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Building the Electronic Clinical Data Infrastructure to Improve Patient Outcomes: CER Project Profiles

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CER Project Profiles

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CER Project Profiles
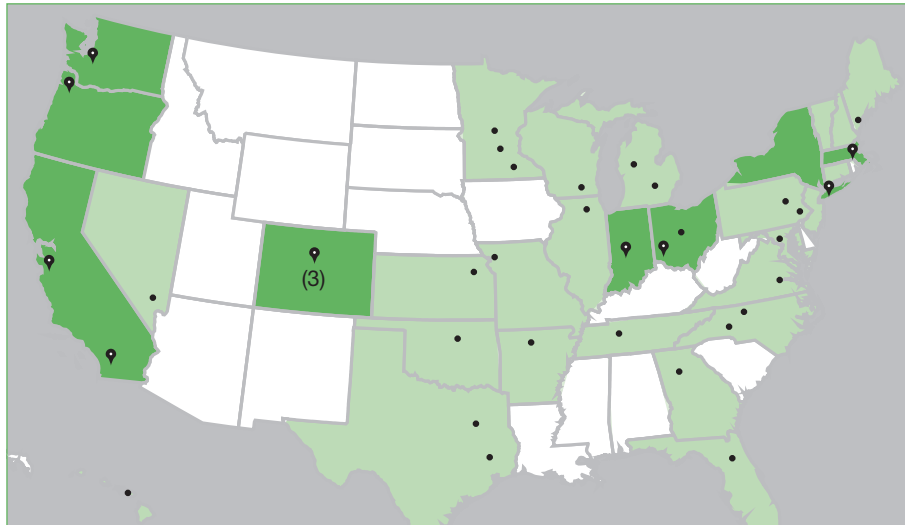
Background of Infrastructure Investments for CER

Comparative effectiveness research (CER) aims to generate evidence regarding the effectiveness of different health care treatments and strategies, specifically answering the question, "what works best, for whom, and under what conditions?" (Department of Health and Human Services, 2010).

Current investments in health information technology and information exchange will significantly enrich data and create new opportunities for conducting CER, patient-centered outcomes research (PCOR), and quality improvement (QI). However, accurately capturing, managing, and analyzing these data in meaningful ways requires improving and expanding the existing research infrastructure (i.e. the data systems, research methods, and professional training to do this work).[1] Improving the capacity of the existing infrastructure in current clinical research activities to integrate complementary data sources and methods, and achieve a level of evidence necessary to support decision-making is a critical goal for CER (Agency for Healthcare Research and Quality, 2010).

Of the $1.1 billion in CER funding within the American Recovery and Reinvestment Act of 2009 (ARRA), approximately $417.2 million was directed to improve and enhance the infrastructure and capacity for conducting CER (see Appendix A). Approximately $100 million of that investment is managed by the Agency for Healthcare Research and Quality (AHRQ) to build the infrastructure for conducting CER with electronic clinical data, including electronic health records (EHR). As part of this initiative, eleven research projects were funded through three programs: the Prospective Outcome Systems using Patient-specific Electronic data to Compare Tests and therapies (PROSPECT) studies; Enhanced Registries and QI and CER; and Scalable Distributed Research Networks (DRN) for CER. This support reflects a forward-looking need to develop innovative approaches for collecting, validating, and utilizing the growing amount of data made available

from electronic clinical data sources, and the need to facilitate use of these data for CER and PCOR. An additional AHRQ-funded project, the AcademyHealth Electronic Data Methods (EDM) Forum, acts as the harmonizing entity for the eleven research projects, engaging key stakeholders and facilitating synthesis and the dissemination of lessons learned in order to advance the science of CER. Dr. Gurvaneet Randhawa, of the Center for Outcomes and Evidence at AHRQ, is the project officer for the 12 projects.

This report provides background on the programs and includes project profiles of the PROSPECT, DRN, and Enhanced Registry projects, and the EDM Forum. Specific aims and elements are provided for each project, including the infrastructure and research aims, outcomes of interest, priority populations and conditions of focus,[2] and key partners involved in the projects. Additional information on the projects, including a list of articles published by each research team, information on the types of data collected (e.g., PRO, biospecimens, etc.), and strategies for organizing and linking data across the network are available in the electronic version of the project profiled on www.edm-forum.org.

ARRA Grant Programs Building Electronic Clinical Data Infrastructure for CER

The goal of the PROSPECT, DRN, and Enhanced Registry research programs is to build a flexible electronic infrastructure that can be used to overcome some of the common challenges in traditional research studies (both randomized control trials and observation studies) and data sources (administrative claims data and electronic health records).

The programs share the goal of building electronic data sharing and/or querying systems that enhance the capacity to conduct CER and QI, and that advance the potential for clinical decision support to improve

patient outcomes (Agency for Healthcare Research and Quality, 2010). All three grant programs are required to conduct CER and generate valid and generalizable conclusions. The programs also must focus on governance, AHRQ priority populations and CER conditions, and develop plans to ensure sustainability. To harness the potential of electronic clinical data for CER, each of the projects links multiple health-care delivery sites and blends data streams from a variety of institutions, data sources, and IT architectures, as well as works with multiple data types including administrative claims, registry, clinical, diagnostic, and patient-reported data. Harnessing these data will support the development of a fuller picture of the patient experience that can be used to inform research, clinical decision support, and QI efforts to improve patient outcomes.

The 11 ARRA-funded research projects represent a range of partnership models and geographic areas, and vary substantially in size. Some are national networks, while others are regional. Two of the eleven projects are concentrated statewide in Washington and Indiana, and one project focuses locally on a specific community in New York City. Overall, 32 states are represented. The networks range in size from 8,000 to 7.5 million individuals. Collectively, the estimated total population covered by the eleven ARRA-funded

projects affiliated with the EDM Forum is estimated to be over 21 million. Many of these projects belong to a larger network such as the HMO Research Network (HMORN), Indiana Network for Patient Care (INPC), or the DARTNet Institute. The estimated number of individuals reached across of all of these networks is 51 million patients.[3]

Each project is undertaking a set of specific research studies to demonstrate the feasibility of using electronic clinical data for CER and PCOR. Thirty-eight such studies are planned or underway on a range of populations and topics. As a whole, the studies address more than half of AHRQ's priority populations and conditions, with several projects focused on low-income populations, racial and ethnic minorities, and disease areas such as hypertension and asthma. The studies are also conducting CER for a range of treatments and interventions, diagnosis and adherence measures, care management strategies, care delivery characteristics, and quality of life measures. Patient-reported outcomes are being collected and analyzed in most of the projects. The number of enrolled participants in the CER studies range from 145 trial participants to more than 380,000 individuals in one observational study.

Specific aims for the three grant programs and the EDM Forum are provided below.

PROSPECT Studies[4]

The six PROSPECT studies are focused on developing new clinical infrastructure and improving the methodology for collecting prospective data from electronic clinical data to generate new evidence on the comparative effectiveness of healthcare interventions. The primary purpose of the PROSPECT Studies is to advance the quality, depth, and scale of the electronic data collection infrastructure as a basis for CER.

PROSPECT studies must include populations typically underrepresented in randomized control trials (RCTs) or that have limited access to healthcare, or both (e.g. patients with multiple co-morbidities, extremes of age, and minorities). An overarching aim of the PROSPECT program is to substantially enhance the nation's capacity to systematically collect prospective data to inform CER on diagnostics, therapeutics, devices, behavioral interventions, and procedures used in clinical care.

Enhanced Registries[5]

The two Enhanced Registries for Quality Improvement (QI) and CER projects are focused on further developing an existing patient registry to track health outcomes, measure quality and performance, and support CER. The primary purpose of these projects is to enhance the electronic clinical capability of an existing registry for two purposes: 1) creating and analyzing valid data for CER, and 2) enhancing the ability to monitor and advance QI in clinical care.

Scalable Distributed Research Networks

The three Scalable Distributed Research Networks (DRN) for CER projects are linking data by building and expanding the existing electronic health data infrastructure with an emphasis on developing the capability of near real-time data extraction and analysis, as well as new data collection at the point-of-care (with minimal impact on clinical workflow). The DRNs must include multiple cohorts (at least four pairs of increasing complexity over time) and at least two unrelated priority conditions, and each must implement near real-time data collection. The projects aim to enable the collection of comprehensive longitudinal data across diverse healthcare delivery settings (e.g. ambulatory, in-patient, and long-term care facilities) in order to evaluate the effectiveness of clinical interventions for a diverse set of health conditions.

Electronic Data Methods (EDM) Forum

The goal of the EDM Forum is to advance the national dialogue on using electronic clinical data for CER, PCOR, and QI to improve patient outcomes. The Forum actively engages investigators from the PROSPECT, DRN, and Enhanced Registry programs, as well as a diverse group of external stakeholders by facilitating collaboration; synthesizing activities and innovations in the field; and disseminating lessons learned in governance, clinical informatics, and analytic methods. The EDM Forum seeks to address issues and challenges of building a learning health system.

The EDM Forum is governed by a Steering Committee chaired by Dr. Ned Calonge of The Colorado Trust. The Steering Committee is comprised of the principal investigators from the 11 ARRA-funded research projects, AcademyHealth, AHRQ, and external stakeholders (see Appendix D).

About the Profiles

The profiles that follow summarize each project with respect to its infrastructure and research aims, and network characteristics. The last profile describes the structure, activities, and contributions of the EDM Forum.

Additional information is available in the electronic project profiles available at www.edm-forum.org.

Endnotes

1. According to the Agency for Healthcare Research and Quality, an electronic clinical data infrastructure refers to the technical system and governance structures needed for the interoperability of a healthcare and research enterprise. To support the use and exchange of data, infrastructure encompasses informatics platforms, tools, and models as well as the workforce and institutional governance required for secure sharing of electronic clinical data. Technical infrastructure components include, but are not limited to, databases, informatics platforms and tools, query exchange systems, clinical decision and workflow support modules, and clinical data capture within electronic health records and numerous forms of research data collection tools. Governance infrastructure components include, but are not limited to, project management, legal and policy oversight (i.e. governing committees or boards), and collaboration among multi-disciplinary teams (Agency for Healthcare Research and Quality, 2009).

2. The projects are conducting CER studies focused on priority populations and conditions outlined by AHRQ. Ultimately, the infrastructure and networks that the projects are building will enable access to a broader set of patient populations and conditions outside of the current CER studies. A full list of the priority populations and conditions can be found on the AHRQ website: http://www.effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen.

3. The total population estimate (51 million) reflects the total number of patients from each partnering institution in each project. Of the seventy organizations participating in the networks, eleven have a role in two or more of the projects, for which reason there is potential for duplication in the estimate of the total number of participating patients.

4. The EDM Forum and the six PROSPECT studies fall under the AHRQ Evidence Generation Awards. More information on these awards can be found on the AHRQ website: http://www.ahrq.gov/fund/recoveryawards/awevgen.htm.

5. The Enhanced Registry and Scalable DRN projects are both data infrastructure award funds provided to AHRQ by the Office of the Secretary (OS) under ARRA. More information on these awards can be found on the AHRQ website: http://www.ahrq.gov/fund/recoveryawards/osawinfra.htm.

Comparative Outcomes Management with Electronic Data Technologies (COMET)
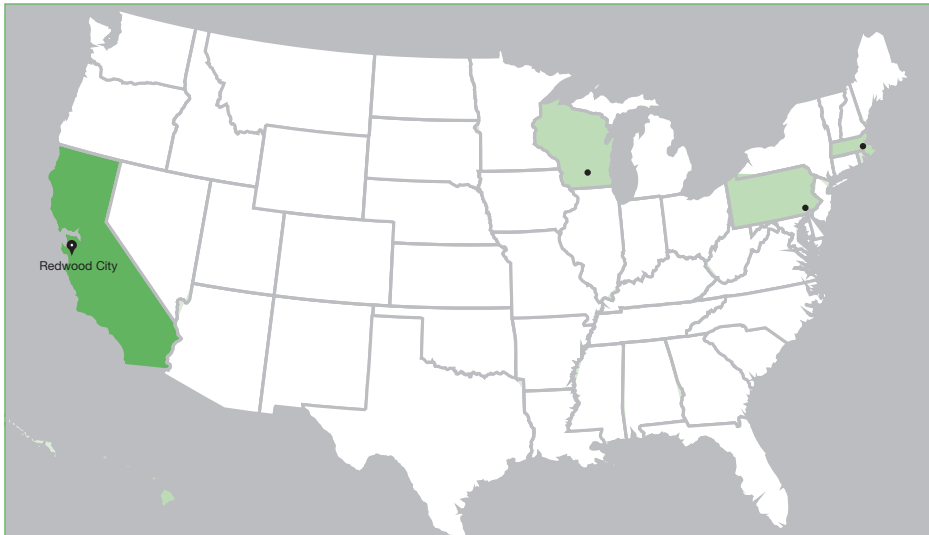
The goal of this project is to develop a new electronic data network infrastructure that will prospectively enable access to and the sharing of clinical and research data between four Clinical Centers (CCs). The development of this new, broad, scalable, and sustainable electronic data network will enable the collection of longitudinal data content (both digital and physical) by each of the four CCs. The electronic network infrastructure developed through COMET will link the prospective information collected from a comparative effectiveness trial via multiple CCs, diverse patient and research participant populations, different patient comorbidities and disease severities, various equipment and test types, and several patient visits. Ultimately, the project will design a single-point access Sleep Research Application that can be sustained by hosting subsequent prospective cohort research projects using a template-based approach. For more information, visit comet.stanford.edu.

Infrastructure Aims

1. Develop a new electronic data network to enable sharing and access across a network of clinical centers;

2. Utilize an informatics platform that integrates data across the clinical centers and builds domain-specific taxonomies, meta data, and content types across the network;

3. Utilize a comprehensive, web-based questionnaire to improve patient care and support ongoing research efforts in the field of sleep medicine; and

4. Integrate various diverse patient-centered data sources, including a variety of device-generated data.

The estimated size of the network is 20,000 patients annually.

Primary Research Aims

To conduct a randomized two-arm CER trial to compare two treatments in patients with obstructive sleep apnea: Positive airway pressure (PAP) and Oral Appliances.

Objective

Develop a new electronic data network infrastructure that will prospectively enable access to and sharing of clinical research data between sleep medicine centers across the United States. Initial data in the network will be collected from a pilot comparative effectiveness project comparing sleep apnea devices and treatments.

Principal Investigator

Clete A. Kushida, M.D., Ph.D., R.P.S.G.T., Professor, Psychiatry and Behavioral Science, Stanford Sleep Medicine Center

CER Study Priority Conditions

- Breathing conditions, with a focus on obstructive sleep apnea
- Heart and blood vessel conditions, with a focus on hypertension associated with sleep apnea
- Obesity

CER Study Priority Populations

- Minority Groups
- Women
- Elderly

CER Studies–Outcome(s) of Interest

Mean nocturnal blood pressure; Flow-mediated vasodilatation (FMD) of the brachial artery; sleep-disordered breathing, sleepiness, mood, and quality of life; cost-effectiveness of PAP and oral appliances; cardiovascular biomarkers; genetic polymorphisms

Study Population Size

190 participants

Healthcare Setting

Specialty clinics (Sleep Medicine Centers)

Major Partners

Stanford Sleep Medicine Center (Lead Site); Academic Alliance for Sleep Research (AASR); participating institutions Stanford University, University of Pennsylvania, University of Wisconsin- Madison, Harvard University); Microflow DBMS, Inc. (Informatics Consultants)

Prospective Outcome Systems using Patient-specific Electronic data to Compare Tests and therapies (PROSPECT) Studies

Indiana PROSPECT
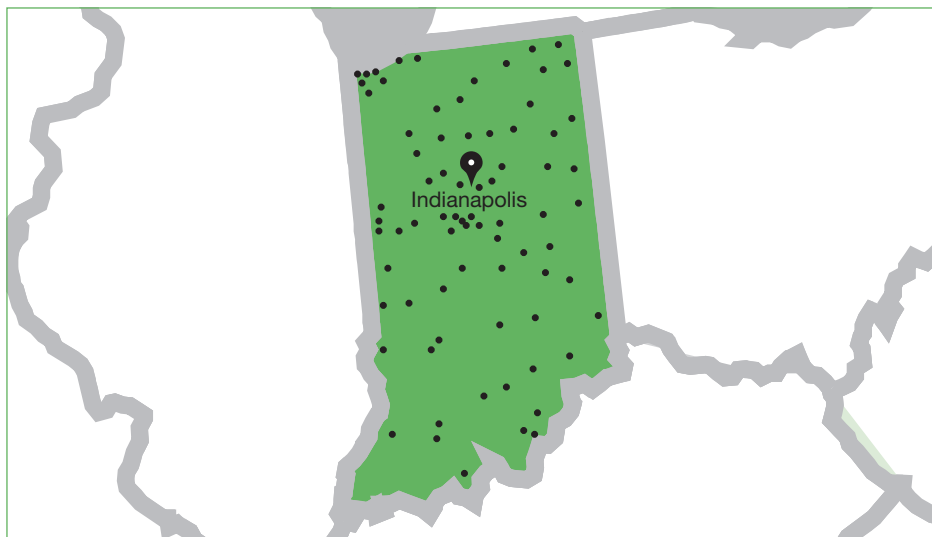
The Indiana PROSPECT builds on the Indiana Network for Patient Care (INPC) which is the nation's largest health information exchange (HIE) that contains over 4 billion structured observations and 78 million text documents for more than 13 million patients across the entire network. This resource is already used for a variety of clinical outcomes and clinical effectiveness research. The project will enhance the infrastructure to capture richer clinical data and enhance the ability to incorporate patient outcomes, improve capture of device utilization data, incorporate genomic and other high throughput results, and identify patient for recruitment and enrollment technologies. For more information visit www.regenstrief.org/indiana-prospect.

Infrastructure Aims

1. Securely leverage and expand the INPC health information exchanges for hypothesis-generating, exploratory, de-identified CER;

2. Improve subject identification and study recruitment methods using clinical decision support software;

3. Facilitate increased electronic capture of patient-centered outcomes from patients, proxies, and primary caregivers using easy, novel software-based approaches; and

4. Support providers', caregivers', and researchers' increasing need to work in teams by providing new tools for communication and co-management (e.g. collaborative care and research).

The estimated size of the network is 1,607,486 patients.

Primary Research Aims

Comparative effectiveness clinical trial of medication treatment for behavioral symptoms of Alzheimer's disease in a group of real-world memory care clinics.

Objective

Enhance the INPC health information exchange to capture richer clinical data and enhance the ability to incorporate patient outcomes, improve capture of device utilization data, incorporate genomic and other high throughput results, and identify patients through recruitment and enrollment technologies. Pilot projects are focused on medication treatment for Alzheimer's patients.

Principal Investigator

Paul Dexter, M.D., Associate Professor of Clinical Medicine, Indiana University School of Medicine, Chief Medical Information Officer and Director of Clinical Effectiveness of Wishard Health Services, Medical Director of ResNet Practice Based Research Network, Scientist of Regenstrief Institute

CER Study Priority Conditions

- Brain and nerve conditions, with a focus on Alzheimer's Disease

CER Study Priority Populations

- Elderly
- Women
- Low-income groups
- Minority groups
- Individuals who live in inner-city areas
- Individuals with disabilities
- Individuals who need chronic care
- Individuals who need end-of-life care

CER Studies–Outcome(s) of Interest

Medication discontinuation and adherence rates, Neuropsychiatric Inventory, and HABC Monitor

Study Population Size

Targeted 300 enrollees

Healthcare Setting

Ambulatory, specialty, and primary care clinics

Major Partners

Regenstrief, Institute Inc. (lead site); Wishard Health Services; Indiana University Health (Methodist Hospital and University Hospital), St. Vincent Health; Community Health Network

SUrveillance, PREvention, and ManagEment of Diabetes Mellitus (SUPREME-DM)
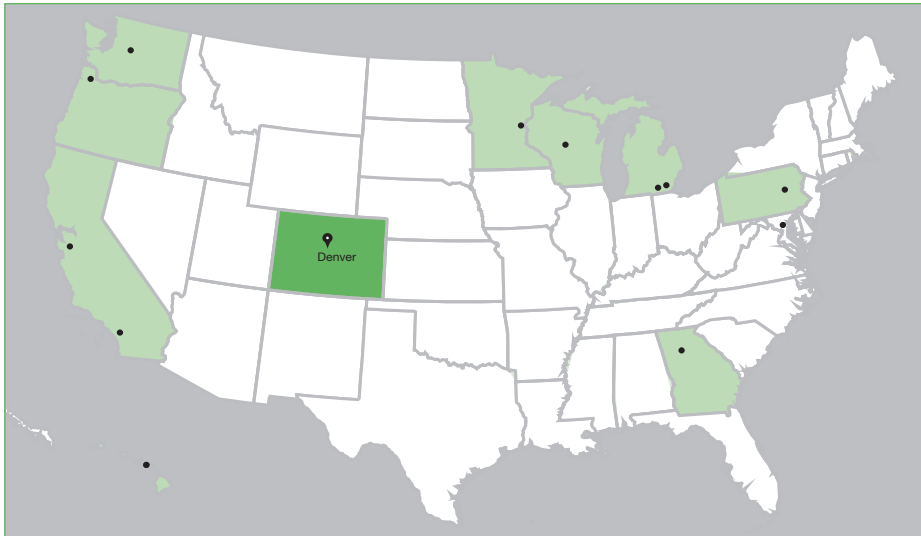
The overall goal of this project is to develop a comprehensive, longitudinal clinical registry of a population of approximately 1.1 million insured patients with diabetes mellitus and a similar database of all members without diabetes from 11 integrated health care delivery systems. The registry will cover the period from 2005-2012, draw from demographic and clinical data elements in EHRs and other system databases, capture patient-reported data where it is already being routinely collected, and calculate and add data on medication adherence. For more information, visit www.supreme-dm.org.

Infrastructure Aims

Create a comprehensive, standardized diabetes registry across the 11 health care systems and utilize this for conducting surveillance (identify and monitor trends in diabetes incidence and prevalence, and in diabetes treatment patterns and outcomes).

The estimated size of the network is 1.1 million diabetes patients.

Primary Research Aims

- Use the data infrastructure to develop a comprehensive, longitudinal clinical registry of a population of patients with diabetes and to conduct surveillance and identify and monitor trends in diabetes mellitus, gestational diabetes mellitus, and pre-diabetes incidence and prevalence, and in diabetes treatment patterns and outcomes;

- Conduct a trial to evaluate the effectiveness of providing brief adherence counseling on "early nonadherence" with newly-prescribed medications; and

- Conduct an observational study of women with recent GDM who have an abnormal postpartum glucose test to understand the effectiveness of various communication, counseling and referral strategies.

Objective

Build a national research network and multi-system distributed database (DataLink) that captures and standardizes detailed demographic and longitudinal electronic clinical data for conducting CER and surveillance in the treatment and prevention of diabetes mellitus.

Principal Investigator

John F. Steiner, M.D., M.P.H., Senior Director, Kaiser Permanente Institute for Health Research, Kaiser Permanente Colorado

CER Study Priority Conditions

- Diabetes Mellitus including Type 1, Type 2, and pre-Diabetes
- Pregnancy, with a focus on women with gestational diabetes
- Obesity
- Heart and blood vessel conditions

CER Study Priority Populations

- Pregnant Women
- Children
- Elderly
- Low-income groups
- Minority Groups
- Individuals who live in inner-city areas
- Individuals who live in rural areas
- Individuals who need chronic care

CER Studies–Outcome(s) of Interest

- Treatment Core Study: To understand the effectiveness of strategies to address early non-adherence and assess if the intervention leads to improved adherence and, in turn improved control of hemoglobin A1c, blood pressure, and LDL-cholesterol

- Prevention of Diabetes Core Study: To understand the effectiveness of follow up approaches including postpartum glucose testing and communication, counseling, and referral strategies, in the prevention of T2DM. The primary outcome is weight at 12 months after delivery in relation to their pre-pregnancy weight and body mass index since overweight/ obesity is a major risk factor for developing T2DM

- NLP Prevention and Treatment Studies: Findings will be examined as potential mediators or modifiers of treatment effectiveness

Study Population Size

1.1 million eligible health plan members with diabetes

- Prevention Study n=730
- Treatment Study n=1901

Healthcare Setting

All healthcare settings

Major Partners

Kaiser Permanente Colorado (lead site); Geisinger Health System; Group Health Cooperative; Henry Ford Health System; HealthPartners; Kaiser Permanente Hawaii; Kaiser Permanente Northern California; Kaiser Permanente Northwest; Kaiser Permanente Southern California; Kaiser Permanente Georgia Southeast; Marshfield Clinic; (sites not contributing data) Johns Hopkins University, University of Michigan, Virginia Commonwealth University

Washington Heights/Inwood Informatics Infrastructure for Community-Centered Comparative Effectiveness Research (WICER)

New York, NY

The WICER project advances comparative effectiveness research (CER) through creating a robust community-focused data infrastructure that supports innovative studies of public health problems. WICER is built on an existing institution-focused data foundation at Columbia University. WICER contains a research data warehouse that integrates patient-level data, including clinical data from multiple facilities, settings and sites of care, with person-level self-reported information collected via community survey. It maps the linked data to variables that support CER studies. WICER also includes tools to support researchers in accessing WICER data resources to perform retrospective analyses and recruit patients for research studies. Three CER studies demonstrating the WICER infrastructure and methods are prospectively studying the diagnosis, treatment and management of hypertension.

Infrastructure Aims

This project will create the following four elements:

1. De-identified research warehouse, which will integrate health care data from multiple disparate data sources, plus community survey data, together in a research data warehouse (RDW) have the option to incorporate additional data during the course of the project if appropriate IRB applications are completed (e.g. dental/oral health information);

2. Research Data Explorer (RedX), a front-end viewer to the de-identified data in the RDW. This allows researchers to browse patient data to look for specific data elements that can be used to generate research queries (identified as a critical component of query creation through years of experience providing mediated queries);

3. Agile, portable, ready to implement research decision support tools (i.e., EHR "plug-ins") that can flexibly work with EHRs to facilitate research tasks in the context of clinical care processes;

4. Data governance policies and procedures

The estimated size of the network is 270,677 people.

Primary Research Aims

Richly characterize the primarily Latino, low-income community of Washington Heights/Inwood from the perspective of social determinates of health. PROs (e.g., health behaviors, symptoms), and clinical data linked through the WICER RDW.

Demonstrate how the WICER infrastructure can support comparative effectiveness studies on the diagnosis, treatment and management of hypertension.

Objective
Create a robust community-focused data infrastructure including a research data warehouse that integrates patient-level data with person-level self-reported information from a community based survey in a predominantly low-income, minority neighborhood in New York City, a Research Data Explorer (RedX) tool to support data queries, and EHR "plug-ins" to facilitate research tasks in the context of clinical care processes. CER studies focus on hypertension diagnosis, treatment, and management.

Principal Investigator
Suzanne Bakken, RN, PhD, FAAN, FACMI, The Alumni Professor of Nursing and Professor of Biomedical Informatics, Columbia University.

CER Study Priority Conditions
- Heart and blood vessel conditions, with a focus on hypertension
- Obesity
- Breathing Conditions

CER Study Priority Populations
- Individuals who live in inner-city areas
- Minority groups, with a focus on Hispanic Americans
- Low-income Groups
- Women
- Elderly
- Individuals with disabilities
- Individuals who need chronic care

Study Population Size
- Community Survey n=8,000
- Hypertension Diagnosis and Treatment n= 450
- Home care management study n=50

CER Studies–Outcome(s) of Interest
Detection, management, and adherence measures for hypertension control

Healthcare Settings
Community Health Center, Ambulatory Care Network Clinics, Inpatient, Community Households, Home Care, Long-Term care

Major Partners
Columbia University Departments of: Biomedical Informatics, Cardiology; Schools of: Public Health, Nursing; Columbia Doctors; New York Presbyterian Hospital; Columbia Community Partnership for Health; Visiting Nurse Service of New York; Isabella Geriatric Center ; Mount Sinai School of Medicine; Community-Based Organizations and residents of Washington Heights/Inwood

The Population-Based Effectiveness in Asthma and Lung Disease (PEAL) Network
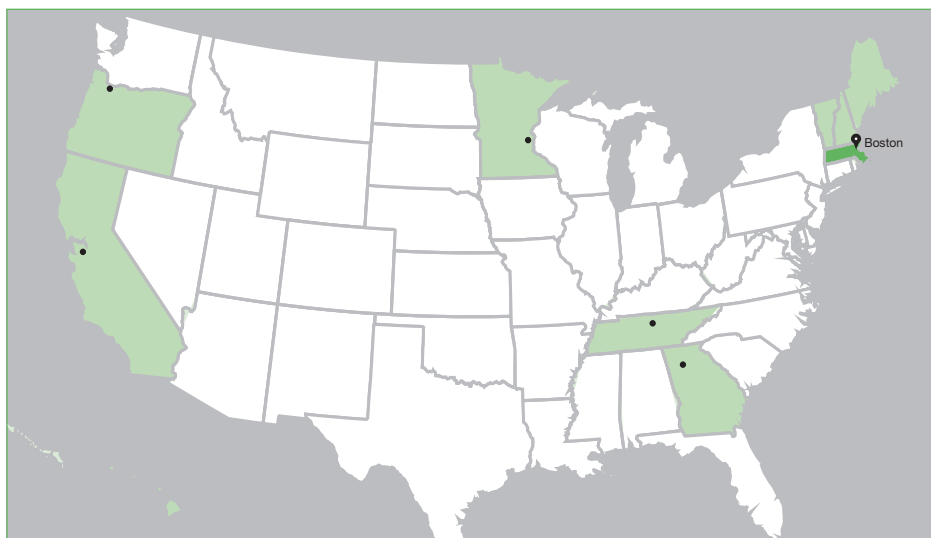
This project will create a new infrastructure to accelerate comparative effectiveness research (CER) in asthma and other lung diseases in diverse populations. The Population-Based Effectiveness in Asthma and Lung Diseases (PEAL) Network will create a highly detailed, standardized, linked computerized dataset from a state Medicaid plan and four health plans. CER will be conducted on asthma controller medications, evaluating adherence and other real-world factors. This project is innovative in that it will link claims, electronic medical records, patient and provider data, and will build new linkages with a Medicaid plan to include vulnerable groups who are disproportionately burdened by asthma. For more information, visit www.pealnetwork.org.

Infrastructure Aims
Build an innovative infrastructure for research on asthma and lung diseases by creating and linking standardized datasets from a state Medicaid population and four health plan populations.

The estimated size of the network is 6.8 million patients.

Primary Research Aims
• Compare real-world adherence to and effectiveness of the major asthma controller regimens in diverse populations; and

• Conduct an applied methodological study that compares different design and analysis approaches for observational comparative effectiveness research.

Objective
Create a new infrastructure that standardizes and links computerized datasets using an integrated data query system (PopMedNet). Data sources include state Medicaid plan and five major health plans to conduct CER on asthma and other lung diseases.

Principal Investigator
Stephen Soumerai, ScD., Professor, Department of Population Medicine, Harvard Pilgrim Health Care

CER Study Priority Conditions
• Breathing conditions, with a focus on asthma and acute respiratory infections

CER Study Priority Populations
• Children
• Individuals who need chronic care

CER Studies–Outcome(s) of Interest
Adherence; prevention of adverse events; costs and cost-sharing; modifiable risk factors (based on PRO and provider surveys); asthma exacerbations and health care use

Study Population Size
6.8 million total participants, 1.48 million total participants with Asthma (study specific cohorts will vary)

Healthcare Settings
Ambulatory, inpatient, specialty, and primary care clinics

Major Partners
Harvard Pilgrim Health Care (lead site); HealthPartners Research Foundation; Kaiser Permanente Northern California; Kaiser Permanente Southeast; Kaiser Permanente Northwest; Kaiser Permanente Mid-Atlantic; Vanderbilt University; Channing Laboratory

The Comparative Effectiveness Research Hub (CER Hub)
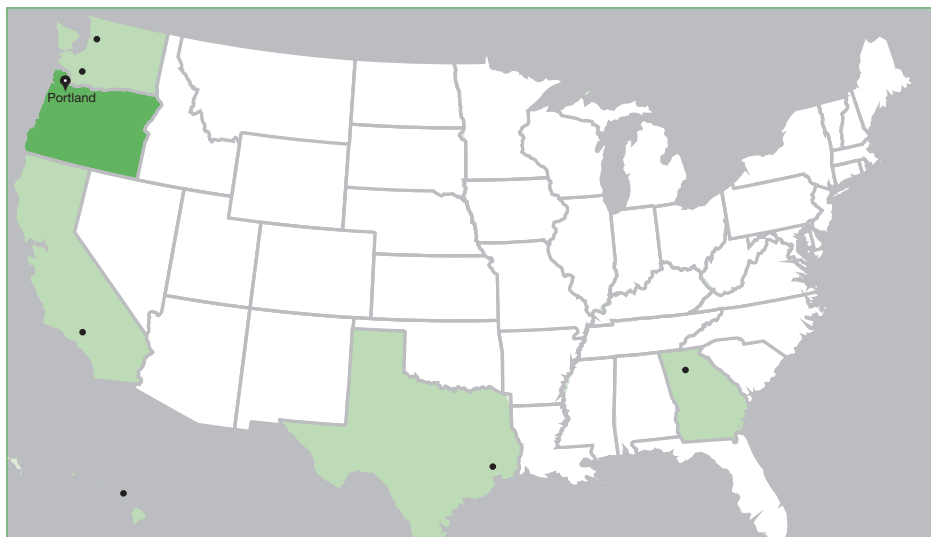
The primary goal of this project is to create and evaluate an Internet-based "Comparative Effectiveness Research Hub" (CER Hub) where researchers can collaboratively develop standardized problem-specific processors of electronic clinical data (with medical classifier applications, or MediClass) in support of CER studies. The project aims to develop a platform for CER with the capacity to generalize along dimensions to function in any EMR data environment, to integrate health care information from diverse settings and clinical practices, and to address any CER questions where both free text and coded EMR data would be required. The project team is a consortium of researchers from 6 diverse health systems assembled to answer key CER questions in asthma control therapy and smoking cessation care delivery. For more information, visit www.cerhub.org.

Infrastructure Aims

1. Create and evaluate a platform for collaborative development and conduct of healthcare research and quality studies that use distributed, heterogeneous, electronic clinical data; and

2. Make a proven natural language processing (NLP) technology broadly available for enhancing use of EMR data.

The estimated size of the network is 2,182,613 patients.

Primary Research Aims

Research projects using CER Hub technologies are formed as investigator-led communities focused on CER. Current projects include observational analysis of heterogeneous clinical data for asthma control therapy and smoking cessation care delivery.

Objective

Develop an internet-based platform where researchers can collaboratively develop standardized problem-specific processors of electronic clinical data in support of CER studies. Pilot projects are focused on asthma and smoking cessation.

Principal Investigator

Brian L. Hazlehurst, Ph.D., Senior Investigator, Center for Health Research Northwest, Kaiser Permanente Northwest

CER Study Priority Conditions

- Breathing conditions, with a focus on asthma for individuals over 12 years old
- Substance abuse, with a focus on smoking cessation for adults over 18 years old

CER Study Priority Populations

- Minority groups, with a focus on racial and ethnic minorities
- Low-income groups
- Individuals who need chronic care

CER Studies–Outcome(s) of Interest

Optimal use of asthma medications; Increased smoking cessation rates

Study Population Size

186,952 Asthmatics; 377,930 smokers

Healthcare Settings

Primarily inpatient and ambulatory primary care clinics

Major Partners

Kaiser Permanente Northwest (Lead Site); Kaiser Permanente Southern California; Kaiser Permanente Hawaii; Kaiser Permanente Southeast; Baylor Health Care System; OCHIN Inc. (a consortium of Community Health Centers and FQHC organizations); Veterans Affairs Puget Sound Healthcare System

Scalable National Network for Effectiveness Research (SCANNER)

The overall goal of this project is to develop a secure, scalable distributed infrastructure that facilitates collaborative comparative effectiveness research (CER) among widely dispersed institutions and provides flexibility to participant sites in the means for data sharing. This flexibility will be implemented by allowing codification of data sharing policies - each institution will specify its own policies. SCANNER will connect diverse healthcare delivery settings with secure infrastructure that utilizes data collected at the point of care. The network will have a main node that manages policies, distributes queries, aggregates results, and maintains trust and security (authentication, authorization, auditing, etc.). Each site will maintain a node that contains data from that site. For more information, visit http://scanner.ucsd.edu.

Infrastructure Aims

This project will create a network infrastructure that allows data sharing across institutions for conducting CER. The network is designed to support (a) retrospective analyses, (b) prospective observational studies, (c) clinical trials, and (d) feedback to point-of-care users. Near real-time collection, analysis, dissemination of results, and feedback to the clinician will be enabled by an infrastructure that allows data to be exchanged according to policies specified by individuals and institutions

The estimated size of the network is 1,607,000 patients.

Primary Research Aims

1. Develop and encode a flexible policy model; and

2. Demonstrate feasibility of the network for observational and interventional CER studies.

Objectives

Develop a scalable distributed research network that facilitates CER among widely dispersed institutions that, utilizing the OMOP common data model, allows data exchange according to policies specified by individuals and institutions. Pilot projects are focused on hypertension, diabetes mellitus, and cardiovascular conditions (acute coronary syndrome, atrial fibrillation, and various thromboembolism)

Principal Investigators

Lucila Ohno-Machado, M.D., Ph.D., Professor of Medicine, Chief of Division of Biomedical Informatics, Associate Dean for Informatics and Technology, University of California San Diego

CER Study Priority Conditions
• Heart and blood vessel conditions, with a focus on hypertension acute coronary syndromes, atrial fibrillation, and venous thromboembolism
• Diabetes

CER Study Priority Populations
• Minority groups, with a focus on Hispanic/Mexican Americans or Latino, American Indian/Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, and Black or African American
• Women
• Elderly
• Low-income groups
• Individuals who live in inner-city areas
• Individuals who live in rural areas
• Individuals with disabilities
• Individuals who need chronic Care

CER Studies–Outcome(s) of Interest
• Policy Development Study: Perspectives of all users of electronic data systems, including patients whose health care data may be incorporated into such models (to inform policy development)
• Medication surveillance: major and minor bleeding
• Medication therapy management: demographic information, clinical endpoints, therapeutic interventions, patient reports (if available)

Study Population Size

- Policy Development Study: Up to 120 total (patients and staff)
- Medication surveillance: to be determined
- Medication therapy management: to be determined

Healthcare Settings

- Policy Development Study: academic medical centers
- Medication surveillance: inpatient and outpatient hospital, medical office settings
- Medication therapy management: ambulatory care clinics at an academic health system (may also include a community-based privately-owned health system and underserved free clinic services)

Major Partners

University of California San Diego (Lead Site); Brigham and Women's Hospital (BWH); Charles Drew University of Medicine and Science; RAND Corporation; Resilient Network Systems; San Francisco State University (SFSU); Vanderbilt University Medical Center & TVHS Veterans Administration Hospital (TVHS VA); University of California Irvine

Scalable Architecture for Federated Translational Inquiries Network (SAFTINet)
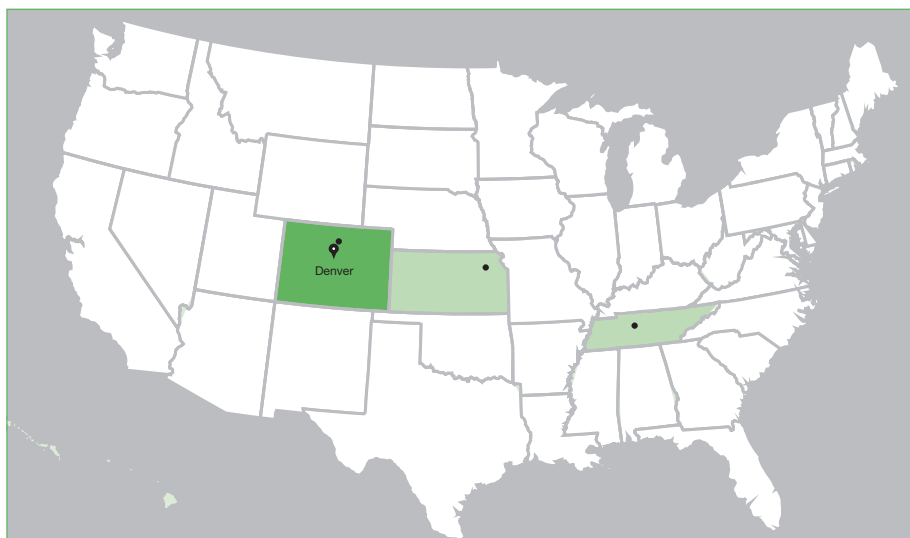
The overall goal of this project is to enhance the capacity and capability of a safety net-focused distributed research network to conduct prospective comparative effectiveness research (CER) using existing electronic health records and claims data. The Scalable Architecture for Federated Translational Inquiries Network (SAFTINet) federates geographically dispersed safety net entities that collectively serve markedly diverse underserved populations. SAFTINet both leverages and extends the established governance and technologic capabilities of the Distributed Ambulatory Research in Therapeutics Network (DARTNet) to support secure, flexible data sharing options based on grid technology. This multi-state project will allow researchers, health policy experts, payers, clinicians, and patients to better understand the impact of a wide variety of health care interventions on health outcomes for minority, underserved and socioeconomically disadvantaged populations. For more information, visit www.saftinet.net.

Infrastructure Aims

This project will establish:

- Learning community of stakeholders invested in the health and health care of safety net populations, including formal processes for stakeholder engagement in research and data governance;

- Common data model for electronic clinical and claims data from diverse healthcare organizations that can support multi-site comparative effectiveness research and quality improvement;

- Mechanism for the extraction, transformation and loading (ETL) of electronic health records and claims data into secure, queryable, federated grid-enabled databases;

- Framework for data quality assessment and transparency; and

- Secure portal for performing federated queries, with user authentication and authorization and logging capabilities.

The estimated size of the network is 440,109 patients.

Primary Research Aims

- To develop and enhance four sentinel cohort pairs of patients with asthma (in children and adults), hypertension, and hypercholesterolemia distinguished by their care delivery characteristics for comparative effectiveness research; and

- To enhance the available data by implementing the collection of clinically relevant patient-reported outcomes.

Objective

Develop a collaborative learning system of stakeholders in the care of safety net populations and a technology infrastructure. TRIAD grid technology and the OMOP common data model will support data sharing and use for research and quality improvement. Pilot projects are focused on the study of healthcare delivery systems and outcomes for cohorts of patients with hypertension, hyperlipidemia, and asthma.

Principal Investigator

Lisa M. Schilling, M.D., M.S.P.H., Associate Professor, University of Colorado Denver School of Medicine

CER Study Priority Conditions

- Heart and blood vessel conditions, with a focus on hypertension and hypercholesterolemia
- Breathing conditions, with a focus on asthma in children and adults

CER Study Priority Populations

- Low-income groups
- Minority Groups
- Women
- Children
- Elderly
- Individuals who live in inner-city areas
- Individuals who live in rural areas
- Individuals who need chronic care

CER Studies–Outcome(s) of Interest

Health care utilization, hospitalizations, and patient-reported asthma control using the Asthma Control Test (ACT); Blood pressure control, timely measurement of blood pressure; Cholesterol control; Medication Adherence

Study Population Size

More than 300,000 patients

Healthcare Settings

Primarily ambulatory primary care clinics

Major Partners

University of Colorado School of Medicine (lead site); American Academy of Family Physicians; Cherokee Health Systems; Colorado Community Managed Care Network and the Colorado Associated Community Health Information Enterprise; Colorado Department of Health Care Policy & Financing; Denver Health and Hospital Authority; Metro Community Provider Network; QED Clinical, d/b/a CINA; Salud Family Health Centers; Ohio State University

Scalable Partnering Network for Comparative Effectiveness Research Across Lifespan, Conditions, and Settings (SPAN)
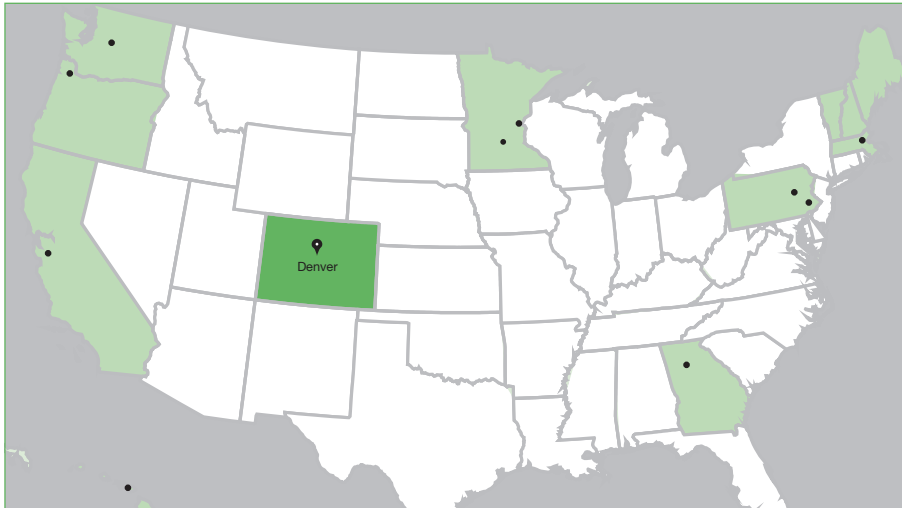
SPAN is developing a distributed research network that is interoperable across a range of health care systems and sites, incorporating large and diverse patient populations. The network infrastructure has the capability to conduct large CER studies using data collected by electronic health records at the point of care. The project addresses the important issue of governance to oversee all aspects of managing and conducting multi-site research with confidential health information. For more information, visit www.span-network.org.

Infrastructure Aims

- Leverage the knowledge gained from an existing distributed research network (DEcIDE DRN2) to design and implement an innovative, sustainable, distributed data network with enhanced capabilities that is interoperable across a range of healthcare systems (the SPAN network) to support CER;

- Develop a research user interface that permits menu-drive querying of multi-site data which is based upon a common data model;

- Incorporate hypothesis-generating tools in the interface that gauge the feasibility of conducting future CER;

- Access selected patient-reported outcomes, if available, and incorporate these into local data marts; and

- Develop and implement a collaborative governance plan for SPAN that incorporates guidelines for: a) electronic health data exchange including data linkage, access, privacy, confidentiality, and security of patient information; b) operational, scientific, and technical concerns related to study design, implementation and analysis - including addressing individual barriers that could impede collaboration; c) review of potential conflicts of interest for SPAN personnel, and d) obtaining input and representation from stakeholder groups regarding data collection, infrastructure, and CER activities.

The estimated size of the network is 7,515,843 patients.

Primary Research Aims

- Increase the generalizability of CER study results by including: a) integrated healthcare delivery systems and b) community partners with differing delivery systems, data structures and patient populations; and

- Build population-based cohorts to perform CER that increase with complexity (i.e., sites, variables, and size) over time.

Objective

Develop a scalable distributed research network that links data across healthcare systems to provide single point access to current, patient-level data for CER through an integrated data query system (the SPAN network). Pilot projects are focused on obesity and attention deficit hyperactivity disorder (ADHD).

Principal Investigator

Matthew F. Daley, M.D., Senior Investigator, Institute for Health Research, Kaiser Permanente Colorado

CER Study Priority Conditions

- Attention Deficit Hyperactivity Disorder (ADHD)
- Obesity
- Mental health, with a focus on depression in patients who are obese

CER Study Priority Populations

- Children
- Women
- Minority groups
- Low-income groups
- Individuals who live in inner-city areas
- Individuals who live in rural areas
- Individuals who need chronic care

CER Studies–Outcome(s) of Interest

- ADHD Sub-Study #1: The validity of ICD-9 codes for identification of incident cases
- ADHD Sub-Study #2: Pharmacotherapy for school-age children with ADHD: practice patterns and consistency with quality metrics
- Obesity Sub-Study #1: Clinical validation of the DeMaria risk score to predict mortality after bariatric surgery
- Obesity Sub-Study #2: Prognostic Risk Scores
- Obesity Sub-Study #3: Cross-site variation in bariatric surgical care management programs
- Obesity Sub-Study #4: Comparative risks of laparoscopic gastric band vs. laparoscopic gastric bypass surgery.
- Obesity Sub-Study #5: Effect of bariatric surgery on chronic opioid use
- Obesity Sub-Study #6: SPAN v. HMORN multisite study process
- Obesity Sub-Study #7: Confounding adjustment in the SPAN's "Comparative risks of laparoscopic gastric band vs. laparoscopic gastric bypass surgery" project

Study Population Size
387,600 patients

Healthcare Settings
All health care settings

Major Partners
Kaiser Permanente Colorado (Lead Site), Denver Health and Hospital Authority, Essentia Institute of Rural Health, Geisinger Clinic, Group Health Cooperative, Harvard Pilgrim Health Care, Inc., Health Partners Institute for Education and Research, Kaiser Permanente Colorado, Kaiser Permanente Georgia, Kaiser Permanente Hawaii, Kaiser Permanente Northern California, Kaiser Permanente Northwest, University of Pennsylvania, University of Colorado, Denver

Surgical Care and Outcomes Assessment Program CER Translation Network (CERTAIN)
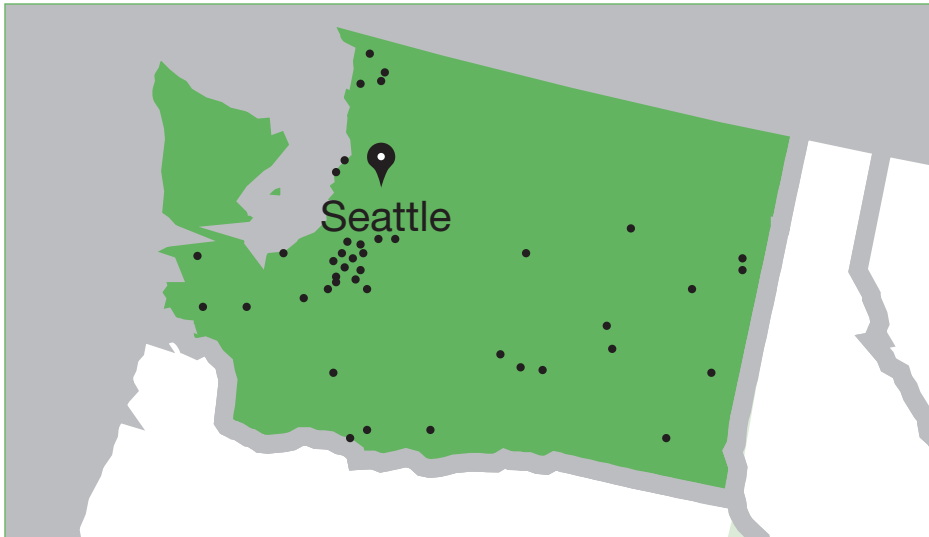
CERTAIN builds a learning health system focused on improving the effectiveness, quality and safety of surgical and interventional care. CERTAIN leverages the success of the registry to improve existing use of data for quality improvement (QI), and to extend the registry into comparative effectiveness research (CER). CERTAIN incorporates patient voices, stakeholder perspectives and real world clinical practice to address questions of comparative benefit and costs for clinicians, patients, payers, industry and policymakers. CERTAIN builds an automated flow of electronic health information using cutting edge informatics tools and evaluates the use and value of automated data retrieval from across diverse healthcare settings including the use of novel text mining tools. Project aims will greatly enhance existing QI by delivering more comprehensive and timely data about performance of evidence-based care, and in relieving manual staff and resource burden to participating hospitals. For more information, visit www.becertain.org.

Infrastructure Aims

• Enhance an existing registry to: automate capture of clinical data; link data across disparate health system data streams; make connections between post-discharge data and patient-reported outcomes (PRO); and establish a platform for CER beyond QI; and

• Deploy Amalga UIS© across CERTAIN hospitals to semi-automate clinical data collection across in-patient and outpatient care delivery sites.

Primary Research and QI Aims

Across Vascular Intervention-SCOAP (VI-SCOAP) sites prospectively compare treatment strategies and outcomes of peripheral arterial disease (PAD).

The estimated size of the CERTAIN network is nearly 8,000 patients.

Objective
Develop an automated data stream retrieval system, using Microsoft Amalga UIS© with ongoing linkages across a variety of practice environments and data sources in Washington State to support QI and CER for surgical outcomes, with pilot projects focused on peripheral arterial disease (PAD).

Principal Investigator
David R. Flum, M.D., M.P.H., Professor, Department of Surgery, University of Washington School of Medicine

CER Study Priority Conditions
• Heart and blood vessel conditions, with a focus on peripheral, carotid, and aneurysm arterial diseases
• Functional limitations and physical disabilities, with a focus on peripheral arterial disease and claudication (angina of the leg), and chronic back pain
• Obesity
• Diabetes
• Cancer, with a focus on lung, breast, prostate, colorectal, esophageal, uterine, pancreas, and kidney cancer

CER Study Priority Populations
• Women
• Children
• Elderly
• Minority groups
• Low-income groups
• Individuals who live in inner-city areas
• Individuals who live in rural areas
• Individuals who need chronic care

CER Studies–Outcome(s) of Interest
6 and 12 month functional and quality of life outcomes, risk-adjusted clinical events, and healthcare utilization

Study Population Size
1,200 eligible participants

Healthcare Settings
Ambulatory primary care clinic, Specialty care clinic, Inpatient Hospital, Patient home

Major Partners
University of Washington (Lead Site), Caradigm, Foundation for Health Care Quality, Allenmore Hospital, Good samaritan Hospital, harborview Medical Center, Lake Washington Vascular, Northwest Hospital, PeaceHealth Southwest Medical Center, PeaceHealth St. Joseph Medical Center, Providence Regional Medical Center Everett, Providence Sacred Heart Medical Center, Dt. Francis Hospital, St. Joseph Medical Center, Tacoma General Hospital, Virginia Mason Hospital & Medical Center

Building Modular Pediatric Chronic Disease Registries for QI and CE Research
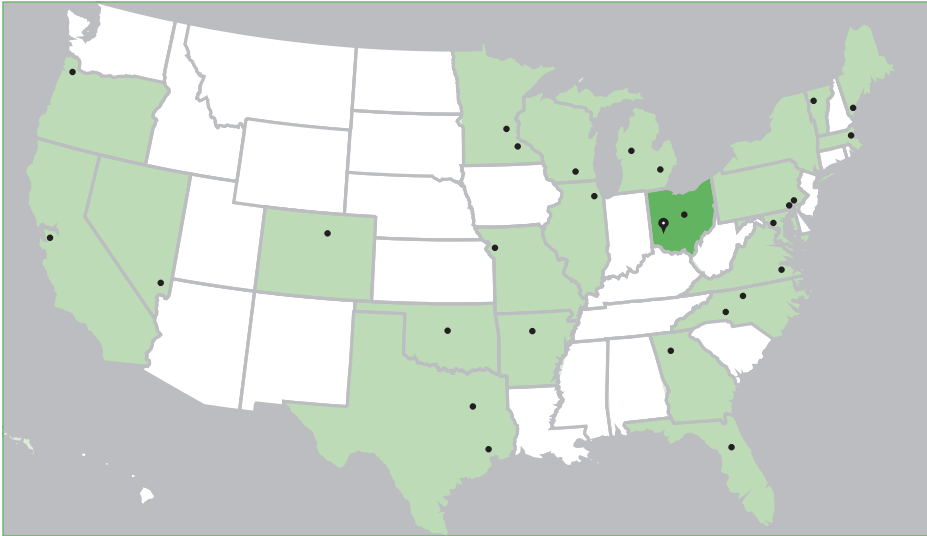
The overall goal of this project is to support a learning health system by building an open-access data sharing network focusing on a pediatric population to improve care and increase patient participation. The modular, versatile, and scalable registry will be populated by electronic health records (EHRs) and used to support quality improvement (QI) and comparative effectiveness research (CER). For more information, visit www.enhancedregistry.org.

Infrastructure Aims

- Develop an open-source reporting, analysis and query toolkit to support QI and CER;

- Link locally-hosted registries into a distributed network through federated queries;

- Allow data collected in the EHR to be uploaded to the registry;

- Design, test, and deploy a patient reported outcome (PRO) system that supports CER and population-level analytics; and

- Develop governance structures for the network that engages patients and provides oversight of privacy, confidentiality, and data access, as well as scientific and technical concerns.

Primary Research and QI Aims

- Design and conduct analyses using existing data and prospectively collected data that evaluate alternative adaptive treatment strategies for newly diagnosed patients with pediatric Crohn's Disease; and

- Test the enhanced registry to improve population care management and increase patient activation management (PAM) in care sight of privacy, confidentiality, and data access, as well as scientific and technical concerns.

The estimated size of the network is 12,000 pediatric IBD patients

Objective

Enhance an existing network of pediatric registries by leveraging i2b2 and SHRINE to populate the registry with "data-in once" and support QI and CER, with pilot projects focused on inflammatory bowel disease (IBD).

Principal Investigator

John Hutton, M.D., Director, Division of Biomedical Informatics, Cincinnati Children's Hospital Medical Center

CER Study Priority Conditions

- Digestive system conditions, with a focus on inflammatory bowel disease (IBD) and Crohn's Disease

CER Study Priority Populations

- Children
- Low-Income
- Individuals who live in inner-city areas
- Individuals who live in rural areas
- Individuals who need chronic care

CER Studies–Outcome(s) of Interest

Timing of biologic agents (anti-TNFα); Councils: families/patients, AHCs, new subspecialty groups

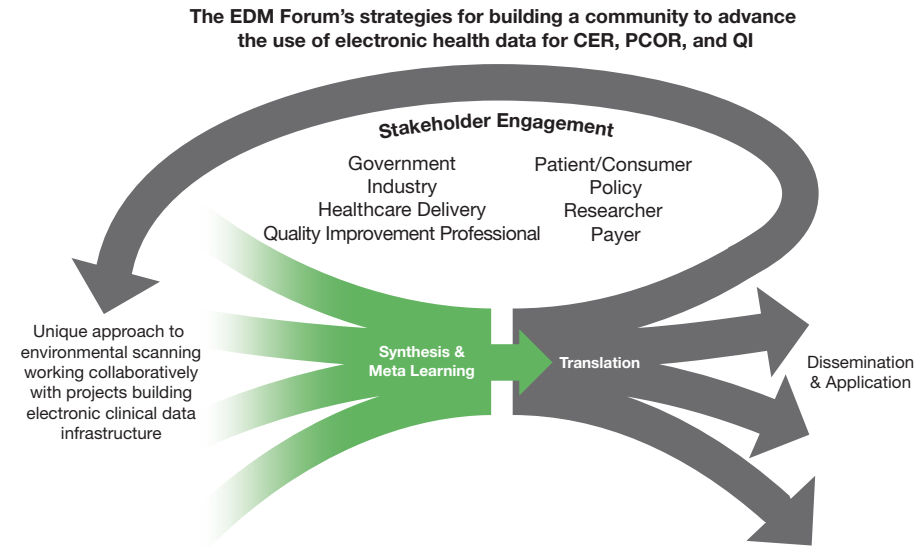## Study Population Size

4,769 enrolled patients

Healthcare Settings

Ambulatory primary care clinics, Pediatric specialty clinics, Academic medical center, Outpatient hospital

Major Partners

Cincinnati Children's Hospital Medical Center (lead site); Epic Corporation; ImproveCareNow Network; Collaborative Chronic Care Network (C3N)

Electronic Data Methods Forum (EDM Forum)

The EDM Forum's strategies for building a community to advance the use of electronic health data for CER, PCOR, and QI

The AcademyHealth Electronic Data Methods (EDM) Forum is an initiative to collect, synthesize, and share lessons learned from research projects that are developing and using electronic clinical data to conduct comparative effectiveness research (CER), patient-centered outcomes research (PCOR), and quality improvement (QI).

Primary Aims

The EDM Forum engages and supports the PROSPECT, Scalable Distributed Research Networks, and Enhanced Registries for QI and CER projects by:

- Providing opportunities for collaborative learning to accelerate the exchange of information and uptake of promising practices among the research projects;

- Brokering connections with stakeholders to engage the community in identifying issues and priorities for the projects and the EDM Forum to address; and

- Ensuring widespread awareness and promotion of the tools, techniques, and findings from the research projects.

www.edm-forum.org

Major Activities

- Facilitate opportunities for members of the EDM Forum Research Network (PROSPECT, DRN, and Enhanced Registries) to collaborate with one another both in-person and virtually;

- Develop products that synthesize major challenges and innovations, including: papers; issues briefs; reports; needs assessments; literature reviews;

- Convene events, including: stakeholder symposia; free public webinars; presentations and collaborations with allied organizations; and

- Disseminate current research, news, and peer-reviewed and grey literature on the use of electronic clinical data for CER, PCOR, and QI.

- *eGEMs* (Generating Evidence and Methods to improve patient outcomes) is a new, open access, peer-reviewed epublication that publishes innovative ideas and practices using electronic clinical data to advance health services research, quality improvement, and improve patient and community outcomes. For more information, visit repository.academyhealth.org/egems.

Objective

Advance the national dialogue on the use of electronic clinical data for the conduct of CER, QI, and clinical decision support by facilitating exchange and collaboration between the PROSPECT, DRN, and Enhanced Registry Projects. Key activities include conducting meta-synthesis of challenges and innovations in the field, engaging stakeholders, and disseminating lessons learned.

Principal Investigator

Erin Holve, Ph.D., M.P.H., M.P.P.
Director, AcademyHealth

Steering Committee Chair

Bruce (Ned) Calonge, M.D., M.P.H.
President & CEO, The Colorado Trust

Products

- Multi-modal environmental scans, including site visits and stakeholder interviews
- Reviews and synthesis of the peer-reviewed and grey literature
- Papers, issue briefs, reports and collaborative projects
- Dissemination of current research, news, and grey literature on the use of electronic clinical data for CER via social media, websites, and *eGEMs*

Partners

AcademyHealth (lead site); AHRQ program staff; EDM Forum Steering Committee (see Appendix D); Investigators from the PROSPECT, Scalable Distributed Research Network, and Enhanced Registries for QI & CER. Collectively, more than 115 investigators are included in the Forum's network.

Stakeholder Perspectives

Efforts to engage stakeholders from a range of backgrounds, including members from industry, research, business/payer, policy, consumer/patient, government and healthcare delivery communities are an important part of the EDM Forum.

For more information

To learn more about the EDM Forum, visit www.edm-forum.org:

- Submit perspectives and find information on CER and PCOR using electronic clinical data; and
- Sign up for updates on news, events, resources, and publications.

About AcademyHealth

AcademyHealth is a leading national organization serving the fields of health services and policy research and the professionals who produce and use this important work. Together with our members, we offer programs and services that support the development and use of rigorous, relevant and timely evidence to increase the quality, accessibility, and value of health care, to reduce disparities, and to improve health. A trusted broker of information, AcademyHealth brings stakeholders together to address the current and future needs of an evolving health system, inform health policy, and translate evidence into action.

Acknowledgements

AcademyHealth acknowledges the Agency for Healthcare Research and Quality (AHRQ) for its support of this work. AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. As 1 of 12 agencies within the Department of Health and Human Services, AHRQ supports research that helps people make more informed decisions and improves the quality of health care services. For more information, visit www.ahrq.gov.

Suggested Citation

"Building Electronic Clinical Data Infrastructure to Improve Patient Outcomes: CER Project Profiles," EDM Forum, AcademyHealth, April 2013.

Also see www.edm-forum.org to access publication.

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APPENDIX A: The Policy Context of CER and PCOR

Comparative Effectiveness Research (CER) and Patient-Centered outcomes Research (PCOR) have emerged to fill gaps in evidence needed by clinicians and patients to make informed decisions in health care. Often, the aim of CER is described as understanding "what works best," and "for whom," and "under what conditions." With recent innovations and advancements in health information technology (HIT), researchers are focusing on how to use electronic clinical data to provide information at a granular level to answer these CER questions and improve healthcare.

Definitions of CER and PCOR

In light of the fact that CER is intended to provide information that helps clinicians and patients choose which option best fits an individual patient›s needs and preferences, it is useful to understand how CER differs from PCOR. Current definitions of each are provided below:

Comparative effectiveness research (CER) is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances (Patient protection and Affordable Care Act, Part D).

Patient-Centered Outcomes Research (PCOR): "Patient-Centered Outcomes Research helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

- *"Given my personal characteristics, conditions and preferences, what should I expect will happen to me?"*

- *"What are my options and what are the benefits and harms of those options?"*

- *"What can I do to improve the outcomes that are most important to me?"*

- *"How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"*

(Patient-Centered Outcomes Research Institute, 2012)

CER and PCOR are viewed as inter-related but distinct. As described by the Patient Centered Outcomes Research Institute (PCORI) Methodology Committee PCOR is not synonymous with CER because "PCOR aspires to give voice to the patient while helping patients improve their experience and decision making in the healthcare system. Not all research that might be expected to help a patient make decisions or improve their experience in the healthcare system is explicitly comparative, and comparative evaluations do not necessarily incorporate the patient's voice, outcomes that matter to patients or comparisons that they value."

However, both CER and PCOR are responsive to specific clinical topics and populations viewed as priority areas for the research. In addition to the AHRQ priority populations and conditions that establish areas of focus for the agency, as part of ARRA, the Secretary of Health and Human Services (HHS) contracted with the Institute of Medicine (IOM) to recommend CER priority projects that should be supported by stimulus funds. The IOM, "Initial National Priorities for Comparative Effectiveness Research" includes a priority list of research topics, and identifies the necessary requirements to support a robust and sustainable CER enterprise (IOM, 2009).

ARRA Funding to Build Infrastructure for CER

The EDM Forum and collaborating projects are supported by the American Recovery and Reinvestment Act of 2009 (ARRA) which provided $1.1 billion for research and development in the area of CER. The purposes of the ARRA funds are to preserve and create jobs and promote economic recovery in the United States, and to provide investments needed to increase economic efficiency by spurring technological advances in science and health.

According to the Department of Health and Human Services (HHS) (Department of Health and Human Services, 2010), ARRA provided:

- $300 million for the Agency for Healthcare Research and Quality (AHRQ)

- $400 million for the National Institutes of Health (NIH), and

- $400 million for the Office of the Secretary (OS) of Health and Human Services

Funding to Advance PCOR

The Patient-Centered Outcomes Research Institute (PCORI), an independent non-profit research organization created by the Patient Protection and Affordable Care Act of 2010 (PPACA), commissions research that will help people make informed healthcare decisions and improve health care delivery. PCORI will award their initial grants for pilot projects in 2012. These pilot projects will: assist PCORI with ongoing development and enhancement of national research priorities for PCOR; support the collection of preliminary data that can be used to advance the field of PCOR; and, support the identification of methodologies that can be used to advance PCOR as well as identify gaps where methodological research needs further development (Patient-Centered Outcomes Research Institute, 2011).

APPENDIX B: AHRQ Priority Populations and Conditions Addressed by the CER Studies Conducted by the PROSPECT, DRN, and Enhanced Registry Projects

All PROSPECT, DRN, and Enhanced Registry projects are required to conduct CER and generate valid and generalizable conclusions. Thirty eight CER studies are planned or underway and collectively address almost all of AHRQ's priority populations and conditions. A full list of all AHRQ priority populations and conditions is provided below.

Categories — Projects:	CER Hub	COMET	Indiana PROSPECT	PEAL Network	SUPREME-DM	WICER	Cincinnati Enhanced Registry	SCOAP CERTAIN	SCANNER	SAFTINet	SPAN
AHRQ Priority Populations											
Low-income groups	♦		♦		♦	⌘	♦	♦	⌘	⌘	♦
Minority groups	♦	♦	♦		♦	⌘		♦	♦	♦	♦
Women		♦	♦		♦	♦		♦	♦	♦	♦
Children					♦		⌘	♦		⌘	⌘
The elderly		♦	⌘		♦	♦		♦	♦	♦	
Individuals with disabilities			♦			♦			♦		
Individuals who need chronic care	♦		♦	♦	♦	♦	⌘	♦	♦	♦	♦
Individuals who need end-of-life care			♦								
Individuals who live in inner-city areas			♦		♦	⌘	♦	♦	♦	♦	♦
Individuals who live in rural areas					♦		♦	♦	♦	♦	♦
AHRQ Priority Conditions											
Arthritis and nontraumatic joint disorders (Muscle, bone, and joint conditions)											
Cancer (Cancer)						♦	♦				
Cardiovascular disease, including stroke and hypertension (Heart and blood vessel conditions)		♦			♦	⌘		⌘	⌘	⌘	
Dementia, including Alzheimer's Disease (Brain and nerve conditions)			⌘								
Depression and other mental health disorders (Mental health)		♦				♦					♦
Developmental delays, attention-deficit hyperactivity disorder, and autism (Developmental delays, ADHD, autism)											⌘
Diabetes mellitus (Diabetes)		♦			⌘	♦		♦	⌘		
Functional limitations and disability (Functional limitations and physical disabilities)		♦				♦		♦			
Infectious diseases, including HIV/AIDS (Infectious diseases and HIV/AIDS)											
Obesity (Obesity)		♦			♦	♦		♦			⌘
Peptic ulcer disease and dyspepsia (Digestive system conditions)							⌘				
Pregnancy, including preterm birth (Pregnancy and childbirth)					♦	♦					
Pulmonary disease/asthma (Breathing conditions)	⌘	⌘		⌘		♦			⌘	⌘	
Substance abuse (Alcohol and drug abuse)	⌘	♦				♦					

Additional information can be found on the AHRQ website http://www.effectivehealthcare.ahrq.gov.

APPENDIX C: Acronyms

Acronym	Name
AHRQ	Agency for Healthcare Research and Quality
CDM	Common Data Model
CER	Comparative Effectiveness Research
CER Hub	Comparative Effectiveness Research Hub
COMET	Comparative Outcomes Management with Electronic Data Technology
DRN	Distributed Research Network
EDM Forum	Electronic Data Methods Forum
EHR	Electronic Health Record
HIE	Health Information Exchange
HIT	Health Information Technology
HL7	Health Level Seven International
HMORN	Health Maintenance Organization Research Network
i2b2	Informatics for Integrating Biology & the Bedside
INPC	Indiana Network for Patient Care
IT	Information Technology
MediClass	Medical Classifier Applications
NLP	Natural Language Processing
OMOP	Observational Medical Outcomes Partnership
PCOR	Patient-Centered Outcomes Research
PEAL	The Population-Based Effectiveness in Asthma and Lung Disease Network
PROSPECT	Prospective Outcome Systems using Patient-specific Electronic data to Compare Tests and therapies studies
QA	Quality Assurance
QI	Quality Improvement
RDW	Research Data Warehouse
SAFTINet	Scalable Architecture for Federated Translational Inquiries Network
SCANNER	Scalable National Network for Effectiveness Research
SCOAP CERTAIN	Surgical Care and Outcomes Assessment Program CER Translation Network
SHRINE	Shared Health Research Information Network
SPAN	Scalable PArtnering Network for Comparative Effectiveness Research Across Lifespan,
SPRINT Trial	Systolic Blood Pressure Intervention Trial
SUPREME-DM	SUrveillance, PREvention, and ManagEment of Diabetes Mellitus
TRIAD	Translational Informatics and Data Management Grid
VDW	Virtual Data Warehouse
WICER	Washington Heights/Inwood Informatics Infrastructure for Community-Centered Comparative Effectiveness Research

APPENDIX D: EDM Forum Steering Committee Members, April 2013

Bruce (Ned) Calonge, M.D., M.P.H.
Chair
President & CEO
The Colorado Trust

Suzanne Bakken, R.N., D.N.Sc, F.A.A.N.,
FACMI
The Alumni Professor of Nursing and
Professor of Biomedical Informatics
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