.

- The National Association of State EMS Directors and similar organizations should educate their memberships about the need for EMS research to improve patient care and strengthen system design.
- States that decide to fund research programs should incorporate appropriate peer review of applications.

*Long-term Goals.*

- State EMS lead agencies should ensure the dissemination of research results to the EMS professionals that they regulate.
- State EMS lead agencies should encourage the timely adoption of research results into the clinical practice of EMS provider organizations within their states.
- State governments should allocate funding to encourage the development of new EMS-oriented researchers.
- State EMS lead agencies should promote pre-hospital research and facilitate the development of relationships between researchers and funding agencies.
- The National Highway Traffic Safety Administration and its federal and nonfederal partners should encourage the development of research funding at the state level using successful programs such as Women-Infant-Children (WIC) or Maternal and Child Health (MCH) block grants as models.
- EMS researchers and their professional organizations should educate the staff of charitable foundations to incorporate EMS issues within their mission.

**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.”<sup>1</sup>

*Background and Discussion.* Many EMS systems and EMS professionals already embrace research as a part of the discipline, but research has yet to be adopted into the overall culture of EMS. For the most part, EMS practices lack an evidence base; EMS education continues to be based primarily on anecdote and clinical experience; and EMS providers are taught little about the importance of research for developing good clinical practices. This recommendation should not be perceived as addressing only field EMS providers. “EMS professional” also includes people involved in EMS from many disciplines, with different backgrounds and roles, such as EMS medical directors and critical care transport nurses. EMS professionals, public health providers, epidemiologists, policy makers, and medical device and pharmaceutical manufacturers should support research in the EMS environment.

There is a continuing need to demonstrate the value of research to EMS professionals. The emphasis should be on showing where research has made a positive difference, using real-life examples to demonstrate the value of research. The widespread acceptance of quality improvement activities in EMS can serve as a useful platform for exposing EMS professionals to the research process. Research includes acquiring and analyzing data, and most EMS quality improvement systems do exactly this. Developing the interest of EMS professionals in benchmarking activities can be an introductory step on the way to becoming research-savvy. This approach may enable participants to view research not as something arcane, but as a natural progression of activities in which they already are involved.

EMS professionals must be exposed to the research process early in their careers. Perhaps the best mechanism for accomplishing this goal is to work in conjunction with EMS education programs. Although some training in research methods is included in the current version of the National Standard EMS curriculum for paramedics, there is concern that the content is too advanced.<sup>17</sup> The need is to provide EMS professionals with an appreciation for the role of research, not with extensive instruction in research methodology. The goal, at least in the early stages of their careers, is to prepare them to be consumers of the product. Specific preparation in research methodology can come later.

The content must be appropriate for the audience. Most paramedics receive their education through technical training programs or associate degree programs, with only a small proportion attending four-year colleges. It is equally important to prepare EMS instructors to present the material. It may be necessary to develop "how to teach research" courses specifically for EMS instructors, or it may be necessary to bring researchers (who otherwise do not teach at that level) into the classroom to provide the research-related EMS course content.

#### **Immediate Actions.**

- At least one EMS continuing educational program should be designed annually to demonstrate the incorporation of research results into clinical practice.
- EMS provider agencies should involve more EMS professionals in processes that obtain and analyze data such as benchmarking and quality improvement activities.

#### **Long-term Goals.**

- The National Association of EMS Educators or similar organizations should provide a model curriculum that will be used by classroom instructors to show students how EMS research

findings are incorporated into practice and will teach students methods for critically reading the EMS literature.

- The National Registry of EMTs examination should include questions that assess understanding of critical reading of research reports and methods for incorporating new research findings into practice.

**Recommendation 6.** "EMS professionals of all levels should hold themselves to higher standards of requiring evidence before implementing new procedures, devices, or drugs."<sup>1</sup>

**Background and Discussion.** The National EMS Research Agenda calls for a change in the culture of EMS. Simply put, it is time to shift from anecdotal- to evidence-based practice. EMS professionals, from the field paramedic who is intrigued by a new device to the medical director who is responsible for establishing protocols, must make decisions based on firm evidence. Studies evaluating effectiveness in the real world of EMS must be included when making these decisions.

Requiring evidence presumes that evidence is available. A number of resources can be accessed to obtain evidence, including review articles in peer-reviewed publications and compilations of reviews in accessible databases. The Cochrane Collaboration maintains one such database. Availability of an EMS section within the Cochrane Collaboration would be helpful for collecting and disseminating evidence-based reviews of important EMS clinical problems. A number of electronic resources are available that can help EMS professionals learn about new evidence as it becomes available. Most medical journals will send their table of contents as an electronic mail message on the day of the release of the journal issue. Some federal agencies publish newsletters summarizing their research results, e.g., the Agency for Healthcare Research and Quality's *AHRQ Research Activities*. Because these publications contain mostly information that is not EMS-related, there is some significant overhead required on the part of the EMS professional to wade through the material to find information useful to them.

Extrapolating research findings to specific EMS systems would be enhanced if there were less variability among those EMS systems across the United States. Developing a mechanism for formally recognizing best practices to standardize EMS practices, education programs, and system operations across diverse settings would accelerate the adoption of research findings into clinical practice.

#### **Immediate Actions.**

- EMS professional groups such as the Prehospital Care Research Forum should work with interested

parties around the world to create a section for EMS within the Cochrane Collaboration.

#### *Long-term Goals.*

- The National Highway Traffic Safety Administration or its federal partners should recognize best practices and disseminate them to EMS systems.
- The National Highway Traffic Safety Administration or its federal partners should disseminate EMS research results that have been federally supported to all EMS professionals in the United States.

**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.”<sup>1</sup>

**Background and Discussion.** There is an existing Uniform Prehospital Data Set (1993), but use of those data elements is voluntary and many states have yet to adopt them. Efforts to improve and standardize EMS data collection are currently under way and include revision of the Uniform Data Set and development of a National EMS Database. Interested readers may learn more at the Web site devoted to that effort at [www.nemsis.org](http://www.nemsis.org).

Encouraging new approaches to data collection is important. Historically, EMS records have consisted of paper charts. Switching to electronic records and data collection would contribute to standardization of data elements and completeness of EMS records. Some advanced EMS systems have begun to collect information electronically, but additional research is needed to ascertain the best methods for accomplishing electronic data acquisition. Additional research also is needed to determine the value of wireless transmission of additional EMS data such as real-time vital-sign and two-way video technology between receiving facilities and EMS professionals in the field.

Although many progressive EMS systems may embrace efforts to standardize data collection, others will participate only if there are methods for enforcing participation. Some states already require EMS agencies to provide data to a central agency, but the ability of states to enforce that requirement is variable. Tying agency reimbursement to participation in standardized data collection activities may be an effective method of encouraging participation.

#### *Immediate Actions.*

- EMS researchers should develop innovative techniques for electronic data collection and determine how new technologies can best be integrated into existing services. These efforts should be sup-

ported through competitive grant applications with appropriate funding agencies.

- State lead EMS agencies should mandate the use of the national EMS data set.

#### *Long-term Goals.*

- The Center for Medicare Services should mandate use of electronic medical records for EMS services that accept reimbursement from the Medicare system.

**Recommendation 8.** “The Food and Drug Administration (FDA) and the Office of 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.”<sup>1</sup>

**Background and Discussion.** The three ethical principles guiding human subject research are respect for persons, beneficence, and justice. It is reasonable to establish laws and regulations to facilitate adherence to these principles, particularly in circumstances in which subjects cannot participate fully in the informed-consent process.

Many EMS researchers perceive that the existing regulations, especially the process of exception from informed consent for emergency research, present a significant obstacle to the conduct of EMS research. Although these researchers recognize the need to protect individual rights, they point out that current rules deter research and therefore deprive society of its direct benefits. There is also a perception that the existing regulations have impeded some projects and may stimulate the relocation of research to countries in which regulation is less restrictive.<sup>18</sup> Ultimately, economic consequences as well as delay of the introduction of new and innovative life-saving technologies into the U.S. health care system may be the result.

Researchers and regulators agree that some aspects of the regulations are difficult to implement and that some aspects are confusing. There is a need to clarify the process of fulfilling the regulatory requirements for both researchers and IRBs. Inconsistency in interpretation and application of the rules creates unique difficulties in the conduct of multicenter trials.

Community consultation and public disclosure are currently required as additional protections for subjects in studies conducted under the regulations allowing exception from informed consent for emergency research.<sup>19</sup> Although intended to allow for

flexibility in interpretation under different circumstances, the regulations may not achieve their intended goal and are often a source of dispute. The processes of community consultation and public disclosure should be reexamined and perhaps modified to ensure that the goal of increasing community awareness regarding active research in emergency situations is effective.

Some of the areas that could benefit from investigation to improve the process include:

- Determining which parts of the regulations are most problematic;
- Determining whether communities perceive community consultation and public disclosure as helpful or successful;
- Describing IRB variability in interpreting and administering the regulations.

#### *Immediate Actions.*

- EMS researchers should develop and disseminate strategies to be used as models that satisfy the regulatory requirements of community consultation and public disclosure. These models need to be inclusive of research subjects from vulnerable populations.
- EMS researchers should ensure that the research budgets allocate sufficient resources to meet regulatory and ethical requirements.
- Journal editors should include community consultation and public disclosure activities and experiences in the methodology sections of peer-reviewed publications.
- EMS researchers should become more active in the IRB process by serving both as reviewers and IRB members.

#### *Long-term Goals.*

- EMS researchers and public policy makers should evaluate both the economic and public health impact of the regulations regarding emergency exception from informed consent.

## CONCLUSIONS

Successful growth and development within a scientific discipline are dependent on several key factors. An understanding of the potential benefits of research for society is foremost. Major technological and clinical innovations must be tested scientifically before their benefits can be confirmed and disseminated widely. Individual researchers with an interest in dedicating their careers to the advancement of the science and practice of EMS must be recruited, and support for the work of these individuals should be accessible. Networks to facilitate multicenter trials and collaborative research training should be available, and

funding for sufficiently large trials must be a priority for all stakeholders. Research regulations must secure individual protections without unduly inhibiting the potential benefit to society that ethical research can impart.

The National EMS Research Agenda has identified the need for a common vision among researchers, EMS professionals, state and federal governments, and stakeholders, as well as the importance of support from community agencies and foundations. Collective efforts to further EMS research according to that vision, with the evolution of a true collaborative spirit and appreciation for research, are imperative to foster the promotion of the science of EMS.

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