

Data Sharing and Data Access in Multi-site Projects: Lessons from the VSD, CRN and CERT Projects

The session leader will be:

Robert L. Davis, MD, MPH, Group Health Cooperative and University of Washington

The panelists will be

Arnold Chan MD, Harvard Medical School

William Barlow PhD, Group Health Cooperative

David Shay, MD, MPH Centers for Disease Control

In this session we will discuss the benefits, and risks, of sharing data in large multisite collaborative projects. We will review the three current methods of sharing data utilized by the Vaccine Safety Datalink Project, the Center for Education and Research on Therapeutics, and the Cancer Research Network. These methods include: (1) The creation of centralized data, with some method centralization, and with the analysis being performed either at the PI's site or at the central coordinating center; (2) The creation of decentralized data, with methods written centrally for an individual project, programs run at each site, only small amounts of centralized data, and analysis centralized; (3) The creation of decentralized data, with methods written at project PI's site, modified by each site, and project data sent to PI's site. In this scenario the analysis is done at PI's site. We will discuss the efficiencies of each method, as well as the problems created. Finally, we will discuss how each of these data sharing arrangements may change in the current climate of concerns over data confidentiality, congressional subpoenas, and HIPAA.

Objectives:

1. Summarize current ways that the Vaccine Safety Datalink, the HMO Research CERT project, and the Cancer Research Network share data across their respective collaborative projects.
2. Assess the strengths and weaknesses of each mechanism.
3. Identify major future challenges and likely changes in light of future federal confidentiality regulations, and increased requests for these types of data by outside parties.

Distributed Data Development In Multi-Site Studies

K. Arnold Chan, MD, ScD, Harvard School of Public Health

The HMO Research Network CERTs has used the distributed data development model for a number of multi-HMO research projects. In this model, programmers/analysts at each study site prepare raw data according to data format specified by the Data Center. For epidemiology or health services research studies, the requisite data are demographic, membership, drug dispensing, and utilization (ambulatory visits and hospitalizations) information. After the standard data files are generated, a series of SAS programs are then distributed from the Data Center and executed at the study sites. These SAS programs are standardized and tested at one or more study sites before distribution and require minimal modification before execution.

For descriptive studies, individual level data are processed at each study site and only aggregate data are forwarded to the Data Center for final analysis. For studies that require individual level data for regression analysis, the SAS programs generate highly refined individual level data with derived variables, replace the health plan identification number with a randomly generated study number, and obscure variables related to personal identification (e.g. date of birth) to protect confidentiality. Only data elements that are needed to support the final analysis are forwarded to the Data Center to generate the final analytic data set. Examples drawn from previous studies will be used throughout the presentation to illustrate the above concept.

Research on Improving Cultural and Linguistic Competence

The session leader will be:
Margaret J. Gunter, PhD, Lovelace Clinic Foundation

The panelists will be
Cindy Brach, MPP, Agency for Healthcare Research and Quality
David R. Nerenz, PhD, Michigan State University
Kathryn Paez, MSN, MBA, Lovelace Clinic Foundation.

This concurrent 1.5 hour session will use the format of a moderator and a panel of three presenters, followed by active audience participation. The purpose of the session is to equip researchers to conduct research on improving health care for minority populations. Key methodological and practical issues will be addressed. Specifically, the session presenters will address the following topics:

- A conceptual model of how culturally and linguistically appropriate services (CLAS) may reduce disparities.
- A literature review on CLAS interventions' impact on health care delivery and outcomes
- The federal research agenda for cultural competence in health care
- Methods for assessing race, ethnicity, and language in a population and barriers to such assessment
- Description of a project to develop a health plan-level report card on CLC and disparities, including a discussion of indicators of relevance to minority populations and emergent research questions to be pursued in subsequent research.

A significant portion of the session will be devoted to interaction between the panel and researchers in the audience, to facilitate the sharing of insights, methods, and tools derived from a variety of managed CLAS care-based studies.

Objectives:

1. Describe a conceptual model of how culturally and linguistically appropriate services (CLAS) may reduce disparities
2. Describe three methods for assessing race, ethnicity, and language in a population and associated barriers
3. Describe key components and research questions of a federal research agenda for cultural competence in health care

Privacy Laws and Compliance: Job Search or Should I Have the Keys?

The session leader will be:

Andrew F. Nelson, MPH – HealthPartners Research Foundation

The panelist will be

Pierre-Andre La Chance – Kaiser Permanente Northwest

A rapidly changing, regulatory environment will forever influence research access to medical information. Will researchers and research collaborations between organizations be permitted to continue? The HIPAA, Gramm-Leach-Bliley and multiple state laws are going to redefine access to identifiable research health data. These complex and often conflicting laws are threatening present and future health research. This session will provide a summary of new regulations, compliance requirement and tools that researchers will need to continue their work. Bring your concerns, knowledge and ideas that will help you and your colleagues survive this new era.

Clinical Information System Research: Current Activities and Future Prospects

The session leader will be:

Dean F. Sittig, Ph.D. - Senior Informatics Researcher
Kaiser Permanente, Center for Health Research - Portland, OR

Other Speakers on the panel:

John Hsu, MD, MBA, MSCE, Physician Scientist
Kaiser Permanente, Division of Research, Oakland, CA

Ted E. Palen, Ph.D., MD, MSPH, Clinician Researcher
Informatics Department, Colorado Permanente Medical Group, Denver, CO

William A. Rush, Ph.D., Research Associate
HealthPartners Research Foundation, Minneapolis, MN

Michael A. Bodily, MBA, Systems Architecture Consultant
Kaiser Permanente, Colorado Region, Denver, CO

Clinical Information Systems (CISs) could drive progress in healthcare in the 21st century. We must accelerate our research efforts to examine both the technical and organizational or social issues surrounding these complex systems to truly understand their potential uses, benefits and impacts on healthcare delivery overall. The goal of this panel presentation is to describe a potential CIS research agenda that could be carried out within any large HMO and to address several key issues that researchers have experienced, or foresee affecting CIS research. Following a brief introduction on these topics, we have four speakers who will each describe various aspects of CIS research projects. Specifically, John Hsu will describe several operational issues he faced during a recent project that examined the use of computers by clinicians in the examination room. Ted Palen will then discuss some of the issues facing those who would like to perform collaborative research using CIS data in light of the impending HIPAA regulations. Next William Rush will describe work that he has been doing to expand the utility of routinely collected CIS data for research purposes. Finally, Mike Bodily will discuss the application of widespread surveillance techniques using data from individual patient charts extracted from a CIS. Following completion of these short presentations, the audience will have the opportunity to ask questions and comment on these ideas.

Preparation for Research: Training and Staff Development A panel discussion

The session leader will be:
Pamela S. Anstine, MA
Associate Director-Operations
Center for Health Studies- Group Health Cooperative

The panelists will be
Patricia Karlen
Assistant Manager, Clinical Services
Center for Health Research-Kaiser Northwest

Ellen J. Gordon, PhD
Program Director- Survey Research
Center for Health Studies- Group Health Cooperative

Virginia Immanuel, MPH
Sr. Manager, Information Technology
Center for Health Studies-Group Health Cooperative

Approaches to training and staff development for a research organization will be examined by looking at resources found at the Center for Health Studies (CHS) and the Center for Health Research (CHR). This discussion will provide an overview of how organizational structure can support and influence methods for training and facilitate the development of the core competencies needed for conducting research. Quality assurance, adherence to research protocols, issues of compliance and quality standards will be addressed. The discussion will focus specifically on the training associated with survey research, programming and statistical analysis and conducting clinical trials.

The Role of Mathematical Models in Designing and Applying Clinical Research: Help, Hindrance Or Hoax?

The speaker will be:
David M Eddy MD, PhD
Senior Advisor for Health Policy and Management
Kaiser Permanente Southern California

Properly designed and validated mathematical models can help with the design, interpretation and extension of clinical research. This talk will illustrate the potential relationship between mathematical models and clinical research by describing and applying a particular model called Archimedes. Archimedes is a comprehensive, object-oriented, continuous-time, physiology-based model. It creates a "virtual world" at the level of detail at which clinical and administrative decisions are made.

Because it can address a high level of physiological and clinical detail, Archimedes can be used to simulate existing and future clinical trials. Independent simulations (which did not use the results of the trials) of four trials of coronary artery disease and two trials of diabetes and its complications have shown very close agreement. This suggests that the virtual world in the model is a fairly accurate representation of the real world, at least for the specific conditions and treatments covered by these trials. The potential role of Archimedes in designing, interpreting and extending clinical research will be illustrated with three examples drawn from the recently published Diabetes Prevention Program.

Empirical observations from clinical research are always preferred to projections from mathematical models. However, when it is not feasible to answer a question by doing new research – because of cost, duration, multitude of options, rapidly changing technologies, or unwillingness of patients or physicians to participate – mathematical models can be helpful in both designing new research and in squeezing the most understanding possible from existing research.

State of the HMO Research Network Address

Dennis D. Tolsma, MPH
Director of Research, Kaiser Permanente, Georgia

The State of the Network is a report from the Chair of the Governing Board to the attendees at the annual meeting. The Chair will discuss attainment of the Network's objectives and strategic planning for the future.

Clinical Trials Compliance Quality Improvement: Avoiding the Belly of the Beast

The session leader will be:

Steven Black, MD - Kaiser Permanente Northern California

The Panelists and their Topics are:

Building Blocks for a Clinical Trials Compliance Program:

The Kaiser Permanente Experience

Nancy King, MPA, MED, Kaiser Foundation Research Institute
and Steven Black, MD, Kaiser Permanente Northern California

Dealing with the Trials of Clinical Trials

Calvin Cohen, MD - Harvard Vanguard Health Program

Web Based Training for Clinical Trials: The HealthPartners Experience

Betty Jo Haggerty, MS, FNP - Health Partners

Over the past decade, HMOs have been increasingly recognized as the ideal location to perform population based health services research. Because of their ability to perform epidemiologic and outcome studies on a defined population, the number of clinical trials performed within HMOs has increased dramatically. In many cases, studies performed within these populations have provided unique contributions to public health knowledge and have speeded the availability of life saving drugs and vaccines.

With growth and expanded scope has come expanded responsibility and scrutiny. The regulatory environment in the Clinical Trials arena has become increasingly complicated and the threat of audits by the FDA and other government agencies increasingly real. During this session we will review the recent history of regulatory activities in this area, discuss the building blocks for developing a comprehensive clinical trials compliance assessment and improvement program, discuss the challenges and barriers to developing such programs from the perspective of the participating institutions, and discuss the various options the participating institutions have explored to bring such a program to fruition. Although all of us face these challenges together, the participating speakers are at different stages of this process and have taken different approaches. We hope to share our "learnings" to date and encourage the audience to participate in discussing problems and potential solutions for improving clinical trials compliance.

Objectives

1. Participants will be aware of the changing regulatory environment for clinical trials research
2. Participants will be aware of the challenges of developing a compliance program for clinical trials
3. Participants will be aware of approaches that have been taken by the presenting organizations to develop a compliance program

Practical Clinical Trials

The session leader will be:
Joe Selby, MD, MPH
Kaiser Permanente Northern California

Panelists:
Sean Tunis, MD, MSc, Center for Medicare & Medicaid Services
Dan Cherkin, PhD, Group Health Cooperative Center for Health Studies
David Campen, MD, Kaiser Permanente Northern California

Objectives

1. To describe the features of practical (pragmatic) clinical trials – Sean Tunis
2. To illustrate the daily examples of questions that can only be answered by practical clinical trials - David Campen
3. To review a successful practical clinical trial - Dan Cherkin
4. To consider the idea that the HMO RN is well positioned to promote the implementation of more such trials and to discuss some of the possible barriers and other issues related to conduct of such trials – Joe Selby and panel

Scientific Sessions of the Cancer Research Network

The sessions presenters are:
Ed Wagner, MD, MPH
Group Health Cooperative

Lisa Herrington, PhD
Kaiser Permanente Northern California

Stephen Taplin, MD, MPH
Group Health Cooperative

Victor Stevens, PhD
Kaiser Permanente Northwest

Objectives:

- 1) To disseminate preliminary scientific findings from three diverse cancer research projects to HMO Network colleagues.
- 2) To provide a forum to discuss what CRN has learned and gained from this complex multi-site collaboration.
- 3) To begin generating ideas for future collaborations.

Hospital Volume and Quality: Weighing the Evidence

The session leader will be:

Michael Finch, PhD

Center for Health Care Policy and Evaluation,
United Health Care Group

The participants are:

Jennifer Frytak, PhD

Center for Health Care Policy and Evaluation,
United Health Care Group

David J. Magid, MD

Kaiser Permanente Colorado

Brent Asplin, MD

HeathPartners Research Foundation

The purpose of the session is to introduce the audience to the hospital volume/quality discussion. Each paper stresses the importance of moving beyond simple description to a better understanding of underlying relationships. One focuses on the use of raw volume standards in the quality purchasing arena, another illuminates the complexity of the underlying relationship between hospital procedure volume and quality. The third paper examines the effects of too much volume: over crowding in emergency departments.

What Are/Should We Be Doing in Patient Safety Research?

The session leader is:

Richard Platt, MD, MSC, Harvard Medical School/Pilgrim Health Care

The panelists are:

Michael Goodman, PhD, HealthPartners Research Foundation

David Magid, MD, MPH, Kaiser Permanente Colorado Clinical Research Unit

David H. Smith, RPh, PhD, Center for Health Research, Kaiser Permanente Northwest

Kathleen M. Mazor, EdD, Meyers Primary Care Institute

This session will assess domains of safety research of interest to HMOs and which HMOs are well suited to perform. It will use current research in Network HMOs on medication safety to illustrate several types of inquiry. These include characterization of the frequency of unsafe medication use, assessment of the impact of practice organization on prescribing safety, design and implementation of interventions to improve prescribing, and communicating with members after an error occurs. These themes will be used to address both strengths and weaknesses of HMOs to address safety needs. Presenters and the audience will discuss the most important patient safety topics that should be addressed."

Objectives:

1. Summarize current HMO Research Network safety research, focusing on medication use.
2. Assess the strengths and weaknesses of HMOs as venues for safety research.
3. Identify major areas of need in patient safety research.

Tobacco Cessation Services in Non-profit Health Maintenance Organizations: A Progress Report from Project HIT

The presenter will be:

Victor J. Stevens, PhD

Kaiser Permanente Center for Health Research

This project assessed implementation of tobacco control policies and cessation outcomes in nine non-profit health maintenance organizations across the United States. These HMOs provide comprehensive care to 8.7 million individuals, including 30% minority enrollment. A survey of 41,677 randomly selected adult, primary care patients provides a description of attitudes toward smoking cessation and a progress report on the implementation of tobacco cessation services. Of the 5,724 respondents who used tobacco in the previous 12 months, 21% reported not smoking at the time of the survey. Of those smoking at the time of the survey, 27% were planning to quit in the next 30 days, and 42% reported seriously considering quitting in the next 6 months. Of those who were smoking at their last primary care visit, 75% reported being asked about tobacco use, more than 60% reported receiving advice to quit, and 28% received some form of assistance in quitting (counseling, pharmacotherapy, or combination). Of particular interest, 82% of the current smokers indicated that they felt that patients should be asked about tobacco use "often" or "at every visit". Smokers receiving advice to quit reported greater satisfaction with their health plan than those who did not receive advice, a finding consistent with several recent studies showing higher patient satisfaction with medical care when they receive advice and assistance in quitting smoking. Results of a one-year follow-up survey of smokers and recent quitters will also be presented including descriptions of smoking cessation services received, and tobacco use outcomes.