The Pediatric Emergency Care Applied Research Network (PECARN): Rationale, Development, and First Steps*

The Pediatric Emergency Care Applied Research Network†

Abstract
Since its formal recognition as a medical specialty, the field of pediatric emergency medicine has made substantial advances with respect to its scope and sophistication. These advances have occurred in clinical practice as well as in the research base to improve clinical practice. There remain, however, many areas in emergency medical services for children (EMSC), in the out-of-hospital as well as the emergency department (ED) and hospital settings, that suffer from a lack of data to guide practice. In an effort to expand the quality and quantity of research in pediatric emergency care, the Pediatric Emergency Care Applied Research Network (PECARN) was created in October 2001. PECARN is the first federally funded national network for research in EMSC. PECARN is the result of Cooperative Agreement grants funded through the Health Resources and Services Administration (HRSA) with the purpose of developing an infrastructure capable of overcoming inherent barriers to pediatric EMSC research. Among these recognized barriers are low incidence rates of serious pediatric emergency events, the need for large numbers of children from varied backgrounds to achieve broadly representative study samples, lack of an infrastructure to test the efficacy of pediatric emergency care, and the need for a mechanism to translate study results into clinical practice. PECARN will serve as a national platform for collaborative research involving the continuum of care within the EMSC system, including out-of-hospital care, patient transport, ED and in-hospital care, and rehabilitation. This article describes the history of EMSC, the need for a national collaborative research network in EMSC, the organization and development of PECARN, and the work plan for the Network.

Key words: emergency medical services for children; pediatric emergency care; PECARN; research.

BACKGROUND
Systematic out-of-hospital triage and care did not broadly impact the civilian population in the United States until 1966, when a seminal treatise issued by the National Research Council identified trauma as "...the neglected disease of modern society." Its publication led to the development of modern-day emergency medical services (EMS) and the idea that patients could benefit from coordinated systems of field triage and transport. The EMS Act of 1973 provided state and local governments with the resources to implement their own EMS systems. The early years of EMS development were focused primarily on field training and hospital coordination to form regionalized networks of care. The care of children in these systems was largely integrated into adult models using principles and approaches extrapolated from adult experience with insufficient early attention to different processes, resources, or provider skill sets for children. As a result, while adult outcomes improved dramatically, similar improvements were not observed among children.

Emergency Medical Services for Children. In 1984, federal legislation (PL-98-555) was passed establishing the EMSC program under the Health Resources and Services Administration (HRSA). Over the past 18 years, the federal EMSC program has provided grants for program development in all 50 states, the District of Columbia, and six territories. In accordance with the recommendations of the 1993 Institute of Medicine report on EMSC, the programmatic priorities have focused on four areas: 1) education and training; 2) equipment and supplies; 3) regulation and funding; and 4) evaluation and research. EMSC is organized on state, regional, and local levels in order to meet the varying emergency care needs of children in their communities. It includes a wide spectrum of services ranging from prevention and out-of-hospital care to stabilization, definitive acute care, and rehabilitation.

The Need for EMSC Research. Over the past several decades, the scope and sophistication of
pediatric emergency services have expanded greatly, presenting unique challenges, needs, and opportunities for rigorous, collaborative research. Annual emergency department (ED) visits have increased from 81 million in 1988 to 102.8 million in 1999, and the rate of rise in annual ED visits is also escalating. Children account for approximately 30% of ED visits, 12% of EMS transports for injuries, and 5.5% of EMS transports for medical conditions. Despite the frequency of pediatric ED use, the impact of emergency medical care on pediatric health outcomes remains largely unexamined. There have been few attempts to measure the quality or efficacy of EMSC in spite of wide variations in training and practice. For example, emergency transport practices for children are not standardized with respect to safety requirements.

In the ED itself, management of common pediatric disorders often varies and often complies poorly with evidence-based practice guidelines. This may be due in part to gaps in knowledge about EMSC quality of care, which were identified in the 1993 Institute of Medicine report and were prioritized by a consensus panel of EMSC experts convened in 1999.

Investigations of optimal therapeutic regimens in the out-of-hospital setting have been particularly lacking, despite the fact that when they have been performed, rigorously conducted studies in this setting have altered clinical practice considerably. One example is a study showing that endotracheal intubation offers no benefit over bag-valve-mask-assisted ventilation for children with respiratory compromise in an urban out-of-hospital setting. To our knowledge, this is the only published randomized controlled trial of a major clinical intervention for children in this environment. Additional examples of important issues for EMSC research in the out-of-hospital setting include the role of out-of-hospital fluid resuscitation and the provision of advanced life support for injured children in the field. These and other important questions about EMSC care can be studied only with rigorous multicenter participation.

Barriers to Research. Despite the need to expand research in EMSC, there are several barriers limiting the ability to conduct valid and generalizable studies. First, serious adverse outcomes are uncommon in pediatrics, limiting the opportunities for patient enrollment, particularly in a single institution or a small group of institutions. In a recent, multicenter study of children with diabetic ketoacidosis, for example, only 61 cases of cerebral edema were identified, despite a 15-year study period at ten major pediatric centers. Similar limitations were experienced in a recent large study involving decision rules for computed tomography (CT) scanning of the brain in mild-to-moderate head injury. Despite the prospective enrollment of 1,044 children from four hospital EDs, and 83 (7.9%) “positive” CT scans, fewer than 1% of children with minor head injury required neurosurgical intervention. Because of the small numbers of children with serious adverse outcomes, a clinical decision rule developed from these data will likely suffer from the data demonstrating unacceptably wide confidence intervals.

Second, EMSC research is typically conducted in tertiary care centers or in EDs with strong pediatric staffing. Such facilities, however, care for a minority of children in the United States. Only 9.4% of EDs are located in specialty pediatric hospitals and most pediatric ED visits occur in nonpediatric specialty hospitals. Therefore, to ensure generalizable results, a research program in EMSC must include patients treated in nonpediatric specialty hospitals.

Third, informed consent for research is difficult to obtain in the setting of life-threatening emergencies. True informed consent is unlikely in an emergency situation and is especially difficult for clinical trials. Historical approaches to this problem have included a brief scripted summary of the study with delayed full consent, or randomization by odd–even medical record number or day of the month without a consent process. Clarification of federal regulations, published in 1996, made the requirements for emergency research more stringent, but nonetheless allow a waiver of informed consent in certain emergency circumstances. Studies implementing the use of the waiver must involve the community in early consultation and dialogue prior to study initiation. Study investigators must keep the community abreast of progress and results. Therefore, an effective research program in EMSC will require substantial input from the communities involved.

Other important barriers to research in EMSC include:

- Difficulty in tracking patients along the continuum of out-of-hospital to hospital care. There is often limited documentation of EMS providers’ field assessments, inconsistent patient identifiers used in out-of-hospital and hospital records, and an absence of a central repository for patient information. As a result, there are lapses in exchange of vital patient information between out-of-hospital and hospital providers.
- Difficulty in maintaining data quality, integrity, and consistency. Emergency personnel must attend to patient needs under hurried and stressful circumstances. Legibility, accuracy, and comprehensiveness of data collection are problematic and data gathering must be planned to minimize burdens on the practitioner.
- The need for an increased number of research studies focused on improving EMSC care and services and the lack of consistent, significant funding for EMSC research.
• The need to recruit and enroll sufficiently diverse patient populations. Results of studies should ideally be applicable across broad groups of patients and therefore participation in research protocols must be sufficiently representative.

• The need for severity adjustment. Intervenational trials or observational studies of patient health outcomes must control for baseline differences in severity of illness. A general severity of illness measurement tool, that is applicable to both traumatic and medical conditions, is required.31,32

• The need to develop methodologically sound outcomes measures in order to identify the effectiveness of EMS interventions.33

• Translating science into practice. There has been no significant infrastructure to facilitate translation of evidence-based knowledge into EMSC practice.

CONCEPTION AND DEVELOPMENT OF PECARN

Conception of PECARN. The barriers noted above led to national discussions in which PECARN was conceived. In 1998 and 1999, EMSC organizational leadership and the Ambulatory Pediatric Association (APA) held two sequential meetings, collectively called the “APA-EMSC Partnership for Children Workgroup Meetings to Address Barriers to Research in Pediatric Emergency Medicine (PEM).” This consortium of PEM/EMSC investigators, health service researchers, and administrators raised the various issues noted above and concluded that one of the most serious barriers to PEM research was the lack of a well-supported infrastructure to conduct multicenter collaborative studies.34

Precedents for a Collaborative Network. There are several examples of productive pediatric collaborative research networks in the United States as well as abroad.35–37 Other pediatric specialties, experiencing similar barriers to research as those identified for EMSC, have created successful multicenter research infrastructure networks. These networks include: a) The Vermont Oxford Network, founded in 1988 as a collaboration of neonatal health care providers, which has grown to involve more than 270 neonatal intensive care units38,39; b) The Pediatric Research in Office Settings (PROS) Network, sanctioned by the American Academy of Pediatrics (AAP) in the 1980s to promote collaborative pediatric practice research, now including more than 470 practices40; and c) The Children’s Oncology Group, established in March 2000, which is a clinical trials cooperative group supported by the National Cancer Institute. Although different in nature, setting, and scope, these collaborative pediatric research networks have successfully conducted and published important studies made possible by federal and private funding of their infrastructures. The general objectives of these networks are broadly applicable to those of a PEM/EMSC research network: to study the process, effectiveness, and costs of medical care of children, and to disseminate the results to the appropriate provider groups.

Within general EM, a few multicenter networks have been created to study disease-specific entities. The Emergency ID Net is an ED-based network dedicated to reporting and studying emerging infectious diseases.41 The MARC collaborative group performs multicenter studies pertaining to respiratory illnesses.42 Notable disease-specific collaborative research in the ED has addressed out-of-hospital airway management of children requiring bag-valve-mask ventilation16 and methods for ruling out cervical spine injuries.43

Within the academic PEM community, there exists a framework for a collaborative research network. The Section on EM of the AAP created the PEM Collaborative Research Committee (PEM CRC) in the 1990s to support and facilitate collaborative PEM research. Although the limited infrastructure of the PEM CRC is not funded, it has provided a platform for the conduct of several important collaborative research projects.23,44–46 With the exception of the PEM CRC, however, there are no collaborative research networks dedicated to PEM/EMSC.

Development of PECARN. In June 2001, the HRSA, Maternal and Child Health Bureau (MCHB), invited proposals from established clinical investigators to participate in the cooperative agreements with the HRSA/MCHB to establish the EMSC Network Development Demonstration Projects (NDDP). The purpose of the EMSC NDDP is to “demonstrate the value of an infrastructure or network designed to be the platform from which to conduct investigations on the efficacy of treatments, transport, and care responses, including those preceding the arrival of children to the hospital” (HRSA/MCHB Guidance for Cooperative Agreements for EMSC NDDP).47 Pursuant to the Public Health Service initiative “Healthy People 2010,” which is a statement of national priorities developed by the Department of Health and Human Services, the EMSC NDDP is designed to address the issues of injury and violence prevention, access to quality health services, and, in particular, the need for public health infrastructure for EMSC-related research. The EMSC NDDP-supported network is designed to eliminate barriers currently limiting progress in establishing EMSC “best practice” guidelines and improve and measure the quality of EMSC care.

STRUCTURE OF PECARN

The NDDP is charged with promoting high-quality, high-priority, and diverse research in EMSC, with a focus on forming collaborative research partnerships
among various academic and community-based hospitals. The network currently consists of four regional node centers (RNCs), located at diverse sites across the country and collectively organized in accordance with the federal guidance as the Pediatric Emergency Care Applied Research Network (PECARN).

Each RNC has entered into a cooperative agreement with HRSA/MCHB to engage in collaborative clinical research. In order to develop its own infrastructure, each RNC hosts a regional network of Hospital Emergency Department Affiliates (HEDAs) for a total of 25 sites across the United States, including the RNC itself. The HEDAs have agreed to participate in observational studies and controlled trials to be conducted either regionally as pilot studies or as part of the national PECARN. The Central Data Management and Coordinating Center (CDMCC), based at the University of Utah, will manage data generated from the network under a cooperative agreement with MCHB. The CDMCC will provide a central repository for data generated by the PECARN research projects. The CDMCC also will work with the entire network to implement standards for data collection and analysis in order to ensure uniformity and quality of the data, and provide safety and regulatory guidance to ensure the timely progress of PECARN studies.

PECARN is overseen by a steering committee, with equal representation from each of the nodes and with membership from the CDMCC, acting as the primary governing body. PECARN has bylaws that outline its purpose, structure, membership, policies and procedures, and code of ethics. The PECARN steering committee has responsibility for reviewing and approving specific PECARN research proposals, as well as formulating and monitoring policies and procedures guiding the research activities of the Network (Figure 1).

**PECARN Subcommittees.** The PECARN subcommittees were established by the PECARN Steering Committee to carry out specific PECARN-related tasks and are advisory to the Steering Committee.

- **Protocol Concept Review and Development Subcommittee (PCRADS):** Reviews and makes recommendations regarding specific research concept(s) and protocol(s) for the PECARN network.
- **Safety and Regulatory Affairs Subcommittee (SRAS):** Assists the principal investigators (PIs) and the Steering Committee to ensure compliance with all institutional, local, state, and federal government regulatory laws, guidelines, and policies. One of the main responsibilities of this committee is to assist with network-wide institutional review board (IRB) proposal preparations and submissions.
- **Quality Assurance Subcommittee (QAS):** Ensures research protocol design, development, and implementation are in compliance with standards for protection of human subjects, rigorous research practices, and accurate and consistent data collection.
- **Data Analysis and Management Subcommittee (DAMS):** Assures the quality of data management activities, facilitates the exchange of information with investigators on matters related to the design.

**Figure 1.** The Pediatric Emergency Care Applied Research Network (PECARN) organizational structure. CDMCC = Central Data Management and Coordinating Center; ACORN Node = University of California–Davis Medical Center; CARN Node = Children’s National Medical Center, Washington, DC; PedNet Node = Columbia University/Harlem Hospital Center; Great Lakes Node = University of Michigan; HRSA/MCHB/EMSC = Health Resources and Services Administration/Maternal and Child Health Bureau; Emergency Medical Services for Children.
and operation of data acquisition systems, and helps to develop and monitor processes involving statistical analysis and reporting of results.

- **Grant Writing and Publication Subcommittee (GWAPS):** Assists PIs in developing, and offers critique of, research grant applications submitted for external funding. This subcommittee also reviews research documents for presentation and publications, and reviews, facilitates, and ensures timely submission and dissemination of research results to scientific and nonscientific communities. Finally, the GWAPS is charged with creating an authorship plan and authorship agreements, reviewing authorship of manuscripts and ensuring equitable participation and attribution.

The subcommittee members are made up of both votingPECARN members and nonvoting HEDA representatives. There is equal nodal representation on all the PECARN subcommittees. These subcommittees serve as working groups of the Steering Committee, with membership based on experience, interest, and expertise. The five subcommittees work in an integrated fashion to facilitate the conduct of PECARN research.

Within the PECARN Subcommittees there are substantial expertise and senior level participation. Overall, Subcommittee participants of PECARN include 17 chairs, directors, or chiefs of emergency medicine or pediatric emergency medicine, and 19 directors or chiefs in a variety of areas, including research and research centers, trauma, intensive care, and residency programs. The PECARN subcommittee expertise extends over the entire spectrum of EMSC research and related areas, including out-of-hospital EMS transport, safety, alcohol and drug-related injuries, psychiatric emergencies, rural ED issues, clinical decision rules, cost-effectiveness, medical education, special needs children, disaster preparedness, and intensive care practices. Many subcommittee members also serve on an array of scientific, clinical practice, research operations, community advisory, bioethics, biostatistics, and National Institutes of Health (NIH) grant review committees and panels. In addition, many subcommittee members contribute to the professional association boards of PEM, AAP, APA, the American College of Emergency Physicians (ACEP), and the editorial boards of major pediatric, emergency, and PEM journals.

**PECARN Nodal Investigator.** The hospitals participating in PECARN serve a large and diverse population across the country in urban, suburban, and rural locations. These hospitals provide differing levels of care and services that are representative of EMSC across the United States. Additionally, across the country, EMSC is delivered in different physical settings and institutional organizations, and this is reflected in the disparate settings of PECARN HEDAs. For these reasons, the research findings from PECARN will be generalizable to the many sites and settings across our country that provide EMSC.

A detailed resource survey was completed by each HEDA to define the EDs and their patient populations. The 25-site PECARN network annually treats 808,454 patients, up to 21 years of age. Participating hospitals are diverse in organization, location, range of services offered, and university affiliations. The racial composition of the patients served is likewise diverse, with 46.6% African American, 43.3% white, 1.6% Asian or Pacific Islander, 0.6% Native American or Alaskan Native, and 7.6% unknown. Nine percent are of Hispanic ethnicity (a category separate and distinct from race). Approximately 48% of patients have some form of government insurance, 39% have private insurance, and 11% are self-pay.

The organization of the 25 participating hospitals and their geographic locations are diverse as well. These hospitals serve urban, suburban, and rural patients. All are nonprofit and include a variety of academic, community, general, and freestanding children’s hospitals (the latter designation includes approximately a third of the HEDAs). Of the 25 hospitals, 17 are Level 1 trauma/pediatric centers, 20 have pediatric intensive care units that treat 22,546 patients annually, and 22 have neonatal intensive care units that treat 31,390 patients annually. The ED practice environments of the participating HEDAs also represent those found across the United States. Seventeen are physically distinct pediatric EDs, five have a pediatric area within a general ED, and three are general EDs without separate pediatric facilities. Most of these hospitals have university affiliations, and PEM is typically situated in divisions of pediatrics or emergency medicine. Many of these institutions also have training programs that include emergency medicine and pediatric residencies, pediatric emergency medicine fellowships, and physician assistant (PA), nursing, emergency medical technician (EMT) and EMT-P training programs.

**Anticipated Work Flow/Protocol Review Process.** PECARN nodal investigators or outside investigators prepare draft research proposals and submit them to the Concept/Protocol Review Subcommittee (PCRADS). PCRADS reviews the proposals for their scientific quality and their appropriateness for implementation in the PECARN network and provides the Steering Committee with recommendations. The proposals are then reviewed and voted on by the Steering Committee. Those proposals that receive Steering Committee approval are then developed into robust proposals by the investigator(s) and simultaneously submitted to the four other subcommittees (Safety, Quality, Data Analysis, Grants and Publications). These subcommittees review, critique, offer technical
advice, and recommend changes to the protocols. The investigator makes the recommended revisions to the protocols and submits the amended protocols to the Steering Committee for final review and approval. Once approved by the Steering Committee, the nodal lead investigators and their teams submit the approved research protocol to federal or nonfederal agencies for funding. When funding is secured, the research protocols will be implemented.

**FIRST STEPS**

HRSA/MCHB funding for the EMSC NDDP cooperative agreement is intended to support the initial development of PECARN research infrastructure, including startup hardware and administrative costs as well as the production of nodal research proposals. Funding to implement the proposals approved by the PECARN Steering Committee will be sought extramurally through other government, foundation, or alternate private funding sources.

To initiate the research process, the PECARN Steering Committee required two pre-proposal submissions from each of the Regional Nodes, each of which were expected to be broadly relevant to published EMSC research agendas\textsuperscript{6,15,48} and to have the potential for widespread impact on a national level. The PCRADS members reviewed the pre-proposals according to standardized review criteria and assigned specific criteria scores as well as overall scores. After reviewing the recommendations of the PCRADS, the Steering Committee organized the pre-proposals into two categories. The first category consisted of proposals that could be implemented in PECARN using existing PECARN resources. The second category consisted of proposals that would need extramural funding to be implemented. The Committee recommended that two proposals, both that sought to characterize the populations served by participating PECARN hospitals through the collection of ED-based epidemiological surveillance data, be combined as the first project implemented using existing PECARN resources. The combined proposals became the “PECARN Core Data Project.” This project will establish and test an ED-based data collection and surveillance system by determining the number and characteristics of all visits to participating sites and identifying core data elements through existing electronic databases and chart review. This study will develop an infrastructure to collect, manage, and transfer data, measure agreement between electronic and medical records data, and map these data using Geographical Information Systems (GIS) software, designed to create geographical maps of disease/injury incidence. Two other proposals were approved for development into extramural funding proposals: 1) “Clinical Decision Rules for Identifying Children at Low and High Risk for Traumatic Brain Injuries after Mild Blunt Head Trauma” is a protocol designed to develop and validate a clinical decision rule for performing head CT in children with minor head injury. 2) “Use of Ultrasonography to Evaluate Pediatric Blunt Abdominal Trauma” is a protocol aimed at determining the sensitivity and specificity of ED-based ultrasonography to detect intra-abdominal injury in children.

**FUTURE GOALS OF THE NETWORK**

PECARN has been established by the EMSC-NDDP to achieve the following goals by the end of its initial three-year funding period:

1. To establish a well-conceived and fully operational infrastructure to conduct clinical trials and observational studies on EMSC priority topics, using rigorous study designs and methodologies;
2. To develop a consensus-derived and well-informed research agenda used to guide the network activities;
3. To institute a research and development process within the network to develop proposals and carry out fully developed investigations with the help of MCHB or other federal agencies;
4. To design and implement a plan to study and encourage the transfer of network findings to EMSC practices; and
5. To foster a collaboration of EMSC personnel, nurses, practitioners, and researchers in order to provide opportunities for bidirectional education and exchange of ideas and information between the treatment and academic communities.

One of the goals of the network is to expand on the current initial infrastructure to include additional HEDAs and outside specialists and consultants. Ultimately, our aim is to establish and maintain a cohesive consortium of clinical researchers to produce a volume of high-quality studies in the area of EMSC.

**LONG-TERM SUSTAINABILITY**

Following PECARN’s initial three-year funding period, the original NDDP awardees will have the opportunity to apply for an additional year of funding. The NDDP will also consider funding two additional nodes (for a total of six) through a competitive grant process. PECARN plans to continue to implement network-wide research that increases and expands its scope, and its ability to promote evidence-based EMSC practices. PECARN will continue to receive infrastructure funding from HRSA/MCHB, pending availability of funds, and seek extramural funding for PECARN research projects. In this way, capabilities will be expanded and partnerships developed as this national research network matures and evolves.
External Participation with PECARN. Recognizing the broad EMSC expertise available beyond the PECARN nodes, the network is open to all investigators, regardless of affiliation with PECARN in general or a specific PECARN node. Investigators interested in using the PECARN structure may submit pre-proposals for PECARN consideration through two mechanisms: 1) they may submit the proposal to one of the PECARN nodes by contacting the node PI directly; or 2) they may submit the proposal directly to PECARN through the PECARN Steering Committee Chair (currently Nathan Kuppermann), who will direct the investigator to the most appropriate PECARN node for project development and collaboration. Individual investigators otherwise unaffiliated with PECARN who submit proposals that are endorsed by PECARN will be admitted to PECARN as associate members and maintain lead management for their proposal as appropriate. Additionally, PECARN members will solicit participation from recognized experts, as appropriate, to contribute to various research proposals.

CONCLUSIONS
Historically, there have been several barriers to effective EMSC research. These include the infrequency of certain pediatric diseases and adverse events in children, the need to include diverse patient populations, the difficulty of obtaining informed consent in emergency settings, and the need for an infrastructure to conduct multicenter research and translate research findings into clinical practice. The PECARN network was established by EMSC/MCHB to address many of these barriers. The conceptual model developed by PECARN capitalizes on the unique research resources of multiple EDs serving the emergency care needs of a broad diversity of children. This network has great potential to conduct meaningful research with the goal of improving the practices and outcomes of EMSC.

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References


