PECARN Core Data Project: Characterizing Patient Populations in the Pediatric Emergency Care Applied Research Network (PCDP)
PECARN Protocol Number 001

Pediatric Emergency Care Applied Research Network
Maternal and Child Health, Emergency Medical Services for Children (EMSC) Program, Department of Health and Human Services

Protocol Version 7.0
Version Date: December 19, 2011

This protocol is PECARN Protocol Number 001, and the lead PECARN investigator for this protocol is Elizabeth Alpern, MD, MSCE, Children's Hospital of Philadelphia.

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PROTOCOL TITLE:

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Lead Investigator and Author:
Elizabeth Alpern, MD, MSCE
Children's Hospital of Philadelphia

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I confirm that I have read this protocol, I understand it, and I will conduct the study according to the protocol. I will also work consistently with the ethical principles that have their origin in the Declaration of Helsinki and will adhere to the Ethical and Regulatory Considerations as stated. I confirm that if I or any of my staff are members of the Institutional Review Board, we will abstain from voting on this protocol, its future renewals, and its future amendments.

Principal Investigator Name: _____

Principal Investigator Signature: _____

Date: _____

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Contents

List of Tables

Abstract

Epidemiological surveillance data are needed to analyze problematic areas in Emergency Medical Services for Children (EMSC). Advisory groups have called for the standardized collection of key clinical data elements for Emergency Department (ED) and Emergency Medical Services (EMS) patients. There is an urgent need to develop a sustainable ED-based administrative database that can provide relevant data for evaluation of epidemiologic questions, hypothesis generation, and evaluation of systems of care all related to pediatric emergency care. An opportunity to conduct such research is presented through the Pediatric Emergency Care Applied Research Network (PECARN) infrastructure. This project is an observational descriptive study that proposes to identify basic epidemiological information about ED patient visits from participating hospitals within PECARN. The collection of such information is instrumental to the network by serving to provide basic epidemiology data on the visits seen at each hospital ED within PECARN for the purposes of hypothesis generation and study design development.

1 Abbreviations

PECARN: Pediatric Emergency Care Applied Research Network
RNC: Research Node Center
HEDA: Hospital Emergency Department Affiliate
DCC: Data Coordinating Center
ED: Emergency Department
EMS: Emergency Medical Services

2 Study Summary

2.1 Hypothesis

The overall objective of this proposal is to continue an established Emergency Department (ED)-based data collection and surveillance system in all EDs within PECARN, a nationwide research network of hospital EDs involved in the care of acutely ill and injured children.

This is an observational descriptive study. This includes collection and analysis of annual information (including all seasonal variations) gathered from existing electronic sources at each HEDA within the network.

This project was initially a three-phase study, Phases 1 and 2 were completed in 2002. The current project includes only the previously designated "Phase 3."

2.2 Specific Aims

The specific aims are:
Aim 1: To determine the basic epidemiology of all visits to the participating sites during the selected study period.
Aim 2: To provide data for the purposes of hypothesis generation and study design development within PECARN.

2.3 Patient Eligibility

Each of the HEDAs within the PECARN network will participate in the study after obtaining independent IRB approval.

2.3.1 Inclusion Criteria

Patients will be included without regard to gender, race, ethnicity, diagnosis, severity of illness, final discharge status, or mode of transportation to the emergency department. All patients registered in the ED in PECARN hospitals will be included.

2.3.2 Exclusion Criteria

There are no exclusion criteria.

2.4 Anticipated Recruitment and Study Duration

Information will be obtained from each HEDA in PECARN for all ED visits during each calendar year. The database already includes 2002-2008 visits, and during the next 10 years data will be added for 2009 through 2019.

2.5 Inclusion of Women and Minorities

The gender, ethnic and racial composition of patients enrolled in all PECARN studies is a function of the underlying referral population at each Clinical Center selected by the Maternal and Child Health, Emergency Medical Services for Children (EMSC) Program, Department of Health and Human

Services to participate in the network. During this study, the Data Coordinating Center (DCC) will monitor patient accrual by race, ethnicity, and gender.

3 Background and Significance

Epidemiological surveillance data are needed to analyze problematic areas in Emergency Medical Services for Children (EMSC). Emergency Departments (EDs) collect substantial amounts of patient data that has the potential of providing answers to many public health questions. However, the capacity to collect and analyze this data has been lacking in the past.[1–3] The limitation exists in great part because of the inability to systematically organize the collected data.[4, 5] Advisory groups from the National Center for Injury Prevention and Control, American Academy of Pediatrics, National Highway Traffic Safety Administration, and Maternal and Child Health Bureau have called for the standardized collection of key clinical data elements for ED and EMS patients.[6–8]

The Pediatric Emergency Care Applied Research Network (PECARN) is the first federally funded national network for research on pediatric emergencies and EMSC, and was established to overcome barriers to such research, including the rare occurrence of high-risk pediatric emergency events, the lack of generalizability of research conducted at single centers, and the lack of standardized outcome measures.[9, 10] PECARN has been successful in uniting up to 23 sites nationally to undertake varied research projects, ranging from data repositories to randomized controlled trials. The network's first project was to design and implement an administrative database of all visits to all sites, the PECARN Core Data Project (PCDP).[11] The PCDP, which has been ongoing since 2002, uses data from extant administrative systems at all participating hospitals. The PCDP currently has over 6 million visits (over 800,000 annual visits yearly since 2002) from the PECARN sites.

The project has been successful in providing basic demographic and injury or illness information to describe the population served by PECARN.[11–13] In addition, we used the data to evaluate the methodology of health services research using extant electronic databases linked to chart review,[14, 15] and practice pattern variation for asthma and long-bone fractures.[16, 17] The PCDP has also been the basis for development of a pediatric emergency visit Diagnosis Grouping System and Severity Classification System.[18, 19] The data have provided benchmarking information among sites and have allowed evaluation of recurrent utilization of emergency services by pedi-

atric patients.[11–13, 20, 21] The PCDP has provided important information to PECARN researchers in planning and developing studies for grant submission, IRB approval, and network-wide implementation. The PCDP has also provided the experience and formalized structure needed to build a large, shared dataset across multiple diverse sites within the network.

In order to engage in collaborative studies within PECARN, basic epidemiological information about ED patient visits is needed from each participating hospital. The collection of such information is instrumental to the network by serving to provide basic epidemiology data on the visits seen at each hospital ED within PECARN for the purposes of hypothesis generation and study design development.

4 Study Methods

This is an observational descriptive study. This includes collection and analysis of annual information (including all seasonal variations) gathered from existing electronic sources at each HEDA within the network.

Retrospective data collection from HEDA administrative databases for a prior calendar year will occur annually from 2009-19.

Data submission: The following steps will occur in collecting electronic data from each site:

1. Each site will identify staff that can export the required data elements from local information systems (see Table 1 on the facing page).

2. Each site will verify that the data set created for submission meets the protocol and manual of operation criteria.

3. Each site will submit the data securely via the Internet using secure and encryption protocols (128-bit Secure Socket Layer - SSL).

4. The DCC will review and process all data submissions. If discrepancies are found, the DCC will notify the site and ask them to re-submit.

5 Data Management

5.1 Data Set Description:

The Table 1 on the next page shows the data elements and usage for each element to be included.

The fourth column, "Database", indicates whether the data element will be included unchanged in the final database, or will be recoded by the DCC to a data element that is consistent with the HIPAA definition of a de-identified data set.

Table 1: Data Elements, Description, Purpose and Database Indications

Data Element	Description	Purpose	Database
Site	The name of the ED where the visit occurred.	Identify the RNC/ HEDA from which data is being collected.	Included
Patient ID	Unique identification number assigned to the patient; may be the medical record number.	Identify multiple discharges for same patient; necessary for accurate projection of patient recruitment volumes and to longitudinally link visits.	Recoded by DCC
Date of Birth	Birth date of the patient.	Accurately calculate age at time of visit.	Recoded by DCC to age (days)
Gender	Sex of the patient.	Descriptive analysis	Included
Race	The race of the patient as recorded by the ED.	Descriptive analysis	Included
Ethnicity	The ethnicity of the patient as recorded by the ED.	Descriptive analysis	Included
Zip Code	Five digit Zip code.	Socio-economic and geographic analyses of patient population.	Linked to census information and recoded by DCC to first three digits.
Triage Category	Triage Acuity Category.	Descriptive analysis	Included
Chief Complaint	Triage Chief Complaint (Up to 3).	Descriptive analysis	Included

continued on next page

Table 1: *continued*

Data Element	Description	Purpose	Database
Procedure Codes	ICD-9, ICD-10, CPT (Up to 15).	Descriptive analysis	Included
Diagnosis Codes	ICD-9, ICD-10 (Up to 15).	Descriptive analysis	Included
E-Code	Any documented e-codes (Up to 3).	Descriptive analysis	Included
Payor Type (primary insurance)	Type of health insurance used by patient.	Descriptive analysis	Included
ED Disposition	What happened to patient after ED admission.	Descriptive analysis	Included
Date Time Fields	ED Triage date and time, ED Discharge date and time	Descriptive analysis of seasonal variation, monthly projections of patient volume	Recoded by DCC to lengths of stay, month of discharge
Mode of Arrival	Method used by patient to arrive at ED	Descriptive analysis	Included

The original data that are submitted to the DCC (patient ID, dates of birth, zip code, ED triage and discharge) will be processed to create the de-identified database in accordance with a Business Associate Agreement (BAA) between the HEDA and the DCC. The patient ID, five digit zip code, and specific dates of birth, triage, and discharge will not be accessed by investigators unless they have been recoded and de-identified.

5.2 Quality Assurance:

Site-specific descriptive statistics for each variable (continuous variables using means and standard deviations or medians and interquartile range IQR; discrete variables using counts and percentages) will be presented to the HEDA investigator to determine face validity. Additionally, a study investigator will review the summary statistics for all data elements from each site to assess face validity. If potential errors or biases are identified, study and site investigators will work towards resolution. This process will be accomplished annually with each site.

6 Data Analysis

6.1 Sample Size Determination:

As the primary aims of this study are largely descriptive, sample size was selected primarily based on pragmatic considerations. A twelve-month period of electronic data capture is essential to ensure an adequate description of the patient populations and available data elements (specific Aims 1 and 2), due to the seasonality of pediatric emergency visits. A ten-year period will allow for analysis over time as well as evaluate changes in epidemiology needed for ongoing hypothesis generation and grant planning (Aims 1 and 2).

7 Human Subjects

No collection or submission of data will occur at any specific HEDA until IRB approval at that Site.

7.1 Ethical Considerations:

This is a minimal risk study without direct patient contact. The goals of the study are primarily descriptive of the PECARN patient population. All data will be collected from pre-existing sources. Thus, we are requesting waiver of informed consent and assent. Data will be acquired from hospital computer systems and medical records, and the primary potential risk to subjects is improper disclosure of medical information.

A waiver of informed consent and assent is requested for three reasons. First, the analyses are aimed at description of the entire network. Exclusion of any patients will destroy the scientific validity of these analyses. Second, it is difficult, if not completely impractical, to obtain informed consent/parental permission from all patients who are being registered to the ED. All data will be sent to the DCC only after care of the patient in the ED is complete and thus they are not available on an ongoing basis for communication or identification for consent. In addition, recorded contact information is likely to be inaccurate. This will make it impossible to complete this project in an expeditious manner, which is crucial to the successful role of the project in PECARN functions. Third, the risks of this study are related to confidentiality and privacy, and are minimal. The data elements form a Limited Use Data Set under HIPAA regulations, and the DCC has offered a Business Associate Agreement to each HEDA to authorize its creation of

a completely de-identified database for use by PECARN investigators and EMSC.

Data collected in this project do not include names, but do include sufficient identifying information (such as date of birth, gender, zip code) that project investigators must protect the confidentiality of the research data in accordance with privacy regulations such as the Health Insurance Portability and Accountability Act (HIPAA). This will be accomplished by the following actions:

- All data will be maintained in secure locations in locked offices, locked filing cabinets, and password protected computers that will shut-down after 15 minutes of non-use.
- All data transmission will be encrypted, as described in Security, Confidentiality, Data Retention section, 8.1. All research staff at the HEDA ED site, the research node center, and the DCC must complete the NIH approved curricula on patient protection and research ethics.
- All DCC staff work under strict confidentiality agreements.
- All analyses and reports will be presented in aggregate fashion.
- No identifiable data will be released by study investigators or the DCC at any time.

7.2 Risks and Side Effects:

This is a minimal risk study without direct patient contact. The goals of the study are primarily descriptive of the PECARN patient population. Data will be acquired from hospital computer systems, and the primary potential risk to subjects is improper disclosure of medical information. This risk is minimized by data management steps outlined in the Security, Confidentiality, Data Retention section, 8.1.

7.3 Benefits:

There are no direct benefits for study participants. This study will provide previously unavailable epidemiological information about childhood illness and injury seen throughout PECARN. This information will provide the basis for large-scale multi-institutional studies to be carried out by the

PECARN that may ultimately improve the clinical care for large populations of acutely ill and injured children throughout the United States. This information will also provide important background information to support major patient care improvement initiatives in emergency departments and hospitals caring for these children. The continuing collection of such information serves to provide data necessary for hypothesis generation, sample size determination, enrollment planning, and study design development.

7.4 Financial Considerations:

Research subjects will not be compensated for their participation, nor will study subjects incur any costs as a result of their inclusion in the study.

7.5 Compliance With Good Clinical Practice Guidelines:

This study will be undertaken in full compliance with Good Clinical Practice Guidelines (ICH E6).

8 Security, Confidentiality, Data Retention

8.1 Security and Confidentiality:

The Data Coordinating Center (DCC) is housed in a building with 24-hour on-site security guards. The DCC coordinates network infrastructure and security with the Health Sciences Campus (HSC) information systems at the University of Utah. This provides the DCC with effective firewall hardware, automatic network intrusion detection, and the expertise of dedicated security experts working at the University. User authentication is centralized with two Windows 2003-2008 domain servers. Communication over public networks is encrypted with virtual point-to-point sessions using secure socket layer (SSL) or virtual private network (VPN) technologies, both of which provide at least 128 bit encryption. All of the DCC Web-based systems use the SSL protocol to transmit data securely over the Internet.

Direct access to data center machines is only available while physically located inside the DCC offices, or via a VPN client. All network traffic is monitored for intrusion attempts, security scans are regularly run against servers, and DCC IT staff are notified of intrusion alerts. Security is maintained with Windows 2003-2008 user/group domain-level security. Users are required to change their passwords every 90 days, and workstations time out after 10 minutes of inactivity. All files are protected at group and user levels;

database security is handled in a similar manner with group-level access to databases, tables, and views in Microsoft SQL Server. Finally, all laptop computers in use at the DCC are whole-disk encrypted.

The DCC will provide separate accounts to PCDP personnel for all information systems to which access is required. The DCC will train all users concerning the proper configuration and use of passwords. The DCC will require all users to sign specific agreements concerning security, confidentiality, and use of our information systems, before access is provided.

All data collected during the study will be treated confidentially by all involved staff at the HEDA ED, the research node center, and the DCC. The staff are bound by their employment agreements to maintain patient confidentiality, and all personnel involved with the DCC have signed confidentiality agreements concerning data encountered in the course of their daily work. All personnel have received Human Subjects Protection and Health Information Portability and Accountability Act (HIPAA) education.

8.2 Retention of Study Data:

The DCC will produce an analytical database for statistical analysis which will not include identifier information (date of birth will be removed and ages will be calculated, 5 digit zip codes will removed and recoded to first three digits, specific dates of service will be recoded, and medical record numbers will be removed and recoded.) After this analytical database is produced, the DCC will encrypt and archive the original study data. At the conclusion of the study, the encrypted data will be destroyed. The DCC will preserve the analytical database (which contains no identifiers) to fulfill archival requirements and to allow potential future research use of the data.

9 Publication

All research publications and presentations arising from this study will be presented in aggregate form, and at no time during or after the study will any research data be released by PECARN, the DCC, or the Federal funding agency (EMSC) of PECARN with patient identifiable fields.

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