

The Pediatric Emergency Care Applied Research Network

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Children account for an estimated 25 million of the total ED visits in the United States each year.¹ Although substantial progress has been made in the education of health care providers concerning the provision of emergency care for children, clinical research in this area has been limited. Despite a general awareness of the importance of pediatric research, pediatric emergency care providers continue to have insufficient research data to guide clinical practice. In particular, studies in prehospital care are lacking. Many common practices used in caring for children have not been studied extensively or standardized.² Children who become critically ill or injured often are admitted to hospitals lacking pediatric resources and expertise, thus making the availability of established clinical guidelines essential.³ Furthermore, research outcomes and clinical protocols in adult medicine often are extrapolated and applied to children despite significant physiologic differences between children and adults; this is especially true in drug development.^{4,5} Researchers in pediatrics must overcome these obstacles by increasing the number of large multicenter research investigations to provide evidence-based pediatric guidelines. The purpose of this article is to describe pediatric emergency care research needs, challenges, and a federally funded program established to respond to these needs—the Pediatric Emergency Care Applied Research Network (PECARN).

Research needs

PEDIATRIC CLINICAL DRUG TRIALS

One of the most critical areas in need of research and standardized clinical guidelines is pediatric drug administration. Many ED nurses might assume that medications

used in the emergency department have been thoroughly researched for use with children. In reality, approximately 75% to 80% of medications approved by the Food and Drug Administration (FDA) have never been approved or labeled for pediatric use.^{4,6} In addition, more than half of newly approved drugs that are used for children are not adequately tested or labeled for pediatric patients.⁵ Thus, emergency physicians are faced with the dilemma of prescribing "off label" drugs with inadequate information and limited product labeling relating to pediatrics. Furthermore, published dosing guidelines for children often are simply scaled down from adult models without thorough research.⁷ Lack of pediatric pharmacologic information potentially exposes children to inadequate dosing, inappropriate use of medications, and possibly life-threatening situations.⁸

Recognizing the difficulties inherent in pediatric clinical trials, federal legislation has been established giving the FDA authority to require pediatric studies of certain drugs and biologic products.⁹ Pharmaceutical companies now have an economic incentive to conduct pediatric research. As a result, the number of pediatric drug studies and subsequent changes in labeling and dosing for common medications used in children have increased dramatically. While recent legislative initiatives have resulted in changes, large gaps in pediatric drug research still exist, along with a notable lack of large-scale, multicenter pediatric clinical drug trials.

EMERGENCY NURSING RESEARCH

Research by nurses in pediatric emergency care settings is evolving; however, investigations and published findings continue to be relatively few.¹⁰ A recent survey of emergency nurses in the PECARN sites revealed that nurses are interested in pediatric research but cite limited experience and research resources, lack of dedicated time, and limited recognition for research contributions as barriers.¹¹ In addition, the opportunities for involvement in research are limited. The unpredictable and acute nature of the emergency department presents difficulties in data collection because of limited staffing and patients' needs. ED nurses have also cited workload and lack of recognition as significant obstacles.¹²

Challenges to conducting research

Randomized controlled trials are considered especially valuable because of their scientific rigor but rarely are used in

pediatric emergency care research because of many inherent difficulties. Conducting research in an emergency department can be a challenge for even the most devoted research team. The often uncontrolled and chaotic ED environment coupled with unpredictable patient load, high acuity, and busy staff does not provide ideal conditions for conducting clinical research. The relatively low incidence of pediatric acute events makes it difficult to obtain representative samples in a single institution.²

Generalizability of research findings is also a challenge. Pediatric emergency research often takes place in large tertiary care centers, yet most children receive care in non-pediatric hospitals.³ Treatment outcomes and research results from large centers may not be applicable to smaller, non-pediatric facilities. Differences between urban and rural pediatric populations may further limit generalizability of findings. For example, study results involving asthma in inner-city children might not be applicable to a rural population. Obtaining research samples representing diverse ethnicities, ages, geographic locations, and other key socio-demographic factors improve the likelihood that research findings can be broadly applied to different pediatric emergency settings.

Finally, there is scant evidence that documents the translation of research findings into clinical practice.² Furthermore, estimates are that it may take as long as 2 decades to integrate research findings into clinical decision making. Large multicenter studies in pediatric emergency settings may hasten the process of moving research findings into standard clinical practice.

The PECARN

One goal of the Health Resources and Services Administration (HRSA) Emergency Medical Services for Children (EMSC) program, established in 1984, is increasing research in pediatric emergency care. The current EMSC 5-year strategic plan calls for promoting and strengthening pediatric EMS research and evaluation.¹³ Research priorities identified by the Institute of Medicine's EMSC report and a previous EMSC Research Consensus Conference emphasizing the importance of conducting large multicenter research studies in pediatric emergency care^{4,14} provided the impetus for establishing the PECARN. Established

TABLE 1
Original PECARN hospital ED sites

Hospital	Location
Morristown Memorial Hospital	Morristown, NJ
Bellevue Hospital Center	New York, NY
Newark Beth Israel Medical Center	Newark, NJ
Children's Hospital of Buffalo	Buffalo, NY
Children's Hospital of Michigan	Detroit, MI
Children's Hospital of New York Presbyterian (Nodal Center)	New York, NY
Children's Hospital of Philadelphia	Philadelphia, PA
Children's National Medical Center (Nodal Center)	Washington, DC
Cincinnati Children's Hospital Medical Center	Cincinnati, OH
DeVos Children's Hospital/Spectrum Health	Grand Rapids, MI
Harlem Hospital Center	New York, NY
Hurley Medical Center	Flint, MI
Johns Hopkins Children's Center	Baltimore, MD
Medical College of Wisconsin and Children's Hospital of Wisconsin	Milwaukee, WI
Primary Children's Medical Center	Salt Lake City, UT
University of California Davis Medical Center (Nodal Center)	Sacramento, CA
University of Michigan (Nodal Center)	Ann Arbor, MI
University of Maryland	Baltimore, MD
Upstate Medical University	Syracuse, NY
University of Rochester Medical Center	Rochester, NY
Washington University	St. Louis, MO
Marquette General Hospital	Marquette, MI
Chicago Memorial Hospital	Chicago, IL
Children's Hospital Boston	Boston, MA
Holy Cross General Hospital	Silver Spring, MD
Howard County General Hospital	Columbia, MD
Central Data Management & Coordinating Center—University of Utah	Salt Lake City, UT

with federal funding in 2001, this newly formed research affiliation is conducting studies in emergency departments nationwide to address some of the deficiencies in pediatric emergency research.

The goal of the PECARN is to conduct meaningful and rigorous multi-institutional research into the prevention and management of acute illnesses and injuries in children. The scope of research includes out-of-hospital care, patient transport, ED and in-hospital care, and rehabilitation. The PECARN currently consists of a data center, 4 coordinating Research Node Centers, and 21 Hospital Emergency Department Affiliates (HEDA) that represent academic, community, and urban hospitals. Cooperative agreements from the HRSA, Maternal and Child Health

Bureau, EMSC program were awarded competitively to the principal investigators of the 4 Research Nodes and the data coordinating center. Node centers provide coordination and oversight for ongoing studies. The original institutions participating in the PECARN consist of both general and freestanding children's hospitals (Table 1). There are 20 trauma centers, and at least 15 hospitals have pediatric ICUs. Each hospital has an identified lead principal investigator (PI) and at least one research assistant (RA). These hospitals provide differing levels of care and services that are generally representative of pediatric emergency care across the United States. The network sites serve approximately 800,000 acutely ill and injured children annually.

In its first 3 years of operation, the PECARN has successfully initiated multiple research studies in participating network emergency departments. Research investigations generally are submitted to network subcommittees by a PECARN HEDA investigator but can be initiated by a researcher outside the network. Projects are subject to internal review and, once approved and funded, are implemented at appropriate network sites. Some studies are funded by research grants that supplement network infrastructure funding. Training sessions for participating RAs, nurses, and investigators occur at quarterly grant-funded network meetings. A PI at each site is responsible for working with the ED physicians, nurses, and other staff to implement specific studies. Depending on the study protocol, data may be collected by the PECARN RA, the PI, or ED staff. Emergency nurses have been valuable to completion of network studies by assisting with patient enrollment, conducting clinical assessments, and working with families participating in the research projects. The PECARN offers opportunities for all ED staff to participate actively and collaboratively in contemporary pediatric research.

PECARN INVESTIGATIONS

Several clinical trials and other research studies are ongoing within the network. Epidemiologic surveillance data are needed to analyze problematic areas in pediatric emergency care. The PECARN Core Data Project is an observational descriptive study that identifies epidemiologic information about ED patient visits at the PECARN sites. These data provide valuable information for hypothesis generation and study design development.

Effectiveness of Oral Dexamethasone for Acute Bronchiolitis: A Multicenter Randomized Controlled Trial studies bronchiolitis, a common serious illness of childhood that lacks evidence-based treatment. This study compares a single dose of oral dexamethasone to a placebo in a multicenter, randomized, double-blind trial, with a primary outcome of hospital admission. The network has enrolled several hundred patients during the past 3 winters. Enrollment was completed in April 2006. ED nurses participated in this study by identifying potential study participants, documenting vital signs, and administering medication.

Another PECARN study, Predicting Cervical Spine Injury in Children: A Multi-Center Case-Control Analysis, is a retrospective case-control study of several hundred

children that describes cervical spine injuries and identifies factors associated with increased risk for these injuries in the pediatric blunt trauma population. Data collection began in 2005.

The overall purpose of the Childhood Head Trauma: A Neuroimaging Decision Rule study is to develop a clinical decision rule for appropriate neuroimaging of children after minor to moderate head trauma. The goal is to create a decision rule that identifies those children in need of emergent imaging (computed tomography scan) and treatment, while reducing the use of head computed tomography scans in children with a minimal risk of brain injuries. This study is a prospective multicenter observational study of thousands of children younger than 18 years with blunt head trauma. Data collection was completed in spring 2006. Emergency nurses assisted with patient identification; enrollment and data collection were done by emergency physicians.

The Lorazepam Study is funded by the National Institutes of Health under the Best Pharmaceuticals for Children Act to study the safety and efficacy of lorazepam for the treatment of pediatric status epilepticus. Approximately 50 patients have been enrolled in this clinical trial. Pharmacokinetic data collection is in progress. The pharmacokinetic study will be completed by the summer of 2006, and the efficacy trial will begin shortly thereafter.

Recent randomized controlled trials in adult populations have reported improved neurologic outcome and survival in patients who received short-term mild hypothermia following out-of-hospital ventricular fibrillation arrest. The efficacy of hypothermia in children following cardiac arrest is not known. In the pilot study, Hypothermia for Pediatric Cardiac Arrest Planning Grant, 15 children's hospitals with ICUs collected data from the medical records of patients who sustained a cardiac arrest with return of spontaneous circulation. This information will be used for planning a future randomized clinical trial of hypothermia following pediatric arrest. Data collection for the pilot was completed in summer 2005. Nurses collected patient data from medical records.

Conclusion

The PECARN is a unique, collaborative network consisting of experienced pediatric investigators and RAs conducting

much needed pediatric emergency care research. Emergency nurses at participating centers have an opportunity to become involved in research by assisting with and initiating research activities. Prospective researchers may collaborate with the PECARN to conduct essential research investigations. The PECARN research is poised to make a significant impact in clinical practice and patient outcomes through its research efforts. Emergency departments and patients outside of the PECARN will benefit from study results and use of the evidence-based findings. This network has demonstrated rapid success, and there is reason to be optimistic that the PECARN can make a substantial impact on emergency care for ill and injured children.

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