PECARN Electronic Medical Record Registry (PECARN Medical Record Registry) PECARN Protocol Number 036

Pediatric Emergency Care Applied Research Network
Emergency Medical Services for Children (EMSC)
Maternal and Child Health Bureau
Health Resources and Services Administration

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This protocol is PECARN Protocol Number 036, and has been authored by Elizabeth R. Alpern, MD, MSCE, Ann & Robert H. Lurie Children's Hospital of Chicago, for implementation with the PECARN investigators.

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PROTOCOL TITLE:

PECARN Electronic Medical Record Registry

Short Title: PECARN Medical Record Registry
PECARN Protocol Number: 036

Lead Investigator and Author:
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Ann & Robert H. Lurie Children's Hospital of Chicago

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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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1 Study Summary

The Pediatric Emergency Care Applied Research Network (PECARN) began collecting data for the PECARN Core Data Project (PCDP) in 2002, using administrative data from all PECARN hospitals. This project now has nearly 15 million visit records in it. However, the PCDP does not include clinically important data about processes and outcomes of care, changes in clinical status, physiologic measures of severity of illness, laboratory data, or narrative reports. These types of clinical data, while important for improving the care of children in our emergency departments, previously have been prohibitively expensive to extract from the (largely paper based) medical record on a large scale.

In 2011, the Agency for Healthcare Research and Quality (AHRQ) funded a grant to create a medical record registry by extracting data from electronic health records (EHR) at four PECARN hospitals and their affiliates (R01HS020270). Technology was developed to extract data for all pediatric emergency department (ED) visits, accomplish substantial deidentification of the extract prior to transmission to the Data Coordinating Center (DCC), and produce a data warehouse registry to use for quality improvement and research. At the present time, this medical record registry includes 1.9 million visits with over 800,000 different patients, and performance report cards are provided to all participating providers on a monthly basis.

This protocol (PECARN Protocol Number 36) continues the registry as the "PECARN Electronic Medical Record Registry (PECARN Medical Record Registry)" and will replace PECARN Protocol Number 30, entitled "Improving the Quality of Pediatric Emergency Care Using an Electronic Medical Record Registry and Clinician Feedback (PECARN Emergency Care Registry)". All data from the PECARN Emergency Care Registry will be incorporated into the PECARN Medical Record Registry.

1.1 Study Objectives

This study has the following objectives:

Objective 1. Continue the PECARN electronic medical record registry for pediatric patients by merging electronic health record (EHR) clinical data from participating hospital emergency departments (ED) for quality improvement purposes and to plan future research.

Objective 2. Continue to use the emergency care visit registry to analyze and describe processes of care and outcomes for injuries and illnesses of patients presenting to

participating hospital EDs.

Objective 3. Continue preparation and dissemination of clinical performance report cards to assess quality improvement initiatives.

2 Background

Children account for over one quarter of the 114 million annual emergency department (ED) visits in the US,[1, 2] yet the needs of children in the ED have received relatively small attention.[3] Recently, there has been increased attention to the unique needs of children during emergencies. Among the areas in need of evaluation are the effectiveness and quality of emergency care, outcomes of different configurations of EMSC, optimal resource allocation and utilization, and cost-effectiveness of EMSC and its components.[4] There has also been documentation of significant variation in the quality of care provided to children in EDs,[5–11] as well as recognition of racial and ethnic disparities in healthcare delivery.[12] The Pediatric Emergency Care Applied Research Network (PECARN) was established in 2001 to address these needs and improve the quality of emergency care for children through the performance of rigorous research.[13, 14]

The network's first project was to design and implement an administrative database of all emergency department visits in PECARN hospitals, the PECARN Core Data Project (PCDP).[15] The PCDP, which has been ongoing with Institutional Review Board (IRB) approval at every PECARN hospital since 2002, uses data from billing and registration systems at all participating hospitals, as well as electronic health record data from some hospitals. The PCDP currently has nearly 15 million visits to the PECARN sites. The project has been successful in providing basic demographic and injury or illness information,[15–18] evaluation of methodology,[19, 20] developing diagnosis grouping and severity systems,[21, 22] and providing limited benchmarking information.[16–18, 23]

In the first year of the PCDP, investigators also collected detailed clinical information for a sample of children seen in PECARN emergency departments by linked manual chart review. Availability of clinical data, in addition to the administrative data available in the overall PCDP database, allowed investigators to evaluate practice pattern variation for asthma and long-bone fractures.[10, 24] Pain was under-documented in children with long bone fractures and only two-thirds of these patients received analgesics in the ED.[24] More than one-third of patients treated for status asthmaticus received potentially unnecessary ancillary testing and the risk for this testing was higher in children cared for at non-children's hospitals and by clinicians without subspecialty training in pediatric

emergency medicine.[10]

This early experience led to funding from AHRQ (RO1HS020270) to build a medical record registry, leveraging the availability of electronic health records (EHR) in selected PECARN sites. The PECARN Emergency Care Registry has detailed information about all children seen in the EDs in four PECARN hospitals as well as their satellite facilities. The EHR vendors include Epic and Cerner. The Registry information from January 2012 through April 2016 is summarized in Table 1.

Encounters	1,943,607
Patients	819,665
Diagnoses	5,960,989
Lab Results	12,005,884
Medication Orders	2,542,557
Radiology Tests	685,515
Narrative Documents	12,226,548

Table 1: Summary of PECARN Registry as of April 2016.

The Registry provides a unique resource for understanding and improving pediatric emergency care. The Registry has been used to create performance report cards for participating sites as part of a quality improvement initiative, and to explore processes of care associated with specific disorders, such as asthma, long bone fractures, and viral infections. This has enabled measurements to determine the effectiveness of specific quality improvement initiatives for these conditions. The narratives (over 12 million) provide a valuable corpus upon which to improve natural language processing methods, critical to deriving meaningful research results from EHRs over the next decade. Continuing the Registry per the present protocol will increase the value of this resource, as additional hospitals are added to the project, which will increase the generalizability of knowledge based on the Registry. Finally, the Registry will provide a structure for development of future research endeavors.

3 Study Population

The Registry will include all patients who are seen at participating PECARN hospitals and satellite facilities. As funding becomes available, PECARN hospitals and satellites

will be added to the original sites, with the goal of including all PECARN centers that have an accessible EHR. The project is anticipated to continue for at least five years, subject to annual Institutional Review Board (IRB) review and approval.

4 Study Procedures

4.1 Data Domains of Interest

The EHR contains a large number of data, including information required for auditing the medical record, and it is not intended to extract all EHR information into the Registry. For example, if a laboratory value is incorrectly entered, and then corrected, both values are retained in the EHR for legal auditing purposes. The Registry will only receive the value final at the time of data transmission. The following data domains are extracted from the EHR for inclusion in the Registry:

Demographic Data. For example, but not limited to: site of care, insurance type, race, ethnicity, birthdate (age).

Clinician Data. For example, but not limited to: independent licensed provider.

Date and Time Data. For example, but not limited to: all date and time values relating to the ED or hospital visit, as well as date and times of all events or findings.

Diagnoses and Procedures. For example, but not limited to: all available diagnoses codes, procedure codes, cause of injury codes, including ICD9 (when still available), ICD10, and CPT.

Review of Systems. For example, but not limited to: review of physical systems as recorded in specific fields, if available. Otherwise derived from narrative text data.

History of Illness. For example, but not limited to: history of illness as recorded in specific fields, if available. Otherwise derived from narrative text data.

Physical Examination. For example, but not limited to: physical examination findings (including weight) and clinical scores (e.g. pain score, asthma scores, GCS scores) as recorded in specific fields, if available, or in narrative text.

Laboratory Testing Data. For example, but not limited to: all laboratory tests sent during the ED visit, including results that may be returned after the ED visit is concluded.

Medications. All medications reported as home medications, ordered or administered in the ED, or ordered as discharge prescriptions, including dosage information.

Treatment Data. For example, but not limited to: radiology orders, EKG orders, respiratory therapy orders.

Vital Sign Data. All vital signs as recorded in specific fields, if available. Otherwise derived from narrative text data.

Narrative Text Data. All available narrative data related to the ED visit, including potentially delayed radiologic dictation reports. Narrative or free text notes may be created by physicians, nurses, or other clinicians, and the author of each narrative will also be extracted.

ED Admission and Discharge Data. For example, but not limited to: Reason for visit, chief complaint, triage category, mode of arrival, urgency, use of an interpreter, discharge location, vital status.

Inpatient Admission and Discharge Data. For ED visits resulting in a hospital admission at the same hospital, the date and time of hospital discharge, vital status at discharge, and hospital discharge summary.

4.2 Adding Hospitals to Registry

For hospitals already included in the Registry, the De-identification Procedures described in Section 4.4 and Data Submission procedures described in Section 4.3 are already optimized. For new hospitals, it is necessary to tailor these procedures to the specific EHR vendor and to optimize the de-identification algorithm for the specific hospital and its location. The steps required include the following general stages:

1. Identify potential sources of relevant data elements in the specific EHR at each site.
2. Finalize the types of data elements that will be extracted.
3. Extract data for one day of data at each clinical site.
4. Transmit one day identified data to the DCC for de-identification.
5. Establish de-identification procedure at each clinical site.
6. Extract and de-identify the same one day sample to verify that de-identification at site works.
7. If site de-identification does not work, revise process and iterate until successful.

8. Extract and de-identify at least two one-month data sets from between the first month of the previous 12 month period and the most recent complete month at each site.
9. Transmit at least two one-month data sets to the DCC.
10. Finalize and test import procedures from two one-month extracts into Registry.
11. Analyze frequencies of missing, out of range, or unexpected values for key data elements.
12. Extract, de-identify, and transmit entire previous 12 months (rolling) data from each site to the DCC.
13. Integrate previous 12 month data (rolling) into existing Registry.

4.3 Database Extraction and Submission

Available data will be extracted from each site's EHR in an automated fashion that is vendor-specific, and is likely to be installation specific (i.e. two different sites may have the same vendor but different preferred extraction methods depending on the vendor features that were purchased or updated). Currently the final extraction format is plain text formatted with extensive markup language (XML) tags. The XML format enables automatic validation of the extracted file. After de-identification procedures are established at each site (Section 4.4 on the next page), these are applied to the extracted information prior to encrypted transmission to the DCC and importing into the Registry database.

The precise manner of database extraction, XML formatting of variables, and technical details of the steps required to accomplish this task are described here for information purposes. The technical approach is likely to evolve in the future, and may be altered without revising this protocol document.

Data that are not available at the time of data transfer, which typically will take place 30 days after the completion of the calendar month in which the ED visit occurred, will be considered unavailable or missing, and no effort will be made to follow up for these delayed data. For example, if a patient has a radiologic procedure but the dictation is not in the EHR within 30 days of the visit, that dictation will not be incorporated into the Registry. This time window is necessary because of the logistical issues of attempting to follow up every potential result, as well as the time constraints relating to producing timely provider-specific performance report cards for Objective Three.

4.4 De-identification Procedures

The text file that is produced by automatic extraction will be fully identified, and sophisticated algorithms will then be used to remove or recode essentially all HIPAA-defined identifying information. There are only four potentially identifying data elements that will remain in the study record after the de-identification procedure is carried out: the site identification, the clinician identification, the month of the visit, and a one-way hash encryption of the medical record number. The first three data elements are needed in order to provide feedback for specific months to specific sites and clinicians. The hash encryption value of the medical record number is required to identify repeat visits by the same patient, enabling longitudinal study of selected pediatric illnesses and injuries seen in the ED setting. Other patient-related identifiers are effectively removed by the de-identification procedure (Fscore 98% to 99%, which is superior to manual de-identification by humans).

The precise technology to be employed may be changed as this project moves forward to reflect improvements in available tools, without revision of this protocol. The purpose of this section is not to constrain the use of state-of-the-art technologies, but rather to describe the principles by which the process is currently implemented. For current sites in the Registry, we will continue the current methods for de-identification. For new sites, it is necessary to finalize and verify the effectiveness of the de-identification for each specific site. In order to accomplish this, the DCC will have access to fully identified records from each new site from a single day from the 12 months previous to implementation, the DCC will de-identify the data, and verify that the de-identification was fully accomplished. The process will then be implemented at each site and we will confirm that the process was effective (for the same day of patient data). After the de-identification procedures have been confirmed, all identifiable records that are at the DCC will be removed from production servers and will not be incorporated into the Registry.

The de-identification is done with software (De-Id) that was developed by other investigators[25] to produce a de-identified public use intensive care database.[26] The DCC has developed a software platform that includes De-Id as well as XML verification software. After the initial de-identification process has been verified, this software will be installed at each hospital, so that the hospital can verify its file structure (XML verification) and execute the de-identification software on its own servers within its own firewall, prior to encrypted transmission of the de-identified data to the DCC.

4.4.1 General Algorithm

The software (De-Id) is a program script that uses multiple dictionaries to identify and remove names and locations from text. A list of known patient names (at an individual hospital) can be the first dictionary used at the site by the script, and this will remove patient names. The software then uses large dictionaries of first and last names to identify other potential names, such as relatives, nurses, doctors, or other clinicians. A similar approach is used for locations — namely, a list of locations that are relevant to each clinical site will be used as a location dictionary, and locations will be removed.

Dates and times present an interesting problem because it is necessary to preserve time intervals and patient ages. The software will remove all dates and replace them with a random patient-specific offset. This shifted date preserves the day of the week and the season to prevent confusion due to free text phrases such as "next Wednesday". The patient's date of birth is treated in the same manner, so that the correct age can be calculated from the replaced dates. The random shift is patient specific and will be consistent for the entire individual patient record and between subsequent visits for that patient.

In order to preserve the month in which the data were submitted, the clinician identification,and site identification, separate database fields will be added to each record when the file is sent to the DCC, so that month-specific feedback can be provided to sites and providers, as already described.

Other identifiers include telephone and fax numbers, Social Security numbers, medical record numbers or other numeric identifiers. The software will remove these throughout. The medical record number will be one-way hash encrypted to allow identification of repeat visits for patients.

4.4.2 Effectiveness of Algorithm

This software has been tested rigorously.[25] Three human de-identifiers manually de-identified text for comparison with the software. On test data consisting of nearly 2,000 free text nursing notes, the software performed better than the average individual human de-identifier, better than the best single human de-identifier, and better than the average consensus of two human de-identifiers. The software has subsequently been used to de-identify the MIMIC II intensive care database previously mentioned,[26] processing approximately 700,000 nursing notes, 30,000 inpatient discharge summaries, and 300,000 radiology reports, containing a total of over 220 million words.

During the AHRQ funded project, the DCC has regularly sampled de-identified data submitted from sites to verify that the de-identification process is effective. This review process has confirmed on-going effectiveness of the current procedures. A sample de-identified attending physician narrative from the PECARN Registry is shown below:

> History of Present Illness HPI [**2013-06-05**], 11:04 PM [**Known patient firstname 1175**] [**Known patient lastname 458**] is a 11 y.o. male brought to the ED by mother for right wrist pain and mild swelling that began after falling and injurying the wrist while ice skating last night around 2130. Pt states another skater bumped into his shoulder and he flipped over, landing with hyperflexion of the right wrist. Mom applied ice to the wrist without relief. He took Ibuprofen last night before bed. The pain is aggravtaed by movement and has no alleviating factors. He has fractured the right wrist in the past. No changes in alertness, activity or appetite. Patient is otherwise healthy with no other concerns or complaints at this time. HPI Documentation is Complete History Review: PMH: No significant problems [**Name (NI) 17**]: Reviewed - no changes Social History: Attends school / daycare and Exposure to tobacco / smoking Family History: Reviewed nursing documentation - no changes Review of Systems Constitutional: Negative for activity change, appetite change and fever. HENT: Negative. Eyes: Negative. Respiratory: Negative. Musculoskeletal: Positive for injury (right wrist), pain (right wrist) and swelling (mild swelling to right wrist). Gastrointestinal: Negative. Neurological: Negative. Skin: Negative for rash.

4.5 Report Card Preparation

The performance report cards contain 20 to 30 pages of tabular and graphic data; examples are provided in this section to illustrate the type of content in the reports. Performance report cards are prepared on a monthly basis for each hospital (Figure 1 on the following page) as well as for clinicians within the hospital (Figure 2 on page 17). In order to make the data more easily interpretable, the report cards also include graphic displays for each measure that include trend over time charts at the hospital level (Figure 3 on page 18) and clinician level (Figure 4 on page 18). Each of these reports includes relevant comparisons as well as the Achievable Benchmarks of Care (ABC)[27] derived from the previous CY data. The ABC serves as the target for performance improvement.

The Data Coordinating Center creates a randomly generated study provider number that links to the email address for each clinical provider. The clinician-specific report

Performance Measure	Your Site	Network	ABC
Time from ED arrival to being seen by any provider who can initiate care (resident, NP, PA, fellow, or attending) for ESI 5 visits	71	47	21
Length of stay (from ED arrival to ED departure time) for all visits	184	173	98
Length of stay (from ED arrival to ED departure time) for admit, observation or transfer disposition visits	329	325	226
Length of stay (from ED arrival to ED departure time) for discharge disposition visits	169	159	96
Left without being seen: visits arrived in the ED but not seen by a provider who can initiate care (resident, NP, PA, fellow, or attending)	4.9%	2.8%	†
Time interval between plain film order and image available for viewing by ED staff; may have more than one image per visit	10	20	†
Time interval between CT test ordered and first radiologist reading available to ED provider for all CT reports; may have more than one image per visit	70	100	†
Time interval between US test ordered and first radiologist reading available to ED provider for all US reports; may have more than one image per visit	67	101	†

Figure 1: Hospital level tabular data from performance report card.

card is anonymized and emailed to the clinician, and is not sent to the hospital nor the clinician's supervisors. The DCC maintains a list of coded clinician identifiers that are linked to the email address of the clinicians.

In order to fully understand the performance improvement measures on the report cards, clinicians may request the Data Coordinating Center to provide encrypted study identifiers for patients included in a specific measure. The encrypted study identifiers are retained at the original hospital with the medical record, enabling the provider to review the medical record to identify ways to improve future performance.

5 Statistical Analyses

Objective 1. Continue the PECARN electronic medical record registry for pediatric patients by merging electronic health record (EHR) clinical data from participating hospital emergency departments (ED) for quality improvement purposes and to plan future research.

Process Measures. During the maintenance of the Registry for current sites, and bringing on new sites to improve the Registry, we will track several process measures to

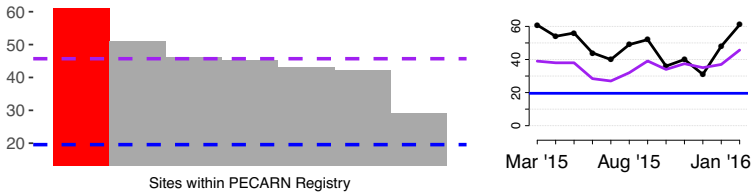
Performance Measure	You	Your Site	Network	Site ABC	Network ABC
Respiratory Diseases (Asthma)					
Systemic corticosteroids given in the ED	100%	95.2%	91.9%	98.2%	99%
Time (min) to first beta-agonist treatment	36	39	47	32	32
Asthma score documented while in the ED	86.7%	89.3%	88.6%	94.9%	99.1%
Patients with moderate or severe asthma score with an improved asthma score documented (admit, observation, or transfer disposition)	50%	52.3%	65.6%	68.6%	92.9%
Patients with moderate or severe asthma score with an improved asthma score documented (discharge disposition)	25%	46.5%	75%	59%	99.6%
Childhood Infections					
Visits with viral diagnoses (excluding visits with chronic care conditions or bacterial infection diagnoses) for which antibiotics were given in the ED or on discharge	0%	1.7%	1.9%	0.2%	0.1%
Pain and Sedation (Long-bone Fracture)					
Pain score documented at any time during the ED visit	92.3%	93.8%	95.8%	97.1%	100%
Patients with moderate or severe pain who had a reassessment of their pain documented	75%	56.8%	72.8%	80.1%	100%
Patients with moderate or severe pain who had a reassessment and reduction of their pain by at least two points on the pain scale	25%	41.8%	63.3%	78%	90.6%

Figure 2: Clinician specific tabular data from performance report card.

ED Flow

Time from ED arrival to being seen by any provider who can initiate care (resident, NP, PA, fellow, or attending) for all visits regardless of ESI

Site (med[IQR]) 61 [29,108] (N=6087)
Network (med[IQR]) 46 [21,88]
ABC 20



Time from ED arrival to being seen by any provider who can initiate care (resident, NP, PA, fellow, or attending) for ESI 2 visits

Site (med[IQR]) 29 [16,50] (N=1139)
Network (med[IQR]) 24 [13,45]
ABC 12

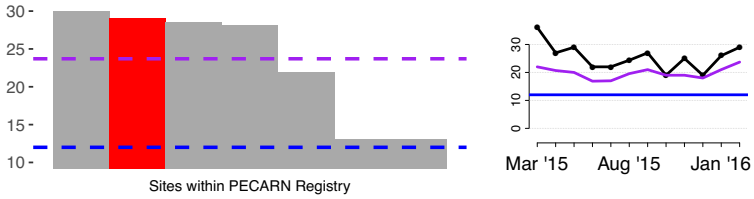
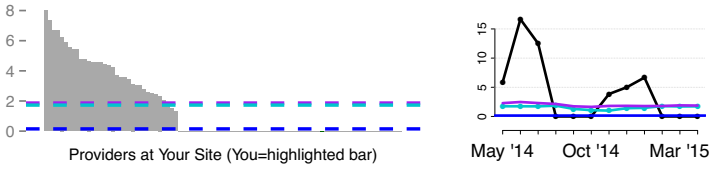


Figure 3: Hospital level graphic display from performance report card.

Childhood Infections

Visits with viral diagnoses (excluding visits with chronic care conditions or bacterial infection diagnoses) for which antibiotics were given in the ED or on discharge

You 0% (N*=17)
Your Site 1.7%
Network 1.9%
Site ABC 0.2%
Network ABC 0.1%



Pain and Sedation (Long-bone Fracture): *All pain and sedation performance measures include only visits with a long-bone fracture in the diagnosis or on radiograph regardless of disposition of the patient*

Pain score documented at any time during the ED visit

You 92.3% (N*=13)
Your Site 93.8%
Network 95.8%
Site ABC 97.1%
Network ABC 100%

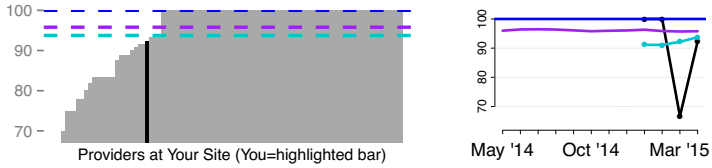


Figure 4: Clinician specific graphic display from performance report card.

assess improved efficiency as technology evolves. For example, measures will include (but are not limited to) the following:

- Total time to generate the data upload for each site
- Total time spent by the DCC and investigators examining and cleaning data
- Number of discrete variables and free text (narrative) fields
- Proportion of missing data for each variable
- Proportion of impossible or nonsensical data for each variable
- Proportion of outlier (out of range) data for each variable

Objective 2. Continue to use the emergency care visit registry to analyze and describe processes of care and outcomes for injuries and illnesses of patients presenting to participating hospital EDs.

Appropriate descriptive statistics and multivariable modeling methods will be used to carry out this objective.

Objective 3. Continue preparation and dissemination of clinical performance report cards to assess quality improvement initiatives.

Report card specific data extracts are created on a monthly basis, and the report cards are generated on a monthly basis. The precise contents of the report cards may be adjusted in accordance with the specific quality improvement initiatives that are being undertaken by participating sites, but will be similar to existing report cards. The reports are generated using SAS and R software.

6 Data Management

6.1 Data Coordinating Center

The Data Coordinating Center (DCC) in the Department of Pediatrics at the University of Utah School of Medicine provides data coordination and management services for a variety of national research networks. Anchoring these services is a state-of-the-art, energy efficient data center completed in 2013. The data center facility supports more than 1200 users around the world and provides a secure, reliable, enterprise-wide infrastructure for delivering critical DCC systems and services. The data center was built using high industry standards and energy efficient cooling solutions. The data center is cooled by Rittal's LCP inline cooling technology, providing efficiency, redundancy and modularity. Cooling is based upon a hot/cold aisle design that allows for even air distribution with

minimal hot spots. The data center electrical power system contains a redundant Mitsubishi uninterruptible power system (UPS) with a diesel backup generator. The data center is protected with a FM200 fire suppression system, early warning smoke detectors and a heat detection warning system to act as a secondary system to the smoke detectors. Security guards are on-site conducting access control and rounds 24/7/365. Entry into the data center is restricted by card access and layered security measures and controls. The data center and external building access points are monitored with video surveillance.

In 2011 the data center began a large scale VMware server virtualization deployment. Currently, the data center has virtualized about 95% of its environment. The virtual environment consists of more than 160 virtual servers and nearly 20 physical servers. The data center's virtualization solution provides key advantages:

- high availability – in the event of hardware failure, virtual servers automatically go back online in a seamless process.
- flexible infrastructure – disk storage, memory and processor capacity can be increased or reallocated at any time.
- rapid deployment – servers can be provisioned on-demand with minimal waiting on hardware of software.

The data center has enhanced its storage resources by implementing a networked storage system to support its virtualized environment. The data center currently manages over 50 terabytes of data. The storage solution consists of Dell's EqualLogic PS Series Storage system for providing a virtualized storage area network (SAN). Some of the benefits that are realized through this technology are:

- storage architecture is not a bottleneck for IT services;
- improved performance;
- tiered storage;
- provisioning and reclamation of SAN disk is efficient; and most important,
- complete redundancy from the SAN fabric architecture.

Production servers running critical applications are clustered and configured for failover events. Servers are backed up with encryption through a dedicated backup server that connects across an internal 10 gigabit network to a tape drive. DCC storage area networking (SAN) applications, clusters, and switch-to-switch links are also on a 10 gigabit network. Incremental backups occur hourly Monday through Friday from 6 am to 6 pm. Incremental backups also are performed each night with full system backups occurring

every Friday. Tapes are stored in a fireproof safe inside the data center facility, and full backups are taken off site on a weekly basis to an off-site commercial storage facility.

In the event of catastrophic failure, such as a fire in the server facility, daily backups would probably survive because of the fire suppression system and fireproof safe, but there would be obvious delay in re-establishing data center function because the servers will not survive such a disaster. Total destruction of the data center facility could cause the loss of up to one week's data. In future investments, the data center is making co-location, disaster recovery and business continuity solutions a top priority.

DCC information systems are available 24 hours a day, 7 days a week to all users unless a scheduled maintenance interruption is required. If this occurs, we notify all users of the relevant systems, and data entry can be deferred until after the interruption is over. Critical systems availability has exceeded 99.9% for the past two years, and there has been no unscheduled downtime in over five years.

6.2 Data Transmission

All data transmission to the DCC 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. No study data will be transferred by email.

6.3 Data Security and Confidentiality

The data center coordinates the network infrastructure and security with the Health Sciences Campus (HSC) information systems at the University of Utah. This provides us with effective firewall hardware, automatic network intrusion detection, and the expertise of dedicated security experts working at the University. Network equipment includes four high-speed switches. User authentication is centralized with two Windows 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 our 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 our offices, or via a VPN client.

All network traffic is monitored for intrusion attempts, security scans are regularly run against our servers, and our IT staff is notified of intrusion alerts. Security is maintained

with Windows 2008 user/group domain-level security. Users are required to change their passwords every 90 days, and workstations time out after 5 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 in the DCC or in the Department of Pediatrics are whole-disk encrypted.

The data center uses control center tools to continuously monitor systems and failure alerts. Environmental and network systems are also monitored to ensure up time. Highly trained system administrators on staff are available to respond in high risk emergency events.

All personnel involved with the DCC have signed confidentiality agreements concerning data encountered in the course of their daily work. All personnel (including administrative staff) have received Human Subjects Protection and Health Information Portability and Accountability Act (HIPAA) education. We require all users to sign specific agreements concerning security, confidentiality, and use of our information systems, before access is provided.

6.4 Data Sharing Plan

It is a Federal requirement to share research data in a project such as this one. When the study is completed, the DCC will prepare a distributable database in compliance with these Federal requirements. This database will be de-identified sufficiently that it will not be subject to 45 CFR §46 nor the Health Insurance Portability and Accountability Act (HIPAA). Note that the limited PHI in the analysis database (month, year, clinician and encrypted medical record number) is used in order to direct performance measure reports, but these variables will not be included in the database produced for sharing with other researchers.

Access to this research database will be managed in accordance with PECARN data sharing policies and applicable Federal laws. Registry data in this study will not be provided back to participating study sites except as outlined in the protocol (specific performance report cards for quality improvement initiatives). Each site, of course, has its own original data and can conduct its own quality improvement activities. Individual clinicians may request the encrypted study identifiers of patients included in their performance report card, in order to enable their review of the medical record to identify opportunities for future performance improvement.

7 Protection of Human Subjects

7.1 Institutional Review Board Approval

Institutional Review Board (IRB) approval will be required from all sites participating in this study, including the PECARN Data Coordinating Center (DCC). The DCC will maintain documentation of initial and on-going approval at each site, and this documentation will be required in order for a site to submit electronic data to the DCC.

7.1.1 Expedited IRB Approval

Expedited IRB approval is requested for this study. Expedited IRB approval procedures are permissible when the research activities present no more than minimal risk to human subjects, and only involve procedures listed in specific categories listed in the regulations at Federal Register 63:29748, 1998, 21 CFR §56.110, and 45 CFR §46.110. For this project, the procedures fall under Category 5, which is research that involves materials (data, documents, records) that have been collected, or will be collected, solely for non-research purposes (e.g., medical treatment, diagnosis). All data in this study are from the medical records produced during the on-going clinical activities of the participating centers.

7.2 Waiver of Informed Consent and Assent

Waiver of informed consent and patient assent is requested for this study. As described in Section 3 on page 9, the participating sites and their component clinicians are the units of analyses in this study. The topic of study is the aggregate behavior of the emergency departments and potential changes in clinician performance measures, and selective consenting or assenting would destroy the scientific validity of the study. Performance feedback, while studied as part of this proposal, will be directed at quality improvement. Any practitioner or site specific feedback will be directed to that individual, identified only by a randomly generated study provider number, or site so that there is minimal risk of adverse financial or professional consequences during the study. Feedback will be provided so that the clinicians can better understand their own practice as a starting point for practice improvement. Practitioners will have the option of not reviewing provided feedback.

Waiver of informed consent from the clinicians is requested because risks to the individual clinicians are minimal (Section 7.4.3 on page 25), the waiver will not adversely affect the rights and welfare of the clinicians, uniform participation is necessary for the

scientific validity of the study, and the clinicians will receive information about their performance during the study. These are the four requirements for waiver of informed consent outlined in 45 CFR §46.116(d).

Waiver of informed consent and assent from patients is requested for this project. Specific patients are not the subjects of study, but rather, their ED visit contributes information about the sites and clinicians, which are the subjects of study. The requirements of 45 CFR §46.116(d) are also met for the patient population, as the risk is minimal, the rights and welfare of the patients are not being affected, and uniform inclusion of all patients is necessary for the scientific validity of the study. There is no provision for providing additional pertinent information to patients, as they are not the subjects of the study.

7.3 Waiver of Written Authorization for HIPAA

Waiver of authorization for use and/or disclosure of protected health information under the the Privacy Rule is requested for this study. Waiver of authorization for the use of patient electronic health record data is permissible under §164.512(i)(2)(ii). The requirements are that the use of the data involves no more than minimal risk to the privacy of the patients, that the research could not practicably conducted without the waiver, and the research cannot be conducted without access to the data. Written authorization is not practicable in the urgent environment of the ED, data are being abstracted long after the patient has departed the ED, and the scientific validity of the study would be destroyed since all visits must be included in order to determine the performance measures. The use or disclosure of the protected health information involves no more than minimal risk to the individuals because:

- There is an adequate plan to protect the identifiers from improper use and disclosure. The PECARN DCC has provided Business Associate Agreements for execution by each participating site, and the security of its information systems has been described in Section 6.3 on page 21.

- There is provision to destroy identifiers before integrating patient data into the registry, and the de-identification procedures are thoroughly discussed in Section **??**.

- The protected health information will not be reused or disclosed to any other persons or entities, except as required by law, or for authorized oversight of the research project.

7.4 Risks to Human Subjects

7.4.1 Research Participants and Characteristics

Number and characteristics of participants. This project will maintain and enlarge an existing registry of electronic health record data including all visits to the base and satellite emergency departments (EDs) of the participating sites for all patients. The registry currently contains data from seven hospitals in four health care systems since CY 2012, and will accrue records from participating sites for at least the next five calendar years.

Inclusion in the registry will be regardless of race, ethnicity, or gender. Inclusion will be regardless of diagnosis or chronic health condition. Clinicians will be included in the protocol regardless of race, ethnicity, or gender.

7.4.2 Sources of Materials

This project includes only data that will be obtained from already completed EHRs. No prospective data will be collected solely for study purposes. Queries of the Pediatric Emergency Care Registry will provide the data for analysis. At each site, the investigators involved in the project, the site research coordinator and information technology contact will have access to identifiable private information about some or all subjects. After de-identification procedures are finalized by the DCC (Section 4.4 on page 13), the procedures will be carried out at each clinical site, on their servers within their firewall. Then the encrypted components of the EHR will be submitted electronically using a secure system hosted by the DCC. At the DCC, the DCC PI, data managers, statisticians, and other staff may have access to a limited set of identifiable information.

7.4.3 Potential Risks

This study is without direct patient contact and utilizes only existing electronic health record data. 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 above.

Provision of performance report cards is anticipated to improve the quality of care, and there are no reasons to anticipate that such report cards will pose risks to patients. Risk to the participating sites or practitioner is the disclosure that any one site or practitioner has quality outcome patterns that greatly differ. This risk is mitigated by use of deidentified practitioner and site study numbers assigned by the DCC for the Registry and report cards.

The DCC maintains a study key to allow for appropriate identification of visits pertaining to each practitioner and also to allow for distribution of the report cards. This decreases the risk to practitioners as identification is not known by the hospital site administration. All individual feedback reports are anonymized to protect the identification of clinicians, and all published results will be presented in aggregate form.

7.5 Adequacy of Protection Against Risks

This project entails the continuation and expansion of an established emergency department electronic health record registry for purposes of quality improvement and research about processes of care for diseases and injuries seen in the pediatric emergency setting. All data will be obtained from already completed electronic health records. We will collect no prospective data solely for study purposes. In every case, final decisions regarding clinical care will have been made between patients, their parents, and clinicians at the bedside, prior to the transmittal of data to the DCC or provision of performance measure information to sites and clinicians. This intervention will in no way mandate clinicians to pursue a specific treatment for a given patient. However, clinicians may be better informed about their own prior performance and will have an opportunity to provide evidence-based improvements in the quality of care they provide to future patients.

7.5.1 Protection Against Risks

Data will be acquired from hospital computer systems and the primary potential risk to subjects is improper disclosure of medical information. Data analysis for this project will be conducted using de-identified data. Data will be housed at the DCC, for which security was previously described (Section 6.3 on page 21).

The performance measures involved in the current report cards have been carefully developed to include only ones with a strong evidence base and endorsement by nationally recognized experts and stakeholders. Audit and feedback concerning clinical care is a regular activity in all health care organizations. All published results will be presented in the aggregate and care will be taken to keep identification of sites and investigators confidential.

7.5.2 Human Subjects Protection Training

All key personnel have completed Human Subjects Protection Training as mandated by involved Institutional Review Boards. This training involves an extensive, web-based,

curriculum emphasizing the safeguards necessary to conduct human subjects research, particularly with children.

7.6 Potential Benefit of Research

This project will continue using the Registry to enable quality performance measures of emergency healthcare for children across participating EDs (base and satellite) in the Pediatric Emergency Care Applied Research Network. It compares quality performance measures of emergency care provided to children across different institutions by using data extracted from electronic health records, enabling hospitals to target best performance. The Registry enables participating hospitals to evaluate the impact of providing provider-specific feedback and benchmarks of care on quality measures that are within the locus of control of the individual provider. The feedback may directly improve the quality of care of future patients treated by the practitioners and the sites.

7.7 Importance of Knowledge to be Gained

In its 2006 report, "Emergency Care for Children: Growing Pains", the Institute of Medicine recommended that pediatric emergency medical systems support the development and measurement of standards for emergency care performance measurement. The ability to accurately and comprehensively assess the process and outcomes of care in pediatric emergency patients is imperative to the evaluation of the quality of care provided. Past endeavors have been limited by the labor intensive nature of obtaining the information needed to determine quality performance measures. The PECARN Registry has allowed for the comprehensive and scalable determination of quality performance measures using an electronic health record registry across multiple sites. It has enabled evaluation of the impact of providing provider-specific feedback and benchmarks of care on quality measures that are within the locus of control of the individual provider. In addition, the systematic and widespread collection and reporting of performance and outcomes, using the same operational definitions, is critical to allow clinicians and other emergency care stakeholders to continue to work together to innovate and improve care beyond the local level. The PECARN Registry has demonstrated potential to improve the care of children in the emergency setting, and continuation of the Registry will enable continued improvement of care to this vulnerable population.

8 Health Insurance Portability and Accountability Act

All relevant data in the electronic health record is being collected in this study, including potentially identifying information, because the entire project aims to create a registry automatically from the medical record. Rigorous de-identification procedures will be conducted to produce the analysis database with a minimum of Protected Health Information (PHI). Specifically, the analysis database will have the month and year of visit. If unexpected additional PHI is detected in submitted data by the Data Coordinating Center, it will be de-identified by the DCC, and feedback will be provided to the clinical site(s) to further refine the de-identification procedures so that this does not recur.

Data elements for race, ethnicity, and gender of subjects will be preserved. These demographic data are required for Federal reporting purposes to delineate subject accrual by race, ethnicity, and gender.

All study sites have been offered a Business Associate Agreement with the University of Utah, which agrees to handle submitted data with the security precautions required for PHI. Copies of executed Business Associate Agreements are maintained at the DCC.

9 Inclusion of Women and Minorities

Data from the emergency department (ED) electronic health record of all patients seen at the protocol sites will be included. Visits will be included without regard to patient race or ethnicity. A diversity of ethnic and racial backgrounds is represented at the selected PECARN sites.

10 Inclusion of Children

Data from the emergency department electronic health record for all visits of patients will be collected from the selected sites. ED visits will be included without regard to age. Members of the investigative team are board certified in pediatrics and pediatric emergency medicine and have extensive experience and expertise in caring for children in this age range. The sites participating all have emergency departments dedicated to the care of children.

11 Access to and Retention of Records

For federally funded studies subject to the Common Rule, records relating to the research conducted shall be retained for at least 3 years after completion of the research. Completion of the research for this protocol should be anticipated to include planned primary and secondary analyses, as well as subsequent derivative analyses. Completion of the research also entails completion of all publications relating to the research. All records shall be accessible for inspection and copying by authorized representatives of the regulatory authorities at reasonable times and in a reasonable manner [45 CFR §46.115(b)].

Bibliography

[1] Health, United States, 2005: Chartbook on Trends in the Health of Americans. Hyattsville, Maryland: National Center for Health Statistics; 2005.

[2] Health, United States, 2009: With Special Feature on Medical Technology. Hyattsville, Maryland: National Center for Health Statistics; 2010.

[3] Institute of Medicine Committee on the Future of Emergency Care in the US Health Care System. Emergency Care for Children: Growing Pains. Washington, DC: National Academy Press; 2006.

[4] Seidel JS, Henderson D, Tittle S, Jaffe D, Spaite D, Dean JM, et al. Priorities for research in emergency medical services for children: results of a consensus conference. Pediatr Emerg Care. 1999 Feb;15(1):55–8.

[5] Chamberlain JM, Patel KM, Pollack MM. Association of emergency department care factors with admission and discharge decisions for pediatric patients. J Pediatr. 2006 Nov;149(5):644–649.

[6] Crain EF, Weiss KB, Fagan MJ. Pediatric asthma care in US emergency departments. Current practice in the context of the National Institutes of Health guidelines. Arch Pediatr Adolesc Med. 1995 Aug;149(8):893–901.

[7] Crain EF, Mortimer KM, Bauman LJ, Kercsmar CM, Weiss KB, Wissow L, et al. Pediatric asthma care in the emergency department: measuring the quality of history-taking and discharge planning. J Asthma. 1999;36(1):129–38.

[8] Hampers LC, Trainor JL, Listernick R, Eddy JJ, Thompson DA, Sloan EP, et al. Setting-based practice variation in the management of simple febrile seizure. Acad Emerg Med. 2000 Jan;7(1):21–7.

[9] Ramenofsky ML, Luterman A, Quindlen E, Riddick L, Curreri PW. Maximum survival in pediatric trauma: the ideal system. J Trauma. 1984 Sep;24(9):818–23.

[10] Stanley RM, Teach SJ, Mann NC, Alpern ER, Gerardi MJ, Mahajan PV, et al. Variation in ancillary testing among pediatric asthma patients seen in emergency departments. Acad Emerg Med. 2007 Jun;14(6):532–8.

[11] Zerr DM, Del Beccaro MA, Cummings P. Predictors of physician compliance with a published guideline on management of febrile infants. Pediatr Infect Dis J. 1999 Mar;18(3):232–8.

[12] Cain VS, Kington RS. Investigating the role of racial/ethnic bias in health outcomes. Am J Public Health. 2003 Feb;93(2):191–2.

[13] Pediatric Emergency Care Applied Research Network. The Pediatric Emergency Care Applied Research Network (PECARN): rationale, development, and first steps. Acad Emerg Med. 2003 Jun;10(6):661–8.

[14] Pediatric Emergency Care Applied Research Network. The Pediatric Emergency Care Applied Research Network (PECARN): rationale, development, and first steps. Pediatr Emerg Care. 2003 Jun;19(3):185–93.

[15] Alpern ER, Stanley RM, Gorelick MH, Donaldson A, Knight S, Teach SJ, et al. Epidemiology of a pediatric emergency medicine research network: the PECARN Core Data Project. Pediatr Emerg Care. 2006 Oct;22(10):689–99.

[16] Alpern ER, Donaldson AE, Alessandrini EA, Gorelick MH, Stanley RM, Teach SJ, et al.; PAS. Epidemiology of pediatric emergency department recurrent visits. PAS. 2005;57:1862.

[17] Mahajan P, Alpern ER, Grupp-Phelan J, Chamberlain J, Dong L, Holubkov R, et al. Epidemiology of psychiatric-related visits to emergency departments in a multicenter collaborative research pediatric network. Pediatr Emerg Care. 2009 Nov;25(11):715–20.

[18] Timm N, McAneny C, Alpern E, Macy M, Ruddy RM. Is pediatric emergency department utilization by pregnant teens on the rise? PAS. 2010;p. 20101494.434.

[19] Gorelick MH, Alpern ER, Singh T, Snowdon D, Holubkov R, Dean JM, et al. Availability of pediatric emergency visit data from existing data sources. Acad Emerg Med. 2005 Dec;12(12):1195–200.

[20] Gorelick MH, Knight S, Alessandrini EA, Stanley RM, Chamberlain JM, Kuppermann N, et al. Lack of agreement in pediatric emergency department discharge diagnoses from clinical and administrative data sources. Acad Emerg Med. 2007 Jul;14(7):646–52.

[21] Alessandrini EA, Alpern ER, Chamberlain JM, Shea JA, Gorelick MH. A new diagnosis grouping system for child emergency department visits. Acad Emerg Med. 2010 Feb;17(2):204–13.

[22] Alessandrini EA, Alpern ER, Chamberlain JM, Gorelick MH. Developing a diagnosis-based severity classification system for use in emergency medical systems for children. PAS. 2007;p. 61670.5.

[23] Dean JM, Chamberlain J, Gorelick MH, Stanley R, Snowdon D, Mahajan P, et al. The PECARN Core Data Project: benchmarking hospitals in a pediatric emergency medicine research network. Pediatr Res. 2004;55:119A.

[24] Stanley R, Alpern ER, Gerardi M, Mahajan P, Teach SJ, Chamberlain JM, et al. Variations in diagnostic testing in the ED for pediatric non-urgent illnesses. PAS. 2005;57:2865.

[25] Neamatullah I, Douglass MM, Lehman LwH, Reisner A, Villarroel M, Long WJ, et al. Automated de-identification of free-text medical records. BMC Med Inform Decis Mak. 2008;8:32.

[26] Saeed M, Villarroel M, Reisner AT, Clifford G, Lehman LW, Moody G, et al. Multiparameter Intelligent Monitoring in Intensive Care II: a public-access intensive care unit database. Crit Care Med. 2011 May;39(5):952–60.

[27] Weissman NW, Allison JJ, Kiefe CI, Farmer RM, Weaver MT, Williams OD, et al. Achievable benchmarks of care: the ABCs of benchmarking. J Eval Clin Pract. 1999 Aug;5(3):269–81.