

The National EMS Advisory Council

Submitted on May 30, 2012

Committee: Medical Oversight and Research

Title: The Next Steps for Prehospital Care Evidence-Based Guidelines

Issue Synopsis

A. Problem statement

The National EMS Research Agenda (2001) published by the National Highway Traffic Safety Administration (NHTSA) and the report on the Future of Emergency Care in the United States (2006) published by the Institute of Medicine (IOM) both set forth recommendations to develop evidence-based model prehospital care protocols for the treatment, triage, and transport of patients, including children. In response to these recommendations, in September of 2008, the Federal Interagency Committee on EMS (FICEMS) and the National EMS Advisory Council (NEMSAC) cosponsored a national meeting, funded by NHTSA, to educate EMS leaders on the role of prehospital care Evidence-Based Guidelines (EBGs) to draft a National EBG Model Process (Appendix A) for the development, implementation, and evaluation of EMS guidelines.

The National EBG Model Process represents a wealth of potential benefit to prehospital emergency medical systems. EBGs are an important element for providing an expert synthesis of the medical evidence and improving the quality of EMS, where location variations in practice are widespread, as they promote a consistent approach by prehospital providers for a given clinical scenario, and thus, in concert with the IOM standards for developing trustworthy guidelines, facilitate creation of standards for measuring and evaluating the quality of prehospital emergency care. However, the National EBG Model Process's ability to impact changes in the field of EMS is limited by the following challenge areas: 1.) the lack of quality prehospital research, EMS expertise, resources, funding, and time to sustain the process of developing and implementing EBGs; 2.) the consensus-based culture of EMS in decision-making and resistance to efforts to implement EBGs in prehospital emergency practice; and 3.) the unknown impact of EBGs on patient health outcomes. The resolution of these limitations is vital to the survival and enhancement of prehospital emergency care and the continued development and sustainability of the National EBG Model Process.

B. Resources/references related to the issue

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Related resources:

- Agency for Healthcare Research and Quality (AHRQ, USA) Healthcare Research and Quality Act of 1999, Part B, Title IX, Section 911(a) directed the AHRQ to examine systems to rate the strength of the scientific evidence underlying health care practices, research recommendations, and technology assessments to make such methods or systems widely available
- US Preventative Services Task Force (USPSTF) The U.S. Preventive Services Task Force (USPSTF), first convened by the U.S. Public Health Service in 1984, and since 1998 sponsored by the Agency for Healthcare Research and Quality (AHRQ), is the leading independent US panel of private-sector experts in prevention and primary care.
- National Guidelines Clearinghouse: (NGC) a public resource for evidence-based clinical practice guidelines. NGC is an initiative of the AHRQ, U.S. Department of Health and Human Services. NGC was originally created by AHRQ in partnership with the American Medical Association (AMA) and the American Association of Health Plans (now America's Health Insurance Plans [AHIP])
- Guidelines International Network (GIN) The Guidelines International Network (G-I-N) was founded in 2002. It has 84 organizational members and partners and represents 37 countries. It is an international not-for-profit association of organizations and individuals involved in the development and use of clinical practice guidelines. The Network claims to have the world's largest guideline library and is regularly updated with the latest

information about guidelines of the G-I-N membership. As at August 2008 more than 5,360 documents are available on their site.

- Cochrane collaboration (England) The Cochrane Collaboration was established in 1993, and named after the epidemiologist, Archie Cochrane (1909-1988), a British medical researcher who contributed greatly to the development of epidemiology as a science. The organization has thousands of contributors worldwide. The Collaboration prepares Cochrane Reviews and aims to update them regularly with the latest scientific evidence. Data from *The Cochrane Library* in 2004 show that there are more than 11,500 people working within The Cochrane Collaboration in over 90 countries.
- Centre for Evidence-Based Medicine (CEBM, Oxford) was established in 1995. The center offers tools and courses of study in EBM.

C. Crosswalk with Other Standards

- The Institute of Medicine's Roundtable on Evidence-Based Medicine
- The Institute of Medicine's *Emergency Medicine at the Crossroads*
- The Institutes of Medicine's *Clinical Practice Guidelines We Can Trust*
- The National EMS Research Agenda
- The National Highway Traffic Safety Administration's *National EMS Scope of Practice Model*
- The National Highway Traffic Safety Administration's *National Emergency Medical Services Education Standards*

D. Analysis

The term Evidence-Based Medicine (EBM) originated in the 1970s and 80s. EBM is defined as the conscientious, explicit, and judicious use of current best evidence in making decisions about patient care. It requires the integration of individual clinical expertise with the best available external clinical evidence from systematic research. EBM deemphasizes intuition, unsystematic clinical experience and pathophysiologic rationale as sufficient grounds for clinical decision making. As EBM has evolved, subspecialties have emerged. EBGs are one of the emerging disciplines from EBM. EBGs are those guidelines developed following principles of evidence-based methods whereby multidisciplinary teams use explicit rigorous methods to appraise the evidence and develop new guidelines and recommendations.

The National EBG Model Process (Appendix A) that was generated in response to the IOM and the National EMS Research Agenda's recommendations that evidence-based protocols be developed for the treatment of EMS patients outlines a structured, eight-step process for the development, implementation, and evaluation of EBGs for local, national, and international EMS systems. The National EBG Model Process is based on the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system, which is a standardized method for summarizing and evaluating the quality of evidence and strength of a given recommendation on two distinct rating scales. High quality evidence does not necessarily imply strong recommendations, and strong recommendations can arise from low quality evidence. The quality of evidence rating is based on whether or not future research is likely to change the recommendation. The strength of the recommendation considers the quality of evidence, but also takes into account contextual factors, such as the balance between desirable and undesirable effects, the variability in values and preferences, and whether or not the intervention represents a wise use of resources. The gaps in EMS research are, hence, identified through the GRADE methodology in the development of EBGs and can be used to prioritize future research in EMS.

The Emergency Medical Services for Children (EMSC) Program used the National EBG Model Process to develop an EBG on pediatric seizure management, which set the stage for the subsequent development of EBGs on the utilization of helicopter EMS and prehospital pain management through a competitively-awarded cooperative agreement between the NHTSA and Children's National Medical Center (CNMC) with support from the EMSC Program. All three EBGs will be available for EMS systems to adopt and use in their respective venues. The protocol developed from the EBG on prehospital pain management was recommended to the Maryland EMS Board for adoption by the Maryland Institute for Emergency Medical Services Systems (MIEMSS) protocol review committee. The EMS Board approved the recommendation in November of 2010 and, following a six-month period of didactic introductory online training, the EBG-derived protocol was incorporated into the Maryland statewide prehospital protocol in July of 2011. Data are currently being collected and analyzed on changes in the quality of care delivered in the field and on the impact of the EBG on patients' prehospital pain scores. A manuscript on the EBG development process has been published in *Academic Emergency Medicine*, and manuscripts on each of the three aforementioned EBGs are currently in development. The process of developing the EBGs was a proof of concept for the GRADE methodology's applicability to the prehospital setting and showed that the National EBG Model Process was invaluable for developing a scientific basis for clinical guidelines that was not reliant on anecdotal consensus. However, the EBG development and implementation processes as well as ongoing evaluation of the National EBG Model Process have uncovered the following challenges to the sustainability of the National EBG Model Process for advancing the field of EMS.

First, the National EBG Model Process is dependent on the availability of prehospital care research, EMS expertise, resources, funding, and time. The development of EBGs depends on both the quality and quantity of evidence from available research in the subject area being investigated. Research in prehospital emergency care is still immature, and, for many subject areas, a dearth of high quality EMS data collection and database management and, subsequently, strong evidence exists to make informed decisions using existing databases and scientific

literature. The current dearth of prehospital research stems from limited funding opportunities for EMS research as well as few credentialed EMS clinicians and professionals who are trained in EMS research. The ability of the GRADE methodology used to develop EBGs under the National EBG Model Process to result in strong recommendations is limited when there is a lack of strong evidence, as is frequently the case in EMS.

Second, the process of developing EBGs is extremely resource and time-intensive, requiring many hundreds of hours. There is a similar demand on subject matter experts in the area of the EBG development. Expertise and research has commonly been drawn from academic emergency medicine departments. However, such expertise specifically in prehospital emergency care is necessary and not accurately extrapolated from emergency medicine expertise. Thus, EMS subject matter experts are rare and all have prior significant obligations in their professional lives, posing challenges to soliciting sufficient input for EBG development. In addition to their time, such professionals must also provide objective information, requiring full disclosure of conflicts of interest by expert panel members.

Another challenge that has been identified is implementing EBGs and ensuring that prehospital field providers are correctly using the EBGs in a timely manner before the evidence becomes outdated. This challenge highlights the need for a short time period between EBG development and dissemination/implementation. Studies have shown that once a guideline has been developed and published, it can take more than a year for the field providers to be trained to use the guideline. This challenge also encompasses the need to ensure that EBGs are incorporated into education standards and practice and that, ultimately, the EBG is accepted by the medical and EMS administrative community. Given the culture of EMS that historically has been based on consensus and anecdotal evidence, there is anticipation that the acceptance of EBGs will be met with resistance in the EMS community. Evidence for this is exemplified by initial American Heart Association (AHA) guidelines, which did not receive universal support upon publication, but only after further efforts to advocate for and implement the guidelines.

Lastly, the National EBG Model Process recommends the measurement and assessment of guideline-related outcomes to ensure that the guideline development increases the quality of patient care. At this time, further efforts are needed to address existing challenges to collecting data on patient outcomes and to determining the impact of the developed EBGs on patient health outcomes. A reportable positive impact of EBGs on patient health outcome will contribute toward the sustainability of the National EBG Model Process and the development of more EBGs.

E. Committee Conclusion

There is tremendous potential for EBM and EBGs to advance the field of EMS and to strengthen the relationship between scientific research and clinical practice and systems in prehospital care. The National EBG Model Process is essential for increasing the quality and safety of prehospital patient care, improving the effectiveness and delivery of EMS systems, and ensuring the rational use of resources. EBGs also represent a means to identify and address research priorities in the

field of EMS. While the principles of EBGs and EBM have primarily been utilized in the hospital setting, there is also potential for the same principles to advance the areas of systems and education, albeit an alternative tool may be needed to evaluate qualitative work.

Despite the opportunities that exist with EBGs, there are currently several major challenge areas that limit the National EBG Model Process's ability to impact changes in prehospital clinical practices. These challenge areas include the following:

- The current culture of EMS, lack of acceptance of EBGs, and the dearth of leaders and medical directors who can advocate for and use the EBGs that have been developed;
- The high demand for resources, funding, time, prehospital research, and EMS expertise to develop EBGs and the current lack of mechanisms to streamline such resources in order to make the process most efficient; and
- The unknown impact of EBGs on patient health outcomes.

The committee recommends that the following actions be made to mitigate these challenges.

Recommended Actions/Strategies:

The continued progress and development of the National EBG Model Process for prehospital care, practice, education, and systems should be supported through the following tasks:

The National Highway Traffic Safety Administration

- **Recommendation #1:** The NHTSA should lead the effort in forming relationships with stakeholder organizations and academic journals in order to hasten the process of publishing EBGs. This relationship would be similar to the relationship the American Heart Association has with the journals *Circulation* and *Resuscitation*. Second, organizations developing EBGs should form partnerships with EMS organizations, State and local EMS agencies, as well as EMS provider agencies in order to assist in decreasing the time to implementing EBGs in the field. Such organizations should also develop implementation toolkits or training curricula to ensure that the EBG is incorporated into providers' clinical practice.
- **Recommendation #2:** As the national EMS education standards are revised and reviewed, the NHTSA should take into account existing standards on EBGs and make efforts to implement such standards into EMS education.

The Federal Interagency Committee on EMS

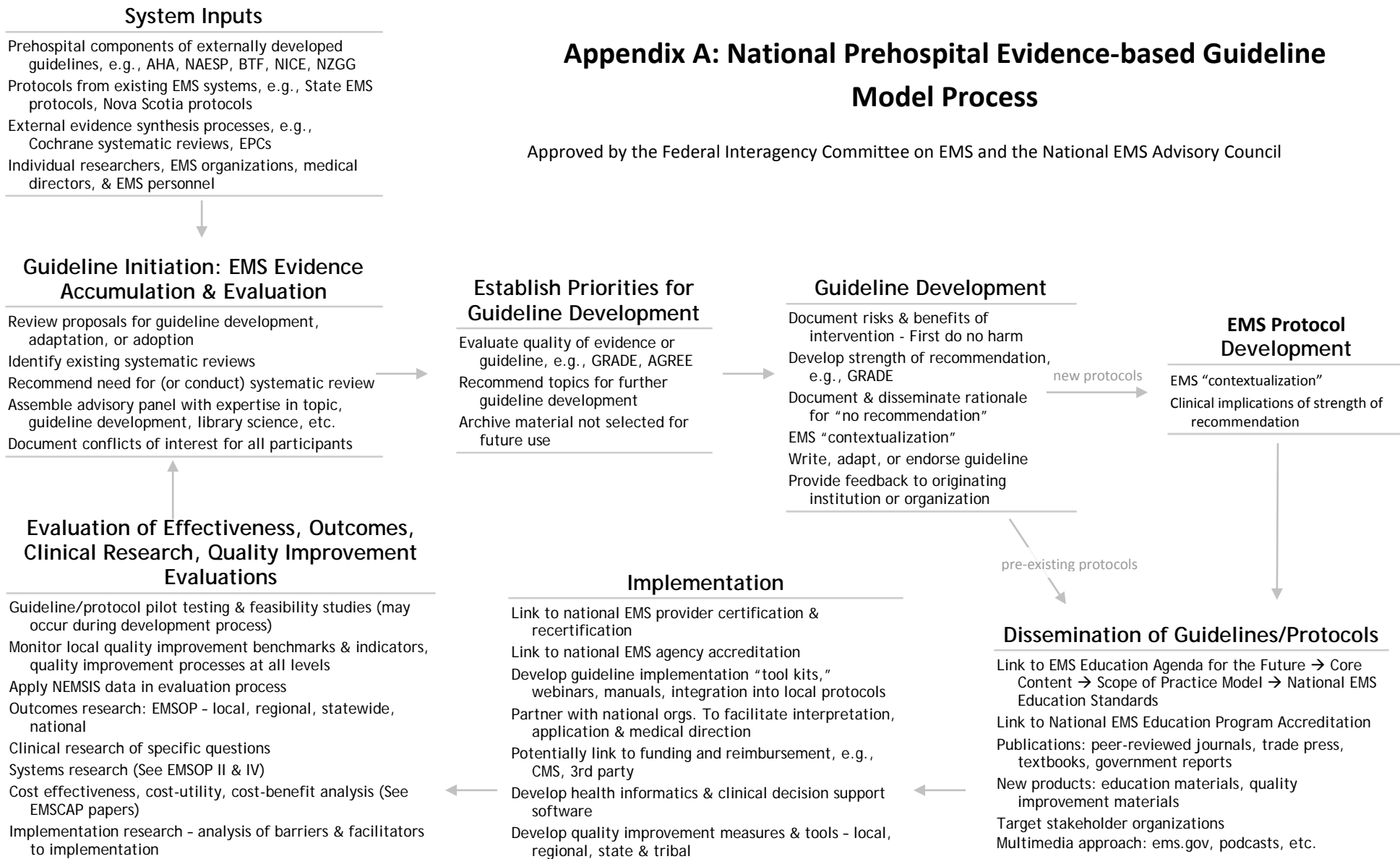
- **Recommendation #3:** The FICEMS should work in coordination with the NHTSA, the National Institutes of Health (NIH), the National Quality Forum (NQF), and the Agency

for Healthcare Research and Quality (AHRQ) to seek means to further the implementation of the strategies presented in the National EMS Research Agenda, specifically the recommendations on defining prehospital patient outcome measures, promoting the training of EMS researchers, and creating funding sources specifically for EMS research, in order to increase the quantity and quality of EMS research and expertise, thereby supporting the development of EBGs. EBG development depends on a solid resource base of scientific prehospital research and EMS expertise in the subject matter areas being investigated. The National EMS Research Agenda details specific strategies to promote research in EMS and to train credentialed EMS clinicians and professionals in research that would indirectly support the development of EBGs.

- **Recommendation #4:** The FICEMS should work with NHTSA, AHRQ, and other member agencies to create Center(s) of Excellence for EMS EBG development. Center(s) of Excellence should serve to ameliorate the challenges of sustaining EBG development amidst resource and time constraints as well as a steep learning curve to developing EBGs. The specific responsibilities of Center(s) of Excellence might be to provide supporting mechanisms to make the process of developing EBGs more efficient as well as to train stakeholders in EBG development.
- **Recommendation #5:** The FICEMS in partnership with the NHTSA and AHRQ should work to make the process of developing EBGs more efficient by creating supporting mechanisms, such as a registry of current EBG efforts with prehospital relevance occurring anywhere in the world as well as a warehouse of evidence syntheses and appraisals. To build capacity in EBG development, the NHTSA should develop training workshops and resources to build expertise in the EBG development process. The EBG development process is very time and resource intensive, making it difficult for many communities to use to develop local guidelines *de novo*.
- **Recommendation #6:** The FICEMS, the NIH, and the AHRQ should request that its member agencies and departments incorporate mechanisms to sustain the National EBG Model Process into Federal grant guidance language. Such mechanisms should specify that the National EBG Model Process be used when distributing funds for protocol development and that an applicable EBG be used for grants related to protocol implementation.
- **Recommendation #7:** The FICEMS should sponsor a regularly-held EBG Scientific Assembly. This assembly should bring together practitioners and academic EMS professionals to network on the EBG Model Process, to determine best practices for developing and implementing EBGs, to prioritize EBGs for future development, to identify research gaps in prehospital care, to acknowledge excellence in prehospital research, and to develop strategies for overcoming barriers that the culture of EMS presents to disseminating and implementing EBGs. The Scientific Assembly should have workshops to assist novice EBG investigators learn how to use the National EBG Model Process and the GRADE methodology in order to build capacity for EBG development.

Appendix A: National Prehospital Evidence-based Guideline Model Process

Approved by the Federal Interagency Committee on EMS and the National EMS Advisory Council



Abbreviations

AGREE - Appraisal of Guidelines Research and Evaluation
 AHA - American Heart Association
 BTF - Brain Trauma Foundation

CMS - Center for Medicare and Medicaid Services
 EMSCAP - Emergency Medical Services Cost Evaluation Project
 EMSOP - Emergency Medical Services Outcomes Project

NAEMSP - National Association of EMS Physicians
 NEMSIS - National EMS Information System
 NICE - National Institute for Health and Clinical Excellence
 NZGG - New Zealand Guidelines Group