

INTRODUCTION

The Children's Hospital of Philadelphia Pediatric Research Consortium (CHOP-PeRC) was established with funding from the Agency for Healthcare Research and Quality (AHRQ) (R21-HS-02-033) in September of 2002.

PeRC, the primary care practice-based research network (PBRN) at CHOP, is dedicated to improving the safety, quality and health outcomes of pediatric care through clinical research. PeRC has been able to take advantage of CHOP's expanded organizational and technological infrastructure in assembling the components of the country's largest pediatric integrated delivery system which includes a primary pediatric healthcare network of 31 pediatric practices located in urban, suburban and rural locations throughout the Delaware Valley.

In addition, PeRC has taken advantage of the implementation of an ambulatory electronic health record (EHR) system – a technological tool that affords immediate, electronic access to clinical information and communication at the point of care – to gather data across the pediatric network to conduct research and develop an array of integrated evidence-based decision support tools at the point of care. The EHR is currently in use in 31 Primary Care Practices throughout the network and over the past fifteen years it has captured data for over 500,000 patients.

PeRC has assembled a talented group of epidemiologists, clinical informaticians and administrators to organize and facilitate the clinical research projects that it agrees to undertake. PeRC's early successes have resulted in an increasing demand for collaboration and access to the primary care network and data in the EHR.

Therefore, over the last fifteen years, PeRC has begun to meet its mission by taking advantage of the primary care network and the EHR.

Research and Related Experience of the PBRN

PeRC has been in existence for fifteen years. Since inception, over 250 clinical research projects have been completed within our PBRN and over 350 research projects have been reviewed through the established PeRC process. Over 150 peer-reviewed publications have resulted from research conducted within our PBRN. Increasingly, PeRC has been called upon to participate in research projects that rely heavily on clinical data in the EHR.

Key Personnel

PeRC Medical Director – Louis M. Bell, MD is Chief of the Division of General Pediatrics at The Children’s Hospital of Philadelphia and is the Medical Director of the CHOP’s Practice-Based Research Network (PBRN). Dr. Bell is a Professor of Pediatrics at the University Of Pennsylvania School Of Medicine and the holder of the Patrick S. Pasquariello, Jr. Endowed Chair in Pediatrics. Sub-specialty board certified in pediatric infectious diseases and pediatric emergency medicine, Dr. Bell’s research career in pediatrics has been focused on the epidemiology and management of pediatric infectious diseases. His ability to design and complete research projects from clinically relevant questions, which ultimately change management, is reflected in 78 peer-reviewed publications.

As Medical Director, Dr. Bell is responsible for the overall success of the CHOP PeRC, including the timely delivery of well designed and thoroughly analyzed clinical

research in response to Funding Opportunity Announcement (FOAs) from AHRQ that are appropriate for the PeRC. The key personnel that Dr. Bell has assembled have been together for over fifteen years and include expert epidemiologists and health service researchers, clinical informaticians and administrators. Biostatistical support and other resources at CHOP and at the University of Pennsylvania are readily available.

PeRC Network Director – Jim Massey, RN, BSN, MBA joined the PeRC administrative structure effective July 6, 2008. His clinical background as a pediatric staff nurse in both inpatient and outpatient arenas, coupled with extensive experience in facilitating clinical research projects from a variety of different sponsors and sub-specialty arenas make him well-suited to lead the PBRN through its continued development as a premier pediatric research network

In his role as Network Director, Mr. Massey is responsible for the operational oversight of the network including administrative and financial planning for future research endeavors. He works closely with many of the investigative teams from initial grant application to development of electronic charting tools and comprehensive data reports. In addition, he serves as a critical liaison between the primary care practices and clinical researchers.

PeRC Associate Medical Director-Alexander G. Fiks, MD, MSCE is the Associate Medical Director of the Pediatric Research Consortium (PeRC) and has been actively conducting research in PeRC since its inception. He is an Associate Professor of Pediatrics at the Perelman School of Medicine at the University of Pennsylvania, a faculty member in the Department of Biomedical and Health Informatics (DBHi), Center for Pediatric Clinical Effectiveness, and PolicyLab at The Children's Hospital of

Philadelphia (CHOP), and a practicing primary care pediatrician. Dr. Fiks is currently leading multiple collaborations between PeRC and the Pediatric Research in Office Settings (PROS) Practice-Based Research Network of the American Academy of Pediatrics. His primary research focuses on improving decision making in and outcomes from pediatric care through the use of shared decision-making and the implementation of health information technology.

Director, Clinical Informatics- Robert W. Grundmeier, MD is board certified in pediatrics and has worked as a pediatrician for over a decade in Primary Care Centers at Children's Hospital. He is the director of clinical informatics in the Department of Biomedical and Health Informatics (DBHi) and leads efforts to use the electronic health record (EHR) for clinical research and knowledge delivery. Dr. Grundmeier is an accomplished programmer with experience in database reporting tools and user-interface design and has served as the physician analyst for the EHR implementation team. He has several years experience-developing software for engineering and medicine needs and is co-inventor of the "Care Assistant".

Dr. Grundmeier has supported a multitude of research projects on topics ranging from documentation completeness, infant feeding, asthma, childhood development, psychiatric disease, and trauma. Dr. Grundmeier is currently working with multiple academic organizations to replicate our successful use of the EHR as a research tool in new settings.

Manager, Clinical Reporting Unit- Marianne Chilutti directs the clinical reporting activities that take advantage of the EHR's extensive data set. The contributions

of Ms. Chilutti and her team are critical to providing accurate, relevant clinical data to the researchers within the PeRC network.

Potential for Conducting Research

The Pediatric Research Consortium (PeRC) is the Primary Care Practice-Based Research Network (PBRN) at The Children's Hospital of Philadelphia. This network is dedicated to improving the safety, quality and health outcomes of pediatric care through clinical research.

The Network's mission is to provide the expertise and infrastructure needed to support both top-down and bottom-up research within the primary care setting. Its overall aim is to support primary care clinicians in the development of research, the results of which will transform the way care is provided within the network and will further enhance the quality and health outcomes of patients. This will be done by optimizing the ever-improving functionality of the electronic health record, developing mentoring relationships with established research methodologists, and supporting research within the context of clinical care. As development continues, the PBRN will become a nationally and internationally recognized entity for the advancement of primary care research. As such, the PBRN will support and enhance the position of The Children's Hospital of Philadelphia as a national and international leader in pediatric research.

PeRC's goals are to:

- Provide high-quality research based on the clinical needs of all primary care practices within CHOP's network.
- Support the development of research questions of clinicians within the primary care network and supply the resources needed to carry out their studies

- Develop the current information systems into a system that can function over a wide range of purposes, including clinical care, education, research, and evaluation.
- Develop a mechanism to translate research into practice and evaluate its impact using the EHR as a starting point.

Size and Diversity of Patient Population

The Primary Care Network represented by CHOP's PBRN includes 31 practice sites live on the EpicCare electronic health record (EHR) and which saw 248,480 patients between January 1, 2017 and December 31, 2017. Three of the practices are teaching sites for the pediatric residency program. One site includes a clinic where adolescent medicine specialists provide primary care and family planning to adolescent patients, and support general pediatricians across the network to do the same. One site is the hospital's General Pediatrics (faculty practice) service. The other twenty-seven sites are primary care pediatrics offices spread throughout Pennsylvania and New Jersey, providing acute and well care to patients in urban, rural, and suburban settings (Figure 12).

The specific demographic profile of each practice varies (Table 7). However, of the total 248,480 children seen in 2017 (total is less than the total listed in Table 7 because one child may appear in more than one site), 53% were white and 27% were African-American. With the exception of adolescent medicine, the population is evenly divided by gender. Due to the extensive focus on family planning, 91% of patients seen in the adolescent care center were female. During 2017, approximately 7% of the patients were less than 12 months old, 13% were 1 to 2 years of age, 54% were 3 to 12 years of age, and 26% were 13 or older. Approximately 76,000 patients were covered through

Medicaid and 16 were reported as “self pay”. The rest of the patients were insured through private payers, mostly Blue Cross or Aetna products.

Prevalence of certain health problems differs markedly between the urban and suburban care locations in the CHOP network, which adds to the diversity of the network.

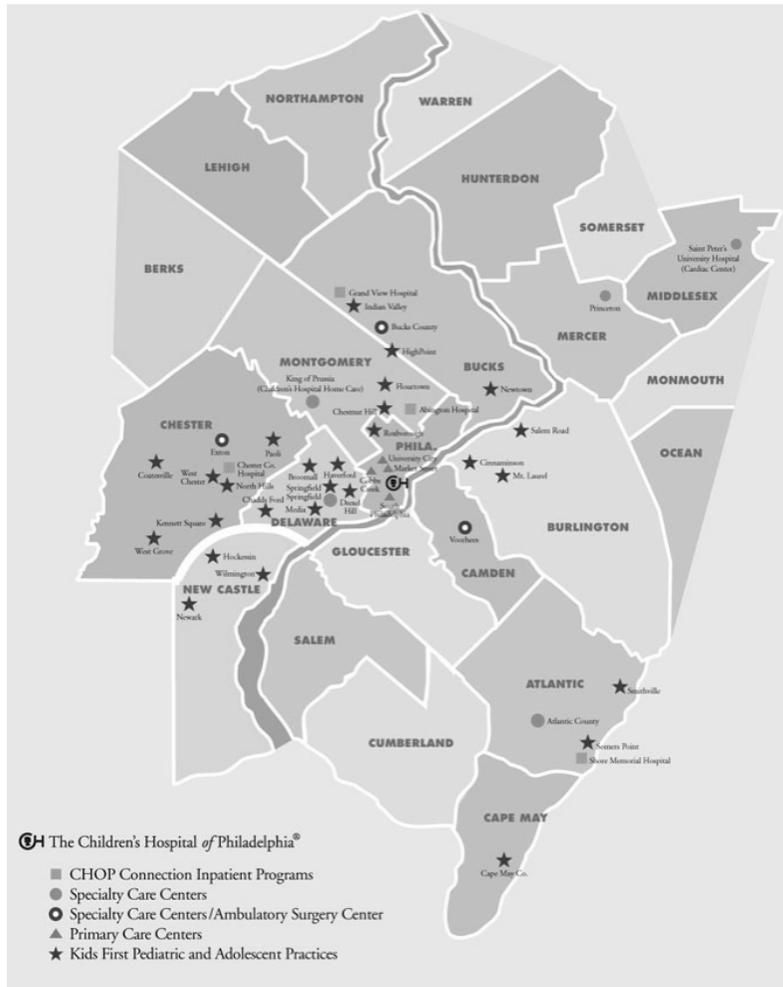


Figure 12: Geographic distribution of CHOP's network.

	Suburban practices (27 sites)	Urban practices (3 sites)	Faculty Practice (1 site)	Adolescent Med (1 site)
Black or African American	14%	74%	45%	32%
White	65%	9%	35%	54%
Asian or Pacific Islander	4%	4%	7%	3%
American Indian, Eskimo or Alaska Native	<1%	<1%	<1%	<1%
Other or Unknown Race	15%	11%	10%	10%
More than one race	2%	2%	3%	1%
Hispanic	7%	8%	8%	7%
Female	49%	50%	50%	91%
Less than 1 year old	7%	8%	9%	0%
1 – 2 years old	12%	15%	15%	0%
3 – 12 years old	54%	55%	48%	9%
13 or more years old	27%	22%	28%	91%
Total Patients	189653	49600	8401	1900

Table 7: Distribution of race, ethnicity, gender, and patient age.

Diversity of Practices

CHOP has established a pediatric healthcare network consisting of 31 regional pediatric practices called the CHOP Pediatric and Adolescent Care Network. It also includes thirteen Specialty Care Centers and six pediatric inpatient units at affiliated community hospitals (CHOP Connection sites), as well as an Adolescent Medicine practice.

The network ensures quality of care, access to care and continuity of care—all-important goals in pediatrics. This multi-site system allows Children’s Hospital to offer its world-renowned care to children throughout the city and region and at sites accessible to their families. With levels of care ranging from basic to well-child care to the most sophisticated surgery and intensive care, the Children’s Hospital is able to guarantee continuity of care across the continuum of care.

Through this network, Children’s Hospital can better fulfill its own commitment to improving the health of children in the city and the region. To this end, CHOP aims to provide continuity of care across the continuum through its integrated delivery system, which provides a shared administrative structure and communication technology across the practices and allows primary care providers the ability to document patient encounters using an electronic health record (EHR) at the point of care.

This healthcare system is unique in the region because it combines an exclusive focus on the health needs of children with a partnership relationship between physicians and one of the nation’s premier children’s hospitals. The system combines the clinical expertise of CHOP physicians and community-based pediatricians with the unique

resources of CHOP. The activities of specific groups within the PBRN are described below.

Suburban/Rural Pediatric Practices – The Suburban and Rural Practices are devoted to providing comprehensive general outpatient care to children from birth to 18 years of age, including well-child and sick visits, immunizations and developmental screenings, as well as health screenings for Tuberculosis, Lead Poisoning and Anemia. Of the 189,653 patients seen in 2017, 65% are Caucasian. There are over 590,000 patient visits each year. The physicians are all board-certified and have staff privileges at CHOP. The physicians are able to access the specialty services of CHOP for their patients either by referring them to the main campus in Philadelphia or one of five Specialty Care Centers in the surrounding counties.

Urban Primary Care Centers – The hospital-owned Primary Care Centers are located at two community-based sites in West Philadelphia and one in South Philadelphia and are staffed by 54 pediatricians and pediatric nurse practitioners. These centers handle approximately 132,000 visits per year. The Primary Care program is a model for pediatric primary care for disadvantaged children. Many of the families who seek care at the Primary Care centers are struggling to raise their children in the face of severe medical and social risk. Over half of the families are living at or below the poverty line and more than 73% receive health coverage through Medical Assistance. Of the over 49,600 patients seen in 2017, 74% were African American. Inherent in the population is a higher than average rate of chronic physical and psychiatric conditions. The West and South Philadelphia neighborhoods where the centers are located are plagued by high rates of

crime, drug use and teen pregnancy. This system represents the largest provider of primary care services for children in the City of Philadelphia.

CHOP Campus– The CHOP Campus is a general pediatric faculty practice in the academic setting at CHOP. The mission is to provide primary care to CHOP’s patient population that draws from the proximal area of West Philadelphia to northern New Jersey to the surrounding areas of Delaware. The care that is entrusted within the practice is both of medically healthy children as well as medically challenged children. The practice encounters approximately 24,000 patient visits per year and covers over 8,401 patients’ lives. Other missions of the practice include medical student education and clinical research. The practice serves as an active site to educate 2nd and 3rd year medical students at the University of Pennsylvania School of Medicine. Areas of clinical research currently include child safety research and combination vaccine trial research.

Adolescent Medicine – The Adolescent Medicine practice at The CHOP Karabots clinic provides primary health care and family planning services to teens. All the attending providers in this practice have completed subspecialty training in the field of adolescent medicine. Nurse practitioners, adolescent medicine fellows and pediatric residents also provide care under the supervision of the adolescent medicine attendings. The providers place special emphasis on the psychosocial well being of their patients at every visit. Research activities of the group include resilience and strengths among adolescents, parent-teen communication, depression and suicide risk assessment and intervention, violence and injury prevention, healthcare transition to adult medicine, family planning services, sexually transmitted infections, health weight maintenance, and teen vaccination. In addition, Adolescent Medicine subspecialty services are provided at

a specialty clinic focused on providing care for adolescents with anorexia or bulimia nervosa, menstrual disorders, complex reproductive health care needs, and HIV infection.

Information Systems

In the last fifteen years the Children's Hospital of Philadelphia has expanded its organizational and technological infrastructure and assembled the components of the country's largest pediatric integrated delivery system supporting a 1,500,000 visit primary and specialty care network, community-based inpatient pediatric and neonatal programs, a rehabilitation hospital, and a home care service.

This expansion compelled CHOP to conduct a process improvement program – an enterprise-wide review of its information infrastructure across clinical care, research education and patient family services. The process improvement program focused on how CHOP's systems work in an integrated fashion for the end user, how the tools can collect meaningful data for clinical, operational and research analysis, and how decision support tools can be utilized in a real-time manner to enhance process and outcomes, with the goal of improving information delivery and sharing capabilities using information technology tools.

CHOP's vision is to turn each clinical encounter into data that will be consistently and continually evaluated for outcomes, compare those outcomes to evidenced-based practice, and provide real-time feedback to clinicians and managers seeking to achieve both the best outcome for the patient, researcher, and/or trainee in the individual situation, as well to offer the best clinical care on an ongoing basis. To achieve this, CHOP is rapidly expanding its use of an ambulatory electronic health record (EHR)

system—a technological tool that affords immediate, electronic access to clinical information and communication at the point of care—to gather data across the pediatric network to conduct research and develop an array of integrated evidence-based decision support tools at the point of care.

CHOP's Outpatient Electronic Health Record System (EHR) – Currently, the EHR is used in all the CHOP Ambulatory Practices. The EHR is used for all aspects of clinical care occurring in these outpatient settings, including office visits, daytime telephone triage, and after-hours telephone triage. This electronic system offers rapid access to patient-specific data, direct routing of orders and results, structured data in key fields, legible documentation, and the ability to manage data from across the patient population. The EHR product is EpicCare®, developed by Epic Systems, Inc, Madison, WI. Key examples of structured data available in the EHR include: the reason for visit, diagnosis codes (ICD-9 format), weight, height, peak flow, pulse oximetry reading, medications prescribed, and telephone triage disposition. Customized data entry forms can be readily built to capture a wide variety of other structured data. Informed by these data, the EHR provides tools for presenting alerts and reminders at the point of care. Links to additional information can also be presented in the EHR.

At CHOP, additional clinical data are available in the EHR by interface. For example, the EHR is interfaced with both the hospital laboratory information system (Meditech) and a major external reference laboratory serving the Delaware Valley region (Quest Diagnostics). All laboratory test results are available in the EHR in a structured format. The EHR at CHOP also receives radiology reports, surgical notes, hospital discharge summaries, and ED summaries. All these data can be routed directly to the

EHR's user so important values may be acted on immediately. Each EHR user has an inbox that functions as a clinical e-mail system and supports workflow with timely and accurate communication.

As the PeRC activities have expanded, the EHR has been increasingly used to support research specific activities. For retrospective projects, historical data can be mined to measure many if not all the research variables that may be required. For prospective projects, automated prompts can be presented to providers at the point of care when an eligible patient is receiving care to facilitate case finding (Figure 13). These prompts are carefully “tuned” to ensure they are highly relevant and perceived as useful by clinicians, patient families, and researchers alike. The PeRC advisory team provides ongoing feedback on these prompts. Recently the ability to automatically print a brief description of the project for patients who indicate interest has also been added. On a weekly basis, the research team receives lists of patients who have expressed interest in being contacted for their study.

	A	B	C	D	E	F	G	H	I	J
	PatientName	MRN	PrimaryCareSource	Provider	DateOfEnc	DateOfBirth	Gender	Race	PhoneNumber	
1	TEST PATIENTA	01234567	MS-MARKET STREET	GRUNDMEIER, ROBERT	12/12/2005	10/1/1989	Female	Black	215-555-1234	OK to contact
2	TEST PATIENTB	01234568	MS-MARKET STREET	WINSTON, FLAURA	12/16/2005	11/1/1989	Male	Black	215-555-1245	OK to contact
3	TEST PATIENTC	01234569	MS-MARKET STREET	SWIETLIK, MARGUERITE	12/9/2005	12/1/1989	Female	Black	215-555-1257	OK to contact
4	TEST PATIENTD	01234570	MS-MARKET STREET	LUBERTI, ANTHONY	12/14/2005	9/1/1989	Male	Black	215-555-1268	OK to contact
5	TEST PATIENTE	01234571	MS-MARKET STREET	GRUNDMEIER, ROBERT	12/9/2005	8/1/1989	Female	White	215-555-1299	OK to contact
6	TEST PATIENTF	01234572	MS-MARKET STREET	WINSTON, FLAURA	12/16/2005	7/1/1989	Male	Black	215-555-1200	OK to contact

Figure 13: Screenshot of research enrollment prompt and weekly enrollment report received by researcher team

For prospective interventional studies, the research intervention protocol is sometimes integrated into the clinical workflow through the EHR. This can be done with randomization at the level of patient, provider, or practice if needed. Screenshots supporting the intervention arm of an obesity prevention study are shown in Figure 14.

Inpatient Systems – The Children's Hospital inpatient units make use of a number of systems that inform and facilitate patient care. These systems allow the PBRN to determine care utilization patterns across the continuum of care including ED and hospital care. The core inpatient information system is Epic, which provides decision support based on allergies, health issues, or medication interactions.

The data from these major systems, including order entry and alerting information from and charge- level detail for labs and services provided, are ultimately stored in the EPIC Reporting database (Clarity) and also in the Clinical Data Warehouse (CDW). Informatics researchers are able to query the Clarity and CDW to answer increasingly complex questions.

Ongoing projects include using Clarity/ CDW to identify matched controls for case-control cohort studies, to search full-text radiology report data to identify patients who had specific complications associated with pneumonia, and to validate the specificity of various ICD-10 codes for specific diseases.

Combined with the Ambulatory EHR and its the information for inpatient care at CHOP, Epic provides a unique and powerful tool for clinical research.

Institution Support and Resources

The Pediatric Research Consortium is supported by The Children's Hospital of Philadelphia (CHOP), Research Institute. There are significant benefits to being a part of a large health care organization. Multiple resources are easily accessible to assist in forming clinical questions, providing relevant clinical data, and conducting research that will lead to improved patient outcomes. The easy access allows clinical experts to

produce quick turn-around studies, the results of which are easily generalized to other geographic areas throughout the country.

Institutional Review Board – All primary care practices that participate in research conducted by the PeRC are guided by the policies and standards adopted by the hospital as well as governed by the rules of the CHOP Institutional Review Board (IRB). The CHOP IRB works closely with the PeRC to review and evaluate studies to be conducted within the network. Prior to final approval, a letter of review is submitted by the PeRC project office on behalf of the Primary Investigator notifying the IRB that the proposed study is appropriate for completion within the primary care network. Only after the IRB receives this documentation will it grant final approval to the Primary Investigator to proceed. While it is common for many PBRNs to be accountable to multiple IRBs, the PeRC is fortunate that as a network of The Children's Hospital of Philadelphia, it is governed by a sole IRB. This allows investigators to submit and receive approval for their projects within a relatively short timeframe.