#### PREHOSPITAL CARE RESEARCH EDRUM Challenging the Inture of EMS

# THE FORUM NEWS

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# Top Abstracts Showcased at EMS Today Conference

Held in the beautiful Kansas City Convention Center, EMS Today 2002 drew over two thousand attendees from across the United States and abroad. The Prehospital Care Research Forum was proud to be part of the event, beginning with a preconference workshop, Demystifying Prehospital Research: Managing Data to Improve Everything You Do. After core lectures, workshop participants selected a research subject area and developed a project from conception to completion. It was the first opportunity for many of the participants to be directly involved with a research project, and the group agreed that the workshop was very beneficial to them as an introduction to successfully conducting research.

Over the next several days the conference offered sessions on many interesting topics including everything from teaching people to be nice, to wild animal attacks and how to manage them. Throughout the week the Convention Center was bustling with activity as exhibitors demonstrated their equipment, and discussed the latest technological advances in EMS.

Mid-week PCRF was proud to showcase the top six abstracts selected from those

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## Research in the Classroom: TASK FORCE UPDATE

Over the last several months many PCRF Associates have been actively participating in one of three Task Forces including Research in the Classroom, Community Peer Review , and Research as a Standard . The following report was provided by the Research in the Classroom Task Force. PCRF Board member Liz Criss served as liaison for Joe Corley, Bill Dunne, Robert Delagi, Thomas Raithby, and Jeremy Wilkinson. Thank you for your hard work and effort, Research in the Classroom Task Force!

#### Introduction:

The task force concept was designed to provide PCRF Associates with the opportunity to participate in short term projects designed to further the goals of the Prehospital Care Research Forum. This is the interim final report for the Research in the Classroom Task Force.

The challenge posed to this (Continued on page 3)

#### Inside The Forum News...

- EMS Today Update
- PCRF and the FDA
- Task Force Updates

# PCRF Speaks to FDA Internal Review Board Guidelines

In March 2002 the Food and Drug Administration (FDA) posted notice that the rules and regulations governing Institutional Review Board (IRB) protocol would be open to public comment to enable interested parties the opportunity to participate in the rule making prior to the adoption of the final rules. Specifically, the FDA is considering whether to amend its IRB regulations to require sponsors and investigators to inform IRBs about any prior IRB review decision. The FDA states that these disclosures could help insure that sponsors and clinical investigators who submit protocols to more than one IRB will not be able to ignore an unfavorable IRB review decision, and that IRB' reviewing a protocol will be aware of what other IRBs reviewing similar protocols have concluded.

The Prehospital Care Research Forum Board of Advisors submitted the following position statement to the FDA.

To Whom It May Concern:

Emergency medical services (EMS) can be one of the most daunting environments in which to conduct meaningful research. In an effort to improve the quality and quantity of EMS research, a group of medical directors and field EMS providers formed the Prehospital Care Research Forum (PCRF) in 1992. The PCRF was founded with the mission "to assist, recognize and disseminate prehospital care research at all provider levels." In fulfilling that mission, we have always advocated for the ethical and responsible conduct of research. We strongly believe that the practice of "IRB shopping" threatens the integrity of the research process. Therefore, the Prehospital Care Research Forum supports the position that an IRB considering a research protocol should be informed of the results of any other IRB review.

Importantly, EMS systems are usually not affiliated with an academic institution, and often have no official relationship with any specific health care institution while necessarily interacting with all of their community's hospitals. Thus, prehospital care studies frequently involve multiple IRBs, and some effort is required to determine which IRB should serve as the primary IRB for a study. Because of this unique nature of the EMS research environment, we do believe it is important to differentiate between activities intended to identify the appropriate IRB(s) and those activities intended to circumvent a negative action by an IRB. The former is a de facto part of many prehospital care studies; the latter is absolutely unacceptable.

While recognizing the need for regulation, the Prehospital Care Research Forum encourages a principle-based approach to the issue of IRB shopping. We would argue that these principles are already well established, albeit indirectly, in existing documents, declarations, guidelines and regulations. Nonetheless, the FDA (and OHRP) should clearly establish that:

> (1) IRB shopping is unethical. Ethical sponsors and investigators may legitimately disagree with the actions of an IRB, but they must be willing to discuss those actions and the basis for their disagreement in all subsequent IRB submissions.

(2) Everyone involved in the research process is responsible for ensuring the ethical conduct of research. Ethical investigators, sponsors, and other individuals involved in the research process must make sure that the IRB(s) reviewing a study has all of the information relevant to that study, including information about the actions of other IRBs, and any new information that develops after an IRB has acted.

These two principles can be used to address all of the questions raised in the advance notice of proposed rulemaking: the FDA and OHRP should deal with violations of these ethical principles in the same manner with which they would deal with any other breach of ethics.

The Prehospital Care Research Forum is committed to supporting all efforts aimed at ensuring that research is conducted in an ethical manner. If we can be of any further assistance to you in this or any other matter, please feel free to contact us.

For more information about the Prehospital Care Research Forum Visit our Web site at www.pcrf.mednet.ucla.edu

#### Forum News

# Community Peer Review Task Force Report

The Community Peer Review Task Force compiled the following report. PCRF Board member Lawrence Brown served as liaison for Chris Ryther, Elaine Christiansen, and Andy Stern. Thank you for your hard work and effort, Community Peer Review Task Force !

#### **Rationale**

The group was asked the question, "What is our rational for how/why PCRF participation would improve the grant review process? There were common threads among all responses often focusing on our expertise, experience, and knowledge of EMS systems--including its variety and jargon--as well as the need to adapt research techniques to the prehospital environment. The following is a composite of all responses:

- EMS is a relatively narrow field of EMS and easily misunderstood. The PCRF represents a wide variety of outstanding academics and providers that have the potential to provide important insight into research projects that might make studies more reliable and valid.
- PCRF associates also offer the perspectives of EMS providers, consumers, researchers and managers with access to EMS educators

and others associated with prehospital care.

- The grant review process usually evaluates from a number of perspectives: technical, methodological soundness, financial, relevance, etc. What needs to be added is an examination of the "continuum of care" and not prehospital care as a singular event.
- Due in part to the difficulty of performing prehospital and out-of-hospital research, a politically neutral reviewer with experience in many models of EMS could be essential. Unlike with medicine, and perhaps nursing, EMS studies are often performed without an eye towards national standards and are therefore less replicable and applicable elsewhere.
- Granting agencies may have little understanding of EMS, in fact EMTs and paramedics are rarely mentioned by government officials in the same breath with police and firefighters.<sup>\*</sup> It stands to reason that they have limited if any contacts within EMS and would not know how to access research assistance and may even be less likely to offer grants because of it.
- We could also offer the ability to apply unique

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# **Research in the Classroom: TASK FORCE UPDATE**

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group was to develop a list of educational programs to include one-day workshops, research books, CD-ROMs, or other tools to increase educator inclusion of research in the classroom. The final product, however, took a broader approach to the goal.

#### Discussion:

The group used an e-mail based format to share ideas and construct the final product. The group entered into a lively discussion that redefined and expanded the scope of the challenge, and several members offered additional curriculum alternatives. Overall the group felt EMS research education was important at all levels of certification and shouldn't be restricted only to the curriculum for advanced level providers. To this end the group developed general objectives and suggested teaching methodologies for each of the major divisions of a research project.

The general objectives outlined by the group included:

- Creating EMS providers that understand the value of validating prehospital care through the research process.
- Creating EMS providers who will be more likely to participate in research projects.

• Demonstrate the collateral benefits of research, i.e., influence and enhance agency or system-wide Quality Improvement programs. The following table details the content and delivery methods identified by the group.

## Research in the Classroom: TASK FORCE UPDATE

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*Summary:* It is the conclusion of this group that EMS research education belongs at all levels of EMS certification. The recommendations included in this report can be easily and successfully adapted for inclusion in all educational programs.

Topic Area	Content Suggestions	Mode of Delivery
Ethical considerations	Historical issues in medical research Role of an IRB Consent	Lecture (classroom, CD-ROM, internet) Interactive CD-ROM
Interpreting published studies	Methodical approaches Applicability to local or regional practice	Small-group project (journal club activity) Lecture (classroom, CD-ROM, internet)
Performing a project	Defining the research question (consider clinical, systems, educational) Interacting with other personnel Selecting a publication, instructions for authors Writing a report Plagiarism and citing references	Lecture (classroom, CD-ROM, internet) Small group projects
Ongoing efforts	Value of original research Creating or joining journal clubs Understanding that education and research are lifelong activities	Lecture (classroom, CD-ROM, internet)
Introduction	Define research Role & value of research Form and format of a research report	Lecture (classroom, CD-ROM, e-learning)
Literature Search	Selecting a topic Differentiate types of publications (peer review, trade publications, anecdotes, with examples) Resources (library, internet, texts, or people) Search Strategies Networking	Lecture (classroom, CD-ROM, internet) Computer Lab Interactive CD-ROM Small group projects One-on-one tutorials
Understanding the research process	Study design Statistical analysis	Lecture (classroom, CD-ROM, internet) Interactive CD-ROM
Study design	Interventional vs. observational Blinding, randomization, sampling, control Sample size, power Qualitative vs. quantitative Variables: dependent, independent, confounding, validity	Lecture (classroom, CD-ROM, internet) Interactive CD-ROM

Do what you can, with what you have, where you are. - Theodore Roosevelt

#### Forum News

# Community Peer Review Task Force Report

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standards to the research and perhaps a threshold for clinical or operational significance. Also of worth would be a promulgation of a "values" statement regarding the role of corporate funding and the I independence of the investigators in addition to meeting certain regulatory and ethical standards.

#### Granting Agencies

Brainstorming possible users of such a service proved more difficult, with state and federal government agencies heading everyone's list. Suggestions included:

- NHTSA
- CDC, NIH, OSHA, NIOSH
- Various healthcare agencies
- State and federal Maternal-Child Health Bureaus
- EMS for Children
- State EMS Directors, commissions and other governing bodies
- Pharmaceutical and EMS equipment manufacturers
- AHA, American Red Cross and their international equivalents
- Managed care organizations and other payers
- Private foundations (e.g. Robert Wood Johnson

#### Foundation, Retirement Research Foundation)

- Emergency Medicine Foundation
- Schools of public health at sufficiently endowed universities
- U. S. military

#### **Development Timeline**

The only guess as to the time needed to develop such a service was "3 to 6 months". Without knowing the scope of the services provided, the number of people involved, etc. it is impossible to make a more educated estimate. It was suggested that all PCRF associates would need to provide some input before launching such an endeavor which would require a meeting, focus group, survey or some other forum. Deciding if the service was a voluntary effort or a potential revenue stream also seems relevant to this issue.

#### **Summary**

The group seems to believe that such a concept is feasible and could prove useful but whether it is desirable is yet to be determined. It will be necessary to flesh out the concept and construct alternative models in order to provide more extensive input to the Board.

### **Top Abstracts**

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submitted to our 2001 Call for Abstracts during the Presenters' Luncheon. Speaking to a full house, the presenters came from around the US to present their work. The Best Research award went to Mark Pinchalk, BS, EMT-P, Pittsburgh, Pennsylvania, for his research, "Comparison of Times to Intubate a Simulated Trauma Patient in Two Positions." June D'Agostino, EMT-P, Rochester, New York, was awarded Best Oral Presentation for her work, "Improving Prehospital Care Reports for Nontransport Encounters." The Best Poster award was presented to Jason B. Snider, MS. NREMT-P, Portland, Oregon for his submission, "Prehospital Aspirin Administration in the Suspected Myocardial Infarction."

A Conference Cexposition

June D'Agostino, EMT-P, (center) receives Best Oral Presentation for her research, "Improving Prehospital Care Reports for Nontransport Encounters." Paul Bishop (I.) and Lawrence Brown (r.) look on.

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## Abstracts

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Twenty posters on various research topics were on exhibit throughout the conference. Selected from many excellent submissions, the top research taken from the PCRF 2001 Call for Abstracts were also published in the supplement to the March issue of JEMS Magazine.

Congratulations to the winners and thank you to everyone who participated in the event.



Novice researchers compile data for a mock research project during the PCRF Demystifying Prehospital Research: Managing Data to Improve Everything You Do workshop.





Abstracts in the category of clinical, systems, management, and personnel will be presented at the 21st Annual EMS Today Conference March 18-22, 2003 in Philadelphia, Pennsylvania. Abstracts in the category of education will be presented at the National Association of EMS Educators Conference September 11-13, 2003 in Nashville, Tennessee.

# Deadline for submissions for EMS Today is October 25, 2002 Deadline for submissions for NAEMSE Is March 29, 2003

Visit www.pcrf.mednet.ucla.edu to submit electronically