



# **Research in the HMO Research Network**

## **Research Process and Partnership Primer**

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Prepared by the HMORN Collaboratory Supplement Team

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# Executive Summary

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**The Science:** The HMO Research Network (HMORN) is a national consortium of research centers that work within or in close partnership with integrated health systems. Established in 1994, the sites in the HMORN are committed to conducting public domain health research on a wide range of diseases and cross-cutting topics including cancer, vaccine safety, heart disease, pharmacoepidemiology, obesity, and organization and delivery of health care. Sites in the HMORN have led and/or variously participated in major national research projects including the RAND Health Insurance Experiment, the Women’s Health Initiative, and the eMERGE (Electronic Medical Records and Genomics) project, among many others. The HMORN has also established topical research networks in cancer, cardiovascular disease, mental health, asthma, and diabetes.

**The Systems:** The participating integrated systems are diverse and complex with respect to the populations they serve, as well as the structure of their health care delivery models. Most health systems offer both insurance coverage and health care. Some HMORN research centers have more complex arrangements, in which partnerships have been established with health systems and insurance plans that serve a defined population. Individuals who make up the population of approximately 10 million HMORN “covered lives” may receive their care, coverage, or both from a given HMORN site. The insurance coverage is highly variable from site to site and may include options such as prepaid managed care, fee-for-service, and Medicare and Medicaid. The most common health care delivery arrangement is a large multi-specialty group practice, however, depending on the types of specialties and facilities that are owned and operated by the health system, individuals may need to go outside the system to receive their care. This complexity is inherently important to understand, as it drives the availability of clinical and claims data for use by local researchers at HMORN sites (and by extension, collaborating researchers).

**The Data:** These health care systems produce copious amounts of data in the course of clinical care and insurance coverage. Many of these computerized data resources are made available to the local research centers, and are relatively comparable from site to site, in that all sites collect data on demographics, health care utilization, pharmacy use, and laboratory tests. However, the manner in which clinical data are aggregated, and the availability and level of detail will vary across sites. Some patient-reported information on behaviors and symptoms and other outcomes are also collected—this is an emerging area of importance. All sites have an electronic medical record (EMR), though the EMRs have been in place for varying lengths of time. Many of the sites use the same software, EpicCare, however, the Epic software installation is also different from site to site. Collectively, the similar array of data resources facilitates collaborative multi-site research among HMORN research partners. Beginning in 2003, the research data experts across the HMORN began a more concerted, purposeful effort to organize electronic data resources in a way that facilitated their use and re-use for multi-site research while preserving local control and autonomy. This common data transformation strategy is known as the HMORN Virtual Data Warehouse (VDW).

**The Infrastructure:** While the HMORN has a long track record of collaboration, it is an informal organization with a modest infrastructure that was largely developed with funding from the NIH Roadmap (Coordinated Clinical Studies Network contract, 2005-2008). The Roadmap contract enabled the HMORN to create a collaboration toolkit, devise a process for streamlining multi-site Institutional

Review Board review, and elevated the need to have core designated staff oversee the HMORN's assets, manage communication, and coordinate the continued development of the VDW. In spite of this relatively thin infrastructure, the HMORN has emerged as a unique resource for population-based health research.

**The Collaboratory:** In March 2010, the HMORN was invited by Dr. Francis Collins, Director of the National Institutes of Health, to develop a concept proposal that described “what it would take” for the HMORN to scale up its enterprise in a fashion that could support pragmatic clinical trials, mega-epidemiology studies that link electronic medical records and biospecimens to advance personalized medicine, and contribute to the science of health care reform (a chief priority enunciated by Dr. Collins). This concept proposal described three areas—science, data and infrastructure—that would need resourcing and development in order to fulfill the goal of serving as a national population laboratory, or Collaboratory. The concept proposal led to a one-year supplement to focus on infrastructure and capacity building in the HMORN, with the anticipation that the HMORN would apply for funding as a Collaboratory Coordinating Center (CCC). Although the funding for the CCC has not been attained, the capacity building activities have benefited the HMORN, as we now have a fuller and more complete understanding of our research capabilities and areas for further development. A description of these research capabilities are the foundation of this report.

**Organization of This Report:** This report provides readers with an overview of the HMORN's composition and evolution, as well as critical detailed information that can be used to guide potential collaborators. It is expected to benefit both external audiences and stakeholders (funding agencies, prospective collaborators in academia), as well as internal research investigators and staff. The report is comprised of five major sections, plus more than a dozen tables and figures. Site-specific profiles and a compendium of HMORN signature projects are also a major part of this report.

## Acronyms

<b>AHRQ</b>	Agency for Healthcare Research and Quality
<b>CER</b>	Comparative effectiveness research
<b>CERT</b>	Centers for Education and Research on Therapeutics
<b>CHR</b>	Geisinger Clinic's Center for Health Research
<b>CHR-SE</b>	Center for Health Research-Southeast (Kaiser Permanente TCHR)
<b>CHR-NW</b>	Center for Health Research-Northwest (Kaiser Permanente TCHR)
<b>CHR-HI</b>	Center for Health Research-Hawaii (Kaiser Permanente TCHR)
<b>CRN</b>	Cancer Research Network
<b>CT</b>	Clinical trial
<b>CTSA</b>	Clinical and Translational Science Award
<b>CVRN</b>	Cardiovascular Research Network
<b>DEcIDE</b>	Developing Evidence to Improve Decisions about Effectiveness
<b>EMR</b>	Electronic medical record
<b>F/U</b>	Length of study follow-up
<b>FFS</b>	Fee for service
<b>GHC</b>	Group Health Cooperative
<b>GHRI</b>	Group Health Research Institute
<b>GHS</b>	Geisinger Health System
<b>HFHS</b>	Henry Ford Health System
<b>HIPAA</b>	Health Insurance Portability and Accountability Act
<b>HMORN</b>	HMO Research Network
<b>HPHC</b>	Harvard Pilgrim Health Care
<b>HPRF</b>	HealthPartners Research Foundation
<b>IRB</b>	Institutional review board
<b>KP</b>	Kaiser Permanente
<b>KPCO</b>	Kaiser Permanente Colorado
<b>KPGA</b>	Kaiser Permanente Georgia
<b>KPHI</b>	Kaiser Permanente Hawaii
<b>KPNC</b>	Kaiser Permanente Northern California
<b>KPNW</b>	Kaiser Permanente Northwest
<b>KPSC</b>	Kaiser Permanente Southern California
<b>LCF</b>	LCF Research
<b>MCRF</b>	Marshfield Clinic Research Foundation
<b>MEPREP</b>	Research Program in Medication Use and Outcomes in Pregnancy
<b>MHRN</b>	Mental Health Research Network
<b>MPCI</b>	Meyers Primary Care Institute
<b>PGRN</b>	NIH Pharmacogenomics Research Network
<b>PHI</b>	Protected health information
<b>PI</b>	Principal investigator
<b>PRO</b>	Patient reported outcomes
<b>QA</b>	Quality assurance
<b>S&amp;W</b>	Scott & White Healthcare
<b>TCHR</b>	The Center for Health Research (Kaiser Permanente)
<b>VDW</b>	Virtual Data Warehouse
<b>VIG</b>	VDW Implementation Group
<b>VOC</b>	VDW Operations Committee

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# I. Introduction

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## Objective

This primer explains the characteristics and operations of research in the HMO Research Network (HMORN). It describes scientific emphases, the scope of existing studies, research infrastructure, data, and the procedures and opportunities for partnering with HMORN investigators.

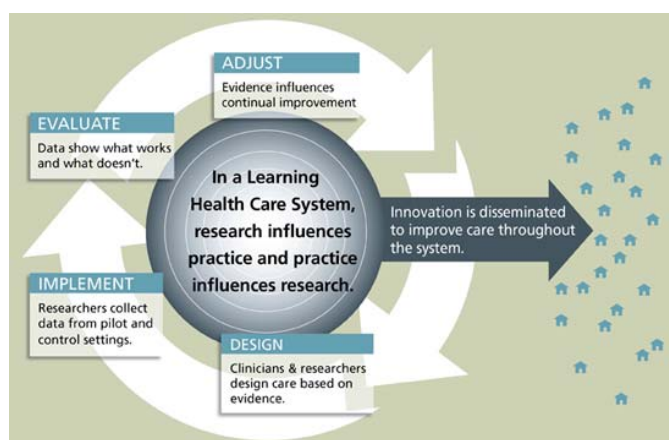
## What is the HMO Research Network?

The HMORN is a consortium of sophisticated research centers that work within or in close partnership with integrated health systems across the United States and in Israel. Established in 1995, the HMORN now includes 16 member health systems providing comprehensive care for approximately 13 million people insured commercially or via Medicare, Medicaid, state-specific gap plans, or other arrangements. Recently, three other health systems with research capabilities joined the HMORN as associate members. Our sites have a rich history of collaborative public domain research focused on improving the quality, availability, and effectiveness of health care.

HMORN sites are characterized by their extraordinary administrative and clinical data resources available for research, including mature electronic medical records and robust disease-specific registries for key health behaviors and chronic conditions such as cancer, heart disease, diabetes, and hypertension. A cornerstone of HMORN collaboration is its ability to coordinate these comprehensive data resources in support of a large, varied program of multi-site, multi-purpose research. One key example is the Virtual Data Warehouse—a one-of-a-kind shared resource created by mapping data from local systems into a common format using data dictionaries.

In addition to unparalleled data resources, the HMORN includes hundreds of faculty with expertise in multiple disciplines who have experience working alongside high-functioning delivery systems. Thus, HMORN research studies benefit from connections forged between our scientists, clinicians, and clinical operations personnel who work together to improve care for the patients they serve. Ultimately, members of the HMORN strive to be part of a rapid learning health care system, where research informs practice, and the successes and challenges of providing care inform the research agenda.

FIGURE 1: A LEARNING HEALTH CARE SYSTEM



## Membership and governance

The HMORN is not a formal legal or business entity, however, there are considerations and by-laws in place that guide membership, governance and operations. Leadership is provided by a Governing Board comprised of the research directors (or their designees) from each site. The Board oversees HMORN activities ranging from participation in large-scale collaborations to an annual conference. The Asset Stewardship Committee, a subcommittee to the Board, develops and oversees HMORN products and processes that collectively contribute to effective collaboration. Examples include the Virtual Data Warehouse (VDW), facilitated Institutional Review Board (IRB) review process, and managing the tacit knowledge that underlies HMORN activities. Regarding membership, a formal two-stage membership process was ratified in 2011. Three new sites\* were voted in as associate members effective September 1, 2011. Associate members have full voting rights; the designation as an associate member affords the research center the time and opportunity to develop its site-based data files that interface with the HMORN VDW.

## HMORN-affiliated research networks

HMORN research centers have been key participants in some of the nation’s most influential federally funded research consortia. Via these networks, participating researchers have developed experience at collaboration and data-sharing, typically involving innovative approaches to data stewardship and interoperability.

Table 1 provides an overview of these networks†, which include the National Cancer Institute’s HMO Cancer Research Network—a 14-site collaboration that has designed and implemented dozens of multisystem cancer research studies addressing prevention, control, cost, and outcomes. Other noteworthy HMORN collaborations include the 13-site Center for Education and Research in Therapeutics—an Agency for Healthcare Research and Quality-funded effort to study the safety, effectiveness, and appropriateness of drugs, biologics, and devices; and the Cardiovascular Research Network—a 14-site consortium funded by the National Heart, Lung, and Blood Institute.

**TABLE 1: HMORN-AFFILIATED RESEARCH NETWORKS**

Project Name	Study period	Funding Agency	# HMORN Sites	Focus
Vaccine Safety Datalink (VSD)	1990-current	CDC	10	Vaccine effectiveness, outcomes
Cancer Research Network (CRN)	1999-current	NCI	14	Cancer prevention, control, outcomes
Centers for Education and Research in Therapeutics (CERT)	2000-2011	AHRQ	13	Safety, effectiveness, appropriateness of use of drugs, biologics, devices
Integrated Delivery System Research Network (IDSRN)	2000-2005	AHRQ	11	Care delivery and research diffusion in integrated healthcare systems
National Bioterrorism Surveillance Project	2000-~2004	CDC	8	Syndromic surveillance methods

\* Three new associate members, effective 9/1/2011: Palo Alto Medical Foundation Research Institute; Essentia Institute of Rural Health, and Mid-Atlantic Permanente Research Institute (research arm of Kaiser Permanente Mid-Atlantic Region)

† We note that participation by all sites in topic-specific research networks is unusual, and may be based on a variety of considerations including population composition, scientific capabilities and interests, and requirements of the funding agency. Even this report was created based on a supplement to support development of the HMO Collaboratory and involves only 14 of the 16 sites that were members at the time the supplement was awarded. It also does not reference recent new groups joining the network as affiliate members in September 2011.

Project Name	Study period	Funding Agency	# HMORN Sites	Focus
Cancer Care and Outcomes Research Surveillance Consortium (CanCORS)	2001-current	NCI	5	Experience of newly diagnosed lung or colorectal cancer patients
Coordinated Clinical Studies Network (CCSN)	2004-2008	NHLBI	10	Creation of a shared, sustainable infrastructure to facilitate research
Developing Evidence to Improve Decisions about Effectiveness (DEcIDE) -1 Network	2005-current	AHRQ	12	Comparative treatment effectiveness and safety
Cardiovascular Research Network (CVRN)	2007-current	NHLBI	14	Cardiovascular disease epidemiology, management, and outcomes
Developing Evidence to Improve Decisions about Effectiveness (DEcIDE)-2 Network	2008-current	AHRQ	14	Comparative treatment effectiveness and safety
Research Program in Medication Use and Outcomes in Pregnancy (MEPREP)	2009-current	FDA	11	Medication exposure during pregnancy and maternal/fetal outcomes using linked data
Mini Sentinel Network (MSN)	2009-current	FDA	13	Development of an active surveillance systems for FDA safety monitoring
Accelerating Change and Transformation in Organizations and Networks (ACTION II)	2010-current	AHRQ	14	Practice-based, implementation-oriented, rapid cycle research
Mental Health Research Network (MHRN)	2010-current	NIMH	10	Conduct rapid and efficient effectiveness trials in mental health
Population-based Effectiveness in Asthma and Lung Diseases (PEAL) Network	2010-current	AHRQ ARRA	4	Accelerate comparative effectiveness research in asthma and other lung diseases in diverse populations
Surveillance, Prevention, and Management of Diabetes Mellitus (SUPREME-DM)	2010-current	AHRQ ARRA	12	Study trends in diabetes incidence and prevalence, and diabetes treatment patterns and outcomes
Scalable PArtnership Network (SPAN) for Comparative Effectiveness Research	2010-current	AHRQ ARRA	10	Distributed data network to support CER

## Data collection

The information in this report comes from written surveys and telephone interviews conducted in the 2<sup>nd</sup> quarter of 2011 with investigators and key staff at the 14 sites who are participating in the HMORN Collaboratory supplement. The survey items were developed via a modified Delphi process in which stakeholders iteratively suggested and refined a slate of topics pertaining to HMORN research that would best describe the scientific capacity and operations of our research centers and health systems. The overall aim was to gather generally comparable information about each site, however, it should be noted that the 14 sites who have contributed data to this report are highly variable with regard to their organization, relationship to parent health system, and research capabilities.

## Glossary

Key terms and phrases used throughout this report are defined below:

**Clinical and Translational Science Award (CTSA):** NIH Roadmap for Medical Research consortium designed to assist institutions to synergize new translational research tools, programs, and researchers.

**Coordinated Clinical Studies Network (CCSN):** An infrastructure-building contract awarded to the HMORN through the NIH Roadmap. Active from 2005-2008, the CCSN spurred a number of streamlining activities pertaining to collaboration, institutional review board review, data use agreements, and other procedures.

**Covered lives:** People who are members and/or patients (see separate definitions of each of these terms).

**Delivery system:** The group of doctors and other clinicians affiliated with an HMORN site who provide care.

**Electronic medical record (EMR):** The electronic record of health-related information on an individual that is created, gathered, managed and utilized by clinicians and staff from a single organization who are involved in the individual's health and health care.

**Health plan:** Used to describe an HMORN-affiliated health insurance provider.

**HMORN site:** An institutional member of the HMO Research Network.

**Integrated system:** An organization that provides a continuum of health care services, which may include both care and coverage.

**Member:** A person insured by the health plan that the research center works in or with. When tabulating members, research centers typically require a period of constant enrollment in order to ensure a minimum amount of data are available for research.

**Overlap population:** People who are both members and patients (see separate definitions of each of these terms). Also referred to as "covered lives in an integrated delivery system."

**Patient:** A person who has had one or more visits to a clinician within an HMORN- associated integrated care system.

**Powerhouse area:** A scientific emphasis area in which an HMORN member regularly consults or has an ongoing portfolio of research.

**Research clinic:** A facility overseen and operated by the research center that is solely for the purpose of the center's research, that is, it is not a clinical care facility.

## II. HMORN Site Organizational Environment

HMORN-affiliated research centers operate in close connection with their parent health plans and delivery systems—either as departments within them or as independent organizations that have carefully negotiated research access to data and patient populations eligible for clinical trials. The primary mission of the health plans and delivery systems is the provision of health care services and coverage. Therefore, all research interactions—be it the use of data or interaction with clinicians or patients—require sensitivity to the need to protect private health information as well as the participating institutions’ fiduciary responsibilities and corporate interests. In addition, successful navigation within these systems, and operability with others, requires relationships built on common trust and understanding. Research agreements (beyond usual IRB approvals) may also be necessary Somkin, Altschuler et al. 2008.

### Current members

As noted above, data for this report were provided by the HMORN research centers who participated in the HMO Collaboratory supplement. These 14 sites, along with their delivery system and health plan partners are summarized below.

**TABLE 2: HMORN SITES DESCRIBED IN THIS REPORT**

Abbreviation	Research Center(s) and Location	Provider Group(s)	Health Plan
GHRI	Group Health Research Institute: Seattle, WA	Group Health Integrated Delivery System	
		Group Health Permanente	Group Health Cooperative
GHS	Center for Health Research, along with other departments and centers; Danville, PA	Geisinger Health System	
		Geisinger Clinic, Geisinger Medical Center, Geisinger Northeast	Geisinger Health Plan
HFHS	Department of Public Health Sciences, along with other departments and centers; Detroit, MI	Henry Ford Health System	Health Alliance Plan of Michigan
HPRF	HealthPartners Research Foundation; Minneapolis, MN	HealthPartners	
		HealthPartners Medical Group & Clinics	HealthPartners Health Plan
HPHC	Department of Population Medicine, Harvard Medical School; Boston MA	Atrius Health	Harvard Pilgrim Health Care
KPCO	Institute for Health Research; Denver, CO	Kaiser Permanente Colorado	
KPGA	The Center for Health Research – Southeast; Atlanta, GA	Kaiser Permanente Georgia	

Abbreviation	Research Center(s) and Location	Provider Group(s)	Health Plan
KPHI	The Center for Health Research – Hawaii; Honolulu, HI	Kaiser Permanente Hawaii	
KPNC	Kaiser Division of Research; Oakland, CA	Kaiser Permanente Northern California	
KPNW	The Center for Health Research – Northwest; Portland, OR	Kaiser Permanente Northwest	
LCF	LCF Research; Albuquerque, NM	Lovelace Health System; ABQ Health Partners	Lovelace Health Plan
MCRF	Marshfield Clinic Research Foundation; Marshfield, WI	Marshfield Clinic	Security Health Plan of Wisconsin
MPCI	Meyers Primary Care Institute University of Massachusetts Medical School; Worcester, MA	Reliant Medical Group	Fallon Community Health Plan
S&W	Academic Operations; Temple, TX	Scott and White	

## Organizational variability: implications for research

The organizational structure and relations of the HMORN-affiliated research centers, health plans, and delivery systems influence the number of services and people for which data are available for research; the mechanisms for obtaining data; and the logistics of pursuing a research study that involves interaction with patients or providers. Key factors include:

- **Common ownership:** When the research center, health plan, and delivery system are owned by the same entity, data access tends to be broader and simpler. When the ownership is not shared, the research center must establish data access agreements and linking procedures.
- **Facilities, clinicians, and services provided:** The number and type of facilities, clinicians and services affects the volume and types of data that are available for research.

HMORN research centers typically have research access to information on the people insured by the health plan(s) that they work with (“members”) and the patients of the delivery system(s). The richest information is on the “overlap population”—those who are both patients and members. Figure 2 depicts the overlap between patient and member data. The extent of convergence varies depending upon the organizational structure of the HMORN-health plan site (Table 3). Table 4 shows the number of covered lives (patients or members), the overlap population (patients and members) and key demographic information.

Even in highly integrated systems, patients and members will not fully overlap due to factors such as:

- The type of facilities included in the delivery system. For example, if the delivery system does not own and operate an emergency room, patients will go to other facilities for those visits.
- Fee for service payments: Some systems accept fee-for-service (FFS) service payments for general medical services. And even closed panel systems that do not routinely accept FFS payments may collect revenue within a FFS structure such as Worker’s Compensation, motor vehicle accidents, property liability coverage, etc.
- Co-insurance: Prepaid members may carry additional outside coverage.

FIGURE 2: PATIENT AND MEMBERSHIP DATA IN THE HMORN

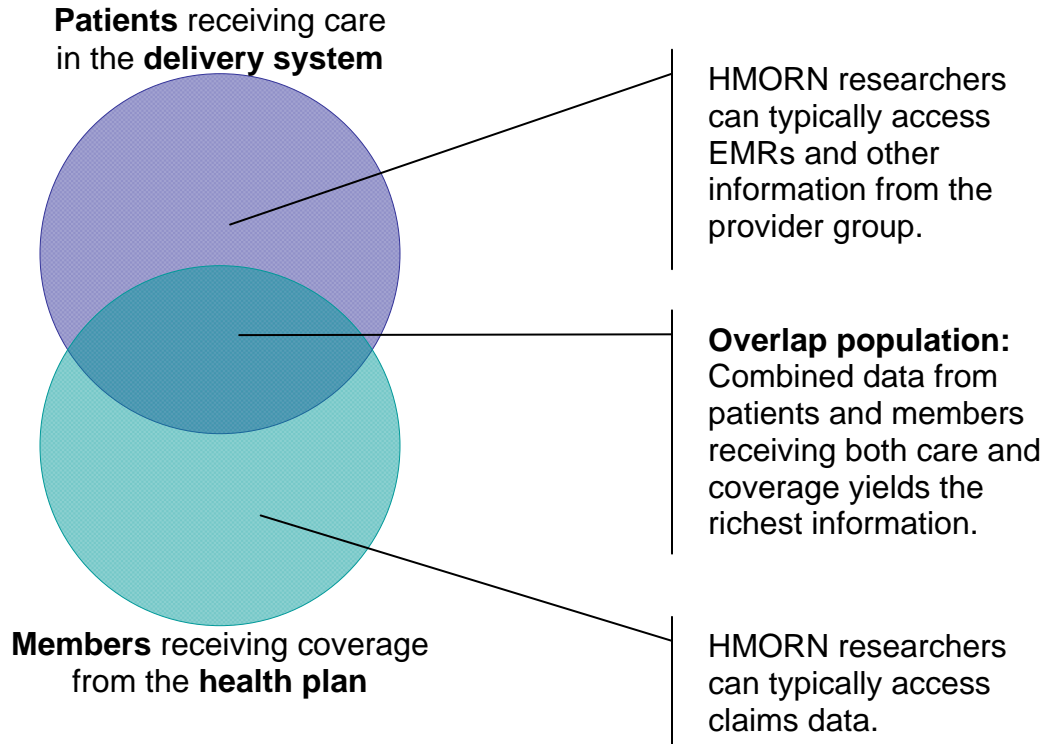


Table 5 and 6 provide more information about the complexity of the health plan partners, showing variation in owned specialty services (Table 5) and facilities and clinicians (Table 6).

TABLE 3: TYPES OF SYSTEMS

	GHRI	GHS	HFHS	HPRF	HPHC	KPCO	KPGA	KPHI	KPNC	KPNW	LCF	MCRF	MPCI	S&W
<b>Characterization: relationship of business entity and delivery systems (not mutually exclusive)</b>														
Health care system that owns / partners with insurance entity	●	●	●				●	●	●	●	●	●		●
Not-for-profit health plan/insurance company	●			●	●	●	●	●	●	●			●	●
Health plan that contracts with multiple provider groups	●			●	●				●			●	●	●
Medical group that contracts with, and receives claims data from, HMOs				●	●				●				●	
Insurance company or medical group that partners with a managed care system									●					
<b>Components: elements of corporate entities based on payment systems</b>														
HMO	●	●	●	●	●	●	●	●	●	●		●	●	●
Contracted	●	●	●	●	●	●	●	●	●	●	●	●	●	●
FFS			●	●	●			●			●	●		●
Point of Service and Third Party Administrator		●		●	●									
PPO		●					●				●			
<p>● Major Component</p> <p>● Some Emphasis (&lt;25% of business model)</p>														

**TABLE 4: POPULATION OVERVIEW, 2010**

Data notes: This information on age, race and ethnicity are reported for individuals who are patients of the partnering health care provider AND members of the partnering health care plan EXCEPT: the following are reporting for the health plan members: MPCl, KPNW, LCF, S&W. The demographics reported for GHS are for the primary care population. GHRI is reporting overlap population except retention is members only. MCRF has 1.7% unknown age. Some sites counted covered lives at any point in 2010, whereas others used enrollment figures as of a specific date. MCRF data is for the period 2008-2010.

	GHRI	GHS	HFHS	HPRF	HPHC	KPCO	KPGA	KPHI	KPNC	KPNW	LCF	MCRF	MPCI	S&W
<b>Enrollment</b>														
Covered lives x1000 <sup>‡</sup>	741	874	425	796	909	535	220	225	3,200	576	204	531	198	706
Covered lives in integrated delivery system, X 1000	413	337	148	361	114	479	219	225	3,200	447	204	235	70	315
<b>Age</b>														
% ≤ 17 yrs	16	19	16	25	22	21	22	20	22	22	38	21	19	22
% 18 – 44 yrs	31	40	27	39	39	34	37	35	35	34	26	32	33	33
% 45 – 64 yrs	35	26	34	29	34	30	32	30	29	31	21	26	29	28
% 65 +	18	16	22	5	4	15	9	15	13	14	15	20	19	17
<b>Race</b>														
% American Indian/Alaska Native	1	0	1	1	0	1	0	1	<1	1	NA	<1	<1	0
% Asian	4	0	3	5	5	3	2	38	17	5	NA	<1	3	1
% Native Hawaiian or Other Pac. Islander	0	1	0	0	0	0	0	33	4	0	NA	<1	0	0
% Black or African	2	1	38	10	12	4	18	1	8	3	NA	<1	2	6
% White	33	98	52	59	83	57	18	27	51	87	NA	68	87	45
% Other or unknown	60	0	0	25	0	36	62	0	0	5	100	30	0	45

<sup>‡</sup> Covered lives = patients with insurance coverage and/or some but not the vast majority of care data available in EMR or other medical records. Claims data only on some of this population. Covered lives in integrated delivery system: Comprehensive clinical data available in EMR, other delivery system data bases and claims data, aka overlap population.

	<b>GHRI</b>	<b>GHS</b>	<b>HFHS</b>	<b>HPRF</b>	<b>HPHC</b>	<b>KPCO</b>	<b>KPGA</b>	<b>KPHI</b>	<b>KPNC</b>	<b>KPNW</b>	<b>LCF</b>	<b>MCRF</b>	<b>MPCI</b>	<b>S&amp;W</b>
<b>Ethnicity</b>														
% ethnicity known	Not specified	Not specified	Not specified	Not specified	Not specified	54	Not specified	Not specified	Not specified	50	Not specified	68	Not specified	Not specified
% known Hispanic or Latino ethnicity	2	1	1	2	4	10	2	4	19	5	40	2	<b>8</b>	<b>7</b>
<b>Member Retention</b>														
% enrolled at 1 yr	82	82	99	88	85	91	82	85	87	83	80	88	95	84
% enrolled at 3 yrs	63	64	86	70	54	66	57	72	75	67	51	82	92	65
% enrolled at 5 yrs	52	47	63	55	45	54	43	63	66	59	40	70	92	53
<b>Insurance Coverage</b>														
% Group	78	78	76	57	98	82	84	78	78	80	50	66	unk	70
% Individual	24	N/A		28	2	12	11	11	12	4		2	unk	15
% Medicaid	5	N/A		8	0	2	0	12	2	3	39	39	6	0
% Medicare	18	15	24	2	0	18	4	14	14	13	10	21	16	15
% Other public	3	7		4			0	12	6	0		17		0

<sup>i</sup> may be > 100% if multiple responses allowed at collection, 'other' may included persons reporting multiple races.

**TABLE 5: OWNED SPECIALTY SERVICES**

Note: this table shows **selected** specialty services owned by the health care provider, which may result in a potential data source available to the research center. Specific services offered vary by facility. Non-owned specialty services are also available to patients, often through contract or partnership arrangements. However, information about those referrals may not be as readily available for research without making a medical records request.

	<b>GHRI</b>	<b>GHS</b>	<b>HFHS</b>	<b>HPRF</b>	<b>HPHC<sup>§</sup></b>	<b>KPCO</b>	<b>KPGA</b>	<b>KPHI</b>	<b>KPNC</b>	<b>KPNW</b>	<b>LCF</b>	<b>MCRF</b>	<b>MPCI</b>	<b>S&amp;W</b>
Allergy	●	●	●	●		●		●	●	●		●	●	●
Behavioral Health	●	●	●	●		●	●	●	●	●		●	●	●
Cardiology	●	●	●	●		●	●	●	●	●		●	●	●
Complementary and Alternative Med.			●			●			●					●
Dental care/Oral Medicine		●		●						●		●		●
Emergency Room facility		●	●	●				●	●	●	●			●
Endocrinology	●	●	●	●		●	●	●	●	●		●	●	●
ENT	●	●	●	●		●	●	●	●	●		●	●	●
Eye care services	●	●	●	●		●		●	●	●		●	●	●
Gastroenterology	●	●	●	●		●	●			●		●		●
Genetics	●	●	●					●	●	●		●		●
Hematology/Oncology	●	●	●	●		●	●	●	●	●		●	●	●
Hospice		●	●	●			●			●		●		●
Hospitalist		●	●	●		●	●	●		●		●		●
Infectious Disease	●	●	●	●		●	●	●	●	●		●	●	●
Long-term care/skilled nursing facility									●					●
Nutrition/Dietetics	●	●	●	●		●	●	●	●	●	●	●	●	●

<sup>§</sup> Full range of specialty services provided in the contracted external provider network for all HPHC enrollees; specialty care provided in Atrius-owned facilities for HPHC members who have an Atrius primary care provider.

	GHRI	GHS	HFHS	HPRF	HPHC <sup>5</sup>	KPCO	KPGA	KPHI	KPNC	KPNW	LCF	MCRF	MPCI	S&W
OB-GYN/ Midwifery/ Women's Health	●	●	●	●		●	●	●	●	●	●	●	●	●
Outpatient (same-day) surgery	●	●	●	●		●	●	●	●	●	●	●		●
Pain	●	●	●	●		●	●	●	●	●		●	●	●
Pediatrics	●	●	●	●		●	●	●	●	●		●	●	●
Physical/Occupational/ Rehabilitation Therapy	●	●	●	●		●		●	●	●	●	●	●	●
Radiology	●	●	●			●	●	●	●	●		●		●
Surgery	●	●	●	●		●	●	●	●	●	●	●	●	●
Urgent Care Center	●	●	●	●		●		●	●	●		●	●	●

TABLE 6: HMORN-AFFILIATED PROVIDER GROUP FACILITIES AND PROVIDERS

	GHRI	GHS	HFHS	HPRF	HPHC	KPCO	KPGA	KPHI	KPNC	KPNW	LCF	MCRF	MPCI	S&W
# hospitals owned/operated	1	5	5	4	0	0	0	1	21	1	4	2	0	12
# clinic sites owned/operated	26	39	36	51	29 (Atrius)	22	28	17	454**	27		63	20	60
# primary care providers (MD/DO/PA/NP) <sup>††</sup>	930	197	379	524	27,000 <sup>††</sup> combined (HPHC)	327	378	135	1500	286	7000 combined	295	120	860 combined
# specialty providers	75	717	715	477		577	111	314	>7000 (est.)	594		500	130	
# in-house pharmacies	26	11	25	15	29	21	29	18	110	20	11	20	0	14

\*\* est. 35 primary care clinics.

†† Primary care provider definition may vary between delivery systems.

†† total contracted providers (primary care and specialty).

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## III. Research Centers and Emphases

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HMORN research centers offer expertise in a broad range of research areas, including observational studies, comparative effectiveness research, clinical trials and social and behavioral science. Partnerships with academic affiliates further expands the scope of expertise. Collectively, the HMORN sites comprise several hundred scientific researchers and each has a well-developed infrastructure. HMORN sites largely specialize in investigator-initiated research, much of which is federally funded.

### Infrastructure

Table 7 provides an overview of each member research center and describes infrastructure components, the amount of funding from federal sources, and clinical trials activity. Clinical trials volume varies widely by site. As this table illustrates, about half the research centers have a research clinic and in-house survey research facility. Most have in-house capabilities to perform lab work for research purposes and dispense study related medications.

### Topical and methodological emphases

The broad topical and methodological expertise in the HMORN varies by site, as detailed in Table 8. Some strong condition-specific emphases include diabetes, cardiovascular disease, cancer, mental health conditions, and asthma. Strong cross-cutting areas include chronic illness care, pharmacoepidemiology, women's health, patient safety, multimorbidity, aging, vaccine safety, and health disparities. Healthy living and prevention are also areas of significant expertise across the HMORN sites, with focuses on obesity, nutrition and physical activity, and tobacco control. Our researchers are especially experienced in real world health systems research including translational research, dissemination, health care provider behavior change, and clinical quality improvement. Methodological experience is wide, including observational studies methods, clinical trial methods, health informatics, cluster randomized trials, cost-effectiveness and genetics. Several sites (Scott & White, Kaiser Permanente in Northwest, Northern California, and Colorado regions, Marshfield, and Geisinger) have a strong clinical trials capacity, conducting more than 50 per year.

### Partnerships for clinical innovation

At the heart of all HMORN collaborations is a commitment to improve health and health care and a commitment to open source research in the public interest. The parent health systems with whom we are affiliated are typically not-for-profit health plans that consider research part of their mission and community contribution. The HMORN's multidisciplinary faculty have extensive experience working with these high-functioning delivery systems to ensure that research advances are translated into improved care. At several sites, clinician-researchers play an active role in both research and either care delivery or clinical quality improvement.

TABLE 7: HMORN RESEARCH CENTERS

	GHRI	GHS	HFHS	HPRF	HPHC	KPCO	KPGA	KPHI	KPNC	KPNW	LCF	MCRF	MPCI	S&W
Began	1983	2003	1983	1989	1969	1987	1998	1991	1961	1964	1990	1959	1996	1985
Research clinic	●		●	●			●	●	●	●		●		
Survey department	●	●	●	●						●		●		
Facility that can do research lab tests	●	●	●	●	●	●	●	●		●	●	●		●
Facility that can fill research prescriptions	●	●	●	●	●	●		●		●	●	●		●
2010 Funding <sup>\$§</sup> – all sources (\$millions)	43.3	10.5	52.4	17.0	32.1	16.6	3.3	4.4	94.4	35.3	5.7	31.9	4.3	13.1
2010 Federal Funding, %	82	16	50	64	84	54	44	62	69	76	91	32	72	22
PI FTE	32	10	82	23	36	10	6	5	48	31	7	31	26	23
Investigator-initiated clinical trials (avg/year)	1-10	>10	1-10	1-10	0	0	1-10	0	>10	>10	0	1-10	1-10	>10
Total clinical trials (avg/year)	<50	50+	50+	<50	<50	50+	<50	<50	50+	50+	0	50+	<50	50+

<sup>\$§</sup> Revenue/expense.

TABLE 8: HMORN SITE SCIENTIFIC EMPHASES

● Powerhouse Area\* (ongoing projects or expertise)

● Some Emphasis

	GHRI	GHS	HFHS	HPRF	HPHC	KPCO	KPGA	KPHI	KPNC	KPNW	LCF	MCRF	MPCI	S&W
<b>Diseases</b>														
Alcohol abuse: understanding, prevention, treatment	●	●	●	●					●	●	●			
Arthritis, musculoskeletal, skin diseases		●	●			●	●	●	●	●	●	●		
Cancer prevention, control, treatment	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Diabetes	●	●	●	●	●	●	●	●	●	●	●	●		
Drug abuse prevention, treatment		●	●						●	●				
Eye diseases				●				●				●		
Cardiovascular disease	●	●	●	●	●	●	●	●	●		●	●	●	●
Infectious disease, including vaccine delivery/surveillance	●		●	●	●	●	●	●	●	●	●	●		●
Mental health disorders	●	●	●	●	●	●	●	●	●	●				●
Neurological disorders		●	●	●			●		●	●	●	●		●
Oral, dental, craniofacial health	●			●						●		●		
<b>Cross-cutting</b>														
Aging	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Complementary and alternative medicine	●		●	●		●	●		●	●				
Global health				●	●	●			●					
Health disparities and racial, ethnic and language disparities	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Multimorbidity	●	●	●	●	●	●	●	●	●	●				

● Powerhouse Area\* (ongoing projects or expertise)

● Some Emphasis

	GHRI	GHS	HFHS	HPRF	HPHC	KPCO	KPGA	KPHI	KPNC	KPNW	LCF	MCRF	MPCI	S&W
Pain management and treatment	●	●	●	●				●	●	●	●	●		
Palliative/end of life care	●		●	●	●	●		●	●	●		●		
Pediatrics and child development	●	●	●	●	●	●	●	●	●	●			●	●
Pharmacoepidemiology	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Radiology and imaging	●	●	●	●		●	●	●			●	●		
Women's health	●	●	●	●	●	●	●	●	●	●	●	●		
<b>Prevention</b>														
Environmental health and exposures		●	●				●		●		●	●		
Obesity, active living, healthy eating	●	●	●	●	●	●	●	●	●	●	●	●		●
Reproductive health		●	●	●	●		●	●	●	●	●			
Social determinants of health	●	●	●	●	●	●	●	●	●	●	●	●	●	
Tobacco control/smoking cessation	●	●	●	●		●		●	●	●	●	●		
<b>Health services emphases</b>														
Quality improvement	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Dissemination science and translation of research into practice	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Health care provider behavior change	●	●	●	●	●	●	●	●	●	●	●	●	●	
Nursing		●	●	●		●								
Patient decision making and health literacy	●	●	●	●	●	●	●	●	●	●	●		●	●

● Powerhouse Area\* (ongoing projects or expertise)

● Some Emphasis

	GHRI	GHS	HFHS	HPRF	HPHC	KPCO	KPGA	KPHI	KPNC	KPNW	LCF	MCRF	MPCI	S&W
Patient safety		●	●		●	●	●		●	●	●		●	●
Translational research	●	●	●	●		●	●	●	●	●	●	●		
<b>Methodological emphases</b>														
Bioethics / responsible conduct of research	●		●	●	●	●		●	●		●			
Clinical trials methods	●		●	●		●			●	●	●	●		
Cluster randomized trials	●		●	●	●	●	●		●	●	●		●	
Community engagement, community-based participatory research	●		●			●	●	●	●	●	●	●		●
Cost-effectiveness	●	●	●	●	●	●	●	●	●	●	●	●		
Genetics, genomics, biorepositories	●	●	●		●	●	●	●	●	●	●	●		
Health informatics	●	●	●	●	●	●	●	●	●	●	●	●	●	
Observational study methods	●	●	●	●	●	●	●	●	●	●	●	●	●	
Qualitative methods	●			●	●	●		●	●	●	●		●	

\*Based on self-reported assessment.

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## IV. HMORN Research Processes

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Procedures for initiating and conducting research studies in the HMORN vary depending on the topic and the involved researchers and institutions. General inquiries are typically triaged through the HMORN web site, however, it is often the case that an inquiry will arise based on learning about the network through a personal interaction or existing relationship with a researcher at one of the sites. Inquiries about whether the HMORN is a potentially suitable setting for a multi-site study are vetted through the Governing Board to ensure equitable opportunities across sites for leadership and participation. Individual sites also have mechanisms in place to share research opportunities with their local researchers, and ensure feasibility and non-duplication with existing research. Many of these site-specific “collaborate with us” mechanisms are housed on the research center’s local web site. Two examples of how studies are initiated (Figure 3a) and assessed for feasibility (Figure 3b) are provided below.

### Establishing partnerships

Partnerships with researchers from HMORN sites are essential to conducting research in the HMORN because of their extensive experience in multiple areas of HMORN research:

- As content experts in specific scientific areas, they can collaborate on the development of relevant research questions.
- Based on their familiarity with available data at their site, HMORN investigators can inform study designs that are efficient and feasible, thus optimizing many aspects of the study process ranging from data capture to participant recruitment.
- Similarly, many HMORN researchers have gained familiarity with data structures and analytic processes across other HMORN sites, facilitating cross-site collaboration.
- The scientific teams also have well-developed networks of collaborators who can contribute to methodological and operational aspects of working in the healthcare environment itself; as studies are completed, the HMORN-based researcher is well-positioned to ensure that relevant findings receive consideration in clinical practice.

HMORN researchers have extensive experience conducting collaborative projects both within the network and with external collaborators. Typical collaborators include other HMORN members, regional universities, Clinical and Translational Science Award networks, regional and disease-specific research networks and public health departments.

### Obtaining and managing funding

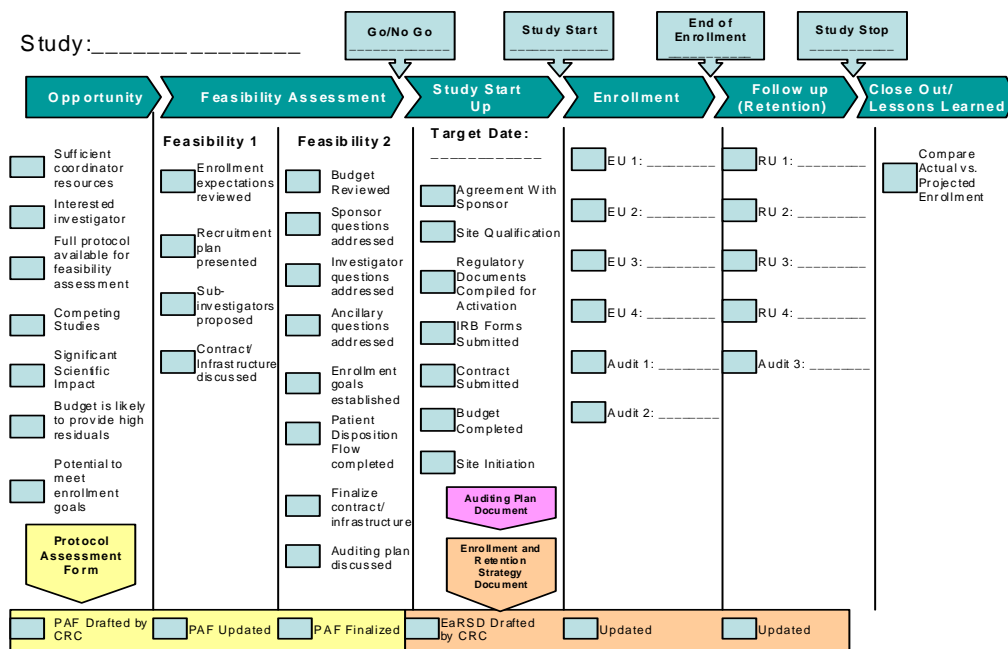
HMORN sites primarily conduct federally-funded investigator-initiated research, and function similarly to academic departments, inasmuch as the HMORN scientists write and compete for grants, and engage with federal sponsors to complete funded investigations. Each site has its own unit that handles grants and contracts as well as human subjects and regulatory compliance to efficiently meet federal reporting standards.

FIGURE 3A: KAISER PERMANENTE DIVISION OF RESEARCH COLLABORATION WEB PORTAL



FIGURE 3B: GEISINGER CENTER FOR CLINICAL STUDIES STUDY LIFECYCLE MANAGEMENT FLOW

For every potential clinical study, the Geisinger Center for Clinical Studies (CCS) conducts a Feasibility Analysis, which frequently includes an EMR data pull to determine the volume of potentially eligible patients. From the Feasibility Analysis, Geisinger can propose realistic enrollment expectations for the study sponsor. CCS has also developed an Enrolling and Retention Strategy Document that evaluates the factors contributing to successful participation, enrollment and retention, and contingency plans for each step. CCS staff follow a standard process for ongoing studies to provide scheduled updates on enrollment and retention. Triggers for implementing contingency plans as outlined in the Enrollment and Retention Strategy are identified as a result of these updates. This process is depicted below.



Abbreviations: PAF = protocol assessment form; EARSD = Enrollment and Retention Strategy Document; CRC = clinical research coordinator; EU = Enrollment update; RU = Retention update

## Protection of human subjects

As stewards of data derived from clinical care, HMORN investigators have an ethical and legal obligation to use these data appropriately. This includes ensuring that the results of scientific investigations have the potential to improve care for study participants and the general population, and abiding by all HIPAA and other regulatory compliance policies.

Each institution has its own institutional review board (IRB) review process. As part of this process, many have arrangements for streamlining the review for multi-site studies. The HMORN has also established a facilitated review process available for a variety of study designs (data only studies, surveys, and other minimal risk research).

## Institutional impact assessment

In addition to IRB review, many institutions require one or more reviews to ensure that new studies are feasible, have scientific merit, have adequate resources, do not pose unreasonable institutional risk, do not duplicate existing projects, and do not interfere with patient care. These review processes are especially important for intervention studies.

## Data access

Data for HMORN investigations are drawn from multiple sources including, but not limited to, standardized data warehouses, site-specific disease registries, EMRs, and pharmacy databases, as well as primary data collection. For most studies, data are accessed at the site level by analytic and data management staff who are familiar with the databases and have institutional permissions to access specialized databases such as pharmacy data and EMR summary data. For multi-site studies that use data from the standardized VDW, efficiencies are achieved by sharing data extraction code that has been written and validated at a single site then deployed at other sites to be run against local VDW files. Data management staff at all sites work closely with site investigators to refine data queries and prepare analytic data sets.

**Data sources and tools are described in more detail in the Section VI.**

## Cohort development and utilization

Analytic cohorts are usually study-specific and initially developed through the data extraction processes described above. HMORN electronic data may be supplemented through data linkages with other sources, such as vital records and cancer registries. Depending on study design, analytic cohorts may also contain data on survey responses, variables from clinical trials, alternatively collected data such as home blood pressure readings, and other data points specific to a given research investigation. Depending on the study, cohorts may be reusable, or a de-identified extract of the data may be made available to other investigators for secondary data analysis. Procedures for re-contact and/or re-consent will vary from project to project. See the data sharing section below for more information.

## Intervention studies

Studies that involve interventions with patients or providers require close partnerships with any involved health care delivery systems or health plans. It is important to make sure that interventions do not interfere with clinical care and that all outreach efforts appropriately protect patient privacy. In some instances, undertaking certain studies may require notifying the primary care provider of the patient/member, since the research could potentially affect care coordination or delivery. An example might be a study that provides participants with a study drug that could interact with other medications the participant takes. Hence, the impact of research on care must be preempted through communication with the health system or patient's care team. As noted above, some sites have embedded research clinics, which can facilitate data collection for interventional trials.

## Methods and analytic processes

HMORN analytic and methodological experts at each site are knowledgeable in biostatistics, epidemiology, qualitative methods and other methods relevant to the research and the often unique data sources available at their site. Special emphases are described in detail in the previous section and in the site profiles (Section VII). Investigators and analytic staff with relevant methodological knowledge participate in study design, analytic plan development, and the conduct and interpretation of analyses and preparation of scientific products. HMORN researchers make regular contributions to methodological literature, publishing on topics that include risk adjustment methods, validation of electronic data and paper medical records, statistical methods, cost-effectiveness and cost-utility analysis, and Bayesian methods.

For multi-site investigations, limited data sets or de-identified data are commonly aggregated and analyzed by the lead site. Depending on the data use agreements in place, some analyses may be undertaken by a site investigator with an interest in a particular aspect of a study.

## Cohort access and re-contacting participants

The HMORN follows federal funding agency and IRB policies regarding post-study access to de-identified data. When specific projects meet criteria for such access, HMORN investigators arrange contact processes for interested parties. Re-contacting study participants may be possible with approval from the principal investigator and IRB for open, ongoing investigations. Re-contacting participants of closed studies is dependent on the original study design and original IRB approvals for managing linkage files between valid participant identifiers and anonymous study identifiers. Certain studies (e.g. those designed as ongoing cohorts such as the Framingham Study) have study designs that incorporate ongoing re-contacting while others are designed to be finite and have linkage files destroyed after a specific time period. In an effort to facilitate data sharing and maximize data utility, the HMORN has developed tools to help streamline the development of data use agreements, as well as guidelines that urge the use of bidirectional or multi-lateral data use agreements.

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## V. Research Data

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HMORN sites have substantial experience acquiring data from various sources at their organization and using it for research. Additionally, many HMORN researchers are skilled at the analysis of merged data from multiple HMORN health systems. This particular data use often requires cross-walks among various coding conventions, interpretation of data in light of local practice and coding practices, and efforts to ensure that data are fully deidentified. Research use of data from clinical systems—be they from electronic medical records, billing claims, or other sources—requires transformation quality checks and careful, knowledgeable interpretation. These data systems are not inherently interoperable and are subject to periodic updates and revisions. The data analysts at the HMORN sites have worked with investigators to develop tested, standardized approaches to handling these issues.

### Data sources

In the HMORN, data sources vary by institution and over time. However, researchers typically have access to health plan claims data, medical record data (which are increasingly electronic), and other information from health care data systems, public records, and other sources. Table 9 summarizes commonly used data sources.

TABLE 9: TYPICAL DATA SOURCES FOR HMORN RESEARCH

Data type	Considerations
<b>Source: health plan</b>	
Health plan claims	Claims data provide a wealth of information, such as diagnoses, procedures, and treating clinician. Because claims data are not created for clinical or research purposes, special attention may be required for interpretation, depending on the clinical domain. Within the HMORN, claims data may include more detailed information than is usually contained in systems such as Medicare, but this means standard approaches from other claims data systems will require substantial review and revisions.
<b>Source: data derived from health care encounters</b>	
EMR data	All HMORN research sites have experience using EMR data. Most members use EpicCare and many of the sites' analysts are expert in pulling and using data using SQL from the underlying database. Most sites have established standard data tables for lab test results, blood pressure measures, and height and weight measures with data drawn from the EMR. Use of other data within the EMR has also progressed, illustrated by one cancer screening research study in which 4 sites have extracted electronic text from cytopathology reports of Pap smear results and established standard data tables of categorized results. Many sites have used natural language processing (NLP) to enable use of the electronic text contained in the EMR, and HMORN scientists and programmers with NLP experience meet monthly by conference calls.

Data type	Considerations
Medical charts	Patient medical charts—both paper and electronic-- are the gold standard for studies that require review of a patient’s history. Typically, medical charts are only reviewed for patients in a medical group that is part of the same covered entity as the researcher; review of charts from other health care providers may occasionally be possible with additional funding and relevant permissions. Several research projects have developed and tested methods for training chart abstractors across multiple sites and accomplish chart abstraction efficiently and accurately.
Lab data	Typically available from EMR or other systems. Coding standards vary around the country. LOINC is the most common coding standard used by HMORN members. Sites that do not use this coding standard have created an internal crosswalk to it. The HMORN has a lab data committee that guides the development of standardized data tables for the lab test results most commonly called for in research studies.
Clinical registries	Several studies have access to registries developed for clinical operations that can be made available for research purposes. The clinical areas vary, but include information on diabetes, heart disease, cancer, genetics, perinatology, chronic diseases and preventive services.
Biospecimen resources	Several HMORN-affiliated sites have large, well-established biobanks. They operate independently. Currently clinical and research repositories differ in terms of consent, material collected and restrictions on use.
Patient reported outcomes	Several sites collect information self-reported by patients including race or ethnicity, language preference, general health, functional or mental status, and preventive health behaviors. Systematic collection of patient-reported data is increasing on a national level. Currently the amount of patient-reported data available for research varies across sites but is increasing.
Data on health care cost, utilization, benefit designs	There is great interest in the ability to link clinical, benefit, and cost data. Sites vary in their capacity based on investigators’ interests and available data.
Pharmacy data	Pharmacy data includes data on two types of transactions: ordering prescriptions and dispensing medications. Data availability may depend on whether the medication was ordered and dispensed in the inpatient or outpatient setting.
<b>Source: Primary data collection</b>	
Survey data	About one third of the research centers have dedicated survey units, or comparable ability to deploy trained survey interviewers to collect telephone, web and in-person survey data.
Clinical trials data	Clinical trials data collection follows carefully designed procedures using a range of commercial and custom-built clinical trial management systems. VDW data, such as that described above, has the potential to facilitate subject sampling and recruitment by narrowing the population based on a trial’s predetermined eligibility criteria.

Data type	Considerations
<b>Source: Secondary data</b>	
Cancer registries	Most HMORN research centers have independent cancer registries. Many others have linked information from state tumor registries.
Medicare/Medicaid	All HMORN research sites can link information from their records to Medicare/Medicaid with appropriate permissions.
Vital records	All HMORN research sites can link information from their records to state birth and death records with appropriate permission.

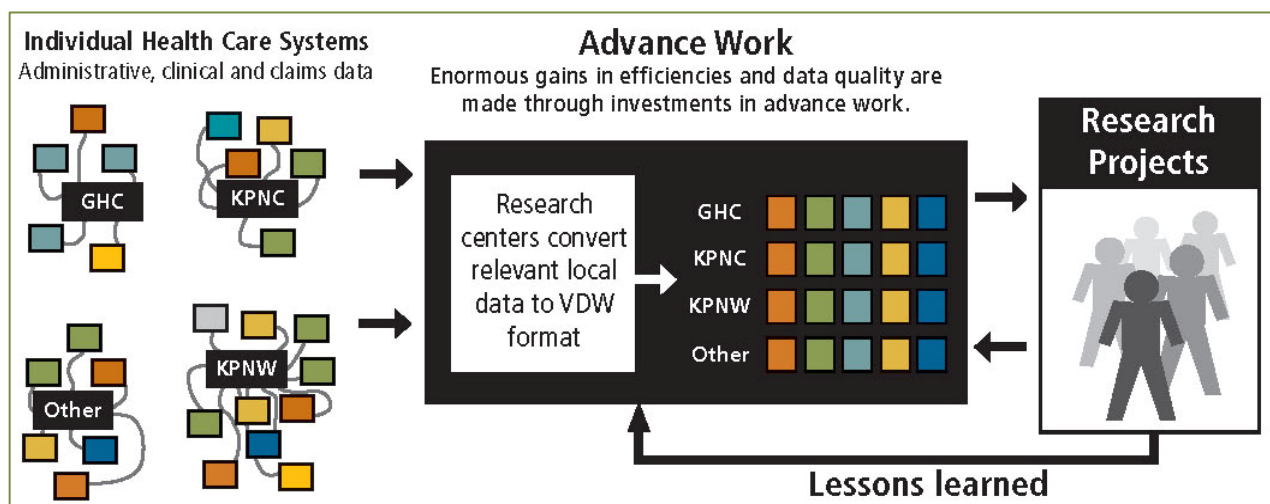
## Site-specific data tools

Each HMORN member research organization has developed a set of tools to access, link and manage data for research. Depending on a study’s specific needs, an HMORN researcher may be able to draw entirely on pre-compiled data in a research warehouse, or may need to work with partners at the health plan, health care provider group, or outside institution or agency to assemble and link new data.

## The Virtual Data Warehouse (VDW)

A cornerstone of the HMORN’s success is the ability to coordinate comprehensive data resources in support of a large and varied program of multi-site, multi-purpose collaborative research. A key example is the Virtual Data Warehouse, or VDW—a one-of-a-kind shared resource which is created by translating data from local systems into a common format based on agreed upon data standards. The VDW combines demographic and clinical information from EMRs, insurance claims, and registries for defined, diverse, and geographically distributed patient populations. Active input of researchers with each successive project has progressively enriched its utility. Figure 4 shows a schematic of the VDW and its use in the research context.

FIGURE 4: VIRTUAL DATA WAREHOUSE WITHIN HMORN



The VDW is a federated or distributed data warehouse. There is no central data repository; data reside at each home HMORN site and sites maintain control over their data and its uses. The VDW model relies upon

computerized datasets stored behind separate security firewalls at participating HMORN sites. Each site's datasets include variables with identical names, formats, and specifications and identical variable definitions, labels, coding, and definitions. **Table 10** provides an overview of the current data domains housed within the VDW. A set of informatics tools—hardware and software—facilitate storage, retrieval, processing, and managing VDW datasets. Specific policies and procedures govern the use of VDW resources. An internal website provides extensive documentation on all components of the VDW, including years of data availability, types of variables contained in a data area, and known anomalies.

This approach allows multi-site data checking, data characterization and analysis to be conducted using a single computer program developed at one HMORN site which is then distributed to all sites and executed locally. Programs written at one site can be run at other sites with a minimum of site-specific customization; sites then review findings and return results or subsets of data (via secure mechanisms) to the requester for merging and further analysis.

Data standardization is a dynamic and active process that involves the following steps: 1) specifying common variable names, labels, coding, and definitions; 2) writing programs to extract and convert variables stored in legacy information systems to the common standards; 3) testing standardized data for consistency and accuracy; 4) standardizing methods by writing macros that are used across projects; and 5) instructing researchers and analysts on how to use the VDW to guide construction of analytic files for approved research projects. The HMORN's VDW Operational Committee (VOC) provides direction to each HMORN site on VDW implementation. The VOC is also responsible for maintaining current documentation of data availability across sites, including site variations and site-specific issues, quality control evaluation of domain-specific data at each site, and policies and procedures for initiation and conduct of multi-site research within the HMORN.

This structure eliminates the potential security risks inherent in a centralized model (where all data are pooled at a single site). Another key advantage of the VDW model is that data remain with health plan staff, data analysts, investigators, and providers who are best positioned to consult on proper use of the data, help interpret findings, and investigate anomalies. Each site extracts, transforms, and loads their local data into the common VDW data model which enforces uniform data element naming conventions, definitions, and data storage formats (i.e., semantic and syntactic interoperability).

## Data availability by site

Research centers have variable access to clinical and health plan generated data, depending on investigator priorities and health plan/provider information system organization. **Tables 11-14** give site-by-site information on EMR, clinical domains, patient-reported information, and biospecimen resources.

## Distributed query tools

A multi-site query tool is under development that will permit investigators at one site to conduct broad queries of site-level data at other HMORN sites and thus create population-level summaries. As part of the proposed Collaboratory Coordinating Center, a public portal would also be created to facilitate external researchers' understanding of the VDW, and enable potential data users to create data queries for prep-to-research (i.e., feasibility) purposes. Such summaries can inform the design of observational studies and/or clinical trials. Open source informatics tools such as i2b2 and SHRINE are also being implemented and tested at some vanguard sites within the HMORN.

TABLE 10: VDW DATA DOMAINS

Domain	Contents
<b>Demographics</b>	Birth, gender, race and ethnicity.
<b>Enrollment</b>	Health plan membership enrollment with indicators for insurance types, benefits, and effective dates of coverage.
<b>Encounters</b>	Outpatient visits and inpatient stays, including the associated diagnosis and procedure codes, type of encounter, provider seen, facility and discharge disposition.
<b>Diagnoses</b>	Dates, diagnosis codes, primary diagnosis flag and diagnosing provider.
<b>Procedures</b>	All procedures including evaluation and management, surgery, laboratory, radiology, and immunization. These include various procedure coding systems (CPT-4, HCPCS, ICD-9-CM, insurance claims Revenue Codes).
<b>Cancer/Tumor Registry</b>	Based on the Surveillance, Epidemiology and End Results (SEER) program standards, the domain consists of detailed stage and grade, date of diagnosis, dates of treatment initiation, and is by far the most complex domain of the VDW.
<b>Pharmacy</b>	Pharmacy dispensing and claims, date of dispensing, National Drug Code or GPI code, therapeutic class, days supply, and amount dispensed.
<b>Ever NDC</b>	Standardized look-up table of all unique National Drug Codes (NDCs) or values of the NDC variable in use across HMORN sites.
<b>Census</b>	2000 Census information based on home address. In addition to a geocode it contains census tract and/or block group level information on education, income, housing, and race for enrolled individuals 2010 data will be added when available.
<b>Providers</b>	Providers' specialty, age, gender, race and year graduated.
<b>Vital Signs</b>	Height, weight and blood pressure readings collected at most in-person encounters. Tobacco use and type is also included.
<b>Death</b>	Date and cause of death.
<b>Laboratory Results</b>	Test type, immediacy, date of test, test orderer, results, indicators of abnormal tests. Sites are adding lab values to this table through a timed priority list with 57 types of lab tests included or in process at this time.

TABLE 11: EMR INFORMATION FOR PATIENTS IN HMORN-ASSOCIATED PROVIDER GROUPS

	<b>GHRI</b>	<b>GHS</b>	<b>HFHS</b>	<b>HPRF</b>	<b>HPHC</b>	<b>KPCO</b>	<b>KPGA</b>	<b>KPHI</b>	<b>KPNC</b>	<b>KPNW</b>	<b>LCF</b>	<b>MCRF</b>	<b>MPCI</b>	<b>S&amp;W</b>
EMR														
Name	Epic	Epic	CarePlus	Epic	Epic	Epic	Epic	Epic	Epic	Epic	Allscripts ***	Cattails MD	Epic	Next Gen; “Home- grown”
Roll-out began	2003	1996	1990	2002	2000	2004	2004	2004	2005	1996	2009	1993	2006	1991
Available for research with approval	●	●	●	●	●	●	●	●	●	●	In progress	●	●	●
Patient portal <sup>†††</sup>	●	●		●	●	●	●	●	●	●	In progress	●	●	

\*\*\* (ABQ Health Partners Independent Physician Group contract providers to the Lovelace Health System)

††† Services vary by system but may include medication lists/refills; secure messaging to and from the health care team, medical test results, after-visit-summaries, allergy lists, immunization history, and appointment requests.

TABLE 12: POPULATION AND DATA SOURCES USED FOR HMORN RESEARCH

(● = claims, ● = EMR AND claims—presumably only getting EMR for patients and getting claims for patients and members)

	GHRI	GHS	HFHS	HPRF	HPHC	KPCO	KPGA	KPHI	KPNC	KPNW	LCF	MCRF	MPCI	S&W
Medical charts (with approval)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Pharmacy	●	●	●	●	●	●	●	●	●	EMR	●	●	●	●
Orders linked to dispensings?	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	N	N	Y	N
Primary care encounter	●	●	●	●	●	EMR	●	●	EMR	●	●	●	●	●
Ambulatory specialty care	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Procedures	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Inpatient facility	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Inpatient physician service	●	●	●	●	●	N/A	●	●	●	●	●	●	●	●
Emergency department	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Mental health	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hospice/home health	●	●	●	●	●	●	●	●	Referral	EMR	●	●	●	●
Durable medical equipment	●	●	●	●	●	●	●	●	●	EMR	●	●	●	●
Nursing home	●	●	●	●	●	●	●	●	Referral	●	●	●	●	●
Dental				●						●		EMR		

TABLE 13: BIOSPECIMEN RESOURCES

	GHRI	GHS	HFHS	HPRF	HPHC	KPCO	KPGA	KPHI	KPNC	KPNW	LCF	MCRF	MPCI	S&W
Clinical repository established (approx)	1977	2006	1989	1990	2000	1990		1983	1970	1960		1985		
Used for research	●	●	●	●		●		●	●	●		●		
Research repository	●	●				In process		In process	●	●		●		

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## VI. HMORN Site Profiles & Publications

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This section provides additional information about each HMORN research site described in this report, including the organizational structure and research services and emphases.

Collectively, the HMORN investigators are highly productive, and have published an array of influential articles that influence health and health care.

# Group Health Research Institute | Group Health Cooperative

## Website

[www.grouphealthresearch.org](http://www.grouphealthresearch.org)

## Population served

Close to 700,000 members in Washington and northern Idaho.

## Research center(s) and services

GHRI was established in 1983 to conduct high-quality scientific research that would contribute to scientific knowledge in the public domain and improve care at Group Health. The Institute's mission is to improve health and health care for everyone through leading-edge research, innovation, and dissemination. This broad mandate includes conducting epidemiologic, health services, and clinical research relevant to the prevention and effective treatment of major health problems, with an emphasis on health behavior change; evaluating the efficacy and cost effectiveness of health care services and technologies; carrying out population-based surveillance of health status within and beyond the Group Health enrolled population; and evaluating Group Health's programmatic decisions.

The GHRI workforce consists of approximately 270 full- and part-time individuals. GHRI operates a research clinic. Its Survey Research Program has 15-25 active survey research

service projects, both web- and phone-based, at any given time.

## Affiliated health care and insurance provider(s)

Group Health Cooperative is a large, mixed-model, nonprofit health care system that coordinates care and coverage. Group Health is based in Seattle, WA, and is one of the few consumer-governed health care cooperatives in the nation.

Group Health provides primary, specialty, hospital, home health, and inpatient skilled nursing care on a pre-paid (capitation) basis. Mental health and substance abuse services are part of the enrollee benefit package. Enrollees choose their primary care medical center and their personal physician within that medical center. More than 70% of members receive comprehensive care in Group Health-owned facilities. Group Health has 26 primary care medical centers and one hospital.

## Example partnerships

- ❖ University of Washington
- ❖ Fred Hutchinson Cancer Research Center/Seattle Cancer Care Alliance
- ❖ HMO Research Network
- ❖ Clinical and Translational Science Award

### Example studies

Title and PI	Study population	Description and available citations
Treatment of Nicotine Dependence in a Health Care Setting, Gary Swan (SRI) & Jennifer McClure (site PI)	1,202 followed for one year	Comparative effectiveness of trial of 3 forms of behavioral smoking cessation intervention; first study to use varenicline post-FDA approval and marketing.  Citations: Catz, Jack et al. 2011; Javitz, Zbikowski et al. 2011; Zbikowski, Jack et al. 2011
Adult Changes in Thought (ACT) Study, Eric B. Larson	About 2,000 (at any one time, new participants are enrolled as others die) followed since 1994. Total enrollment to date > 4,000 including >400 research quality autopsy specimens.	An ongoing longitudinal study following adults over age 65 to identify risk factors for cognitive decline with aging and related conditions, such as Alzheimer's disease.  Citations: Gray, Anderson et al. 2008; Breitner, Haneuse et al. 2009; Ehlenbach, Hough et al. 2010; Gray, Walker et al. 2011; Trittschuh, Crane et al. 2011

Title and PI	Study population	Description and available citations
Electronic Medical Records and Genomics (eMERGE) Network, Eric B. Larson and Gail P. Jarvik	<p>Phase 1: included a re-consent study of 365 (one-time survey)</p> <p>Phase 2: planning for about 32,000 participants per study</p>	<p>The primary goal of the eMERGE Network is to develop, disseminate, and apply approaches to research that combine DNA biorepositories with electronic medical record (EMR) systems for large-scale, high-throughput genetic research.</p> <p>Re-consent study: The first study to ask research participants' opinions about the need for informed consent for sharing their own information. 1340 ACT study participants were asked whether their "de-identified" (anonymous) genetic and medical record information could be shared in the database, and 1159 (86 %) said yes. In a survey of 365 of the consenters, 90 % said they thought it was important to have been asked for this re-consent.</p> <p>Citations: Ludman, Fullerton et al. 2010; Trinidad, Fullerton et al. 2010; McCarty, Chisholm et al. 2011; Trinidad, Fullerton et al. 2011</p>
Effect of Massage on Chronic Low Back Pain, Daniel C. Cherkin	400 followed for one year	<p>First study to compare structural and relaxation (Swedish) massage for chronic low back pain; the randomized controlled trial found that both types of massage worked well, with few side effects.</p> <p>Citations: Cherkin, Sherman et al. 2009; Cherkin, Sherman et al. 2011</p>
Consortium to Study Opioid Risks and Trends, PI: Michael Von Korff	9,940, data review from 1997-2005	<p>The first study to explore the risk of overdose in patients prescribed opioids for chronic non-cancer pain in general health care; linked risk of fatal and nonfatal opioid overdose to prescription use—strongly associating the risk with the prescribed dose. The findings helped guide Group Health in implementing a major new opioid prescribing safety initiative.</p> <p>Citations: Dunn, Saunders et al. 2010; Trescott, Beck et al. 2011</p>

Title and PI	Study population	Description and available citations
Transforming Primary Care: Evaluating the Spread of Group Health's Medical Home, PI: Robert J. Reid	7,018 followed for two years	<p>An evaluation of the effects of the patient-centered medical home model of primary care on patients' experiences, quality, burnout of clinicians, and total costs; results showed improvements in patients' experiences, quality, and clinician burnout—with and estimated total savings of \$10.3 per patient per month.</p> <p>Citations: Reid, Fishman et al. 2009; Reid, Coleman et al. 2010</p>
A Randomized Trial of Liaison Psychiatry in Primary Care (PATHWAYS, 3 <sup>rd</sup> renewal; TEAMcare, 4 <sup>th</sup> renewal), PI: Wayne J. Katon and Michael Von Korff	<p>PATHWAYS: 3,922 followed for five years</p> <p>TEAMcare: 214 followed for one year</p>	<p>PATHWAYS: An epidemiological follow-up study tracking primary-care patients with diabetes; over five years patients with diabetes and depression had a higher risk of developing advanced microvascular and macrovascular complications.</p> <p>TEAMcare: A primary care intervention, in which nurses worked with patients and health teams to manage care for depression and physical disease together, using evidence-based guidelines; results showed patients had less depression, better control of blood sugar, blood pressure and cholesterol, and improved quality of life.</p> <p>Citations: Katon, Lin et al. 2010; Lin, Rutter et al. 2010</p>
Population-Based Management of Depression, PI: Gregory E. Simon	600 followed for two years	<p>The largest randomized controlled trial to date (at that time) to study structured, phone-based cognitive behavioral psychotherapy for depression; results showed significant benefits persisted over two years, with only modest rises in cost.</p> <p>Citations: Simon, Ludman et al. 2004; Ludman, Simon et al. 2007; Simon, Ludman et al. 2009</p>

Title and PI	Study population	Description and available citations
Electronic Communications and Home BP Monitoring (e-BP), PI: Beverly B. Green	778 followed for one year	<p>The first large randomized controlled trial to use Web-based care and a patient-shared electronic medical record to improve treatment outcomes of a chronic disease; Web-based care nearly doubled the percentage of people whose blood pressure was controlled after one year.</p> <p>Citations: Green, Cook et al. 2008; Green, Ralston et al. 2008</p>
Influenza vaccination and risk of community-acquired pneumonia in immunocompetent elderly people, PI: Lisa A. Jackson	3,500 followed for 3 flu seasons	<p>The largest case-control study of flu vaccine in the elderly; no link was found between flu vaccination and risk of pneumonia during three flu seasons.</p> <p>Citation: Jackson, Nelson et al. 2008</p>
Evaluation of Value-Based Health Plan Design, PI: David Grossman	9,000, to be followed for 3 years (funded 8/1/2010)	<p>This study is currently examining whether an innovative value-based health insurance plan can improve health and productivity among employees of a large healthcare organization; results will provide evidence about the potential impact of value-based insurance designs on costs, quality, and health outcomes.</p>
Program for Readability In Science & Medicine (PRISM), PI: Jessica Ridpath	founded in 2005	<p>PRISM is a research-centric plain language program focused on improving the readability of study consent forms and other print materials for research participants. The program provides plain language training, editing, and consultation to researchers and other health care professionals nationwide.</p> <p>Public-domain tools and training:  PRISM Readability Toolkit, <a href="http://www.tinyurl.com/prismtoolkit">http://www.tinyurl.com/prismtoolkit</a>  PRISM Online Training, <a href="http://prism.grouphealthresearch.org">http://prism.grouphealthresearch.org</a></p> <p>Citation: Ridpath, Wiese et al. 2009</p>

## Geisinger Health System

Includes Geisinger Clinic, Geisinger Health Plan, Geisinger Medical Center, and Geisinger Northeast

### Website

[www.geisinger.org/research](http://www.geisinger.org/research)

### Population served

GHS serves over 2.6 million people in 43 counties in Pennsylvania, including rural and underserved populations. The Geisinger Health Plan covers approximately 30% of Geisinger's patients.

### Research center(s) and services

The formal research units in the health system are organized within the Geisinger Clinic and include the Center for Health Research (CHR), the Center for Clinical Studies (CCS), and The Sigfried and Janet Weis Center for Research (WCR). The CHR's focus areas include: The Science of Health Care Delivery; Comparative Effectiveness Research (CER); Epidemiology; Genetic Epidemiology, Genomics and Biomarker Research; Clinical and Molecular Diagnostics; Behavior Health and Community and Environmental Health. CHR manages research service units including: a Survey Research Unit that offers computer-assisted telephone interviewing (CATI), a Research IT Management Environment designed to simplify the development and testing of web applications for use in clinical care, a Rapid Biomarker Testing Process in collaboration with the Geisinger Medical Laboratory, a Biostatistics and Research Data Core, and, in collaboration with Johns Hopkins, an Environmental Health Institute. The CCS promotes and supports clinical trials (medications and devices) throughout the Geisinger system. The WCR provides a focus for laboratory-based translation research, investigating molecular, cellular and genomic

mechanism, with an emphasis on diseases related to obesity, cancer, neuroscience, and cardiovascular biology.

### Affiliated health care and insurance provider(s)

Geisinger Health System encompasses the GHP, the Geisinger Clinic, hospitals, and a diversity of other services. These different entities within the health system largely function as independent business units.

Geisinger Health System (GHS) is a vertically integrated system. One of the largest employers in Pennsylvania, GHS has over 12,000 employees, including 700 physicians with more than 75 specialties, 2,400 registered and licensed practical nurses, and more than 43 non-physician scientists.

The Geisinger Health Plan is an award winning plan that is a separate operating unit with the Geisinger Health System. GHS has a national reputation for quality of health service delivery and has repeatedly been named one of the Best Hospitals in America.

### Example partnerships

- ❖ Johns Hopkins University: collaborations in epidemiology, health services, and environmental health
- ❖ University of Pennsylvania collaborative studies
- ❖ University of Maryland - Mid-Atlantic Nutrition and Obesity Research Center
- ❖ Pharmacogenomics Research Network
- ❖ Translational Genomics Institute, Phoenix, AZ

## Example studies

Title and PI	Study population	Description and available citations
<b>Heart and vascular, lung or blood disease</b>		
Genetic Basis of Abdominal Aortic Aneurysms, PI: David Carey, PhD	An existing research cohort of aneurysm cases with biobanked blood, serum, and DNA samples for research, plus population controls, and ability to recruit families for pedigree-based genetic studies: 1,000 AAA cases; 200 probands with reported family history; >1,200 population controls	The primary goal is to carry out genome wide association studies and next generation DNA sequence analysis to identify genetic variants associated with genetic risk of AAA.
Predicting Diagnosis of Heart Failure in Primary Care, PI: Walter “Buzz” Stewart, PhD	More than 6,000 primary care incident heart failure cases and 30,000 group matched controls	<p>We are using machine learning and natural language processing tools applied to primary care electronic medical record data to predict diagnosis of heart failure. Success in developing such a tool may open opportunities to develop diagnostics in the future based on predictive model algorithms.</p> <p>We compared logistic regression, support vector machine (SVM), and boosting methods. Logistic regression and boosting performed similarly with AUCs of 0.77 and 0.75 respectively. SVM did not perform as well. Only 10 to 15 variables were used in models. While these results were very promising, we used relatively few features of the available data, did not use all available data (e.g., not simply the last measure but repeated measures), and did not include text field data. Moreover, we did not explore whether different combinations of variables and related features are relevant to defined patient subgroups or at different times before HF diagnosis.</p> <p>Citations: Wu, Roy et al. 2010</p>

Title and PI	Study population	Description and available citations
<p>Diagnostic Biomarkers for CHF, PI: Walter “Buzz” Stewart, PhD</p>		<p>Leverages Geisinger Medical Laboratory System infrastructure to store serum that is left over from clinical care. Used a predictive model to identify primary care patients who were at risk of a future heart failure diagnosis. A tracking file was created on 13000 patients (high, moderate, and low risk patients). Among the 6000 to 8000 blood samples that come to the Geisinger Medical Lab each day, approximately 200 to 300 matches were identified each day with the tracking file. Each day, serum was extracted from matching blood samples once the lab no longer needed the sample. Over a two year period, 220 newly diagnosed heart failure cases were identified. We examined three biomarkers as potential predictors of future diagnosis. Two of the three biomarkers predicted future diagnosis.</p>

Title and PI	Study population	Description and available citations
eCVD-II, Walter “Buzz” Stewart, PhD and JB Jones	>2,000 patients screened for CVD risk; 128 patients in the intervention group used the SDM tool	<p>Shared decision-making (SDM) rarely happens in routine primary care due to time constraints and other challenges. In this project, the HIT-based SDM decision aid and the associated process were designed for and integrated into the workflow of a primary care clinic. In addition, the SDM tool was integrated with the clinic's electronic medical record.</p> <p>The eCVD-II study used an integrated IT-based care model to detect cardiovascular disease (CVD) risk and facilitate shared decision making for its management at the primary care level. The study included the automated data capture of behavioral risk factors, an on-line quantitative risk assessment and calculation, CVD risk communication, a patient preference-based care plan, and tailored real-time clinical decision support. Participants were men aged 45-75, women aged 55-75, and adults over 18 with coronary artery disease. The randomized controlled pilot study was conducted in the family practice departments at Scenery Park and Grays Woods clinics. All eligible patients completed an on-line questionnaire to determine risk of heart attack in the next 10 years. Patients with moderate-high CVD risk and modifiable risk factors were randomized into one of two groups. The intervention group (N=100) had the opportunity to select their preferences for managing their risk and their providers received clinical decision support that was tailored to the individual patient. The control group (N=100) was not managed for CVD risk by the study. Analysis evaluated if the study tools facilitated improved detection of CVD risk factors, increased delivery of guideline-based care for the management of CVD risk, facilitated shared decision making, improved short-term outcomes in CVD behavioral measures, and improved patient activation and adherence.</p> <p>Citations: Jones, Bruce et al. 2011; Jones, Shah et al. 2011</p>

Title and PI	Study population	Description and available citations
<b>Arthritis, musculoskeletal, skin diseases</b>		
Rheum Pacer, PI: Walter “Buzz” Stewart, PhD and Eric Newman, MD	Clinical Redesign: more than 1000 patients participated	Rheum-PACER is a technology-based approach to collecting, aggregating, exchanging, and displaying data about patients with rheumatologic disorders and delivering that information to their healthcare providers (rheumatologists, nurses) and their EMR. By measuring the results of this new methodology, Geisinger researchers will be able to determine if the methodology can be expanded effectively to other clinical areas.
eLow Back Pain, PI: Walter “Buzz” Stewart, PhD and JB Jones		A pre-post randomized controlled study that builds and improves upon the functionality of current and past e-Projects and introduces new features in the clinical decision support tool. Objective: to determine if a systematic, patient centered, guideline-based approach to primary care management of low back pain care improves appropriate use of care, patient outcomes and satisfaction with the care received. The study will take place in the Family Practice department at Lycoming clinic. Patients > 18 where back pain is one of their reasons for seeing their provider, will be randomized into two groups. Patients enrolled in Phase I will receive a portion of the Primary Care Low Back Pain Management System (PC-LBPMS). In Phase II, patients enrolled and randomized in the intervention group (N=150) will receive the full protocol including: 1) an automated web-based questionnaire, 2) a clinical decision support tool displaying patient reported and EMR data, a recommended physical exam and a recommended care plan with the ability to generate and import orders and a progress note into the patient’s EMR, 3) an after-visit summary that provides a tailored care plan and information to patients regarding their low back pain, and 4) follow-up interviews to assess patient satisfaction with the care received and pain and functioning over time. Patients in the control group (N=150) will receive an abridged questionnaire and the follow-up interviews to assess patient satisfaction with the care received and pain and functioning over time. Analyses will determine how often expert advice was offered and used and evaluate if the PC-LBPMS improved low back pain care, treatment rates, and impact on satisfaction, functioning and quality of life.

Title and PI	Study population	Description and available citations
<b>Diabetes, digestive, kidney diseases</b>		
Predicting the Progression of CKD, PI: Walter "Buzz" Stewart, PhD	167,327 from 2004-2009	<p>Relatively little is known about the clinical characteristics of identifying patients who are at risk for progressive loss of kidney function that could be directly translated into useful protocols for clinical practice. A predictive model, that will leverage EMR data, has not been previously applied to predicting CKD progression.</p> <p>The goal of this retrospective cohort study was to develop a model for stage 3a and 3b+ not-on-dialysis (NOD) CKD patients and determine factors associated with progression to later stage NOD CKD, and renal replacement therapy (RRT) (dialysis or transplantation). The specific objectives focused on 1) describing the natural history of CKD and related transition rates among CKD stage 3a and 3b, stage 4 or worse, specifically describing the rate of change in eGFR by stage of CKD and assessing the factors associated with the risk of transitions among the CKD stages, and 2) completing a comparative predictive validity analysis of the models developed under this proposal to models previously developed in other studies by Johnson et al (Johnson 2008), Keane et al (Keane 2006), and Bash (Bash 2010).</p>

Title and PI	Study population	Description and available citations
<p>Patterns of Care for Anemia of CKD in the Geisinger Clinic Population, PI: Robert M. Perkins, MD, FACP</p>	<p>34,403</p>	<p>Currently, more than 20 million individuals in the United States may have chronic kidney disease (CKD), and it is expected that greater than 700,000 individuals will reach end-stage renal disease (ESRD) and require renal replacement therapy by 2015, an increase of nearly 40% from current levels. Morbidity, mortality, and health-care expenditures all increase with progressive loss of kidney function. Patients with advanced CKD have a four- to five-fold increased risk of death over a matched patient without CKD; have a high likelihood of having heart disease; and consume health care dollars at a rate which may be four to five times greater than that of patients without CKD. There is growing recognition that these trends are unsustainable, from both a medical, economic, and public-health standpoint. This study is a series of phased projects to answer a set of related but unique questions within the anemic CKD population regarding transfusion requirements (and other resource utilization), time to transplant, iron and ESA utilization, and key cardiovascular and renal outcomes. Addressing questions regarding anemia in the CKD is challenging, because typically a large cohort must be followed with intensive measurements for many years. We believe that longitudinal data from electronic medical records can be used to describe resource utilization and outcomes of interest across the range of clinically important levels of anemia (e.g. Hgb &lt;10 g/dl, 10-12 g/dl, &gt;12 g/dl). Based on prior experience with other chronic diseases (e.g. diabetes, CVD and asthma) we can quantify the economic impact associated with different degrees of anemia in patients with CKD in the Geisinger Clinic.</p>

Title and PI	Study population	Description and available citations
eDiabetes, PI: Walter "Buzz" Stewart, PhD	100 intervention / 100 control (currently enrolling)	<p>Similar to eCVD-II, the eDiabetes system is a software-based system designed to screen primary care patients with Type II diabetes for risk of diabetes disease progression based on data from their electronic medical record and patient-reported questionnaire data. Participants are individuals 18 years of age and older who have been diagnosed with Type II diabetes, and the pilot study will take place in the family practice department and internal medicine departments at Selinsgrove clinic. Once eligible patients are identified, they complete an online questionnaire to determine their 10-year risk of macrovascular event (i.e., heart attack or stroke), while a background process determines if their most recent HbA1c value is out of control. Patients with moderate to high macrovascular risk or elevated HbA1c levels are then randomized into two groups. As in eCVD-II, the intervention group has the opportunity to select their preferences for managing their specific elevated risk factors. The providers of these patients receive clinical-decision support tailored to the patient's specific risk factors. Patients randomized to the control group do not receive any type of management from the eDiabetes system. Analyses will evaluate if the study tools increased detection of patients with uncontrolled diabetes, increased delivery of guideline-based care for the management of Type II diabetes, facilitated shared decision making, improved short-term outcomes in Type II diabetes clinical measures, and improved patient satisfaction and adherence.</p>
<b>Clinical quality improvement</b>		

Title and PI	Study population	Description and available citations
Diabetes Bundle, PI: Walter “Buzz “Stewart, PhD	10,092 followed for 2 years	<p>This is the first examination of how Geisinger's diabetes program impacted health outcomes of stroke, MI, retinopathy, and amputation.</p> <p>Diabetes Mellitus (DM) is a common condition associated with increased risk of microvascular and macrovascular complications. This study was conducted in order to determine if a system of care for DM using an all-or-none bundle of measures improved microvascular and macrovascular complications compared to usual care. In 2006, a diabetes system of care using a 9 component all-or-none bundle of measures was implemented for some members of the Geisinger Health Plan. A cohort of 4579 patients using the diabetes bundle system of care is compared with the patients not in the system of care in a case control study. Measurements include cumulative hazard rate at 2 years for microvascular events of retinopathy and amputation and macrovascular events of stroke and myocardial infarction(MI). Results: 4579 patients cared for with this system of care were compared to patients not under this system of care after 2 years. The adjusted hazard ratios for MI, stroke, retinopathy and amputation were all significantly lower in the patients cared for with bundled care. The hazard ratio (95% CI) for MI was 0.78 (0.68-0.90), for stroke was 0.74 (0.63-0.88), for retinopathy was 0.82 (0.70-0.95) and for amputation was 0.69 (0.41-0.92). The number of patients needed to treat (NNT) to prevent one event over 2 years was 33 for MI, 50 for stroke, 59 for retinopathy and 1000 for amputation. Limitations: Population is limited to those enrolled in a health plan (GHP) in rural Pennsylvania. Conclusions: Geisinger Health Plan patients with DM cared for under a system of care that includes an all-or-none bundle of measures had a reduction in cumulative hazard rate for microvascular outcomes of retinopathy and amputation and macrovascular outcomes of stroke and MI in the first 2 years after implementation.</p> <p>Citation: Weber, Bloom et al. 2008</p>

Title and PI	Study population	Description and available citations
<p>Understanding Heterogeneity in Medical Home Implementation: Lessons for Spread, PI: Jove Graham</p>		<p>This project will provide unique insight into both quantitative and qualitative aspects of implementing a novel patient-centered medical home model across diverse clinic settings, something no other medical home demonstration or pilot project is currently positioned to do.</p> <p>The Patient Centered Medical Home (PCMH) model involves enhancing the role of primary care practices as the central location for integration and coordination of care, an approach that evidence suggests is successful in improving quality, efficiency and cost outcomes for patients. Geisinger Health System has implemented its version of the PCMH, known as ProvenHealth Navigator, since 2006 and reports of the promising outcomes from that model have made a significant contribution to the current PCMH literature. Many payers, policy makers, health system leaders and other physician leaders are interested in adapting their own versions of the PCMH model, but seek a better understanding of which components or features of PCMH are most important (i.e., most highly associated with improvements in outcomes). This understanding would guide not only decision-making around which features need to be maintained or strengthened in existing models, but also reveal which features are most important to standardize and emphasize when training new personnel or translating PCMH models to new environments. Geisinger is extremely well-positioned to advance this understanding because of its multi-year experience with designing, implementing and analyzing a working PCMH model in practice.</p>

Title and PI	Study population	Description and available citations
<b>Environmental health and exposures</b>		
<p>Population-based Evaluation of Primary Care Patients with MRSA in Relation to Animal Feeding Operations in Pennsylvania, PI: Brian Schwartz, MD, MS</p>		<p>The past decade has witnessed an alarming expansion in the burden of staphylococcal disease; particularly disease caused by methicillin-resistant Staphylococcus aureus (MRSA) strains. The emergence of community-associated MRSA (CA-MRSA) strains accounts for much of this increase. CA-MRSA and hospital-associated MRSA (HA-MRSA) cases differ demographically and clinically, and their respective isolates are evolutionarily distinct. In particular, the USA300 CA-MRSA clone has become a primary cause of community associated disease, and an increasingly important source of health care-associated infection.</p> <p>The primary objective of this study is to determine whether proximity to AFOs is a risk factor for MRSA infection in the GHS primary care patient population.</p> <p>It is the only study of MRSA to date that leverages a large EMR to do case ascertainment using multiple methods (i.e., MRSA ICD-9, Staph ICD-9 + V09 resistance code, MRSA culture, Staph culture + oxacillin resistance, Staph ICD-9 + oxacillin resistance) to fully characterize community and health care epidemics over the past 10 years.</p> <p>It is also the only study of MRSA to date to do population-based assessment of community MRSA in relation to animal feeding operations, by geocoding patients and linking to detailed farm data using sophisticated geo-processing and spatial statistics.</p>

Title and PI	Study population	Description and available citations
eMigraine, PI: Walter "Buzz" Stewart, PhD	191 consented as of July 2011	<p>This project uses sophisticated touchscreen questionnaires to screen primary care patients for migraine; patients with migraine can receive specialty-level care from their primary care provider via the highly-tailored decision support built into the eMigraine application.</p> <p>The eMigraine study is a pre-post randomized controlled pilot study to determine if a systematic guideline-based approach to migraine detection and management can improve processes and outcomes and address the gap between what is known in this area and what is practiced at the primary care level. The study is being conducted in the family practice department at Mt. Pocono clinic. Participants are adults aged 18-45 and are randomized into two groups. Patients in the intervention group (N=400) receive the full protocol of the Primary Care Headache Management System (PCHMS), a set of tools which includes a web-based questionnaire used to screen patients who warrant clinical attention and to look for gaps in care, provider clinical decision support that is tailored to individual patients, and an after-visit summary that provides tailored treatment and management information to patients regarding their headaches. Patients in the control group (N=100) receive an abridged questionnaire and an after-visit summary that provides general guidelines on how to reduce headaches. Analyses will determine how often expert advice was offered and used and evaluate if the PCHMS improved migraine detection, treatment rates, and migraine impact on quality of life.</p>

Title and PI	Study population	Description and available citations
<b>Genetics, genomics, biorepositories</b>		
Geisinger MyCode Project, PI: Walter “Buzz” Stewart, PhD, Glenn Gerhard, and David Carey	20,000	<p>Creates a population-based repository of blood, serum and DNA samples linkable to electronic medical record data for broad genomics research</p> <p>The major goal is to enroll adult primary care patients of Geisinger Clinic into a longitudinal research study; enrolled patients provide blood samples for broad research use and authorization to link samples to data in the Geisinger electronic medical record system for research use. To date, MyCode samples have been used for genetic/genomic research in the following areas: pharmacogenomics of Plavix; impact of MC4R mutations on weight loss; FTO gene and breast cancer risk; genetic susceptibility for obstructive sleep apnea; genetic risk factors for preeclampsia; genetics of lymphedema; genomics of epilepsy. Many of these are pilot studies, some of which have led to external funding (e.g. the FTO/breast cancer study, which is funded by the Cancer Research Network of the HMORN) or NIH grant applications (e.g. the MC4R/obesity study).</p>
eMERGE Network – Phase II, PI: David Ledbetter, PhD and David Carey, PhD	>3,000 (with potential for up to 35,000)	<p>Leverages Geisinger’s large existing biorepositories that are linkable to electronic medical record data</p> <p>The goals are to: 1) use existing biospecimens and EMR-generated phenotypes to identify genetic variants associated with disease risk or treatment response; 2) develop and test approaches to incorporate genomic data into clinical care; and 3) identify sociocultural concerns of patients in rural areas regarding genomic research and return of genomic results.</p>

Title and PI	Study population	Description and available citations
Myoproliferative Neoplasms – JAK2 Prevalence Study, PI: David Carey, PhD and Glenn Gerhard, MD	6,000	<p>Utilizes existing, large, population-based DNA biorepository from geographically-dispersed Geisinger patients</p> <p>The goals are to: 1) determine the population prevalence of a somatic mutation in the JAK2 gene that is associated with the myoproliferative neoplasm polycythemia vera; 2) correlate the somatic mutation burden with clinical phenotypes; 3) determine the association of the somatic mutation with a germ-line susceptibility haplotype; and 4) compare somatic mutation burden among distinct geographic regions in the Geisinger service area.</p>
<b>Obesity, active living/exercise and healthy eating</b>		
Genetic Determinants of Weight Loss and Resolution of co-Morbidities, PI: Glenn Gerhard, MD	3,500 with 3+ years F/U on >80% of patients	<p>Utilizes large research cohort of gastric by-pass patients at Geisinger, with biobanked blood, serum, DNA, and tissue for research and long-term clinical follow-up</p> <p>The goal is to use a large single-center cohort of gastric bypass patients with extensive long-term clinical data and biospecimens to identify genetic variants associated with post-surgery weight loss and resolution of co-morbid conditions</p>
Physical Activity and the Built and Social Environment, PI: Walter Stewart, PhD, MPH and Brian Schwartz, MD., M.S.	65,000	<p>Links health outcomes to a combination of biomarkers and to features of the built and social environment</p> <p>This study involves the analysis of longitudinal EMR data on BMI from primary care patients between 5 and 18 years of age. Approximately 65,000 patients are in the cohort and reside in the 31 county catchment area in central and northeastern Pennsylvania. Patient addresses have been geocoded. Analysis have been completed on BMI trajectories and features of the built and social environment including measures of available food quality and physical activity resources. A nested study is underway to more accurately characterize environments of a sample of patients and to obtain buccal swabs.</p>

Title and PI	Study population	Description and available citations
<p>Developing the Paradigm for the Science of Healthcare Delivery, PI: J.B. Jones, PhD, MBA</p>	<p>18 semi-structured interviews; 3 focus groups</p>	<p>This project applies an innovation framework derived in a non-healthcare setting in order to determine whether it can help identify opportunities for innovation in healthcare service delivery.</p> <p>Leading companies outside of health care delivery are increasingly using scientific methods to identify opportunities for product or service innovation, as well as to design, develop, and implement innovations that have a high likelihood of market success. This proposal applies an existing (i.e., developed in non-health care setting) outcomes-oriented framework to identifying opportunities for innovation in health care delivery. In this proposal, “outcomes” refer to the metrics by which patients and/or providers evaluate their ability to satisfactorily achieve a specific “job” or “task” associated with cardiovascular (CVD) care. With respect to this framework, our proposal has two major foci: 1) developing a strategy for adapting and applying the outcomes-focused framework to health care settings; 2) conducting focus groups with patients and providers to elicit their detailed views on the “tasks” associated with CVD care and the metrics by which they define success in completing the task. The long term goal of this initiative is to create a signature “science of health care delivery” program that could serve as a cornerstone for training, a trademark for a new approach to discovery and translation, and serve to foster inter-institutional interactions among researchers, practitioners, and executives.</p>

# Henry Ford Health System

## Website

[www.henryford.com/body.cfm?id=45206](http://www.henryford.com/body.cfm?id=45206)

## Population served

Annually, care provided by Henry Ford includes over 3.1 million patient visits, 78,000 ambulatory surgeries and 93,000 hospital admissions. More than 1 million southeast Michigan residents receive health services from Henry Ford, and annually, care provided by HFHS includes over 3.1 million patient contacts. Approximately 35% of the HFHS patient population is African American, creating special opportunities for research and quality improvement in the area of health care disparities.

## Research center(s) and services

The Department of Public Health Sciences conducts independent research and supports research of investigators within the institution. This department has over 100 full-time staff including epidemiologists, biostatisticians, computer programmers, data managers, project managers, medical record analysts and survey researchers. Research is also conducted within clinical departments and within specialized centers. The specialized centers include the Center for Health Services Research, the Center for Health Policy and Health Services Research, the Center for Health Promotion and Disease Prevention, the Health Disparities Research Collaborative, the Institute on Multicultural Health, the Center for Allergy, Asthma and Immunology Research, and the Center for Cancer Epidemiology Prevention and Control. Research services include an interviewing facility, research laboratory, and biorepository facility.

## Affiliated health care and insurance provider(s)

The Henry Ford Health System (HFHS), one of the nation's leading vertically integrated health care systems, is a Michigan non-profit corporation organized in four regions encompassing Metropolitan Detroit, with the goal of offering primary care, acute care, and specialty services within each area. The regions include the Detroit Urban Region, the Suburban Wayne Region, the Oakland Region, and the Macomb-Eastern Region.

## Example partnerships

- ❖ The Detroit SEER program investigators are frequent collaborators for research projects of joint interest.
- ❖ Wayne State University (WSU) and HFHS have a long history of research collaboration. A mechanism has been established to fund joint pilot projects using pooled funds from WSU and HFHS to encourage collaboration and external funding.
- ❖ Sarcoidosis Genetic Analysis Consortium (SAGA)
- ❖ Men of African Descent and Prostate Cancer (MADCaP)

### Example studies

Title and PI	Study population	Description and available citations
Prostate, Lung, Colorectal and Ovarian cancer Screening Trial (PLCO), PI: Paul Kvale	154,000 followed 14 years	<p>Very large population followed for &gt; 10 years with extensive clinical and biological data. Intervention trial of cancer screening conducted at 10 sites assessing impact of screening on cancer mortality.</p> <p>Citations: Ford, Havstad et al. 2008; Pinsky, Ford et al. 2008; Croswell, Kramer et al. 2009; Gren, Broski et al. 2009; Henson, Mouchlianitis et al. 2009; Nyante, Black et al. 2011</p>
Chronic Hepatitis B and C cohort Study (CHeCS), PI: Stuart Gordon	<p>Phase 1: 13,000 patients with evidence of hepatitis between 2006 – 2008, followed to present</p> <p>Phase 2: 2,000 to 5,000 additional patients with hepatitis between 2009 and 2010</p>	<p>This large retrospective cohort uses VDW administrative data, medical chart review and participant survey to assess the longitudinal impact of hepatitis B and C on quality of life, healthcare utilization and mortality. Detailed treatment and response data allow for assessment of the effectiveness of drugs in a real-world setting. Henry Ford Health System, Kaiser Permanente Northwest, Kaiser Permanente Hawaii and Geisinger are the practice sites for study funded by the CDC Foundation.</p>
Gene and Environment Interaction in Prostate Cancer (GECAP) Study, PI: B. Rybicki	637 African American and white prostate cancer cases and 244 age, race frequency matched controls ascertained between 2001 and 2004	<p>The objective of the GECAP study was to test whether combinations of selected gene-environment combinations increased prostate cancer risk. Using a sampling scheme that was weighted heavily toward cases, we collected extensive occupational, dietary and other risk factor data and genotyped a wide array of SNPs in prostate cancer candidate genes. A biomarker sub-study of 400 cases also examined the determinants of DNA adducts in prostate cancer tissues.</p> <p>Citations: Rybicki, Rundle et al. 2004; Rybicki, Neslund-Dudas et al. 2006; Tang, Liu et al. 2007</p>

Title and PI	Study population	Description and available citations
Prostate Cancer Study Of Methylation and DNA Adducts (PROMA), PI: B Rybicki	573 African American and white prostate cancer cases and matched controls nested in a cohort of 6,692 men with a benign prostate tissue sample from 1990-2002	The objective of the PROMA study was to determine whether pre-malignant biomarkers, i.e., DNA methylation and DNA adducts, measured in the benign prostate tissue samples of 573 African American and white prostate cancer matched case-control pairs increased risk of subsequent prostate cancer. Extensive pathologic characterizations of benign prostate tissue samples and a detailed medical record review were also conducted.
Ancestry Mapping of Sarcoidosis Susceptibility Genes (AMASS), PI: B Rybicki	A sample of 1,357 African-American sarcoidosis cases and 703 unaffected controls with clinical and epidemiologic data and DNA samples	<p>The objective of the AMASS study was to map sarcoidosis susceptibility genes using previously derived collections of African-American sarcoidosis cases controls from three separate studies. The ACCESS case-control study (272 cases and 286 controls) was a matched case-control design conducted across clinical 10 centers. Two family-based studies contributed an additional 1,085 cases, and 417 controls. SAGA was a 12-center affected sib pair linkage study. The remainder of family samples was derived from a Henry Ford-based study of sarcoidosis nuclear families.</p> <p>Citations: ACCESS Research Group 1999 ; Iannuzzi, Malinarik et al. 2003; Rybicki, Hirst et al. 2005; Rybicki, Levin et al. 2011</p>
Race, Treatment and Cardiovascular Health: A Study of Men with Prostate Cancer, PI: Andrea E. Cassidy-Bushrow	2,000 men followed 5 years	Focus is to examine the race-specific relationship of prostate cancer treatment, in particular, androgen deprivation therapy, on cardiovascular risk factors and events in a single health system
Racial disparities in childhood health: role of chronic stress and inflammation, PI: Andrea E. Cassidy-Bushrow	300 children 14-17 years (cross-sectional)	The goal of this project is to examine if psychosocial stress and chronic inflammation are associated with cardiovascular risk factors (blood pressure, body size and renal function) in adolescent children (ages 14-17 years) from the Detroit, MI area. The role of race in mediating these associations will be explored.

Title and PI	Study population	Description and available citations
Predictors of Adjuvant Endocrine Therapy Adherence in Women with Breast Cancer, PI: Sharon Hensley Alford	Recruitment Target: 765 Total (380 Total at Henry Ford)	Breast Cancer is the leading cancer diagnosed in women and the second highest cause of cancer death. Hormonal therapy is recommended for women with hormone receptor (HR) tumors. Despite its proven benefit, only 50% of women complete the full 5 year course of hormonal treatment. This study will explore clinical, psychosocial and healthcare delivery factors that predict adherence. Racial and ethnic differences in adherence to hormonal therapy will also be examined. Study findings will be useful in identifying women most at risk for stopping treatment and to develop interventions to help women remain on therapy.
Statins & Lymphoid Malignancy Risk in a Large Multi-Site Population Based Cohort, PI: Christine Cole Johnson; Co-PI Marianne Ulcickas Yood	HMO populations 40+ years from six CRN sites	Nested case-control study within a retrospective cohort of plan members age 40+ years from 1998-2007. Cases are in incident cases of all lymphoma types (n ~ 18,000). Hypothesize that use of statins decreases risk and that this effect will be stronger among those with selected auto-immune diseases.
Childhood Allergy Study, PI: Christine Cole Johnson	Birth cohort (n=835) born in 1987-1989, still being followed	Study of home environment factors that contribute to risk of allergy and asthma, biorepository of parental and cohort bloods.
Wayne County Health, Environment, Allergy & Asthma Longitudinal Study (WHEALS), PI: Christine Cole Johnson	Birth cohort (n=1258) born in 2003-2007, still being followed, 60% African American	Study of environmental and genetic factors that contribute to immune development. Biorepository of parental, cord, and infant bloods, breast milk and infant stool samples & dust samples from homes.

Title and PI	Study population	Description and available citations
<p>Making Effective Nutrition Choices: the MENU Study (MENU U19-CA079689) PI: Christine Cole Johnson</p>	<p>2,500 adults followed for 12 months</p>	<p>MENU is a cancer prevention, health promotion study comprised of a 5-site, three-arm randomized intervention to test the effectiveness of an online tailored intervention with the tailored intervention with email counseling support based on Motivational Interviewing compared to the online intervention without tailoring. This study recruited from a diverse, population based group of individuals in Seattle, Denver, Minneapolis, Atlanta and Detroit with the goal of improving fruit and vegetable intake.</p> <p>Citations: Rolnick, Calvi et al. 2009; Stopponi, Alexander et al. 2009; Alexander, McClure et al. 2010; Couper, Alexander et al. 2010</p>
<p>Encouraging Young Adults to Make Effective Nutrition Choices: MENU GenY (R01) PI: Gwen Alexander</p>	<p>1,624 generally healthy young adults, followed 12 months</p>	<p>A 2-site, three-arm randomized trial to evaluate an age-targeted web-based intervention designed to improve the diet, specifically improve intake of fruits and vegetables, of young adults (ages 21-30), as they navigate a new life stage of greater independence. Theory from social marketing guides our aim to refine e-strategies for engaging young adults, and compare This study builds on a previously successful, randomized web-based intervention of CRN collaboration of 5 sites (MENU U19-CA079689) which relied solely on e-media (Internet and email) for enrollment, presenting the intervention, and collecting follow-up data. This real-world study will recruit subjects from two distinct geographic areas, HFHS (Detroit urban area) and Geisinger (rural Pennsylvania).</p>
<p>Inflammation Pathways and COPD in the Development of Lung Cancer, PI: Ann Schwartz, PhD Karmanos Cancer Institute, HFHS Site PI: Ben Rybicki, PhD Christine Neslund-Dudas, PhD</p>	<p>1,950 Lung Cancer Cases 1,950 Smokers without lung cancer 600 Smokers with COPD</p>	<p>Develop a genetic profile based on single nucleotide polymorphisms (SNPs) and copy number variation (CNV) in inflammatory pathway genes that predicts susceptibility to lung cancer in response to tobacco exposure. Develop inflammatory pathway gene expression profiles in lung tumor tissue from patients with and without COPD and evaluate the association between these gene expression signatures in relation to the genetic profiles.</p>

Title and PI	Study population	Description and available citations
Southeast Michigan Partners Against Cancer (SEMPAC), PIs: Terence Albrecht, Karmanos Cancer Institute, Robert Chapman, MD, Henry Ford	Older, underserved African Americans throughout Southeast Michigan	SEMPAC will create regional partnerships that will build awareness and educate residents about cancer treatment options; provide tools to help elderly African Americans in Southeast Michigan make better health care decisions related to cancer care; and increase the understanding of the importance of biospecimens to advance research. Previous studies leading up to SEMPAC have shown improvements in other health outcomes unrelated to cancer when these types of services are provided for cancer.
The Multiplex Initiative, PI: Sharon Hensley Alford	Population: 25 – 40 years of age during 2004 - 2005	Advances in technology have made individual access to personal genetic information foreseeable in the near future. Policy makers and the media forecast that the ready availability of personal genetic profiles will benefit the individual and the health care system by improving outcomes and decreasing cost. However, a significant gap lies between having access to genetic data and either wanting or understanding the information it provides. To address questions related to personalized genetic risk profiles, we began the Multiplex Initiative; a collaborative study between the National Human Genome Research Institute, Henry Ford Health System, and Group Health. Healthy, insured individuals, 25-40 years of age, were recruited from a large, integrated health system where primary and specialty care is available. Study participants were offered personalized genetic risk information on eight common chronic health conditions. Social groups historically known not to participate in genetic research (men, African Americans, those from lower education neighborhoods) were over sampled.

## HealthPartners Research Foundation | HealthPartners

### Website

[www.hprf.org/](http://www.hprf.org/)

### Population served

HealthPartners is the largest consumer governed non-profit health care organization in the country, serving more than 1,000,000 medical and dental members in the Minneapolis-Saint Paul area

### Research center(s) and services

HealthPartners Research Foundation (HPRF) is a 501c(3) non-profit foundation, dedicated to conducting high quality, public domain health research, often in collaboration with other academic and research organizations throughout the world. HPRF includes two centers of research focus, the Alzheimer's Research Center and the Critical Care Research Center. A third, Center for Chronic Care Innovation, will debut in fall 2011.

HPRF features a Data Collection Center on the premises, dedicated to gathering high quality, high response rate data from mail or telephone surveys, in-person interviews, and chart abstraction. HPRF has a clinical trials unit including a research clinic as well as extensive experience with other types of clinical studies.

### Affiliated health care and insurance provider(s)

Founded in 1957, HealthPartners is an integrated health care system with the mission of improving the health of its members, patients, and community. It provides medical insurance to 800,000 people and dental insurance to 250,000. with the care provided through both owned and contracted medical and dental clinics.

HealthPartners has formal relationships with hospitals and clinics throughout Minnesota and western Wisconsin, including Westfield Hospital (New Richmond, WI), Lakeview Hospital

(Stillwater, MN), Hudson Hospitals and Clinics (Hudson, WI), and Physicians Neck and Back Clinic (Roseville, MN).

Approximately 1/3 of HealthPartners medical members receive care in the HealthPartners Medical Group staff-model clinics while the other 2/3 receive care in the many contracted medical groups, mostly via an open access system. Included under HealthPartners' umbrella is Regions Hospital, a tertiary care hospital located in the center of St. Paul. HealthPartners Dental Group is a staff model group practice of more than 55 dentists, including specialists in oral surgery, periodontics, endodontics, prosthodontics, and pediatric dentistry.

### Example partnerships

- ❖ HMO Research Network
- ❖ ICSI - Institute for Clinical Systems Improvement
- ❖ Clinical and Translational Science Award
- ❖ Minnesota Department of Health
- ❖ Midwest Research Network

### Example studies

Title and PI	Study population	Description and available citations
Home Blood Pressure Telemonitoring and Case Management to Control Hypertension, PI: Margolis, Karen	451 followed for 18 months	The dual role of home telemonitoring with pharmacist case management utilizing the telemonitor data makes this study unlike other telemonitor studies. This study evaluates the effectiveness of a home blood pressure telemonitoring system paired with MTM Pharmacist case management at controlling high blood pressure.
A Nurse-Led Physician-Directed System for Providing Optimal Cardiac Care, PI: Kottke, Thomas	Ongoing study with 18 months follow-up	The intervention is the implementation of a care management model for the delivery of cardiac care, led by an RN. The study provides general direction-pointing toward optimal cardiac care outcomes; however, specific steps to reach goals are individually tailored by the team providing care within each of the 5 participating primary care clinics. The assessment of the intervention is a non-equivalent control group design that compares optimal cardiac outcomes in the 5 primary care clinics to optimal care outcomes for patients in a diabetes mellitus care program in the same medical practice. The treatment for patients who have coronary heart disease is well-defined. However, many patients get only some but not all of these treatments. Systems that are put in place in medical care settings help more patients get treated fully. This study will evaluate whether a system that uses a nurse to help provide that care will result in more patients getting more complete treatment.

Title and PI	Study population	Description and available citations
<p>Dental Practice-Based Research Network (DPBRN), PI: Rindal, D. Brad</p>	<p>The DPBRN has conducted more than 20 studies over the seven years of initial NIDCR funding. Enrollment of patients and providers has varied widely to facilitate the sample sizes required for primary and secondary analysis. A data-only retrospective cohort study on osteonecrosis of the jaw was able to evaluate the medical records of over 527,000 patients. A study on the repair or replacement of dental restorations included data from nearly 200 dentists and nearly 6,000 patients. Nearly 7,300 patients responded to a survey on patient satisfaction. DPBRN study design has also varied depending on the aims of the project. Those conducted to date have successfully included 1-week, 3- and 6-month, and 1-, 2-, and 3-year follow up phases.</p>	<p>The Dental PBRNs' primary scientific aims are to : (1) accelerate the development and conduct of clinical research; (2) perform relatively short-term studies to compare effectiveness of preventive and treatment methods; and (3) strengthen the knowledge base for clinical decision-making. A highlight of the DPRBN involvement at HPRF has been our collaboration with the network-wide study PI, Don Nixdorf, DDS (University of Minnesota) as the lead site for a study on Peri-operative and Persistent Pain and Root Canal Therapy. The aims of this study are to identify prevalence of pain associated with endodontic treatment as modifiable and non-modifiable risk factors: a topic of supreme relevance to patients and providers. Also important to investigate was whether the more substantive protocol associated with this study could be conducted successfully within the context of busy clinical practice settings. This study involved, across all regions of the network, 62 dentists and endodontists and 708 patients. Analysis is underway on outcomes of clinical interest, but the feasibility question has been answered. The DPRBN appears a highly suitable environment for conducting a study of this nature. The project also demonstrated the ability of the existing network to grow in capacity through the engagement of dental specialists when study activities involve a topic of interest and importance to providers and their patients.</p> <p>The current structure of the DPBRN includes regions across the US and Scandinavia and has engaged of a diverse group of practitioners and patients within a variety of clinical settings. DPBRN involvement is unique in that projects address research questions that are perceived by providers as highly relevant to clinical care. Enrolled practitioners are surveyed about topics of interest and an Executive Committee composed of representative practitioners drives the research agenda of the network. That being said, results are highly transferrable to practice. The process of practice-based research involvement for practitioners does not end at data collection, but instead includes the dissemination and discussion of study results regionally and across the entire network. This stands to promote and support a culture of evidence-based decision making and to decrease the historical delay of translating new knowledge into patient care.</p> <p>Citations: Gordan, Garvan et al. 2009; Gilbert, Qvist et al. 2010; Gordan, Bader et al. 2010; Fellows, Rindal et al. 2011; Gilbert, Richman et al. 2011</p>

Title and PI	Study population	Description and available citations
E-Health Records to Improve Dental Care for Patients with Chronic Illnesses, PI: Friction, James	10890	Using Health Information Technology to alert dentists or patients to chronic medical conditions that patients have which impact their dental care. The primary goal of this proposal is to evaluate the effectiveness of an integrated electronic health record system that includes an eMedical Record (EMR) eDental Record (EDR), and a Personal eHealth Record (PHR) to improve the quality and safety of dental care for patients with chronic illnesses.
Physician Intervention to Improve Diabetes Care (SimCare), PI: O'Connor, Patrick	,	<p>This randomized trial will test the hypotheses that (a) a physician opinion leader intervention, (b) a "narrative process trace" physician feedback intervention, or (c) the combined intervention (a + b), are no more effective than (d) usual care in improving the clinical care of adult patients with type 2 diabetes.</p> <p>Citations: Dutta, Biltz et al. 2005; O'Connor, Crain et al. 2005</p>
Journey for Control of Diabetes: the IDEA study, PI: Sperl-Hillen, JoAnn	623 participants with sub-optimally controlled type 2 diabetes. 12 months follow-up with potential for ongoing follow-up	<p>First study to rigorously evaluate the U.S. Diabetes Conversation Map Program For patients with established type 2 diabetes, who are not achieving optimal glycemic control, this prospective randomized trial will formally compare the impact of an interactive group-based learning experience using Conversation Maps®, called IDEA (Interactive Dialogue to Educate and Activate), to the following interventions: (1) Individual education (IE) delivered through an ADA-recognized education program, and (2) usual care (UC) or (3) care as recommended through the patient's usual providers.</p> <p>Citations: Beaton, Sperl-Hillen et al. 2010</p>

Title and PI	Study population	Description and available citations
Healthy Homes, Healthy Kids, PI: Sherwood, Nancy	175 subjects currently enrolled; enrollment goal is 400 parent/child dyads; 2 years follow-up	The pediatric primary care setting has been discussed as an important setting in which to address obesity prevention, however, very little research has been conducted in this area. The Healthy Homes/Healthy Kids study is evaluating the efficacy of a pediatric primary care based obesity prevention intervention that integrates brief counseling delivered by pediatric primary care providers during well-child visits and phone coaching delivered by health behavior change experts to support parents in making changes at home to promote healthy eating and physical activity. This study tests the efficacy of brief pediatrician counseling with phone coaching follow up on rate of weight gain in children. The research extends prior work by this team on adherence, parent-child interaction, and provider and telephone based systems for treating obesity in the pediatric primary care setting.
Child Hypertension and Obesity: Diagnosis, Care and Cost, PI: O'Connor, Patrick	396,844 in the study population based on data from the three sites from 2007-2010. Another year of data (2011) will be added: 5 years follow-up	There is only a very limited understanding of the stability over time of blood pressure in children and adolescents and little is known about patterns of care provided to children and adolescents with elevated blood pressure, or the resource use implications of elevated blood pressure in these age groups. This project will address these critical gaps in knowledge using detailed clinical data extracted through electronic medical records at three large medical groups in Minnesota, Colorado and California. Assess in detail the stability over time of the recently developed categories of Pre-Hypertension (Pre-HT) and hypertension (HT) in children and adolescents, as well as care and impact on health resources.

Title and PI	Study population	Description and available citations
<p>MN Center For Childhood Obesity Prevention, PI: Sherwood, Nancy (co-PI Simon French at UMN)</p>	<p>Enrollment goal for full-scale trial is 500 with 3 years follow-up.</p>	<p>There has been increasing recognition that to be effective and to address the complexity of factors that influence obesity, childhood obesity interventions should encompass multiple levels and settings. Previous research has focused in a single setting (e.g., schools, day care centers), and usually addressed behavior at the individual level, with limited local microenvironment changes. The goal of this Center grant is to translate a novel integration of primary care, home, and community-based intervention strategies developed in community settings into a comprehensive program that links intervention strategies across settings to promote sustained patterns of change in food intake, physical activity, and body weight among low income, ethnically diverse children. Critical to the success of this intervention will be creating linkages among the settings to support parents in making home environment and parenting behavior changes conducive to healthy growth and development in their children. A collaborative study with the University of Minnesota, this project proposes the creation of The Minnesota Center for Pediatric Obesity Prevention, comprised of an interdisciplinary investigative team with extensive experience in community, school, primary care, and family pediatric obesity interventions. The goal of this Center is to translate a novel integration of primary care, home, and community-based intervention strategies developed in community settings into a comprehensive program that links intervention strategies across settings to promote sustained patterns of change in food intake, physical activity, and body weight among low income, ethnically diverse children.</p>

Title and PI	Study population	Description and available citations
<p>DIAMOND STUDY: Evaluation of a Natural Experiment to Improve Statewide Depression Care in Minnesota, PI: Solberg, Leif</p>	<p>2,400 study patients, 84 clinics, and 3-400 clinic leaders, with 1-year follow-up for patients; 2-year follow-up for clinics</p>	<p>This study illustrates partnership research methods for a statewide initiative to improve primary care of depression as well as testing a new rigorous research design for observational studies. It also will provide extensive quantitative information about the implementation process, the costs of transformation and the new care model, and how to sustain change. The study takes advantage of the staggered implementation of the Initiative by using a multiple baseline design. This proposal's overall goal is to evaluate the effects on depression care of an impending statewide change in reimbursement combined with facilitated implementation of that best practice model.</p> <p>Citations: Fischer, Solberg et al. 2001; Solberg, Fischer et al. 2001; Solberg, Glasgow et al. 2010; Bao, Casalino et al. 2011; Beck, Crain et al. 2011; Margolis, Solberg et al. 2011</p>
<p>Reciprocal Relationship between Diabetes and Depression, PI: O'Connor, Patrick</p>	<p>40,000</p>	<p>This study developed algorithms to identify depression through iterative examination of electronic data including diagnostic data and pharmacy data. Systematic use of such algorithms, which have acceptably high positive predictive value, but marginal sensitivity, could improve the identification and treatment of depression in large groups of patients, such as those with diabetes or other chronic disease or conditions that may predispose to depression. This retrospective cohort study will evaluate the relationship and mutual impact of depression on diabetes care, and diabetes care on depression care in 10,000 adults with diabetes and 10,000 matched adults without diabetes who are patients within HPMG.</p> <p>Citation: O'Connor, Crain et al. 2009</p>

Title and PI	Study population	Description and available citations
Intranasal Deferoxamine to Precondition Against Stroke, PI: Frey, Bill (Prime PI: Scott Pantner, N CA Research Institute)	Animal study	<p>A non-invasive treatment to treat stroke and to protect the brain against stroke. Coronary artery bypass graft (CABG) surgery is a procedure after which patients manifest significant neurological dysfunction, including stroke and cognitive impairment. In fact, patients in high-risk groups have an incidence of adverse cerebral outcome greater than 16%. The studies of this proposal are directed toward a model that utilizes a technique that may reduce per surgical neurological problem by preconditioning the brain to be more resistant to ischemic insults.</p> <p>Citation: Hanson, Roeytenberg et al. 2009</p>
Intranasal Tat: A mouse model for NeuroAIDS and Aging, PI: Frey, Bill	Animal study	<p>A non-invasive method to examine a potential new model for Neuro-AIDS. The overall goal of this research is to develop a model of NeuroAIDS using intranasal delivery of Tat, a protein that is a key trans-activator of the HIV-1 virus.</p>
Women's Health Initiative, site PI: Margolis, Karen	total n=161,000; Minneapolis Field Center n= approx. 5,000. 15 years follow-up.	<p>The Women's Health Initiative is a national health study focused on chronic disease prevention in postmenopausal women of all races and socioeconomic backgrounds. WHI is one of the most definitive, far-reaching clinical trials of postmenopausal women ever undertaken in the US. This is an observational follow-up study of post-menopausal US women ages 50-79 with randomization to hormone replacement, dietary intervention, and calcium/ vitamin D supplementation.</p> <p>Citations available at: <a href="http://www.nhlbi.nih.gov/whi/references.htm">http://www.nhlbi.nih.gov/whi/references.htm</a></p>

Title and PI	Study population	Description and available citations
<p>Long-term Survivorship in Older Women with Early Stage Breast Cancer, PI: Pawloski, Pamala</p>	<p>4000, followed 15 years post-diagnosis</p>	<p>This study collected additional information about the parent study (BOW I) cohort through 15 years after diagnosis and a matched comparison cohort of women without breast cancer were enrolled. The parent study (Breast Cancer Treatment Effectiveness in Older Women - BOW I) studied 1859 women 65+ years of age with early stage breast cancer and provided strong evidence that variations in care have substantial consequences for older women: less-than-standard treatment is associated with increased rates of recurrence and breast cancer-specific mortality, while mammography surveillance during the first 5 years after diagnosis is associated with a reduced rate of breast cancer mortality. This renewal project (BOW II) will collect additional information about the BOW I breast cancer cohort through 15 years after diagnosis. or older. While breast cancer-specific mortality rates have declined among women less than 70 years old, they are either stable (70-79 year olds) or are increasing (80+ year olds) among those 70 years or older. We propose an historical cohort study of a group of older women (&gt;65 years of age) diagnosed with early stage breast cancer between 1990 and 1994.</p> <p>Citations: Enger, Thwin et al. 2006; Buist, Ichikawa et al. 2007; Geiger, Thwin et al. 2007; Lash, Fox et al. 2007; Field, Doubeni et al. 2008</p>
<p>Women's Eating &amp; Physical Activity Habits: The Influence of Work-Family Balance, PI: Martinson, Brian</p>	<p>302, 1 year follow-up</p>	<p>First full-scale observational study of work-family-balance examining INTRA-INDIVIDUAL changes using four repeated measures over a one-year period assessing WFB, diet and PA, and their inter-relations. Despite Widespread public health initiatives, attempts to promote healthy physical activity and eating habits have been met with limited success, particularly among women of early child-rearing age as well as black women and women with little formal education. The goal of this project is to determine the value of targeting the work-family balance in workplace-based interventions designed to promote healthy physical activity and eating habits.</p>

Title and PI	Study population	Description and available citations
Organizational Characteristics and Chronic Disease Care (QUEST), PI: O'Connor, Patrick	3,548	<p>Project QUEST demonstrated that high levels of medical group and clinic participation in quality improvement research is possible. The project identified several types of clinic and medical group variables that are significantly related to clinical outcomes of patients cared for in these settings. This project is a prime example of a successful, regional collaborative for improving quality of diabetes care. A prospective cohort study of the relationship of health plan, medical group, and clinic characteristics to measures of chronic disease care and resource utilization for patients with diabetes mellitus (DM) or coronary heart disease (CHD). Health plan, medical group, and clinic characteristics are drawn from a conceptual model based on both health services and organizational science, and data on relevant characteristics will be sought using standardized measures whenever possible.</p> <p>Citations: O'Connor, Asche et al. 2004; Gilmer, O'Connor et al. 2005; Solberg, O'Connor et al. 2005; Gilmer, O'Connor et al. 2006; O'Connor, Rush et al. 2008; Rush, Whitebird et al. 2008</p>
Personalized Physician Learning Intervention to Improve Hypertension Control, PI: O'Connor, Patrick	132 primary care physicians, 1 year follow-up	<p>This project tests novel approaches to personalized physician learning and presents a unique opportunity to apply automated, cost effective, personalized, yet standardized methods across multiple clinical domains. In this project we assess the impact of two PPL interventions that differ in how they identify patterns of physician decision making in HT care. The first intervention, REAL-PPL, uses real EMR-derived data to direct the personalized learning intervention. The second intervention, SIM-PPL, uses physician performance on simulated cases to direct the personalized learning intervention.</p>

Title and PI	Study population	Description and available citations
<p>Prioritized Clinical Decision Support to Reduce Cardiovascular Risk , PI: O'Connor, Patrick</p>	<p>ongoing, 2 years follow-up</p>	<p>This project is in the process of developing a sophisticated point of care EHR-based clinical decision support that not only identifies, but prioritizes all available evidence-based treatment options to reduce a given patients cardiovascular risk. Developing personalized prioritization algorithms is a unique aspect of this project. The objective of this project is to develop and implement sophisticated point-of-care EHR-based clinical decision support that (a) identifies and (b) prioritizes all available evidence-based treatment options to reduce a given patient’s cardiovascular risk (CVR).</p>
<p>DPBRN Studies 17 and 18: Peri-Operative Pain, Persistent Pain, and Root Canal Therapy, PI: Rindal, D. Brad</p>	<p>The DPBRN has conducted more than 20 studies over the seven years of initial NIDCR funding. Enrollment of patients and providers has varied widely to facilitate the sample sizes required for primary and secondary analysis. A data-only retrospective cohort study on osteonecrosis of the jaw was able to evaluate the medical records of over 527,000 patients. A study on the repair or replacement of dental restorations included data from nearly 200 dentists and nearly 6,000 patients. Nearly 7,300 patients responded to a survey on patient satisfaction. DPBRN study design has also varied depending on the aims of the project. Those conducted to date have successfully included 1-week, 3- and 6-month, and 1-, 2-, and 3-year follow up phases.</p>	<p>A highlight of the DPRBN involvement at HPRF has been our collaboration with the network-wide study PI, Don Nixdorf, DDS (University of Minnesota) as the lead site for a study on Peri-operative and Persistent Pain and Root Canal Therapy. This aims of this study are to identify prevalence of pain associated with endodontic treatment as modifiable and non-modifiable risk factors: a topic of supreme relevance to patients and providers. Also important to investigate was whether the more substantive protocol associated with this study could be conducted successfully within the context of busy clinical practice settings. This study involved, across all regions of the network, 62 dentists and endodontists and 708 patients. Analysis is underway on outcomes of clinical interest, but the feasibility question has been answered. The DPRBN appears a highly suitable environment for conducting a study of this nature. The project also demonstrated the ability of the existing network to grow in capacity through the engagement of dental specialists when study activities involve a topic of interest and importance to providers and their patients. Goals for these pain and root canal therapy studies: 1) assess the frequency and intensity of pre-operative pain; 2) evaluate the occurrence and intensity of intra-operative pain; 3) evaluate the occurrence and intensity of post-operative pain; 4) estimate the frequency of occurrence and intensity of persistent tooth pain; 5) assess the interference of persistent tooth pain with daily life; and 6) identify a limited set of risk factors related to the development of persistent pain.</p>

Title and PI	Study population	Description and available citations
TMJ Implant Registry and Repository, PI: Friction, James	2,371 followed for 5 years	<p>The major goals of this project are collection of data and specimens from patients with Temporomandibular joint implants and TMJ disorders to maintain a registry and repository for researchers.</p> <p>Citations: Friction, Look et al. 2010; Friction, Ouyang et al. 2010</p>
Patient-Based Strategy to Reduce Errors in Diabetes Care (MOVES), PI: O'Connor, Patrick	133 physicians; 2775 patients	<p>First study in a long line of research to gather information for customized case-based clinical decision support for physicians and patients. Although the results were negative, many important lessons were learned and knowledge gained has contributed significantly to successful projects involving physician decision support. Diabetes medical errors affect 80% of adults with diabetes in the U.S. The leading cause of error is inappropriate or inadequate pharmacologic action that fails to achieve specific clinical aims. Diabetes medical errors lead to tens of thousands of preventable diabetes complications in the U.S. each year, and to \$3.9 billion a year of potentially avoidable health care charges. This project evaluates a HPMG effort to reduce error rates through customized direct feedback of diabetes quality of care data to diabetes patients and their physicians.</p>

Title and PI	Study population	Description and available citations
Improving Diabetes Care through Empowerment, Active Collaboration and Leadership (IDEAL), PI: O'Connor, Patrick	4549	The "IDEAL" model was developed to improve the system and process of care for patients with diabetes as a model for all chronic diseases. The intervention incorporates facilitation of leadership actions in support of change, training for the leader and facilitator of an intraclinic multidisciplinary continuous quality improvement (CQI) team, and consultative and networking support of the change process. This was a novel approach to systems and quality improvement. The key elements of this project include 1) description and analysis of current diabetes care patterns, patient/provider knowledge, attitudes, beliefs, behaviors, capabilities of HealthPartners data systems to facilitate understanding and care of diabetes. 2) development of a CQI based intervention that HP can use to facilitate implementation of the ICSI guideline or any HMO could use to improve diabetes care. 3) pilot-testing of this intervention in two to three HP primary care clinics. 4) randomized controlled trial of the tested intervention in a larger group of HP clinics. 5) description, evaluation, and recommendations of the process and outcomes of the intervention. 6) development of manuals and materials that HP or any HMO could use to replicate this intervention model. 7) development of community and work site strategies to complement the clinic strategies. 8) dissemination of the approach within HP and to other HMOs locally and nationwide.
Improving Disease Prevention in Primary Care (IMPROVE), PI: Solberg, Leif	13,000 patients; 450 clinic doctors and nurses; 2 years follow-up	One of the largest randomized controlled tests of quality improvement methods for clinical preventive services among 44 clinics, with multiple surveys of clinic staff and patients Our overall mission is to use a randomized clinical trial to test whether an HMO (health maintenance organization) can improve specific adult clinical preventive services delivered in its contracted primary care clinics by assisting them to understand and apply the concepts and tools of CQI and systematic prevention processes.

Title and PI	Study population	Description and available citations
Simulated Diabetes Training for Resident Physicians, PI: Sperl-Hillen, JoAnn	341 internal medicine and family medicine resident physicians from 19 residency programs around the country	The learning program, called SimCare Diabetes, uses simulated case-based scenarios to teach important principles of diabetes management through an EHR-like interface. Learners schedule multiple encounters to help the patient achieve recommended clinical goals. Literature-based treatment response formulas calculate change in patient state at each encounter based on the treatment actions. Between encounters, providers learn through seeing the clinical effects of their actions and receiving a critique of past actions along with treatment suggestions. The objective of this study is to improve the safety and effectiveness of diabetes care delivered by primary care residents through an innovative simulated learning intervention that overcomes a number of current obstacles to outpatient diabetes care training in primary care residency programs.
Maintaining Physical Activity in Older Adult MCO Members, PI: Martinson, Brian	1,049 with 2 years follow-up	<p>First ever full-scale behavior intervention targeting maintenance of physical activity in older adults, vs. PA initiation. This study will evaluate the efficacy of a population-based approach to promoting PA maintenance among currently active older adults in a managed care setting. We will use mail and phone-based screening of a random sample of HealthPartners members to identify and recruit newly active older male and female members (age 50-70 years old).</p> <p>Citations: Martinson, Crain et al. 2008; Sherwood, Martinson et al. 2008; Crain, Martinson et al. 2010; Martinson, Crain et al. 2010; Martinson, Sherwood et al. 2010</p>

Title and PI	Study population	Description and available citations
<p>The Minnesota Memory Project: A Registry of Brain Aging in Normal Adults with Memory Loss Together with Their Care Partners, PI: Hanson, Leah</p>	<p>Ongoing study</p>	<p>Longitudinal data will be collected over time in and serve as a registry of people interested in participating in research studies of normal brain aging, dementia, and caregiving. A wide range of research studies approved in separate research applications could recruit from this registry or utilize the data. The Minnesota Memory Project is a community based registry that will gather information about memory function, health history, and lifestyle information in three populations: 1) normal aging adults 55 years of age and older; 2) persons 40 years and older with diagnosed memory loss including mild cognitive impairment or a dementia like Alzheimer's disease; and 3) care partners 18 years and older of those with memory loss.</p>
<p>Propagating the Uniform Research Integrity Climate Assessment (U-RICA), PI: Martinson, Brian</p>	<p>1,267 randomly selected biomedical and social science faculty and postdoctoral fellows from 251 departments across 40 academic health centers in top-tier research universities in the U.S.</p>	<p>This project facilitated the creation, validation and initial propagation of a measure (the Survey of Organizational Research Climates) for use by research institutions in self-inspection and self-regulation to ensure working climates for academic researchers that foster research integrity. The dual goals of this R21 project are, 1) to develop a tool - the Uniform Research Integrity Climate Assessment instrument (U-RICA) - that would allow AHCs to collect reliable, valid, and actionable data to stimulate internal discussions and initiatives to promote research integrity, and 2) to lay the groundwork for the adoption and dissemination of this tool within the framework of the CTSA Consortium.</p>

Title and PI	Study population	Description and available citations
Procedural Justice, Identity, and Research Integrity, PI: Martinson, Brian	1,701 academic faculty and postdocs, randomly selected from and nested within 500 departments, nested within 50 top-tier research universities in the U.S.	<p>Self-reported measures of research-related behavior ranging from the ideal to the undesirable, to misconduct, collected in conjunction with measures of perceived organizational justice with respect to one's academic department, university, IRB/IACUC, and peer review processes. Using an appropriately nested random sample of 5,000 scientists in the health sciences, medicine, biology, chemistry and social sciences, recruited from 50 top-tier research universities, this study will examine the relationships between scientists, perceptions of procedural justice and their behaviors, both positive and negative, related to the integrity of their research.</p> <p>Citations: Martinson, Anderson et al. 2005; Anderson, Ronning et al. 2010; Martinson, Crain et al. 2010</p>
Novel Approaches to Weight Loss Maintenance, PI: Sherwood, Nancy	419, 2 years follow-up	<p>Long term weight loss maintenance remains one of the most critical challenges for obesity treatment. As the novelty of weight loss treatment fades, enthusiasm for diet and exercise tends to wane in the maintenance phase. Given the recognition of obesity as a chronic disorder requiring continued engagement in weight-control behaviors, there is a need to identify cost-effective and supportive therapies that can sustain motivation. The Keep It Off study is designed to enhance weight-loss maintenance using therapeutic phone contact with recent weight losers throughout the period in which they are at highest risk for weight regain. The goal of this project is to test whether a phone and mail-based program designed to help people who have recently lost weight helps them keep the weight off over a 2 year period.</p>
Weigh 2 Be, PI: Sherwood, Nancy (Prime PI: Allen Levine at UMN)	1,800, 2 years follow-up	<p>The Weigh to be study was one of the first large scale trials designed to evaluate the effectiveness of weight-loss interventions in a managed care setting. Evaluate effectiveness of weight-loss interventions in a managed care setting through a three-arm randomized clinical trial: usual care, mail, and phone intervention.</p>

Title and PI	Study population	Description and available citations
Clearway Incentives, PI: Solberg, Leif	184,000, 1 year follow-up	<p>This study used existing EMR data from a large medical group along with health plan claims data to evaluate disparities in delivery and adherence to smoking cessation efforts among racial, ethnic, and income groups, along with a variety of other available variables. There is little quantitative information for Minnesota about any differences in smoking prevalence and use of cessation medications among racial/ethnic minorities, pregnant women, young adults, and low income patients. The purpose of this proposal is to obtain such information from the electronic records of patients of HPMG, whose diversity is very similar to that of the metropolitan area. Such information would help to identify disparities for the purpose of both understanding why they might exist and for developing interventions designed to address those disparities.</p> <p>Citations: Solberg, Flottemesch et al. 2008; Parker, Solberg et al. 2010; Solberg, Parker et al. 2010</p>
Computer-Assisted Tobacco, PI: Rindal, D. Brad	548	<p>Developed decision support software to assist dental providers with assessments of tobacco dependence and delivery of tobacco cessation assistance. Surveyed patients within three days of dental visit to measure provider use of the decision support software. This project will examine whether dentists and hygienists will assess interest in quitting and deliver a tobacco intervention more frequently when provided with computer assisted guidance compared to a control group.</p>

Title and PI	Study population	Description and available citations
Reducing Clinical Inertia in Diabetes Care, PI: O'Connor, Patrick	61 primary care physicians, 1 year follow-up	This study facilitated the creation, validation, and implementation of 2 distinct, yet synergistic decision support tools for primary care physicians. The tools were successful in improving glucose and hypertension control in adult diabetes patients. One of the tools, an EMR based decision support has been adopted by the Medical Group to be implemented system wide. This study is an excellent example of translation of research into practice. Clinical inertia is a major obstacle to high quality diabetes care and contributes to many potentially preventable macrovascular and microvascular complications, premature disability and mortality, and at least \$4 billion a year of potentially preventable health care charges in the U.S. In this randomized trial we evaluate two conceptually distinct but potentially synergistic interventions designed to reduce clinical inertia in the outpatient care of adults with type 2 diabetes.
ACCORD, PI: Margolis, Karen	305, average of 5 years follow-up	The largest cohort study of its kind to evaluate intensive intervention for diabetes control. Largest long term follow up ever done to test outcomes of intensive control of these types of patients. The objective of ACCORD-CNN is to determine if the rate of major cardiovascular events in diabetes mellitus type 2 patients can be reduced by intensive interventions.  Citations: <a href="http://www.nhlbi.nih.gov/health/prof/heart/other/accord/q_a.htm">http://www.nhlbi.nih.gov/health/prof/heart/other/accord/q_a.htm</a>
Aspirin in Reducing Events in the Elderly (ASPREE), PI: Margolis, Karen	Ongoing (total n=19,000), 5 years follow-up	Largest international trial ever funded by NIA. The first comprehensive clinical trial assessing the risks and benefits of low dose aspirin for those over 70. ASPREE is a 5 year primary prevention clinical trial aimed at assessing whether daily treatment of aspirin prolongs healthy lifespan through the prevention of heart attack, stroke, cognitive decline, physical decline and some cancers.

Title and PI	Study population	Description and available citations
<p>Priorities Among Recommended Clinical Preventive Services, PI: Maciosek, Michael (Prime PI: Jennifer Jenson at Partnership for Prevention)</p>	<p>Simulation study</p>	<p>This study assesses a broad range of preventive services using a single methodology to ensure accurate comparisons of services relative value. The aim of this study is to develop evidence-based models to produce consistent estimates of the preventable burden and cost-effectiveness of clinical preventive services, as recommended by the U.S. Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices. This study's primary modeling approach is to use microsimulations of Markov-based processes. As an input to our Markov model for cardiovascular disease prevention, we are proposing to use de-identified Framingham Heart Study data, which will be provided by the National Heart Lung and Blood Institute (NHBLI) upon successful application for use of the data which includes documentation of local IRB approval.</p> <p>Citations: Coffield, Maciosek et al. 2001; Andrade, Graham et al. 2005; Maciosek, Coffield et al. 2006; Maciosek, Coffield et al. 2009; Maciosek, Coffield et al. 2010</p>
<p>Measuring and Comparing the Value of Community Preventive Services to Increase the Impact of Public Health Agencies, PI: Maciosek, Michael</p>	<p>Simulation study</p>	<p>Results will provide information on the value of preventive services delivered in community settings. In the next stage of this work, an online tool will provide community-specific estimates based upon comprehensive microsimulation models of tobacco and physical activity behaviors which incorporate race, ethnicity and social economic status. Community Preventive Services is a 3-year study to set the stage for performance measures for public health agencies by developing and applying methods to quantify and compare the value of evidence-based community interventions.</p>

Title and PI	Study population	Description and available citations
TransforMN Study: Evaluating the Statewide Transformation of Primary Care to Health Care Homes, PI: Solberg, Leif	Up to 250 clinics, 1 year follow-up	This is a study of a statewide natural experiment to transform primary care to health care homes designed and conducted through a partnership with state agency leaders of the initiative as well as a public reporting agency. It requires enrolling all certified clinics and obtaining surveys from the medical leaders and managers of each one in order to gain a quantitative understanding of the transformation process, what clinic features and strategies are associated with success and high quality patient outcomes. The Minnesota legislature has required a new payment system for all payers to primary care clinics that provide advanced patient-centered services through transformation to health care homes for their patients. This study will work with the state agencies leading this conversation to learn how to help clinics make this transformation and whether doing so improves patient quality, experience, and costs.
CER in Genomics & Personalized Medicine of Colorectal Cancer, PI: Pawloski, Pamala	180 at HP; 5,150 across all 7 sites	This study is a novel approach to incorporate evidence synthesis with evidence generation to study colorectal cancer-related genomics and personalized medicine applications and validate these applications in a real world setting. Recently genomic or other molecular tests have been recommended for clinical practice in the area of cancer treatment. They are used to identify individuals at high risk, screen, and perform early detection, identify prognostic markers, and guide course of therapy. We propose a focused program of research that will investigate the comparative effectiveness of several tests related to colorectal cancer (CRC). This research in CRC will build the experience, data systems, and methods that can apply to other cancer-related genetic or molecular tests in the future (e.g. UGT1A1 testing for irinotecan therapy, Oncotype OX and CYP2D6 testing for breast cancer).

Title and PI	Study population	Description and available citations
Chronic Care and Access Changes Need Good Evaluation (CHANGE), PI: Solberg, Leif	,	This project provides an opportunity to evaluate the effect of two system changes on the quality of care of patients with diabetes, cardiovascular disease, and/or depression, as well as the effect on health care costs and preventive services rates of these patients. This project provides an opportunity to evaluate the effect of changes on the approach to patient access on the quality of care of patients with diabetes, cardiovascular disease, and/or depression, as well as the effect on health care costs and preventive services rates of these patients.

# Harvard Medical School, Department of Population Medicine | Harvard Pilgrim Health Care

## Website

populationmedicine.org

## Population served

1.1 million individuals in Massachusetts, New Hampshire, and Maine

## Research center(s) and services

The Department of Population Medicine (DPM), formerly the Department of Ambulatory Care and Prevention, is the nation's only medical school appointing department co-sponsored by a health plan. Examples of the department's research strengths include child health, obesity and its prevention, drug policy (domestic and international), safety and effectiveness of drugs and vaccines, medical ethics, diffusion of electronic medical records, and population-based systems for monitoring infectious diseases. In teaching, the department leads Harvard Medical School's Center for Population Health Education; DPM, Atrius, and Brigham & Women's Hospital jointly sponsor a primary care residency; DPM hosts a range of graduate and post-graduate research fellows.

## Affiliated health care and insurance provider(s)

Harvard Pilgrim Health Care is a large health insurance company with diverse enrollees across New England. Atrius Health is a non-profit alliance of six large medical groups in eastern Massachusetts.

## Example partnerships

- ❖ Harvard University and affiliated institutions: DPM is an appointing department of Harvard Medical School and conducts teaching and research on population medicine for medical students and postgraduates; DPM faculty have a broad range of research collaborations with faculty in other HMS departments, other Harvard faculties, and affiliated Harvard hospitals and institutions.
- ❖ Massachusetts Department of Public Health: DPM collaborates with the Mass DPH in research on novel mechanisms for reportable disease surveillance, infectious disease control, obesity and diabetes prevention and control, and other important public health problems.
- ❖ Eastern Massachusetts Epicenter: DPM leads research on prevention and management of healthcare-associated infections involving multiple partners, including Brigham & Women's Hospital; Massachusetts General Hospital; and North Shore Medical Center, and Children's Hospital, Boston.
- ❖ Mini-Sentinel Initiative: DPM serves as the Coordinating Center for the FDA-funded Mini-Sentinel Initiative and leads the collaborative endeavors conducted by a large group of Data and Academic Partners.
- ❖ World Health Organization: DPM is a WHO Collaborating Center in Pharmaceutical Policy and leads global training and research on medicines policies in established and emerging insurance systems in Africa, Asia, and Latin America.

### Example studies

Title and PI	Study population	Description and available citations
Mini-Sentinel, PI: Rich Platt	Aiming for 100 million lives. Length of follow-up depends on data partner.	<p>The Sentinel Initiative is being developed in response to the Food and Drug Administration Amendments Act (FDAAA), passed by Congress in September 2007, which requires the FDA to collaborate with public, academic, and private entities to develop methods for obtaining access to disparate health data sources and to validate means of linking and analyzing health care safety data from multiple sources. The objective of the Mini-Sentinel pilot project is to inform and facilitate development of the Sentinel System and to carry out mandates delineated in FDAAA. With Mini-Sentinel, the FDA seeks to support new activities intended to develop the scientific operations required to build an efficient, valid, and reliable Sentinel System. The Mini-Sentinel pilot funds development of a single Coordinating Center based at DPM that:</p> <ul style="list-style-type: none"> <li>• Provides the FDA a "laboratory" for developing and evaluating scientific methods that might be used in a fully-operational Sentinel System</li> <li>• Affords the FDA the opportunity to evaluate safety issues using existing electronic healthcare data systems</li> <li>• Allows FDA to learn about the barriers and challenges to building a viable and accurate system of safety surveillance for FDA-regulated medical products</li> </ul> <p>Publications available at <a href="http://mini-sentinel.org/publications/">http://mini-sentinel.org/publications/</a></p>

Title and PI	Study population	Description and available citations
Project VIVA, PI: Matt Gillman	2400 mothers and children followed up to 8 years (currently and ongoing).	<p>Project Viva is a ground breaking longitudinal research study of women and children. The goal of Project Viva is to find ways to improve the health of mothers and their children by looking at the effects of mother's diet and other factors during pregnancy on her health and the health of her child. This information enables VIVA in investigators to examine the effects of diet on child development and obesity, how diet and the environment influence the development of asthma in children, and how a woman's pregnancy is affected lifetime experiences of racism or violence.</p> <p>A list of VIVA publications is available at:  <a href="http://www.dacp.org/viva/Project%20Viva%20Publication%20List%209.12.08.pdf">http://www.dacp.org/viva/Project%20Viva%20Publication%20List%209.12.08.pdf</a></p>
Vaccine Safety Datalink, PI: Tracy Lieu	About 500,000 children at HPHC/Atrius followed from birth through age six years.	<p>The Vaccine Safety Datalink (VSD) Project is the nation's premier system for actively monitoring the safety of all childhood and adult vaccines after they are licensed and in use. It is sponsored and organized by the Centers for Disease Control and Prevention and now includes 10 health care systems, most of which are HMOs. The combined current cohort is more than 9 million persons, or approximately 3% of the U.S. population. VSD's past studies have been seminal in evaluating potential associations of national public health significance, including:</p> <ul style="list-style-type: none"> <li>• Rotavirus vaccine and intussusception</li> <li>• Thimerosal (a vaccine preservative that has now been removed from almost all U.S. vaccines) and neurodevelopmental disorders, including autism</li> <li>• Measles-mumps-rubella-varicella vaccine and febrile seizures</li> <li>• Pandemic influenza vaccine and Guillain-Barre syndrome</li> </ul> <p>The CDC's Immunization Safety Office contracts with America's Health Insurance Plans, the prime contractor. AHIP subcontracts with the 10 health care systems involved. Each study is led by an investigator at either CDC or a collaborating site. DPM investigators have two special roles: Rapid Cycle Analysis Coordinating Center, along with CDC and Northern California Kaiser Permanente; and lead for VSD's annual studies of influenza vaccine safety, in close collaboration with CDC and other sites.</p>

Title and PI	Study population	Description and available citations
		Since 1990, VSD investigators have published more than 75 scientific articles.
HMO Research Network Center for Education and Research on Therapeutics (CERT), PI: Rich Platt	Together, HMORN CERT members have nearly 11 million members, representing ~4% of the U.S. population	The HMORN Center for Education and Research on Therapeutics (CERT) is one of 14 CERT Networks, whose shared mission is to conduct research and provide education that will advance the optimal use of drugs, medical devices, and biological products; increase awareness of the benefits and risks of therapeutics; and improve quality while cutting the costs of care. The HMORN CERT has been continuously funded by AHRQ since 2000 and is made up of 13 HMORN member organizations. Since 2000, the HMORN CERT has received more than \$30 million in grants from AHRQ, NIH, FDA, and industry supporting over 30 core multi-center studies.

# Kaiser Permanente Colorado Institute for Health Research | Kaiser Permanente Colorado

## Website

kpc-ihr.org

## Population served

Over 500,000 members in the Denver-Boulder-Colorado Springs metropolitan area

## Research center(s) and services

The Kaiser Permanente Colorado Institute for Health Research (IHR) is the research department of Kaiser Permanente Colorado. IHR's mission is to develop, conduct and translate high quality research into practice and to promote evidence-based practices and service-oriented, cost-effective medical care. The IHR includes a centralized Clinical Trials office that provides all regulatory and research support including implementation and clinical flow work processes. The Center for Health Dissemination and Implementation Research (CHDIR) was recently founded to conduct applied research to build the scientific basis for a field of translational studies. In the HMO Research Network, the IHR has been at the leading edge of orienting new sites to the VDW.

## Affiliated health care and insurance provider(s)

The Kaiser Permanente Colorado (KPCO) region, established in 1969, is a closed-panel, group-model HMO. KPCO has approximately 875 physicians and 5,500 employees who provide integrated health care services to over 500,000 members (covered enrollees) in the Denver-Boulder metropolitan and Southern Colorado area. KPCO operates 18 outpatient medical clinics spread out across the Denver/Boulder metropolitan area plus two in Southern Colorado. KPCO members choose a Primary

Care Physician (PCP) and obtain most clinical services at their nearest medical clinic. Each medical facility provides primary care, pharmacy, X-ray and laboratory services. Urgent care services are offered in the evenings and on weekends at four clinics located strategically throughout the region. Ambulatory mental health care services are provided at three separate facilities. KPCO provides specialty care for members at two large "hub" facilities.

## Example partnerships

- ❖ University of Colorado: multiple partnerships including the Colorado Clinical & Translational Sciences Institute, Cancer Center Consortium
- ❖ VA: multiple partnerships, primarily cardiovascular
- ❖ HMO Research Network
- ❖ Cancer Research Network

## Example studies

Title and PI	Study population	Description and available citations
Multi-Institutional Consortium for CER in Diabetes Treatment and Prevention (SUPREME-DM), PI: John Steiner	HMORN patients with diabetes mellitus	This multi-site project is generating a “next-generation” multi-system diabetes registry. It is intended to serve as a resource for a wide range of Comparative Effectiveness Research on both individual therapies and system-level interventions, and specifically to support examination of heterogeneity in effectiveness across patient subgroups defined by race/ethnicity, age, co-morbidities, or psychosocial variables, and across systems.
Scalable PARTnering Network for CER: Across Lifespan, Conditions and Settings, PI: Matt Daley	1. Children with Attention Deficit Hyperactivity Disorder (ADHD); 2. Children and adults with obesity	This is a multi-site project within the HMORN to develop a Distributed Research Network, the Scalable PARTnering Network for CER: Across Lifespan, Conditions, and Settings, or SPAN network. This network will create linkages across health care systems to provide access to current patient-level data that supports a dynamic foundation for conducting observational investigations and improves recruitment for interventional research. Over time, the SPAN network will expand to facilitate study of broad spectrums of treatments for multiple health conditions in complex and diverse populations across multiple types of health delivery systems. The project includes proof-of-process comparative effectiveness research projects on treatments for ADHD and outcomes of bariatric surgery. Findings will inform evidence-based health care and improve the national allocation of health care resources.
An Evaluation of an Interactive Social Media Website for Parents who are Concerned about Immunizing Their Children, PI: Jason Glanz	Parents of young children eligible for preventive vaccines	At present, data on the relative benefit of using professionally moderated social media to influence health outcomes are lacking. This is a mixed methods pilot study to develop and evaluate an interactive, social media website for parents who are concerned about vaccinating their children. The website will feature a range of social media applications, including a blog, a discussion forum, and a social networking service. The website will also be a resource for providers who are interested in obtaining information about the newest vaccine-related concerns or discussing vaccine-related topics with parents. For this investigation, the website will be available to

Title and PI	Study population	Description and available citations
		Kaiser Permanente Colorado (KPCO) patients and KPCO physicians. The site will be moderated by physicians and vaccine researchers at the KPCO Institute for Health Research (IHR). Our proposed pilot investigation will help inform future research to implement a larger, integrated behavioral health intervention to reduce parental concerns about vaccinations and increase immunization rates over time.
Longitudinal Studies of Implantable Cardioverter Defibrillators for Primary Prevention , PI: David Magid	patients with LVSD (ejection fraction <50%) who receive an ICD for the primary prevention of SCD from one of seven health care systems during the 4-year period between January 1, 2006 and December 31, 2009	The objectives of this data-only cohort study are to evaluate who receives Implantable Cardiac Defibrillator (ICD) therapy and to identify the patterns and determinants of complications, morbidity, mortality, and costs of ICDs in a large, community-based population. In addition, we will also gain understanding of the patterns and appropriateness of device shocks among patients in community practice undergoing ICD implantation for primary prevention of sudden cardiac death.
Feasibility Study for Microbiome and Breast Cancer, PI: Heather Fiegelson	Post menopausal women age 55 - 69	After menopause, breast cancer occurs at higher frequency in women who have high levels of estrogens. What determines differences in estrogens levels is largely unknown. This study seeks to understand how bacterial diversity in the colon (i.e. the microbiome) is related to levels of circulating estrogens, and ultimately, how that may relate to breast cancer risk. The Breast and Colon Health (BranCH) feasibility study aims to enroll 60 healthy women between the ages of 55 and 69 years at KPCO who have recently had a normal screening mammogram. Participants complete two questionnaires and provide biologic samples.
Outcomes for Complex Patients: Continuity of Care and Patient Perspectives, PI: Elizabeth Bayliss	Persons age 65+ with 3 or more chronic medical conditions.	The objective of this prospective cohort investigation is to determine prospective associations between multiple patient level factors and a range of health outcomes for complex patients. It will also determine whether continuity of care with one or more different clinicians mediates any of these associations.

Title and PI	Study population	Description and available citations
Efforts to Develop the Sentinel Initiative: Data Holder Common Data Model Infrastructure (Mini-Sentinel), PI: Marsha Raebel	Representative subset of the US population	The Mini-Sentinel is a multi-site FDA-supported safety monitoring system for drugs and medical devices. Through this system, the FDA has the capacity to “query” the electronic health information of more than 100 million Americans, posing specific questions to evaluate and monitor the safety of approved medical products. Outcomes from the pilot program will be used to inform the structure and operations of the full Sentinel System Initiative. The larger Sentinel System will augment the FDA’s existing, but largely passive, post-market safety surveillance systems.
Cancer Research Network (CRN) Clinical Communication Research Center, PI: Jim Dearing	Broad cancer population	The major goal of this project is to identify and test optimal communication and coordination processes that facilitate patient-centered cancer care in clinical settings. This will be accomplished by leveraging the existing Cancer Research Network infrastructure and supporting 3 investigator-initiated research projects as well as the development of pilot projects.
Mindfulness-Based Cognitive Therapy for the Prevention of Perinatal Depression, PI: Arne Beck	Pregnant women	The major goal of this project is to compare the effectiveness of mindfulness-based cognitive therapy to usual care for pregnant women at risk for depression who are receiving prenatal care at Kaiser Permanente
CHD Lifestyle Modification for Latinas with Diabetes (Viva Bien!), PI: Debra Ritzwoller	Hispanic women with diabetes	The primary goal of this project is to extend a promising lifestyle change program to an underserved population at high risk for CHD--Hispanic American women with diabetes.

## The Center for Health Research—Southeast | Kaiser Permanente Georgia

### Website

[kpchr.org/research/public/aboutus.aspx?pageid=57](http://kpchr.org/research/public/aboutus.aspx?pageid=57)

### Population served

About 220,000 members throughout the Atlanta-metro region

### Research center(s) and services

The Center for Health Research-Southeast (CHR-SE) is a program of the Center for Health Research. Researchers at TCHR conduct professionally independent research within the managed-care context of Kaiser Permanente Northwest (KPNW), Kaiser Permanente Hawaii (KPHI), and Kaiser Permanente Georgia (KPGA), and also collaborate broadly with scientists at institutions around the country and internationally. CHR-SE conducts research within KPGA's integrated health care system. Research includes clinical trials and CHR-SE maintains a research clinic. CHR-SE engages in research on health services, chronic disease, and vaccines and pharmaceuticals.

### Affiliated health care and insurance provider(s)

KPGA operates 28 full-service medical offices throughout metropolitan Atlanta area that include services for primary, pediatric, behavioral health and specialty care as well as laboratory, radiology and pharmacy services that enable performance of clinical trials and/or collection of clinical specimens.

### Example partnerships

- ❖ CHR-SE engages in collaborative partnerships with universities, industry and via a Clinical and Translational Science Award.

### Example studies

Title and PI	Study population	Description and available citations
<p>A Feasibility Research Pilot to Determine the Practicality of Using the HMO Research Network to Research the Genetics of Drug-Induced Serious Adverse Events (SAEC), PI: Robert Davis, MD, MPH.</p>	<p>Cohort of 73 to 400</p>	<p>First study to leverage the strengths of the HMORN to electronically identify very unique phenotypes across many HMOs. We are collecting biospecimens from an ethnically diverse group of patients with Stevens-Johnson Syndrome, Drug-Induced Liver Injury, and Extreme Weight gain among users of atypical antipsychotics for genotyping. Aims: 1. To develop standardized definitions of serious skin rashes; 2. To develop a feasibility cohort; 3. To develop an analytic file.</p>
<p>Genetic Risk Factors for Idiopathic Thrombocytopenic Purpura following the First Dose of Measles-Mumps-Rubella Vaccination in Children (ITP-MMR). PI: Robert Davis, MD, MPH</p>		<p>We are working with the FDA to enroll patients from the Vaccine Adverse Event Reporting System (VAERS) and from the HMORN. This will be the first study to attempt to identify the genetic underpinnings of this vaccine adverse event.</p> <p>The study aims are to 1) Identify candidate genes from the medical and genetic literature to derive an understanding of the basic biology underlying ITP. Genome Wide Association Studies (GWAS) will be utilized to investigate common polymorphic sites in the human genome. Polymorphisms within the candidate genes will be examined for 450 individuals and their proportions will be compared between cases and controls using SNP arrays; 2) Explore genetic associations between ITP after MMR and structural variation in the human genome using data from structural variation typed by specific markers on the genome wide array and through an analysis of SNP markers to identify new variants that may underlie ITP after MMR; and 3) Perform DNA sequencing of the coding regions of all &gt;17,000 genes in the human genome on six unrelated individuals with a mendelian form of ITP. These efforts could identify novel candidate genes or pathways that underlie familial ITP that can be explored in patients with ITP post-MMR.</p>

Title and PI	Study population	Description and available citations
<p>Genome-Wide Association Studies in African-Americans with Rheumatoid Arthritis (RA), PI: Lou Bridges. Site PI: Robert Davis, MD, MPH</p>		<p>A large multisite NIH study to look at rheumatoid arthritis in African Americans.</p> <p>The study aims are 1) To perform a Genome Wide Association Study in 800 African –Americans with CCP+RA and 800 Controls to identify novel genetic associations; 2) To replicate putative associations identified in Specific Aim 1 for susceptibility to CCP+RA among African –Americans and 3) To further characterize genetic regions associated RA in African-Americans and to analyze genome-wide associations with radiographic severity; BMD in early RZ and healthy controls; and eQTLs of genes expressed in peripheral blood mononuclear cells (PBMC), particularly those associated with radiographic severity.</p>
<p>Human Genetic Variation and Response to Metformin Therapy (Metformin)- study completed, PI: Kathleen Giacomini, PhD. Site PI: Robert Davis, MD, MPH.</p> <p>Human Genetic Variation and Response to Metformin Therapy: Concomitant Medication Sub-Analysis (PMT3 Metformin), Kathleen Giacomini, PhD</p>		<p>Collaboration between the HMORN and the PGRN, leveraging the large electronic databases of KP to identify non-responders to metformin therapy and enroll them for genetic analyses. The study aims are to 1) collect biospecimens from 400-500 African American patients who are greater than 35 yrs. old with newly diagnosed diabetes T2DM, and on metformin monotherapy; 2) genotype the first stage of the cohort using the Illumina Human 1M-Duo+ Bead Chip; 3) undertake a two-stage GWAS to identify loci associated with glycemic response to metformin and 4) fine map putative regions uncovered by GWAS.</p>

Title and PI	Study population	Description and available citations
<p>Minority Health Genomics and Translational Research Biorepository Database Network: A Genomics Resource for Health Disparity Research (MH-GRID), PI: Gary Gibbons, MD. Site PI: Robert Davis, MD, MPH; Melissa Butler, PharmD, MPH, PhD</p>		<p>Collaborative project between minority serving organizations (Morehouse School of Medicine, Jackson Heart Study, Jackson –Hinds Comprehensive Clinic) for genetic studies of drug resistant and drug sensitive HTN in African Americans.</p> <p>The primary objectives are: 1) establish an organizational framework for the MH-GRID Network as a consortium of academic medical centers and minority-serving safety-net medical care facilities; 2) establish an electronic health record-linked bioinformatics/ biorepository infrastructure that facilitates in-depth genotyping, phenotypic characterization and longitudinal surveillance of minority patients and 3) demonstrate the unique utility of the MH-GRID resource with a "use-case" project that defines the genetic, personal, and social-environmental determinants of severe hypertension (HTN) in African-Americans.</p>
<p>Impact of Health Promotion Programs on Managed Care Organization (MCO) Family Health, PI: Edmund, Becker, PhD; Site PI: Douglas Roblin, PhD</p>		<p>Evaluates the effectiveness of work site wellness programs to employer groups that contract with MCO.</p> <p>The study objective is to evaluate the effects of exposure to these three alternative sources of health promotion services 1) work-site wellness program, 2) health education classes, and 3) primary care practices on the health outcomes of working age adults and their families receiving health benefits through a managed care organization (MCO)</p>

Title and PI	Study population	Description and available citations
<p>Effectiveness of Screening Colonoscopy in Reducing Deaths from Colorectal Cancer, PI: Michael Goodman, MD, MPH; Site PI: Douglas Roblin, PhD</p>		<p>A multi-year, multi-site (initially KPCO and Kaiser Permanente Georgia (KPGA)), retrospective, observational study of the rates of chemotherapy regimen adherence for a cohort of HMO cancer patients, before and after the implementation of the coinsurance benefit at one of the two sites.</p> <p>The specific aims are 1) estimate the effectiveness of screening colonoscopy in reducing death from colorectal cancer among average-risk adults when compared to no screening 2) determine the impact of completeness of the examination (cecal intubation) or quality of bowel preparation on the effectiveness of colonoscopy for reducing death from colorectal cancer and 3) determine the effectiveness of colonoscopy in reducing deaths from relative to flexible sigmoidoscopy.</p>
<p>Promoting Adherence to Improve Effectiveness of Cardiovascular Disease Therapies (PATIENT), PI: William Marion Vollmer, PhD; Site PI: Suma Vupputuri, PhD</p>		<p>Large scale intervention study using automated reminders to improve medication adherence.</p> <p>The study aim is to compare the effectiveness of two low-intensity, population-based interventions designed to promote adherence to selected medications known to prevent cardiovascular morbidity and mortality among high-risk members of a large health maintenance organization.</p>

Title and PI	Study population	Description and available citations
<p>BRFSS "Actions to Control Blood Pressure": Reliability and Validity, PI: Edmund R. Becker, PhD; Site PI: Douglas Roblin, PhD</p>		<p>In 2005 we were selected to participate in a study; the BRFSS added an optional module consisting of 10 questions-“Actions to control High Blood Pressure”. To date, the reliability and validity of these questions remains unevaluated.</p> <p>The specific aims for the first year include: (1) defining a diverse population (gender, age, race/ethnicity) adults with diagnosed hypertension and BP measurements in 2006 who are enrolled with Kaiser Permanente Georgia (KPG); (2) administering a brief survey that includes the "Actions to Control High Blood Pressure" measures by telephone to a random sample (N=3,000) of these patients; and (3) linking the survey results with clinical data and assessing; (a.) the discriminant validity of patient self management and physician advice with respect to BP levels and antihypertensive medication use. (b.) differential item functioning with respect to patient gender, age group, or race/ethnicity (adjusted for BP levels). In the second year, we propose to explore the reliability and validity of the "Actions to Control High Blood Pressure".</p>
<p>Improving Care of Osteoporosis: Multi-modal Intervention to Increase Testing and Treatment (ICOMMITT), PI: Kenneth Saag, MD; Site PI: Douglas Roblin, PhD</p>		<p>Using formative analysis with input from physicians and patients, we developed and pilot tested a multi-modal intervention to improve osteoporosis testing and treatment with system, patient, and provider components.</p> <p>The Specific Aims (SA) of our proposal are: 1) Using formative analysis with input from physicians and patients, develop and pilot test a multi-modal intervention to improve osteoporosis testing and treatment with system, patient, and provider components; 2) Conduct a group-randomized trial involving three different interventions targeting women ≥ 65 years of age not previously tested or treated for osteoporosis; 3) To determine the differential impact of the three interventions on BMD testing, we will test the following main and exploratory (E) hypotheses (H) 12 months following the intervention delivery; 4) To further determine the impact of the three</p>

Title and PI	Study population	Description and available citations
		<p>interventions on additional outcomes, we will survey study patients 12 months post-intervention to evaluate: a) osteoporosis-related patient-provider communication using a validated instrument and b) self-reported use of calcium and vitamin D.</p>
<p>Diabetes Social Support Using Mobile Telecommunications Technology: Pilot Feasibility Study [Diabetes Social Support Study](DSS), PI: Douglas Roblin, PhD</p>		<p>Social and behavioral theories, and both observational and interventional studies, indicate that strategies that direct patient attention to specific health measures or lifestyle on a routine basis – such as keeping a daily diary of weight – can yield improvements to patients in adherence to recommended self-management practices and to health outcomes.</p> <p>Our overall study objective is to compare the effectiveness of: 1) automated feedback enabled through mobile ICT (self-monitoring group) and 2) social networking enabled through mobile ICT (peer monitoring group) compared to usual care for achieving incremental improvements in SMBG adherence and glycemic control. Our proposed study will create a partnership between an integrated health care system, Kaiser Permanente Georgia, and a technology company, Diabetech, which has an established track record in development and application of mobile ICT systems for SMBG.</p>
<p>A Patient Activation Intervention to Enhance Bone Health in Older Adults, PI: Peter Cram, PhD; Site PI: Douglas Roblin, PhD</p>		<p>The study aims are 1) To assess the impact of the patient activation intervention on bone-related quality of care in adults who have undergone DXA scans; 2) Assess the impact of the patient activation intervention on patient satisfaction, quality of life and osteoporosis specific knowledge and 3) Assess the cost-effectiveness of the patient activation intervention.</p>

Title and PI	Study population	Description and available citations
<p>Improving Orthopedic Outcomes: Through a National Total Joint Replacement Registry, PI: Patricia Franklin MD, MBA, MPH; Site PI: Douglas Roblin, PhD</p>		<p>We will obtain the commitment of the surgeons at our Clinical Center to enroll patients in the registry and work with the clinicians and clinic staff to tailor the patient and data flow to meet the registry's need. We will participate in the regular research team meetings, data analysis and interpretation.</p> <p>The primary objectives are 1) to establish a national registry of over 33,000 diverse patients of 130 orthopedic surgeons representing all regions of the country and varied hospital and surgeon practice settings to ensure that the registry and analyses and research reflect typical clinical practice thereby providing optimal guidance for patients, clinicians, and national healthcare policymakers; 2) develop new and transformative comparative effectiveness tools and conduct research useful to both clinical practice and healthcare policy; 3) broadly disseminate surveillance reports for adverse sequelae such as implant revision, hip dislocation, knee manipulation, and identify important variation to inform quality improvement priorities and 4) establish resources to insure sustainability beyond the four years of this proposal.</p>
<p>High Deductible Health Plans and Receipt of Cancer Prevention Services, PI: Douglas Roblin, PhD</p>		<p>We propose to compare receipt of breast cancer screening (screening mammograms) and cervical cancer screening (Pap smears) among age-eligible women enrolled in HDHPs to receipt of these services in a cohort of women enrolled in HMPs over a 7-year period in KPGA and KPCO.</p> <p>The specific aims of the study are to: 1) Construct a longitudinal dataset over a 4-5 year period using MCO electronic data at 2 of the participating centers; 2) Create cohorts of women in HDHPs and traditional HMO plans matched on age and comorbidities; 3) Test hypothesis of the impact of HDHPS vs. traditional HMO plans on receipt of mammograms, pap smears, and HPV vaccinations using the matched cohorts.</p>

Title and PI	Study population	Description and available citations
<p>Chemotherapy and Coinsurance: The Effect of Cost Sharing on Cancer Care (CRN3-Pilot Study), PI: Edward H. Wagner, MD, MPH; Site PI: Douglas Roblin, PhD</p>	<p>8,000</p>	<p>A multi-year, multi-site (initially KPCO &amp; KPGA) retrospective, observational study of the rates of chemotherapy regimen adherence for a cohort of HMO cancer patients, before and after the implementation of the is coinsurance benefit at one of the two sites. month-by-month measurement of the proportion breast, colorectal, and lung cancer patients who receive first-choice cancer chemotherapy services. Use time-series regression methods to test the overall hypothesis that patients facing the implementation of the coinsurance will be less likely, over time, to receive the same level chemotherapy services (adjusting for age, gender, stage, geocoded proxy measures of SES, etc).</p> <p>The specific aims of our study are: 1) Construct a set of time series for the period 2006-2008 with month-by-month measurement of the proportion of breast, colorectal, and lung cancer patients who receive first-choice cancer chemotherapy services – as defined by American Society of Clinical Oncologist (ASCO)-derived guidelines, which are currently employed by all Kaiser regions. 2) Use time-series regression methods to test the overall hypothesis that patients facing the implementation of the coinsurance will be less likely, over time, to receive the same level chemotherapy services (adjusting for age, gender, stage, geocoded proxy measures of SES, etc).</p>

# The Center for Health Research—Hawaii | Kaiser Permanente Hawaii

## Website

[kpchr.org/research/public/aboutus.aspx?pageid=13](http://kpchr.org/research/public/aboutus.aspx?pageid=13)

## Population served

About 230,000 members throughout Hawaii. The most ethnically diverse population in the United States

## Research center(s) and services

The Center for Health Research-Hawaii (CHR-HI) is a program of the Center for Health Research. Researchers at TCHR conduct professionally independent research within the managed-care context of Kaiser Permanente Northwest (KPNW), Kaiser Permanente Hawaii (KPHI), and Kaiser Permanente Georgia (KPGA), and also collaborate broadly with scientists at institutions around the country and internationally. CHR-HI focuses on research issues uniquely suited to its position within a large integrated health care system serving an extraordinarily ethnically diverse, defined population. CHR-HI maintains a research clinic and local laboratory analyses are performed at the Regional Clinical Laboratory at Moanalua Medical Center.

## Affiliated health care and insurance provider(s)

Kaiser Foundation Health Plan, Inc. (KFHP) Hawaii Region is a mixed model Health Maintenance Organization (HMO) serving 230,000 members on the islands of Oahu, Maui, Hawaii, and Kauai. KFHP contracts with Kaiser Foundation Hospital (KFH) for inpatient services and the Hawaii Permanente Medical Group, Inc. (HPMG) for professional services. HPMG is a partnership of more than 449 physicians, who comprise a wide range of medical specialists and sub-specialists. The Hawaii Region is collaboratively co-managed by KFHP (the insurer), KFH (care facilities), and HPMG (the caregivers).

## Example partnerships

- ❖ KP Regions (CESR, Patient- KPNW, CanCORSII- KPNW, Metformin KPNC, TVAX - KPCO, Oncology Clinical Trials KP NC, Supreme–KPNC)
- ❖ CDC (Vaccine Safety Datalink Surveillance Project)
- ❖ Cancer Research Network (Health Literacy, CRN SEER Study, SEARCH)
- ❖ Cardiovascular Research Network
- ❖ Mental Health Research Network

### Example studies

Title and PI	Study population	Description and available citations
Impact of Early Gestational Diabetes Screening in High-Risk Populations, PI: Hillier	In addition to bi-directional-data collected both retrospectively and prospectively on a previously studied cohort, a subsample of 200 pregnant women will be recruited for additional laboratory testing at a KP to improve our ability to understand the value of early GDM screening. Typical screening time for GDM is 24-28 weeks gestation. However, in these high-risk women, the region is trying to screen women as early as possible after the first prenatal visit (and ideally <20 weeks gestation).	<p>This study addresses the need for research in Early Gestational Diabetes Mellitus to inform clinical practice. Specifically, the study aims to compare early versus usual GDM both in prevalence of diagnosis and to compare how these groups differ in outcomes for mother and baby; to determine the impact of measured maternal weight (both initial and gain during pregnancy) as an independent predictor of GDM-associated maternal and perinatal outcomes; and to determine the sensitivity and specificity of screening tests for early GDM</p> <p>Data from both KPNW and KPHI regions provides an opportunity to examine a high-risk multi-ethnic population of over 59,000 pregnant women and their babies (118,000 total). This study also supports the KPHI region in a new quality assurance screening program for high-risk obese women early in pregnancy.</p> <p>Related citations: Hillier, Pedula et al. 2007; Hillier, Pedula et al. 2008; Pedula, Hillier et al. 2009</p>

Title and PI	Study population	Description and available citations
Practice Variation and Care Outcomes (PRAVCO), PI: Vogt	This project uses an electronic medical record in a population of 16,000 adult persons with diabetes who are enrolled in a large integrated care health system to determine the relation of variations in clinical prevention and management to the trajectories of diabetic and CVD morbid events over a 5-8 year period. The study focuses on the variations over time in care management at the practitioner level.	<p>Diabetes is a major risk factor for cardiovascular disease (CVD) and for disabling complications. This study will clarify the degree to which deviation from guidelines has an impact on morbid and mortal events among diabetic patients and on costs of providing care. These data may lead directly to improved adherence to care guidelines.</p> <p>Related citations: Vogt, Feldstein et al. 2007</p>
Work, Weight and Well Being (3W), PI: Vogt	32 hotels in Hawaii were pair matched.	<p>In Hawaii, as in many other states, tourism is a large industry. Most hotel jobs require little education or training, and hotels employ large numbers of low SES persons and immigrants. Hawaii, with the world's most ethnically diverse population, has high rates of obesity and diabetes, particularly among those of Polynesian ancestry (about 20-22% of the population). This study is a comprehensive lifestyle change program delivered through worksites in partnership with a large health care system. The goal is to increase physical activity, improve diet, and reduce obesity of hotel employees. The primary outcome is change in BMI among employees of intervention versus control hotels. Secondary outcomes address effects of the intervention on ethnic and occupational subgroups, stage of change and other issues.</p> <p>Related citations: Williams, Vogt et al. 2007; Novotny, Williams et al. 2009; Meenan, Vogt et al. 2010; Nigg, Albright et al. 2010</p>

Title and PI	Study population	Description and available citations
<p>Personality and Health: A Longitudinal Study, site PI: Vogt</p>	<p>Cohort of middle aged adults for whom unique and irreplaceable teacher personality assessments were obtained about 40 years ago in Hawaii.</p>	<p>The broad objectives of this project are to test the models and mechanisms by which childhood personality traits predict adult health-related behaviors, health status, and eventually, mortality. The specific aims are to test three increasingly complex versions of a health-behavior model in which personality traits influence health through health behaviors, and to evaluate any cultural influences on these models. The participants comprise a cohort of middle aged adults for whom unique and irreplaceable teacher personality assessments were obtained about 40 years ago. Specifically, 1,770 members of the original population of Hawaiian schoolchildren have been located and 1,055 have been recruited to participate in this longitudinal study of personality and health. The recruited sample is representative of the original population in terms of personality attributes and gender. Over the next five years, information about the participants' personality traits, health behaviors, and health outcomes will be obtained. The personality measures will be based on several different theoretical perspectives including the five-factor framework. Health behaviors will include dietary practices, physical activity levels, and tobacco and alcohol usage. Health outcomes will include objectivity assessed physical fitness and flexibility, obesity, and cholesterol level. Assessment methods will include self-reports, reports from knowledgeable others, observer ratings, physical/medical examinations, and laboratory tests. Frequency and appraisals of stressful life events, coping strategies, and constructs from the Theory of Planned Behavior will also be assessed to evaluate the more complex versions of the proposed health-behavior model. The effects on these models of cultural variables, socioeconomic status, and gender will be examined. The cross-sectional and longitudinal influences of personality traits will be evaluated by bivariate and multivariate linear models and structural equation modeling. This project will create a longitudinal data archive that will be a treasure chest for the scientific community for years to come.</p> <p>Related Citations: Hampson, Goldberg et al. 2006; Hampson, Goldberg et al. 2007; Hampson, Goldberg et al. 2009</p>

## The Center for Health Research—Northwest | Kaiser Permanente Northwest

### Website

[www.kpchr.org/research/public/default.aspx](http://www.kpchr.org/research/public/default.aspx)

### Population served

About 470,000 members in Northwest Oregon and Southwest Washington.

### Research center(s) and services

The Center for Health Research (TCHR) conducts professionally independent research within the managed-care context of Kaiser Permanente Northwest (KPNW), Kaiser Permanente Hawaii (KPHI) and Kaiser Permanente Georgia (KPGA), and also collaborate broadly with scientists at institutions around the country and internationally. Center for Health Research-Northwest (CHR-NW) conducts research within KPNW's integrated health care system.

CHR-NW has a long and successful history of creating coordinating centers and participating in collaborative intervention trials. CHR-NW has a centralized Recruitment and Survey Interviewing department with over 30 years of experience. CHR-NW recently renovated a laboratory to create a state-of-the-art biorepository facility. CHR-NW also has particular strength in health services and health economics research, and includes an evidence-based practice center.

### Affiliated health care and insurance provider(s)

KPNW serves about 470,000 members in Northwest Oregon and Southwest Washington and employs more than 700 physicians. The Northwest is the only Kaiser Permanente region to provide prepaid dental services. With about 180,000 members, it is one of the largest group-practice dental programs in the country. Facilities include the Kaiser Sunnyside Medical Center, 27 outpatient medical offices, and 16 dental offices. A second hospital, Kaiser Westside Medical Center, will open in 2013.

### Example partnerships

- ❖ Oregon Health & Science University (OHSU): ongoing consortium
- ❖ OCHIN: ad hoc investigator partnerships
- ❖ Kaiser Permanente Center for Effectiveness and Safety Research (CESR): ongoing consortium
- ❖ HMO Research Network: ongoing consortium
- ❖ Cardiovascular Research Network (CVRN): ongoing research consortium
- ❖ Cancer Research Network (CRN): ongoing research consortium
- ❖ Dental Practice-Based Research Network: ongoing consortium
- ❖ Oregon Evidence-based Practice Center: Ongoing collaboration with OHSU and the Portland Veterans Affairs Medical Center

## Example studies

Title and PI	Study population	Description and available citations
<b>Mega Epi</b>		
<p>Maternal Morbidity in a Managed Care Setting (CDC Contract Number: 200-2009-31663), PI: Mark C. Hornbrook</p>	<p>Pregnant women and newborns in two KP regions: Northwest and Georgia. This project collected and analyzed data on the extent of antepartum, intrapartum, and postpartum morbidity among women who received care in a managed care setting, from conception through six weeks postpartum.</p>	<p>This project is a multi-year, multi-site collaborative program on maternal and fetal outcomes in two Kaiser Permanente regions (Northwest and Georgia). CHR investigators and CDC scientists are using comprehensive pregnancy registries, linked to other information, to study the incidence and prevalence of maternal morbidities among pregnant women enrolled in these HMOs, including: depression and gestational diabetes. This program has analyzed racial differences in maternal morbidity rates among HMO enrollees, identified increased health care utilization associated with obesity during pregnancy, and examined patterns of postpartum weight retention and term newborn size among obese pregnant women with weight gain outside the 2009 Institute of Medicine recommendations.</p> <p>Citations: Dietz, Williams et al. 2007; Bruce, Berg et al. 2008; Chu, Bachman et al. 2008; Dietz, Vesco et al. 2008; Vesco, Dietz et al. 2009; Vesco, Sharma et al. 2011</p>
<b>Information Technology</b>		
<p>Enhancing Clinical Effectiveness Research with Natural Language Processing of EMR (NLP Hub) (AHRQ Grant Number: R01 HS019828), PI: Brian Hazlehurst</p>	<p>The tobacco-using and asthma patient populations of 6 diverse health systems.</p>	<p>This study is building a centralized website where CER researchers can build software applications that will process electronic medical records, including both text notes and coded data, to create standardized datasets that permit comparative effectiveness research. This study's results will demonstrate the utility of this infrastructure by conducting CER studies investigating the effectiveness of interventions in asthma and smoking across six participating health systems.</p>

Title and PI	Study population	Description and available citations
<p>Is Use of Kaiser’s Shared Electronic Medical Record Associated with Increased Adherence to Well-Child Care Visit and Immunizations? (Garfield Foundation Funded), PI: Jeffrey Tom</p>	<p>Children aged 0-2 years and their parents in the KP-Hawaii and KPNW health systems.</p>	<p>This study is examining parents’ use of the kp.org interactive medical website for members in KP-Hawaii and KPNW and its association with higher adherence to well-child visits and immunizations among children aged 0–2 years. This relatively new technology was introduced in 2004, and adopted by KP in 2005. Since this time, KP has gained more users for this innovative technology than any other health care provider in the nation, which gives this study a unique vantage point for evaluating its potential benefits.</p>
<p><b>Clinical</b></p>		
<p>Internet CBT for Depression: Comparing Pure, Guided, and Stepped Care, (NIMH Grant Number: R01 MH087505), PI: Gregory Clarke</p>	<p>Adults (18 and over) who seek community treatment for depression.  Participants will be recruited from 8 healthcare organizations representing a range of diverse populations (rural/urban; employed/disadvantaged; ethnic-racial, socioeconomic minorities) and organizational characteristics (private/public; small/large; HMOs/fee-for-service).</p>	<p>This effectiveness RCT tests high-fidelity, self-help, Internet-delivered cognitive behavioral therapy (CBT) for depression to maximize treatment availability and quality, as well as to reduce costs. The trial is being implemented in two HMORN sites, 3 to 5 safety-net, federally qualified health centers (FQHCs) in the OCHIN-Safety Net West (SNW) practice-based research network, and 3 to 5 rural primary care practices in the Oregon Rural Practice based Research Network (OPRPN). The primary hypothesis this study is that Guided self-help CBT (with phone coach assistance) will result in greater depression symptom improvement than Pure self-help CBT. This study also includes a cost-effectiveness analyses comparing the two study arms.</p>

Title and PI	Study population	Description and available citations
<p>Promoting Adherence to Improve Effectiveness of Cardiovascular Disease Therapies (AHRQ Grant Number: R01 HS019341), PI: William Vollmer</p>	<p>Members of the KPNW health plan who are at high risk for developing diabetes and cardiovascular disease.</p>	<p>PATIENT is a randomized clinical trial comparing the effectiveness and costs of two low-intensity, population-based interventions to promote adherence to medications known to prevent cardiovascular morbidity and mortality among high-risk members. An Adherence Reminder (AR) intervention is employing automated phone calls to educate patients about their medications and help them refill their prescriptions. An Enhanced Adherence Reminder (AR+) intervention augments the phone-based AR intervention with tailored, personalized mailings to participants and their providers. The trial is being conducted in three Kaiser regions: Northwest, Hawaii, and Georgia.</p>
<p>Prospective Investigation of Human Papillomavirus Infection and Cervical Dysplasia (NCI NO1-CP-21025), PI: Andrew Glass</p>		<p>This study assembled a cohort of 23,702 women who had cervicovaginal lavage during routine Pap smears and tested these samples for HPV DNA. These slides and blocks were added to a library of cervical tissue that has been retained permanently since 1971. The HPV cohort was followed extensively, and this cohort has supported almost two dozen ancillary studies. The HPV project confirmed long recorded associations with cervical cancer, helped to isolate the implicated strains, and contributed significantly to the development of the HPV vaccine.</p> <p>Citations: Sherman, Lorincz et al. 2003; Insinga, Glass et al. 2004; Castle, Schiffman et al. 2005; Khan, Castle et al. 2005; Castle, Schiffman et al. 2006; Gravitt, van Doorn et al. 2007; Pratt, Sirajuddin et al. 2007</p>

Title and PI	Study population	Description and available citations
<p>Weight Loss Maintenance Trial Coordinating Center—WLM, PI: Victor J. Stevens</p>	<p>1032 overweight or obese adults (38% African American, 63% women) from four clinical centers-Duke University, Johns Hopkins University, Pennington Biomedical Research Center, and the Kaiser Permanente Center for Health Research.</p>	<p>The Weight Loss Maintenance (WLM) Trial examined different methods for helping people maintain weight loss (see PREMIER). As a WLM coordinating center, CHR performed various tasks promoting communications, training, data transfer, and analysis. We also helped develop the study processes, track trial progress, and write peer-reviewed articles and research presentations on study findings.</p> <p>Citations: Ard, Kumanyika et al. 2008; Brantley, Appel et al. 2008; Hollis, Gullion et al. 2008; Stevens, Funk et al. 2008; Svetkey, Stevens et al. 2008; Jerome, Young et al. 2009; Meenan, Stevens et al. 2009; Young, Jerome et al. 2009; Funk, Stevens et al. 2010; Funk, Stevens et al. 2011; Svetkey, Ard et al. 2011</p>
<p><b>Genetics</b></p>		

Title and PI	Study population	Description and available citations
<p>Comparative Effectiveness Research in Genomics &amp; Personalized Medicine (NCI Grant Number: RC2 CA148471), Co-PIs: Katrina Goddard, Evelyn Whitlock, Lawrence Kushi</p>	<p>Varies with study, e.g., <i>Oncotype DX</i> is used for profiling tumor gene expression in patients with Stage-II colon cancer to predict recurrence risk and inform treatment decisions following surgery.</p>	<p>This study examines several genetic tests related to colon cancer to determine which patients get tested and which therapies patients should receive. Additionally, this study summarizes research that has already been published and analyzes cost information about the use of these tests. The Comparative Effectiveness Research in Genomics &amp; Personalized Medicine for Colorectal Cancer (CERGEN) project is a collaboration of eight Cancer Research Network members and four academic partners. CERGEN is collecting primary data to evaluate KRAS and Lynch Syndrome genetic tests and is conducting secondary data collection that will facilitate evidence synthesis for these genomic applications and cost-effectiveness analyses. To complement these data, this project is conducting patient and physician interviews to illuminate how genetic test results are used by patients and physicians to inform decisions. The CERGEN project will ultimately garner experience, data systems, and methods that will be translatable to other cancer-related genetic or molecular tests.</p> <p>Citation: Webber, Lin et al. 2010</p>

# Division of Research | Kaiser Permanente Northern California

## Website

[www.dor.kaiser.org](http://www.dor.kaiser.org)

## Population served

More than 3.2 million members in Sacramento and the Bay Area

## Research center(s) and services

Kaiser Permanente Division of Research (DOR) is the research department of Kaiser Permanente Northern California and a division of the Permanente Medical Group. DOR research seeks to understand the determinants of illness and well being and to improve the quality and cost-effectiveness of health care for Kaiser Permanente members and society at large. The Division of Research offers expertise in health services research, clinical trials, epidemiology, genetics/pharmacogenetics, pharmacoepidemiology, sociology, qualitative research, medical informatics, and quality measurement and improvement.

Research services include a data entry department, medical record coder unit for chart review purposes, and clinical examination and laboratory facilities.

The Comprehensive Clinical Research Unit facilitates research collaborations between DOR investigators and internal and external collaborators and maintains explicit procedures and policies with respect to external collaborators.

## Affiliated health care and insurance provider(s)

Kaiser Permanente Northern California is an integrated healthcare system serving more than 3.2 million members in Sacramento and the Bay Area.

## Example partnerships

- ❖ The Division of Research has led and co- led several research initiatives as part of the HMORN.
- ❖ UCSF: collaborative research projects including through a Clinical and Translational Science Award and the Kaiser Permanente Research Program on Genes, Environment and Health (RPGEH)
- ❖ Stanford University (e.g., cardiovascular disease), Berkeley (e.g., statistics, public health, epidemiology) and UC Davis (e.g., emergency medicine): collaborative research projects
- ❖ Internal collaborations with clinicians in health centers
- ❖ CDC SHEPherD, “Services for Healthcare Acquired Infection Prevention Research Implementation,” with KPNW and KPHI

### Example studies

Title and PI	Study population	Description and available citations
<p>Early Markers for Autism (EMA) Study PI: Lisa Croen</p>	<p>The cohort of infants born July 2000-September 2001 to women who participated in the prenatal screening program in Orange County, California. Cases (AU; n = 84) were children receiving services for autism at the Regional Center of Orange County. Two control groups were included: children with mental retardation or developmental delay (MR; n= 49) receiving services at the same regional center; and children not receiving services for developmental disabilities, randomly sampled from the California birth certificate files (GP; n = 160).</p>	<p>This case-control study of autism is examining several biologic markers of disease susceptibility and exposure in maternal blood specimens collected during midpregnancy and neonatal specimens collected at birth.</p> <p>Citations: Croen, Braunschweig et al. 2008; Croen, Goines et al. 2008</p>
<p>The Diabetes Study of Northern California PI: Andy J. Karter</p>	<p>The survey was completed by 20,188 persons. The participation by ethnicity was 3,420 African Americans (16.9%), 2,312 Asian (11.4%), 4,602 Caucasians (22.8%), 2,404 Filipinos (11.9%), 3,717 Latinos (18.4%), 2,222 multi-racial (11.0%) and 1,511 South Asian, Pacific Islander, Native America, Eskimo or other/unknown (7.5%). The distribution by mode was 10,429 CATI (51.7%), 4,288 written survey</p>	<p>From the Diabetes Registry, consisting of 199 123 members as of January 1, 2005, the investigators selected an ethnically stratified, random sample of 40 735 health plan members, aged 30–75 at baseline, to receive the DISTANCE Survey: 6871 African American (17%), 11 197 Asian (27%), 4233 Caucasian (10%), 7018 Latino (17%) and 11 417 members of unknown ethnicity (28%). The DISTANCE Survey was in the field from May 5, 2005 until December 31, 2006.</p> <p>Citations: Karter, Parker et al. 2009; Moffet, Adler et al. 2009; Sarkar, Karter et al. 2010; Callaghan, Feldman et al. 2011; Moffet, Parker et al. 2011</p>

Title and PI	Study population	Description and available citations
	(21.2%), 2,393 short version (11.8%) and ,3078 web (15.2%).	
Kaiser Permanente Research Program on Genes, Environment and Health (RPGEH) PI: Cathy Schaefer	The completed resource will link together comprehensive electronic medical records, data on relevant behavioral and environmental factors, and biobank data (genetic information from saliva and blood) from 500,000 consenting health plan members.	Next generation genome-wide association tool: design and coverage of a high-throughput European-optimized SNP array.  Citation: Hoffmann, Kvale et al. 2011
The Coronary Artery Risk Development in Young Adults Study (CARDIA) PI: Steve Sidney		The CARDIA Study is a multicenter, longitudinal observational study designed to describe the development of risk factors for coronary heart disease in young black and white men and women. The study population was recruited from four geographic areas by community-based sampling in Birmingham, Alabama, Chicago, Illinois, and Minneapolis, Minnesota, and by sampling from the Kaiser Permanente Health Plan membership in Oakland, California.  Citations: Friedman, Cutter et al. 1988; Iribarren, Sidney et al. 2000; Sternfeld, Liu et al. 2008; Gunderson, Quesenberry et al. 2010
Chronic Renal Insufficiency Cohort Study II PI: Alan S. Go	1,120,295 adults in whom serum creatinine had been measured between 1996 and 2000 and who had not undergone dialysis or kidney transplantation. Examined the multivariable association between the estimated GFR and the risks of death, cardiovascular events, and hospitalization.	Seven clinical centers recruited adults who were aged 21 to 74 yr and had CKD using age-based estimated GFR (eGFR) inclusion criteria. At baseline, blood and urine specimens were collected and information regarding health behaviors, diet, quality of life, and functional status was obtained. GFR was measured using radiolabeled iothalamate in one third of participants. Go AS, Chertow GM, Fan D, McCulloch CE, Hsu CY  Citations: Go, Chertow et al. 2004; Lash, Go et al. 2009

## LCF Research

### Website

[www.lcfresearch.org](http://www.lcfresearch.org)

### Population served

Approximately 200,000 people in New Mexico of diverse ethnic backgrounds (nearly 40% of the Lovelace Health Plan population is Hispanic).

### Research center(s) and services

LCF Research is an independent non-profit health services research institute. LCF Research focuses on developing, implementing and evaluating interventions to improve the quality and cost-effectiveness of health care. In recent years, LCF Research has expanded its activities beyond Lovelace Health Systems to conduct community-wide research initiatives, including the development and evaluation of a statewide health information exchange network.

### Affiliated health care and insurance provider(s)

Lovelace Health Systems is a health care delivery system based in Albuquerque, New Mexico that serves approximately 200,000 members statewide and includes Medicare, Medicaid, and commercial plans. The delivery system includes four hospitals. LHS has an affiliation with ABQ Health Partners, a 200-physician medical group, which operates 15 healthcare centers.

### Example partnerships

- ❖ ABQ Health Partners (State of New Mexico largest independent physician-owned group): ongoing consortium under a Master Research Agreement. Individual projects must be approved by ABQ HP as they arise.
- ❖ University of New Mexico School of Medicine (CTSA): Ad hoc investigator partnership
- ❖ Albuquerque VA: Ad hoc investigator partnerships.
- ❖ New Mexico Department of Health: Ad hoc contracts.

### Example studies

Title and PI	Study population	Description and available citations
<p>Evaluation of an Intervention to increase colorectal cancer screening in primary care clinics, PI: Montano, Daniel (Battelle Memorial Institute); Gunter Margaret (LCF Research)</p>	<p>2700 Patient Surveys; 714 Patient Intervention Educational Materials mailed; followed 13 months.</p>	<p>Real world intervention in primary care clinics based on patients scheduled primary care appointments made. The primary goal of the study is to evaluate and understand the effect of patient- and clinic-focused intervention components on CRC screening rates in primary care clinics. The specific objectives of the study are: (1) To successfully implement a patient-focused intervention and a clinic-focused intervention, designed to increase the CRC screening among average-risk male and female patients aged 50-75 years seen by primary care physicians, in two managed care organizations: Henry Ford Health System and Lovelace/ABQ Health Partners; (2) To assess the effects of the patient- and clinic-focused interventions and their interaction on increasing CRC screening, measured by the provision of FOBT, flexible sigmoidoscopy; colonoscopy, and/or double contrast barium enema; (3) To assess the effects of the patient- and clinic-focused interventions and their interaction on the intermediate outcomes of patient and clinician/clinic staff attitudes, opinions, beliefs, and social influence surrounding the CRC screening; (4) To assess and describe a casual/structural relationship between the patient- and clinic-focused interventions, intermediate outcomes (patient and clinician attitudes and beliefs) and CRC screening.</p>
<p>A New Method for Examining the Cost Savings of Reducing COPD Exacerbations, PI: Doug Mapel</p>		<p>Completely new cost modeling approach that uses actual COPD utilization data and exacerbation events to estimate the cost-benefit of newer COPD treatments. Background: Some treatments for COPD can reduce exacerbations, and thus could have a favorable impact on overall healthcare costs. This project evaluates the potential cost benefit of newer COPD controller medications based on the incidence of exacerbations and their related resource utilization in the general population. Methods: COPD patients (N = 1074) enrolled in one regional managed care system were identified using administrative data and divided by their medication use</p>

Title and PI	Study population	Description and available citations
		<p>into three groups (Albuterol, Ipratropium, and Salmeterol). Exacerbation events were captured using ICD-9 and CPT codes, and logistic regression models were created from this data that described the risk for exacerbations for each comparator group and exacerbation type over a 6-month period. A Monte Carlo simulation was then applied 1000 times to provide the range of potential exacerbation reductions and cost consequences in response to a range of hypothetical examples of COPD controller medications. Results: Exacerbation events for each group could be modeled such that the predicted events by the Monte Carlo estimates were very close to the actual prevalences. The estimated cost per exacerbation avoided depended on the incidence of exacerbation in the various subpopulations, the assumed relative risk reduction, the projected daily cost for new therapy, and the costs of exacerbation treatment. Conclusions: COPD exacerbation events can be accurately modeled from the healthcare utilization data of a defined cohort with sufficient accuracy for cost-benefit analysis. Treatments that reduce the risk or severity of exacerbations are likely to be cost-effective among those patients who have frequent exacerbations and hospitalizations.</p> <p>Citation: Shires, Divine et al. 2011</p>
<p>A population-based observational study examining the incidence of pneumonia among COPD patients using Advair, PI: Mapel, Douglas, LCF Research</p>	<p>5245 individuals who used some form of inhaled treatment during the study period, 2154 of whom had at least one pneumonia confirmed by chest X-ray or hospitalization.</p>	<p>Uses ‘real-life’ clinical data to examine the safety of COPD treatments. In recently published randomized clinical trials, COPD patients using inhaled corticosteroids (ICS) alone or in combination with long-acting beta-agonists (LABA) were found to have an increased risk for adverse event reports of pneumonia. The purpose of this project was to assess risk of diagnosed pneumonia among COPD patients in the general population who used a salmeterol/fluticasone propionate combination inhaler (SFC), ICS, or LABA, either alone or in combination as separate products, as compared to those using only short-acting bronchodilators (SABD). Methods: COPD patients were identified in three integrated health systems from different regions in the United States. Nested case-control methods were used to calculate</p>

Title and PI	Study population	Description and available citations
		<p>adjusted odds ratios (OR) for the risk of pneumonia while on therapy. Results: Relative to SABD, the only treatment associated with a non significant increased risk of pneumonia was ICS used alone (OR=1.29; 95%CI: 0.96-1.73; p=0.09). Users of LABA alone (OR=0.92; 95%CI: 0.69-1.22) or SFC (OR=1.03; 95%CI: 0.74-1.42) had no increased risk for pneumonia relative to SABD. Advanced age and severity of lung disease were strongly associated with increased risk for pneumonia. Conclusions: In this retrospective analysis of a large COPD cohort, treatment with an ICS or ICS and LABA in combination was not associated with a significantly increased risk for developing pneumonia.</p> <p>Citation: Mapel, Schum et al. 2010</p>
<p>Survival and hospitalizations among COPD patients using Fluticasone / Salmeterol in combination (Advair) versus other inhaled steroids and bronchodilators alone, PI: Mapel, Douglas, LCF Research</p>		<p>Uses 'real life' clinical data to examine the survival benefit of newer COPD treatments</p> <p>Citation: Mapel, Nelson et al. 2007</p>
<p>Journey for Control of Diabetes, PI: Sperl-Hillen, JoAnn, Health Partners; Beaton, Sally, LCF Research</p>	<p>621 patients randomized to three arms followed 48 months</p>	<p>Results of this trial could shed landmark evidence on several important questions: (1) Can a group education program improve behavioral and clinical outcomes for patients with diabetes who are not achieving optimal blood sugar control, (2) Can a group experience emphasizing group interaction and dialogue improve clinical and self-efficacy outcomes over existing individual based-education delivery.?</p> <p>The quality of diabetes care in the US is sub-optimal and has not</p>

Title and PI	Study population	Description and available citations
		<p>substantially improved over the last decade. Patient behavioral change and empowerment for self-management activities are key to improving diabetes care, but few patients currently receive the support they need to attain self-efficacy. Conversation maps, used as a conduit to facilitate interaction between providers and patients in a group self-management education setting, show promise to improve self-efficacy and thereby lead to improved self-management and better clinical outcomes. For patients with established type 2 diabetes not achieving optimal glycemic control, this randomized trial will formally compare the impact of an interactive group-based learning experience using conversation maps called IDEA (Interactive Dialogue to Educate and Activate) to the following interventions (1) education delivered on an individual basis by a nurse educator and dietitian consistent with maximum allowable reimbursement through Medicare and (2) usual care (care as recommended through the patient's usual providers). IDEA may provide a more effective model to improve quality of diabetes management and outcomes in many of the 21 million Americans with this devastating chronic disease.</p> <p>Citation: Beaton, Sperl-Hillen et al. 2010</p>
<p>A Report Card on Health Care for Minority Populations, PI: Nerenz, David (Overall PI, Henry Ford Health System); Gunter, Margaret (Site PI, LCF Research)</p>		<p>Early assessment of reasons for the lack of health plan data collection on race and ethnicity of members; led to increased national interest in issue, given its importance for population-based analysis of disparities among minority populations; also involved the assessment of disparities for African American and Hispanic members in two health plans--Henry Ford and Lovelace--which had the capability of identifying race and ethnicity of their members. Primary objective was to assess race and ethnic disparities in care among health plans. Since few health plans collected data on race and ethnicity of members, project sought to determine whether health plans could collect such data for various quality measures and whether these data could be used to create a report card on quality of care delivered to different racial and ethnic groups. In Phase II, eight health plans</p>

Title and PI	Study population	Description and available citations
		<p>participated in a demonstration project in which they collected race and ethnicity data from multiple sources (e.g., HEDIS) Results: Analyses indicated that minority groups often had lower rates than Caucasians in such areas as lower rates for African Americans in hemoglobin testing and appropriate asthma follow up. On some measures, however, especially for Medicaid plans, minority groups had higher quality of care scores than non-minority members. Recommendations: all health plans should be required to collect data on race and ethnicity of their members as part of accreditation by NCQA</p> <p>Citation: Nerenz, Bonham et al. 2002</p>

## Marshfield Clinic Research Foundation (Marshfield Clinic; Security Health Plan of Wisconsin)

### Website

[www.marshfieldclinic.org/Research](http://www.marshfieldclinic.org/Research)

### Population served

Marshfield Clinic serves 375,000 unique patients each year, 80,000 of which are part of a population-based geographically defined research study cohort (known as MESA). About 175,000 members are enrolled in the healthplan (SHP).

### Research center(s) and services

The Marshfield Clinic Research Foundation (MCRF) is a division of Marshfield Clinic. There are 5 research centers, including Epidemiology, Human Genetics, Clinical Research, Biomedical Informatics, and the National Farm Medicine Center.

The Epidemiology Research Center's Research Studies Unit provides survey and other data collection services to investigators at MC and close affiliates (e.g., UW).

The Clinical Research Center facilitates clinical research including clinical trials.

In addition to 25 doctoral level investigators in MCRF and an additional number of support scientists, the Clinical Research Center in MCRF also facilitates research conducted by around 150 clinicians throughout the Clinic system.

### Affiliated health care and insurance provider(s)

Marshfield Clinic is a multispecialty group physician practice with 740+ physicians that provides care to 370,000 unique patients each year and also owns and operates a mixed/network model HMO, Security Health Plan of Wisconsin, Inc. (SHP). The Clinic was incorporated under Wisconsin law in 1916 and operates as a charitable corporation. SHP was formed in 1986. SHP affiliated providers work primarily in 3 separate medical networks: Marshfield Clinic, Aspirus, and Ministry Medical

Group, but also include other individual providers and smaller group practices. However, most of SHP's ~175,000 members use the Marshfield Clinic network for their providers. Marshfield Clinic also recently took ownership/joint ownership of 2 hospitals that are among the 14 hospital affiliates of the Clinic in the region.

### Example partnerships

- ❖ University of Wisconsin Institute for Clinical and Translational Research – NIH CTSA award. As the University's primary external partner in this initiative, Marshfield Clinic is integrated throughout the cores of the Institute.
- ❖ HMO Research Network and related networks
- ❖ Wisconsin Genomics Initiative
- ❖ CDC and other organizations involved in influenza and influenza vaccine effectiveness research
- ❖ Wisconsin Network for Health Research
- ❖ Various National Farm Medicine Center collaborators in agricultural health and safety

### Example studies

Title and PI	Study population	Description and available citations
Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO), Local PI: Reding	~160,000 total; ~17,000 recruited by Marshfield Clinic Research Foundation; 13 years follow-up	<p>This is the largest cancer study done at Marshfield Clinic Research Foundation, one of just 10 sites in this 17+ year study; MCRF recruited and followed over 17,000 subjects from across the state. The project is a two-armed randomized clinical trial of 16 years duration involving ~78,000 females and ~78,000 males aged 55-74 at entry. Subjects will be randomized to two arms each containing 39,000 females and 39,000 males. Individuals in the control group will receive their usual medical care. Individuals in the group randomized to screening will receive screening examinations for lung and colorectal cancers and, depending on sex, either prostate or ovarian cancer.</p> <p>Citations: Buys, Partridge et al. 2011</p>
Community Clinical Oncology Program (CCOP), PI: Weiss		<p>Marshfield Clinic's CCOP program is one of 50 centers in the United States and one of two in the State of Wisconsin. This program has received sustained funding by the National Cancer Institute (NCI) since 1983. The goal of the CCOP program is to provide access to state-of the art cancer therapy in community based institutions. CCOP protocols are available through a broad network of cancer groups and projects including Eastern Cooperative Oncology Group (ECOG), National Surgical Adjuvant Breast and Bowel Project (NSABP), Children's Oncology Group (COG) University of Rochester Cancer Center (URC) MD Anderson Cancer Center (MDACC) CCOP research base, Cancer Trials Support Unit (CTSU) and Southwest Oncology Group (SWOG) Prostate Cancer Prevention.</p>

Title and PI	Study population	Description and available citations
Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) study., Local PI: Vidaillet	4060 from all centers, with 4 years follow-up	<p>In brief, the AFFIRM study was a multicenter trial which randomized 4060 patients with AF to either a rhythm-control or rate-control strategy. Patients were either &gt;65 years or, if &lt;65 years, had at least 1 risk factor for stroke. All patients received warfarin for anticoagulation. The goal for anticoagulation with warfarin was an international normalized ratio of 2 to 3.</p> <p>MCRF was the largest recruitment center among the 200 centers in the study.</p> <p>Citation: Fenwick, Marshall et al. 2008</p>
The Marshfield Epidemiologic Study Area (MESA), PI: Greenlee	80,000 at any given time. >160,000 in dynamic cohort since 1991. Up to 20 years follow-up for some cohort members.	<p>The Marshfield Epidemiologic Study Area (MESA) is a geographic region defined by zip codes where the great majority of residents choose to receive medical care at Marshfield Clinic, its regional centers and affiliated hospitals. Because Marshfield Clinic databases capture nearly all residents of the MESA region, research using MESA represents an entire population, not only specific subpopulations typically studied by major HMOs and insurance companies. In addition, through provision of primary, secondary and tertiary care, the full clinical spectrum of disease is represented, not only the more severe cases often studied at hospital- or referral-based research centers. Unlike most other research facilities, MESA researchers can monitor the residency of individuals on a daily basis by using updates of births, deaths, new patients, and name and address changes to Marshfield Clinic databases. This allows researchers to track the health of a community over time by linking this residency information with the extensive inpatient and outpatient health care information available in Marshfield Clinic databases and medical records</p> <p>Citations: Greenlee 2003; Greenlee and Vidaillet 2005; Sharma, Greenlee et al. 2007; Mareedu, Abdalrahman et al. 2010; Penniston, McLaren et al. 2011</p>

Title and PI	Study population	Description and available citations
Dental Informatics and Dental Care Delivery, PI: Acharya		<p>Marshfield Clinic Dental Centers were launched through a collaboration that includes Marshfield Clinic, Family Health Center of Marshfield, Inc., and federal and state agencies, in order to address the growing need for dental care in underserved areas. Currently, there are seven dental clinics in operation.</p> <p>To help integrate dental and medical health records and improve collaboration between dental and medical providers, Marshfield Clinic is one of few organizations nationally to develop an integrated dental module as part of its Cattails Software Suite. CattailsMDTM is the first provider-developed ambulatory electronic health record in the nation to achieve Certification Commission for Healthcare Information Technology certification and is used by about 14,000 providers and staff.</p> <p>Citations: Acharya 2009; Acharya 2010; Acharya, Mahnke et al. 2011</p>
Pharmacogenomics research; PI: Caldwell	20,000 in Personalized Medicine Research Project Database, plus collaborating site subjects.	<p>Makes use of our large population-based DNA biobank linked to extensive electronic medical record data, and longitudinal follow-up.</p> <p>Citations: Caldwell, Awad et al. 2008; McCarty and Wilke 2010</p>
Influenza Vaccine Efficacy and Influenza Control Research, PI: Belongia	Geographically-Defined Population-based outcomes not easily obtained elsewhere	<p>Dr. Belongia and colleagues are in the middle of project funding from the U.S. Centers for Disease Control and Prevention (CDC) to continue studies of influenza vaccine effectiveness for 3 years., in addition to CDC-supported flu vaccine effectiveness studies for the previous 4 years. New sites collaborating on this project include the University of Michigan, University of Rochester, and Vanderbilt University.</p> <p>Citations: Belongia, Kieke et al. 2011; Donahue, Coleman et al. 2011</p>

Title and PI	Study population	Description and available citations
<p>CMS Physician Group Practice Demonstration Project, PI: Praxel</p>		<p>10 large physician group practices evaluating the utility of enhanced management of selected chronic conditions in to improve outcomes and reduce costs for Medicare.</p> <p>One of only 2 out of 10 participating organizations to achieve targeted savings in all 5 years. Marshfield Clinic saved Medicare over 118 million dollars while improving the health of the targeted population.</p> <p>Citation: Iglehart 2011</p>
<p>Personalized Medicine Research Project, PI: Brilliant; McCarty (now at Essentia</p>	<p>20,000 with follow-up up to 20 years</p>	<p>Genetic information from our 20,000 participants forms a database enabling scientists to study which genes cause disease, which genes predict reactions to drugs, and how environment and genes work together to cause disease.</p> <p>The goal of this project is to learn how to apply genetic science to human health. This knowledge will help researchers develop new medications and diagnostic tests, and will enable physicians to prescribe medications that work best for a particular person.</p> <p>Citations: Giampietro, McCarty et al. 2010; McCarty, Chisholm et al. 2011; McCarty, Garber et al. 2011; Strobush, Berg et al. 2011</p>

Title and PI	Study population	Description and available citations
Biomedical Informatics, PI: Linn; Starren (now at Northwestern)		<p>Marshfield Clinic is a leader in development of electronic medical record systems, and in applied biomedical informatics research to improve clinical care delivery and quality.</p> <p>Biomedical Informatics at MCRF is organized into six units: Informatics Research Scientists; Biostatistics; Infrastructure and Central Resources (ICR); Research Analytics and Data Management (RADM); Interactive Clinical Design Institute (ICDI); Administrative Informatics Support (AIS)</p> <p>Citations: Huser, Rasmussen et al. 2011; Rasmussen, Peissig et al. 2011</p>
Institutional Clinical and Translational Science Award (CTSA), Dresner (UW Madison); Local PI: Vidaillet		<p>The objective of the award is to create an environment that facilitates the transformation of research at the University into a continuum extending from investigation through discovery to translation into practice, thereby linking even the most basic research to practical improvements in human health.</p> <p>MCRF is the only non-UW institution formally partnered on the award. MCRF director serves as associate director of the CTSA funded institute, and MCRF people serve in other leadership roles throughout the institute. MCRF work is embedded throughout the institute cores.</p> <p>Citation: Bernstam, Hersh et al. 2009</p>

# Meyers Primary Care Institute/University of Massachusetts Medical School | Fallon Community Health Plan | Reliant Medical Group

## Website

[www.umassmed.edu/meyers/index.aspx](http://www.umassmed.edu/meyers/index.aspx)

## Population served

200,000 members in Massachusetts.

## Research center(s) and services

Meyers Primary Care Institute (MPCI) is a joint endeavor of a health plan, medical group, and medical school: Fallon Community Health Plan, Reliant Medical Group, and University of Massachusetts Medical School. The Institute's mission is to promote primary care practice and population health through innovative research and educational initiatives.

## Affiliated health care and insurance provider(s)

Fallon Community Health Plan serves 200,000 members throughout Massachusetts. In 2007, it was rated by US News and World Report as having the nation's top Medicare and Medicaid Plans. Reliant Medical Group is a large multi-specialty medical group practice located throughout Central Massachusetts. Reliant Medical Group has more than 250 doctors providing healthcare services in more than 20 medical facilities.

## Example partnerships

- ❖ University of Massachusetts Medical School: Division of Geriatric Medicine and Departments of Pediatrics, Medicine, Family Medicine and Community Health, and Quantitative Health Sciences.

### Example studies

Title and PI	Study population	Description and available citations
<b>Heart and Vascular, Lung or Blood Disease</b>		
Worcester Heart Attack Community Surveillance Study (Worcester Heart Attack Study WHAS), PI: Goldberg	Study period 1975-2003	<p>The Worcester Heart Attack Study is an ongoing population-based investigation examining changing trends (1975-2003) in the incidence rates, hospital and post discharge death rates, occurrence of major clinical complications, and use of different management approaches in greater Worcester (MA) residents hospitalized with independently validated acute myocardial infarction (AMI) at all metropolitan Worcester hospitals. Secondary goals of this project are to examine changes over time in duration of prehospital delay following the onset of acute coronary symptoms and community mortality related to coronary heart disease (CHD) in the greater Worcester population.</p> <p>Citations: see <a href="http://clinicaltrials.gov/ct2/show/NCT00005196">http://clinicaltrials.gov/ct2/show/NCT00005196</a></p>
Monitoring Community Trends in Heart Failure (Worcester Heart Failure Study WHFS), PI: Goldberg	Study period 1995-2000	<p>The study uses residents of the Worcester (MA) metropolitan area (1990 census 437,000) and examines changes over time in these and additional outcomes for patients with validated heart failure during 1995 and 2000. Complimenting the hospital surveillance of heart failure, newly diagnosed cases of heart failure occurring in members of the largest HMO in Central Massachusetts during 1995 and 2000 will be identified and monitored over time. To accomplish the study objectives, the medical records of residents of the Worcester metropolitan area hospitalized with a discharge diagnosis of heart failure and related diagnostic rubrics will be individually reviewed and validated according to pre-established diagnostic criteria. The use of traditional criteria for heart failure as well as development of new criteria for the epidemiological study of heart failure will be an important focus of this observational study. Records for additional hospitalizations and death certificates will be reviewed to examine trends in long-term survival of</p>

Title and PI	Study population	Description and available citations
		<p>discharged hospital patients through the year 2005.</p> <p>Citations: Goldberg, Glatfelter et al. 2005; Goldberg, Spencer et al. 2005; Saczynski, Darling et al. 2009; Chinali, Joffe et al. 2010</p>
<b>Patient safety</b>		
Adverse Drug Events in the Nursing Home , PI: Gurwitz	18 nursing homes followed for 1 year	<p>Identified adverse drug events in 18 community nursing homes in Massachusetts during a 12 month period.</p> <p>Citations: Gurwitz, Field et al. 2000; Field, Gurwitz et al. 2001</p>
Adverse Drug Events in the Ambulatory Geriatric Setting, PI: Gurwitz	30,397 person years followed for 1 year	<p>Identified all adverse drug events among a cohort of older Medicare enrollees during a one year period.</p> <p>The specific aims for this study are to evaluate, among a population of older adults discharged from the hospital, the impact of an enhanced medication reconciliation system initiated upon transition to the ambulatory setting (1) on the rate of follow-up by an outpatient provider within 14 days of hospital discharge; (2) on the prevalence of appropriate monitoring for selected high risk medications at 30 days from the time of hospital discharge; (3) on the incidence of adverse drug events (ADEs) 30 days after discharge; and (4) on the rate of emergency department visits and hospital readmission within 30 days of discharge. A secondary aim for this study is to determine costs directly related to the development and installation of the HIT-based transitional care intervention. This research allows for the examination of an integrated HIT intervention on the quality of follow-up, outpatient clinician workflow, occurrence of ADEs, and health care utilization to gain insights into the effective use of clinical alerts and coordinated delivery of actionable information to outpatient clinicians in the management of ambulatory elderly patients subsequent to hospital discharge.</p>

Title and PI	Study population	Description and available citations
		<p>Citations: Gurwitz, Field et al. 2003; Field, Gurwitz et al. 2004; Field, Gilman et al. 2005; Field, Mazor et al. 2007</p>
<p>Improving Medication Safety Across Clinical Settings, PI: Bates and Gurwitz</p>	<p>25 nursing homes followed for 1 year</p>	<p>Study of incidence and preventability of warfarin-related adverse drug events in nursing homes.</p> <p>The common theme for this Center of Excellence is improvement of drug safety across the continuum of care in diverse patient groups. The six projects and two cores in this application extend previous studies to new populations and settings, as well as bring researchers together in synergistic ways through new working relationships.</p> <p>Citation: Gurwitz, Field et al. 2007</p>
<p>Enhancing the Safety of Warfarin in the Nursing Home, PI: Gurwitz</p>	<p>26 nursing homes followed for 1 year</p>	<p>Randomized trial of SBAR to improve warfarin management in nursing homes. Toolkit is now available on chainonline.org.</p> <p>Citations: Tjia, Mazor et al. 2009; Field, Tjia et al. 2011</p>
<p>Proactive Risk Reduction in Medication Prescribing in the Ambulatory Setting, PI: Field</p>	<p>N/A</p>	<p>Preparation for developing interventions. Two teams of clinicians developed fault trees to describe the system failure underlying adverse drug events.</p> <p>Aims are to 1. Use probabilistic risk assessment to a. characterize systemic and behavioral elements that increase the risk of serious errors in prescribing and monitoring medications for older adults in the ambulatory care setting and b. identify potentially high-yield and likely-to-be-successful interventions for lowering rates of preventable adverse drug events in that setting. 2. Estimate likelihood that interventions at any given step would be successful in reducing errors at that step and select interventions for implementation. 3. Develop action plans for implementing identified interventions.</p>

Title and PI	Study population	Description and available citations
Risk Informed Intervention to Improve Ambulatory Drug Monitoring and Safety, PI: Field		<p>Series of interventions to improve medication prescribing and monitoring, developed based on findings in the proactive risk reduction study.</p> <p>Citations: Fischer, Tjia et al. 2010; Tjia, Field et al. 2010; Tjia, Fischer et al. 2011</p>
Talking to Patients About Medical Errors: A Focus on Medication Errors, PI: Platt; Project Lead: Mazor	958	<p>This study will bring a patient-focused, evidence-based approach to discussions about disclosure of medical error. The study will gather information on patient preferences, the impact of specific communication strategies, and attitudes and beliefs about medical error. This information will guide providers in informing patients of medical errors and will help to reduce the barriers to openly discussing errors and preventable injuries.</p> <p>Citations: Mazor, Simon et al. 2004; Mazor, Simon et al. 2004; Mazor, Simon et al. 2005</p>
Talking to Patients About Medical Errors: A Focus on Medication Errors, PI: Mazor	307	<p>This study will bring a patient-focused, evidence-based approach to discussions about disclosure of medical error. The study will gather information on patient preferences, the impact of specific communication strategies, and attitudes and beliefs about medical error. This information will guide providers in informing patients of medical errors and will help to reduce the barriers to openly discussing errors and preventable injuries.</p> <p>Citation: Mazor, Reed et al. 2006</p>

Title and PI	Study population	Description and available citations
Teaching of Tomorrow, PI: Mazor	115	<p>Preceptors must respond to trainees' medical errors, but little is known about what factors influence their responses. In this study, 115 primary care preceptors from 16 medical schools responded to two medical error vignettes involving a trainee. Nine trainee-related factors were randomly varied. Preceptors indicated whether they would discuss what led to the error, provide reassurance, share responsibility, express disappointment, and adjust their written evaluation of the trainee. Results: Almost all preceptors would discuss what led to the error; relatively few would express disappointment. The trainee's prior history of errors, knowledge level relative to peers, receptivity to feedback, training level, emotional reaction, offering to apologize, and offering an excuse were predictive of preceptors' responses; gender and time-in-office were not.</p> <p>Citation: Mazor, Fischer et al. 2005</p>
<b>Health informatics</b>		
Reducing Adverse Drug Events in the Nursing Home, PI: Gurwitz and Field	2 nursing homes followed for 1 year	<p>Initial development of a computerized decision support system to improve safety of medication use in nursing homes.</p> <p>Medications are the single most common form of treatment in the long-term care setting, and often represent the most efficacious (and cost-effective) therapeutic modality used in this clinical setting. However, the residents of nursing homes are at increased risk for experiencing adverse drug events. This risk is increased by the physiologic decline and pharmacologic changes that occur with aging, and also by the special clinical and social circumstances that characterize institutional long-term care. This study tests whether a computer-based clinical decision support system can lower the rate of adverse drug events (ADEs) and potential ADEs in the long-term care setting. The study design is a randomized trial based in the resident care units of two large long-term care facilities. Within each</p>

Title and PI	Study population	Description and available citations
		<p>facility, half of the resident care units will be randomized to an intervention arm receiving the computer-based clinical decision support system which will display warnings, messages, and prompts based on resident and drug use characteristics; with over-rides by the prescriber required for some warnings. Rates of ADEs and potential ADEs will be tracked by the study's on-site clinical pharmacists prior to and during the intervention period. Rates will be compared between units receiving and not receiving the computer-based clinical decision support system and to baseline, pre-intervention rates in the same units. We will track all project costs directly related to the development and installation of the computer-based clinical decision support system. We will also develop and test the sensitivity and specificity of a computerized adverse drug event monitor and assess the validity of a nursing home resident risk model developed in our prior study of adverse drug events in the nursing home setting.</p> <p>Citations: Gurwitz, Field et al. 2005; Judge, Field et al. 2006; Rochon, Field et al. 2006; Gurwitz, Field et al. 2008</p>
<p>Health Information Technology in the Nursing Home, PI: Gurwitz</p>	<p>1 nursing home followed for multiple projects</p>	<p>Further development of HIT-based interventions to improve safety of medications in the nursing home setting.</p> <p>In this study, we intend to determine the extent to which a computer-based clinical decision-support system (accompanying computerized provider order-entry) can improve the quality of medication ordering and monitoring for residents in the long-term care setting through a randomized trial. We will track the costs associated with this system and the system's impact on the productivity of providers. We will also assess the culture of U.S. nursing homes and the organization of the nursing home setting with respect to readiness to incorporate computerized provider order-entry with computer-based clinical decision support. Our project addresses specific areas that are of particular interest to AHRQ with special relevance to the delivery of high-quality care to a priority population--the frail elderly</p>

Title and PI	Study population	Description and available citations
		<p>patient population residing in nursing homes. The project will assess the economic implications of health information technology in the nursing home environment that will be of interest to key stakeholders, including physicians, pharmacists, nurses, payers, policymakers, the nursing home industry, and pharmaceutical vendors to long-term care institutions.</p> <p>Citations: Subramanian, Hoover et al. 2007; Field, Rochon et al. 2008; Wolfstadt, Gurwitz et al. 2008</p>
<p>Improving Posthospital Medication Management for Older Adults Through HIT, PI: Gurwitz</p>	<p>1 hospital and 1 medical group followed for 1 year</p>	<p>Intervention connecting follow-up care needs of patients discharged from the hospital with primary care practitioners.</p> <p>The specific aims for this study are to evaluate, among a population of older adults discharged from the hospital, the impact of an enhanced medication reconciliation system initiated upon transition to the ambulatory setting: (1) on the rate of follow-up by an outpatient provider within 14 days of hospital discharge; (2) on the prevalence of appropriate monitoring for selected high risk medications at 30 days from the time of hospital discharge; (3) on the incidence of adverse drug events (ADEs) 30 days after discharge; and (4) on the rate of emergency department visits and hospital readmission within 30 days of discharge. A secondary aim for this study is to determine costs directly related to the development and installation of the HIT-based transitional care intervention. This research allows for the examination of an integrated HIT intervention on the quality of follow-up, outpatient clinician workflow, occurrence of ADEs, and health care utilization to gain insights into the effective use of clinical alerts and coordinated delivery of actionable information to outpatient clinicians in the management of ambulatory elderly patients subsequent to hospital discharge.</p>

Title and PI	Study population	Description and available citations
Using HIT to Improve Transitions of Complex Elderly Patients from SNF to Home, PI: Field		To facilitate high-quality transitions from the subacute to the ambulatory setting and support interdisciplinary communication, the investigators will use the EMR to assure that physicians in the ambulatory setting and visiting nurses receive key health information and alerts. In order to evaluate the impact of their HIT-based transitional care intervention, the investigators propose a randomized controlled trial with three arms: (1) HIT-based delivery of key health information and alerts to the primary care physician; (2) HIT-based delivery of key health information and alerts to both the primary care physician and the visiting nurse; and (3) usual care.
<b>Aging</b>		
Breast Cancer Treatment Effectiveness in Older Women (BOW I) and Long-term Survivorship in Older Women with Early Stage Breast Cancer (BOW II), PI: Silliman		<a href="http://www.appliedresearch.cancer.gov/research/highlights/older.html">http://www.appliedresearch.cancer.gov/research/highlights/older.html</a>
Optimizing Chronic Disease Prevention and Management in Advanced Dementia, PI: Tjia	Minimum Data Set – Part D – OSCAR – Medicare data for 5 large states. 2 years F/U.	An estimated 1.8 million people in the United States are living with advanced dementia and are unable to recognize family, unable to communicate, and are physically dependent in activities of daily living. These patients use excessively complex medication regimens without good evidence that doing so will improve their survival or quality of life. Since unnecessary and inappropriate medication use in this population increases the risk of injury from adverse drug events and contributes to rising healthcare costs, this comparative effectiveness study seeks to improve prescribing by examining medication effectiveness and drug withdrawal safety in this vulnerable and understudied population.

Title and PI	Study population	Description and available citations
Patient Centered Prescribing for Medically Complex Older Adults with Cancer, PI: Tjia	30 hospice patients and their caregivers with advanced cancer followed for 2 years	Citation: Tjia, Rothman et al. 2010 Dr. Tjia will use a combination of qualitative interviews and quantitative medication assessments to understand how current approaches to patient-physician communication and interdisciplinary care coordination affect medication management of older patients with cancer. The goal of her work is to develop a structured approach to help reduce the burden of unnecessary medication use in older adults with life limiting illness.
<b>Aging and Pharmacoepidemiology</b>		
iADAPT: Off-Label Use of Antipsychotics in the Nursing Home, PI: Gurwitz		AIM 1: NEEDS ASSESSMENT To conduct a needs assessment for the NH setting relevant to the AHRQ Comparative Effectiveness Research Summary Guide (CERSG) entitled "Off-Label Use of Atypical Antipsychotic Drugs." The assessment will identify: (a) interest in and barriers to the use of the AHRQ atypical antipsychotic CERSG in the NH setting; (b) the key audiences and stakeholders that influence atypical antipsychotic drug use in NHs; and (c) approaches to integrating comparative effectiveness research products into the NH setting. AIM 2: PRODUCTION OF THE TOOLKIT Guided by the needs assessment, the investigators will produce a toolkit containing tailored CERSG-based products targeting key audiences and stakeholders in the NH setting. The target audience(s) of the final CERSG-based products will be identified in Aim 1, and will potentially include: (a) facility leadership [NH administrator, Medical Director, Director of Nursing]; (b) prescribers and consultant pharmacists; (c) nursing staff [registered nurses, licensed practical nurses, and certified nurse assistants]. AIM 3: EVALUATING THE EFFECTIVENESS OF THE TOOLKIT To evaluate the effectiveness of the toolkit and three dissemination strategies using a matched, cluster randomized trial. NHs in the first arm will receive the toolkit only and web access to the materials; NHs in the second arm will receive the toolkit, web access, periodic audit and feedback reports of antipsychotic prescribing to NH leadership, and faxed educational messages adapted from the AHRQ

Title and PI	Study population	Description and available citations
		<p>atypical antipsychotic CERSG to prescribers; and NHs in the third arm will receive the previous items plus face-to-face academic detailing. Primary outcomes of the evaluation are the RE-AIM evaluation domains (reach, efficacy, adoption, implementation, and maintenance).The investigators will also include an assessment of facility-level changes in the use of atypical antipsychotic drugs.</p>
<p>Impact of MMA Drug Exclusions on Dually-Eligible Medicare Residents in Nursing Homes, PI: Briesacher</p>	<p>861,082</p>	<p>OBJECTIVES: To assess the impact of Medicare Part D in the nursing home (NH) setting. DESIGN: A population-based study using 2005/06 prescription dispensing records, Poisson regressions with generalized estimating equations, and interrupted times series estimation with segmented regression methods. SETTING: Nursing Homes. PARTICIPANTS: A nationwide sample of long-stay Medicare enrollees in NHs (N=861,082). MEASUREMENTS: Probability of Part D enrollment, changes in source of drug payments, changes in average number of monthly prescriptions dispensed per resident. RESULTS: In 2006, 81.0% of NH residents were enrolled in Part D, 16.1% had other drug coverage, and 3.0% (n=11,000) remained without drug coverage, which was the same rate of no drug coverage as in 2005. NH residents who did not enroll in Part D were the oldest (relative risk (RR)=0.82, P&lt;.001), had no drug coverage in 2005 (RR=0.84, P&lt;.001), and had high comorbidity burden (RR=0.94, P&lt;.001). The proportion of prescription drugs paid out of pocket decreased from 11.0% in 2005 to 8.1% in 2006 (P&lt;.001). Average monthly prescription use per resident in 2006 decreased by half a prescription from 2005 levels (9.6 vs 10.1, P=.003). CONCLUSION: Part D decreased some out-of-pocket drug costs but did not expand drug coverage in the NH population or reach some vulnerable segments. Part D was also associated with some disruption in NH drug use, especially right after implementation.</p> <p>Citations: Briesacher, Soumerai et al. 2009; Briesacher, Soumerai et al. 2010; Chen, Briesacher et al. 2010</p>

Title and PI	Study population	Description and available citations
<b>Patient Decision Making and Health Literacy</b>		
Health Literacy and Cancer Prevention: Do People Understand What They Hear?, PI: azor	1074 followed for 5 years	<p>The specific aims are: 1) to develop and validate a psychometrically sound test of Health Literacy-Oral, 2) to investigate the relationship between health literacy-oral and cancer prevention behaviors and 3) to develop and test recommendations for improving oral communication about cancer prevention and screening. Test development will include identification of authentic health messages about cancer and cancer prevention. Item development will be iterative, with items generated and reviewed by a team of experts in psychometrics, physician-patient communication, health communication, language comprehension and cancer.</p> <p>Citation: Mazor, Calvi et al. 2010</p>
<b>Qualitative Methods</b>		
Cluster Randomized Trials: Ethical Issues and Practical Constraints, PI: Platt; Project Lead: Mazor	84 qualitative in-depth telephone interviews were conducted; 50 with health plan members, 21 with providers, and 13 with purchasers.	<p>The purpose of this study is to learn more about stakeholders' views about a particular type of research design called a cluster randomized trial (CRT). The study will focus on opinions about using CRTs in large healthcare organizations to study the relative effectiveness of alternative medications.</p> <p>Citations: Mazor, Sabin et al. 2007; Sabin, Mazor et al. 2008; Mazor, Sabin et al. 2009</p>
<b>Qualitative Methods &amp; Patient Safety</b>		
Effective Communication for Preventing and Responding to Oncology Adverse Events, PI: Mazor and Gallagher		<p>Background: Effective patient-provider communication is essential for high quality healthcare, and involves both preventing lapses in quality from occurring and responding to adverse events and medical errors when they happen. Effective communication with patients is especially challenging in oncology where communication breakdowns lead directly to adverse events or errors, such as when confusing instructions impair patients'</p>

Title and PI	Study population	Description and available citations
		adherence to chemotherapy. Specific aims: 1. To describe patients' experiences with communication around adverse events and errors in cancer care; 2. To describe providers' experiences with communication around adverse events and errors in cancer care; 3. To develop practical recommendations, provider training materials and patient informational materials for improving communication around adverse events and errors in cancer care; 4. To disseminate the recommendations and materials (Aim 3) through three health plans; 5. To conduct a preliminary evaluation of the perceived usefulness and impact of the materials.
Teaching and Learning about Medical Errors Teaching of Tomorrow, PI: Mazor	35 parents; 38 primary care preceptors	Citation: Mazor, Fischer et al. 2005
<b>Pharmacoepidemiology</b>		
Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP), PI: Richard Platt	Large cohort of pregnant women receiving care from 11 organizations in 9 states, allowing assessment of medication use during pregnancy and birth outcome. Includes 1.2 million infants delivered to 933,000 women from 2000-2008.	Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP), a collaborative research program between the U.S. Food and Drug Administration and three contract sites. The eleven research institutions collaborating on the project provide access to health plan data of approximately 12 million current enrollees within nine states, covering geographically and ethnically diverse populations with a broad age range for a wide array of medical care delivery models. To support multi-site studies, the health plans have extracted information on maternal and infant enrollment, demographics, outpatient pharmacy dispensings, and outpatient and inpatient health care encounters from their administrative and claims databases. They have linked the health plan data to the birth certificate data obtained from the state departments of public health, which include information on sociodemographic, medical, and reproductive factors, such as gestational age, race/ethnicity, and parity. All data have been transformed into de-identified, standardized datasets.

<b>Title and PI</b>	<b>Study population</b>	<b>Description and available citations</b>
Assessing and Improving Arthritis Medication Adherence: Gout as a Model, PI: Harrold	Up to 4,200	Provides a comprehensive evaluation of nonadherence with urate-lowering drugs in gout patients and the barriers to adherence. Lays the foundation of an intervention study.
HMORN CERT3-Risk of Serious Infection with Biological Therapy, PI: Herrinton; Co-Investigator Harrold	Up to 33,500	The aims of this project are to enhance the ability of the HMORN and collaborating health plans to advance therapeutics knowledge by leveraging data sources within a large, generalizable population and to develop and implement new methods for disseminating and promoting best therapeutic practices.

## Scott & White Division of Research & Education

### Website

researchers.sw.org/home

### Population served

Approximately 200,000 members in 18 counties of central Texas, including a large rural area and a high concentration of military families with specific health concerns.

### Research center(s) and services

Scott & White's mission is to provide the most personalized, comprehensive, and highest quality health care, enhanced by medical education and research. The Center for Applied Health Research (CAHR) is a federation of research programs formed with the support of Scott and White Healthcare, the Central Texas Veterans Health Care System, and the Texas A&M Health Science Center. CAHR's mission is to facilitate the integration of health research focused on improving care delivery and the wellbeing of our community. Its research efforts are supported by Academic Operations, which provides services to researchers in all disciplines and at all Scott & White campuses. Additional research services include a laboratory and GMP manufacturing facility.

### Affiliated health care and insurance provider(s)

Scott and White is a not-for-profit, multispecialty academic medical center affiliated with the Texas A&M Health Science Center and one of the largest multi-specialty group practices in the United States. Scott and White now provides for the health care needs of the majority of Central Texans. The network includes more than 60 facilities (clinics, hospitals and administrative offices). Scott & White offers a complete service line. It owns and operates a 636-bed specialty care and teaching hospital in Temple, Level-I Trauma center, 76-bed acute care hospital in Round Rock, 50-bed long term care hospital in Temple,

clinics throughout Central Texas, and additional specialty care facilities.

### Example partnerships

- ❖ Texas A&M Health Science Center College of Medicine – School of Rural Public Health
- ❖ Central Texas Veterans Health Care System
- ❖ Baylor University
- ❖ Texas AgriLife Research
- ❖ University of Texas, College of pharmacy: Over 15 years of collaboration, especially in health Economics and Outcomes Research.

### Example studies

Title and PI	Study population	Description and available citations
Community Research Center for Senior Health, PI: Alan Stevens	Three year follow up	<p>This project involves development of a multidisciplinary comprehensive senior healthcare center, implementation of various needs assessments and training for stakeholders and researchers, and process and outcome evaluation of these initiatives. Center activities will address three specific aims. Aim 1 is focused on the creation of a sustainable infrastructure that promotes an interdisciplinary and multi-contextual approach to Senior health intervention research. Aim 2 is about further developing community-academic health center relationships which foster community participation in research planning, study participation, and dissemination of findings. Aim 3 is to provide guidance and support to investigators and community leaders in research design, evaluation, and data analytic techniques that balance the need for rigorous science and the practical realities of conducting health research in community settings.</p> <p>The project is significant in its adaptation of the Expanded Chronic Care Model as a theoretical basis. It involves a strong team of academic, community and public service partners, including senior networks, to address social and behavioral aspects of the health of seniors.</p>
Scott & White Family Caregiver Program, PI: Alan Stevens	Six month follow up	<p>The goal of the Scott &amp; White Family Caregiver Program (FCP) is to identify hospital patients with dementia and their family caregivers, identify the needs of the family caregiver, provide effective support to family caregivers by integrating an evidence-based intervention into standard practices of care within Scott &amp; White. This project targets individuals with dementia who are hospitalized because this is a time in which the patient and family caregiver are at high risk for poor outcomes, including institutionalized long term care for the patient and high levels of stress for the family caregiver.</p>

Title and PI	Study population	Description and available citations
The Central Texas Community Living Program, PI: Alan Stevens	149 followed for 10 months	<p>The project targets persons at risk of nursing home placement and spend-down to Medicaid.</p> <p>The goal of this study was to establish a nursing facility diversion program for individuals at imminent risk for nursing home placement and spend down to Medicaid using more flexible administrative processes and funding mechanism.</p>
Patterns of Late-Life Healthcare among VA Patients with Schizophrenia, PI: Copeland	242,898 followed for 4 years	<p>Nationwide cohort of older patients with chronic disease (schizophrenia and/or diabetes) identified mortality risks associated with losing contact with the healthcare system for 12 or more months and failure to test for or treat patients at risk for dysglycemia.</p> <p>The goals of the study were to analyze VA health care data (FY02-FY05) on veterans age 50 or older with schizophrenia, diabetes, or both schizophrenia and diabetes to compare patterns of care (inpatient, outpatient, medical, psychiatric, prescription profiles and clinical monitoring), and assess the impact of patterns of care on mortality.</p> <p>Citations: Copeland, Zeber et al. 2009; Copeland, Parchman et al. 2010; Dassori, Copeland et al. 2011</p>

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## VII. References

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