INTRODUCTION

For the past several decades, most prehospital research has been conducted with adult participants, largely because it is less difficult to access and study the adult patient population. However, decades of research focusing only on adults have left gaps in critical treatment information for children, which is disturbing because approximately 5% to 10% of EMS calls are for children. Pediatric emergency care is a relatively young field; as recently as the late 1970s, there were no pediatric emergency medicine textbooks or journals. In addition, although the quantity of research conducted in pediatric emergency care has increased considerably over the past 25 years, there is still little evidence on which to base the prehospital treatments for children. Gaps in knowledge include such basic information as developing the EMS system to include consideration for pediatric patient care. Further, many of the treatments and management strategies practiced by EMS providers today are not supported by scientific evidence. The lack of adequate data and limited research funding are among the most serious barriers to the advancement of research in pediatric emergency care.

Despite an increase in the amount of pediatric emergency care research in the past two decades, a corresponding increase in research to guide optimal prehospital treatment of children for most conditions remains scarce. The reasons for this deficiency are numerous. One obvious issue is that conducting pediatric prehospital research involves navigating both the barriers imposed by conducting prehospital research as well as those obstacles related to conducting pediatric research. This chapter will discuss issues unique to conducting pediatric prehospital research.

THE NEED FOR PEDIATRIC PREHOSPITAL CARE RESEARCH

Children represent one fourth of the U.S. population, which translates to more than 73 million infants, toddlers, school-aged children, and adolescents. Furthermore, each age group has very different emergency care needs. For example, the Ontario Prehospital Advanced Life Support (OPALS) study group found that pediatric cardiopulmonary arrest patients were more likely to have unwitnessed cardiac arrests and receive no bystander CPR. The most common arrest etiologies reported were trauma, sudden infant death syndrome (SIDS), and respiratory disease. Studies such as OPALS provide important information about pediatric patient demographics and the epidemiology of the illnesses and injuries encountered by EMS providers, which is essential to the design and conduct of more in-depth pediatric prehospital care research. Although some of this preliminary research has been done, basic questions still remain. For example, the age distribution of patients treated by EMS, their typical illnesses and injuries, and preexisting medical problems are poorly understood. This type of descriptive research could...
assist in designing prehospital systems and could also provide baseline data for future analyses by allowing researchers to determine areas of potential study, feasibility of the study within a system, and study planning information such as sample size calculation data.

 STATUS OF PEDIATRIC PREHOSPITAL RESEARCH

The Institute of Medicine’s (IOM) comprehensive report developed by the Committee on the Future of Emergency Care—“Emergency Care for Children: Growing Pains”—and published in 2006 focused on how pediatric emergency services are (and are not) integrated into the healthcare system. Among issues discussed were those of emergency care planning, preparedness coordination, funding for pediatric emergency care, training of pediatric emergency care professionals, unique characteristics and needs of pediatric populations, and pediatric emergency care research. The report indicated that, although some progress has been made since the first IOM report on EMS for children was published in 1993, there is still a long way to go to improve the accessibility, quality, and cost of emergency care for children in this country. From the development of the National EMS Research Agenda in 2001 to the publication of the National EMS Research Strategic Plan in 2005, there has been an exponential increase in prehospital research, yet there is still little research that has been conducted on the prehospital care of children. The 2006 IOM report characterizes the state of pediatric emergency care as a multifaceted crisis, affecting all aspects of emergency care. To drive continued improvements in care, the report asserts that pediatric prehospital care research must become a priority.

It is important to note the progress made by the relatively recent development of some federally funded research networks with the mission of conducting high-quality multicenter collaborative research throughout the United States. One is the Pediatric Emergency Care Applied Research Network (PECARN), initially funded in 2001; the other network is the National Institutes of Health (NIH)—funded Resuscitation Outcomes Consortium (ROC). Although these networks can potentially conduct pediatric prehospital research, little has emerged to date.

 CHALLENGES FOR PEDIATRIC PREHOSPITAL RESEARCHERS

Many challenges must be overcome when conducting pediatric prehospital research. Many of these are similar to those barriers encountered when conducting general prehospital research and have been covered in other chapters. In addition to these, however, the research population itself presents some unique challenges. These include defining a “pediatric” patient, the limited numbers of pediatric patients seen by a typical EMS agency, and the different ethical standards to which pediatric research is held. Specifically, compared to adult studies it can be more difficult to recruit pediatric research participants, to obtain community support for exception from informed consent, and to obtain assent from parents/guardians.

Defining the “Pediatric” Patient Population

A clear definition of the age groups under investigation is critical for anyone conducting quality pediatric prehospital research. One must be clear on how the term “pediatric” or “child” will be defined. Whereas the legal definition of a minor in the United States is a person younger than 18 years of age, the definition of “adult” versus “child” can be highly variable in both the hospital and prehospital setting. Chapter 26 (“Prehospital Trauma Research”) notes that, although most prospective prehospital trauma studies limit inclusion to adult patients, the definition of “adult” can vary from individuals 15 and older up to those aged 18 years and older. “Growing Pains” cites data for children as those younger than age 19 years. The Centers for Disease Control and Prevention (CDC) statistics, hospitals, and others often use data in which children are considered “adult” at age 15, 14, or even at 13. However, the federal Emergency Medical Services for Children (EMSC) program defines “children” as ages 0 through 21 years, in accord with the American Board of Pediatrics, which defines the field of pediatrics as encompassing patients 0 through 21 years of age. There is no common age-based definition of pediatric, which hinders researchers’ ability to compare findings across studies. It is therefore important for the prehospital researcher to very clearly define the study population. The upper age range for pediatrics is the source of most debates over inclusion criteria. Although heterogeneity in age may confound...
a study’s findings due to anatomic, physiologic, and developmental differences, it is important to note that postpubertal patients between 15 and 20 years of age are anatomically and physiologically similar.

It may be even more important for an investigator to recognize that as a child matures toward mid-adolescence, he or she undergoes many developmental, anatomical, and physiological changes. Therefore, studies must often be stratified by age so that developmental differences do not bias the study results. Also, if there is sufficient sample size, a multivariate analysis could be conducted with age included in the model as a continuous variable. The box shows some commonly used age ranges for stratifying data.

**Sample Size**

When planning for a randomized controlled trial, population-based, or other pediatric study, the researcher must recognize that no single hospital or EMS agency is likely to have access to sample sizes large enough to answer important questions about critically ill or injured children. The few existing studies on pediatric EMS demographics have shown that these patients account for approximately 10% of EMS call volumes, of whom only 10% to 20% actually have a critical complaint. This presents researchers with a problem in obtaining a sample size sufficiently large to conduct a meaningful study. This challenge is not unique to pediatric prehospital research, however, because it occurs in most pediatric research. One solution is the use of research networks; when researchers from different institutions pool data, these challenges are successfully met. The large number of patients included in the networks allows researchers to carry out trials designed to evaluate rare conditions or complications. The problem is that solutions such as multisite research or establishing collaborative research networks are challenging in any environment but even more so in prehospital research. Although pediatric emergency medicine networks do exist, true pediatric prehospital research collaborative groups do not. Therefore, there is really no mechanism to support the multisite research needed to achieve the numbers required for a research study. As a result, researchers frequently must establish their own multisite collaborative networks.

Because the accessible sample for pediatric research is limited, it is imperative that, whenever possible, pediatric prehospital researchers use standard definition sets and variables. This will permit combination of data sets and allow meta-analyses to be conducted. One data definition standard that could be used for pediatric prehospital research is the Pediatric Utstein Style. This consensus document is an attempt to provide an organized method of reporting pediatric ALS data in the out-of-hospital, emergency department, and in-hospital settings. Further work is needed to establish broader data definition standards for pediatric EMS research.

**Institutional Review Board Approval**

Other chapters have covered the issue of obtaining Institutional Review Board (IRB) approval and the unique obstacles faced by prehospital researchers. Ethical issues regarding pediatric patients can be even more controversial and challenging. For example, a child younger than 18 years of age cannot legally give consent as a research participant; the child must give his or her assent to participate and have a parent or guardian provide consent. Further, when children are research participants, IRB members may be more hesitant to approve studies that utilize waiver or exception from informed consent. This is ostensibly because pediatric subjects are considered a more vulnerable population, but there may also be an element of cultural and moral reluctance to “experiment on children.”

**Informed Consent—Pediatric Assent**

Pediatric studies requiring consent are more complicated than adult studies because subject assent is necessary in addition to the consent of a participant’s legal guardian. This means that, at a minimum, two groups of people must agree to participate in the study. Similar to consents, assent documents must be submitted to the IRB for approval. Depending on the age of the children involved in the study, there may
need to be several forms available that are appropriate for each age group. It is also recognized that not all children have the developmental ability to provide assent; children who are too young may not need to give formal written assent. For those who can understand the issues addressed and questions asked, obtaining the child’s assent must be part of the process. Further, the assent document may be more detailed for adolescents than it is for younger children.

PRIORITY AREAS OF PEDIATRIC RESEARCH

One could ask an abundant number of questions when conducting pediatric prehospital research. Several have tried to prioritize the questions to direct researchers to first answer what are considered the most important questions for the field. Examples of these attempts include the Pediatric Emergency Medicine Research Agenda, EMSC priorities, and recent research highlights in the 2006 IOM report. Some examples of areas that are priorities for research include but in no way are limited to the following:

• Although pediatric skills deteriorate quickly without practice, continuing education in pediatric care for many EMTs is not required by law or standard practice, or availability is extremely limited. The ability of prehospital providers to acquire pediatric skills, the training needed, and the ability to retain these skills has not been widely studied.

• All prehospital pediatric protocols are based on the assessment by the prehospital provider, yet there are no studies of the accuracy of such assessments.

• Many medications prescribed for children are “off-label,” meaning they have not been adequately tested or approved by the U.S. Food and Drug Administration (FDA) for use in pediatric populations. Further study is needed to verify that these medications, including some used in the prehospital setting, are safe and effective in children.

• Pediatric treatment patterns vary widely among emergency care providers: Many of these providers do not properly stabilize seriously injured or ill children, many undertreat children in comparison with adults, and many fail to recognize cases of child abuse. Investigations into the occurrence of these issues and efforts to mitigate the deficiencies are needed.

• Many of the challenges faced in pediatric prehospital care are exacerbated in rural areas, where dedicated, well-intentioned prehospital providers often lack any specialized pediatric training or resources. Research into the abilities and effectiveness of those not specifically trained in pediatric care is needed.

Finally, in a 2008 publication addressing a PECARN-specific research agenda, Miller et al. provide a ranked list of 16 multicenter EMSC research topics.9 Priorities for the PECARN researchers included respiratory illnesses/asthma, prediction rules for high-stakes/low-likelihood diseases, reduction of medication errors, injury prevention, and acuity scaling. These are all topics that can be answered through the multicenter network and it is hoped will provide answers to some of the important clinical questions they represent.

MOVING FORWARD: CHALLENGES AND OPPORTUNITIES

Clearly the researcher who addresses the prehospital care of children has opportunities to gain knowledge and improve care that far outweigh the challenges posed by the nature of this diverse, vulnerable, and complicated population. Several key gaps still remain, most of which have been identified in the IOM reports and, more recently, by the PECARN research agenda. In pediatrics as well as in other prehospital research, there are times when traditional clinical research methods based on directed questions and conducted in a limited number of sites to control all the factors do not translate well to the uncontrolled, multitasking EMS environment. Unfortunately, in some cases the inability to conduct research has led to the use of treatments and practices that have never been studied.

Fortunately, there are now several resources and some databases available to research teams. These include assistance from professional associations such as the American Academy of Pediatrics, American College of Emergency Physicians, National Association for EMS Physicians, and Emergency Nurses Association as well as academic institutions, state departments of health and EMS, federal agencies (e.g.,
the federal EMSC program housed at the Maternal and Child Health Bureau, the Agency for Health Care Research and Quality, the CDC’s National Center for Health Statistics and National Center for Injury Prevention and Control, and the National Institute for Child Health and Human Development), and federally funded resource centers and research collaborations (e.g., PECARN). There are fewer excuses in the 21st century to exclude children from prehospital research and myriad compelling reasons to include this population and improve the care of children in the prehospital setting.

REFERENCES


RESOURCES

EMSC National Resource Center (www.hrsa.gov/emsc) includes research and research funding links for pediatric emergency health research.

National EMS Information System (www.nemisis.org) is a national initiative to collect data on a regional and state level; then national data can be obtained as well. (Coordinated by the National Highway Traffic Safety Administration [NHTSA] and co-funded by NHTSA and the federal EMSC program.)

Organizations with EMS/EMSC Research Interest

Center for Pediatric Emergency Medicine (CPEM) (www.c pem.org) is at New York University Medical Center and Bellevue Hospital Center in
New York City to improve EMS for children in the United States through education, research, and systems development.

Emergency Nurses Association (ENA) (www.ena.org/research) has research resources available and an annual scientific assembly.

National Association of EMS Physicians (NAEMSP) (www.naemsp.org) has research resources available, including PowerPoint presentations from the nationally renowned faculty of a January 2005 pediatric prehospital research workshop. Publishes the journal Prehospital Emergency Care.

National Adolescent Health Information Center (nahic.ucsf.edu) is a Maternal and Child Health Bureau (MCHB)–funded national resource for adolescent health information and research.

National Association of Health Data Organizations (www.nahdo.org) addresses the development and improvement of health systems informatics. They provide information about ambulatory and hospital discharge data sets as well as a database of annotated links to more than 200 on-line health-related data sets.

National EMS Data Analysis Resource Center (NEDARC) (www.nedarc.org) is a federally funded resource center with statisticians and other staff who assist with research design, data collection, and analysis related to EMS for children.

Pediatric Academic Societies (PAS) (www.pas-meeting.org) hosts an annual research meeting that brings together the Ambulatory Pediatrics Association, American Academy of Pediatrics, American Pediatric Society, and Society for Pediatric Research.

Society for Academic Emergency Medicine (SAEM) (www.saem.org) is an excellent resource for researchers in emergency medicine, including tips on scientific grant writing. Publishes the journal Academic Emergency Medicine.

UCLA David Geffen School of Medicine, Center for Prehospital Care (www.cpc.mednet.ucla.edu/SRRS/).

Research Agendas with EMS/EMSC Interest

• The National EMS Research Agenda (www.nhtsa.gov/people/injury/ems/ems-agenda/EMSRResearchAgenda.pdf) was commissioned by the NHTSA and MCHB and published in 2001. Developed over 3 years by national representatives as a follow-up to NHTSA’s National EMS Agenda for the Future, this research agenda provides a template for EMS and EMSC researchers interested in studying prehospital care. The National EMS Research Strategic Plan was published in 2005. For this article and more information on related national EMS research initiatives, visit www.researchagenda.org

• The Acute Injury Care Research Agenda (www.cdc.gov/ncipc/dir/ACRAgenda.pdf) was developed by the CDC’s National Center for Injury Prevention and Control. The revised agenda was released in May 2005. Its focus is on improving acute injury care systems and the care received by individuals of all ages, encompassing prehospital care through EMS, ED assessment, treatment, stabilization, and in-hospital care.

The federal EMSC Program sponsors the Interagency Committee on EMSC Research (ICER), a federal collaborative effort begun in the mid-1990s to improve the quality and quantity of EMSC research. Participating agencies currently include the following:

Agency for Health Research and Quality (AHRQ): www.ahrq.gov
Centers for Disease Control and Prevention (CDC): www.cdc.gov
National Center for Injury Prevention and Control (NCIPC): www.cdc.gov/ncipc
National Center for Health Statistics (NCHS): www.cdc.gov/nchs
Food and Drug Administration (FDA): www.fda.gov
Health Resources and Services Administration (HRSA): www.hrsa.gov
MCHB/EMSC Program: http://bolivia.hrsa.gov/emsc/Index.aspx
MCHB Research Program: http://mchb.hrsa.gov/research/
Office of Rural Health Policy: http://ruralhealth.hrsa.gov/policy/
National Highway Traffic Safety Administration: www.nhtsa.dot.gov/portal/site/nhtsa/menuitem.a8131659c3e0a2381601031046108a0c/
Office for Human Research Protections (OHRP): www.hhs.gov/ohrp/
Substance Abuse and Mental Health Services Administration (SAMHSA): www.samhsa.gov/Matrix/matrix_families.aspx
Pediatric Emergency Care Applied Research Network (PECARN) (www.pecarn.org) is the first federally funded research network to focus on the emergency care of children and is an excellent resource and collaborator for prehospital researchers. Use the training module to understand the workings of the network and how to access it for collaboration.