

Sixth Annual HMO Research Network Conference

April 4-5, 2000
Grand Hyatt Atlanta in Buckhead
Atlanta, Georgia

Conference Summary

AGENDA 2000:
Research
that
net Works

*Co-hosted by Kaiser Permanente Georgia and USQA
Center for Health Care ResearchTM, with sponsorship
from the Agency for Healthcare Research and Quality
and the Centers for Disease Control and Prevention*

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Session Chair: Nancy King, Kaiser Foundation Research Institute
Speakers: Steve Stoller, PhD, MPH, Kaiser Foundation Research Institute

2000 HMO Research Network Conference

Overview

Nearly 200 researchers attended the sixth annual conference of the HMO Research Network held in Atlanta, GA, April 4-5, 2000. The conference was co-hosted by Kaiser Permanente Georgia and USQA Center for Health Care Research™. This report captures the content of the conference sessions, as recorded by volunteer note-takers (to whom we are very grateful) and reviewed by conference staff. In addition to the regular speaker plenaries and concurrent sessions described in this report, highlights of the 2000 conference included:

- Two poster sessions with 48 research and collaborative organization presentations
- A reception welcoming junior investigators to the Network
- Roundtable discussions for networking opportunities
- 13 study-specific work sessions.

Acknowledgements

The HMO Research Network gratefully acknowledges the following organizations for their financial support and assistance with this conference: Agency for Healthcare Research and Quality and Centers for Disease Control and Prevention.

HMO Research Network Governing Board (current April 2000)

Arne Beck	Kaiser Permanente Colorado
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Joe Selby	Division of Research, Kaiser Permanente Northern CA
Dennis Tolsma	Kaiser Permanente Georgia
Tom Vogt	Kaiser Permanente Hawaii
Ed Wagner	Group Health Cooperative of Puget Sound

Conference Coordination

Kaiser Permanente Georgia and the USQA Center for Health Care Research™ gratefully acknowledge the exceptional work of the conference planning committee, session organizers, staff and volunteers who have all contributed to the success of this conference.

Conference Planning Committee

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Ed Wagner	Group Health Cooperative of Puget Sound

Conference Staff and Volunteers

Toya Arrington, USQA; Robby Diseker, KP-GA; Jonathan Hawley, USQA; Robin Hudson, USQA;
Judy Hughes, KP-GA (staff); Jeanne Jordan, KP-GA; Melissa Roberts, KP-GA; Maddie Saluzzi, KP-GA;
Linda Schuessler, USQA (staff); Doug Sinclair, KP-GA (staff); Beverly Terrell, USQA (staff);
Michelle Tropper, ACHP; Roseanne Waters, USQA; Candy Webster, KP-GA (staff)

*A special thanks to the session volunteer note-takers: Michelle Tropper, Robin Hudson, Melissa Roberts,
Doug Sinclair, Roseanne Waters.*

Conference Planning Support

Finally, we gratefully acknowledge the planning support and guidance of Jill Arent, Galen Miller, and Barbara Ketcham at AAHP.

OPENING PLENARY

Clinical Trials

Session Chair: Joe Selby, MD, MPH, Division of Research, Kaiser Permanente Northern CA
Speakers: Martin Brown, PhD, National Cancer Institute
Charles M. Cutler, MD, MS, American Association of Health Plans
Carol Somkin, PhD, Division of Research, Kaiser Permanente Northern CA
Gil Welch, MD, MPH, Effective Clinical Practice

Charles M. Cutler

Dr. Cutler discussed access to clinical trials and the importance of translating evidence from clinical trials into clinical practice guidelines. The link between clinical trials and coverage decisions is the implementation of research into clinical practice. AAHP and NIH have come to an agreement to work together to increase participation in clinical trials and for health plans to cover routine care costs associated with participation in clinical trials. In order to achieve this, the two groups are working on a definition of "routine patient care", developing tools for health plans to evaluate clinical trials, and putting together work groups to address return on investment for participation in clinical trials. Currently, participation in clinical trials is largely driven by state mandates. The major concern for AAHP is that not all trials are high quality - it will be important for health plans to examine therapeutic intent, best interest of patients, and rigorous scientific basis.

Martin Brown

NCI-Sponsored Studies on Costs of Cancer Clinical Trial Patients

What is the incremental cost of patient care of patients enrolled in clinical trials?

- No empirical data on this
- Need large number of patients enrolled in clinical trials
- Good, reliable cost data

What would it cost to treat a patient if not enrolled in a clinical trial?

- Commissioned studies at Group Health Cooperative, Mayo, Kaiser and Rand
- Costs vary widely by characteristics of the trial

NCI-approved clinical trials:

- Variance of costs wider amongst patients receiving normal standard of care versus those enrolled in a clinical trial
- Highly "protocolized"
- Shared design features of Group Health Cooperative, Mayo, and Kaiser studies
- Case-control design

- Controls identified using registry data similar to cases
- Controls selected using chart review - eligibility criteria

Cost data - HMOs - used internal accounting systems:

- Mayo - applied unit Medicare fees to resource use
- 135 matched pairs - good size
- cost ratio does vary by trial type

Limitations: Small sample sizes; embarked on more ambitious study with Rand

Carol Somkin

Barriers to Participation in Clinical Trials in MCOs

Characteristics:

- Large population
- Sophisticated, computerized data systems
- Commitment to evidence-based decision-making

Patient Barriers:

- Lack of understanding process; informed consent
- Unwillingness to be randomized
- Transportation/ frequent visits
- Mistrust

Physician Barriers:

- Time constraints
- Lack of awareness
- Concerns - doctor-patient relationship

Organizational Barriers:

- Mission, function, culture
- Inhospitable to research

Characteristics of Clinical Trial Process:

- Complexity of protocol
- Eligibility criteria
- Research questions
- Incentives to participate

Clinical Trials Expert Team:

- Increase participation
- Building a referral network
- Developing an early identification and notification system

- Notifying physicians prior to patients' participation

Automating process of identifying potentially eligible patients

- Weekly - providing research nurses with information on patients meeting eligibility criteria
- Increase the number of physicians who refer patients to clinical trials

Least well studied barriers:

- Pilot study of organizational barriers
- Better understand variation in research culture

Gil Welch

How to Gauge the Quality of Clinical Trials

Dr. Welch discussed developing a scoring system for gauging the quality of clinical trials because quality is supported by health plans. Randomized control trials are difficult, hard work; many will be funded, however, not all are equally important. Therefore, health plans should be selective.

Dr. Welch presented the following criteria for a clinical trial scoring system:

1. High potential for an individual patient to benefit
 - Illness for patient has high serious consequences
 - Current therapy has either low effectiveness or high toxicity
2. High Information value to the population
3. Well-designed protocol
 - Intervention - does the protocol most accurately reflect realities of current practice?
 - Are the outcomes relevant to patients?
 - Blinded - to what extent are researchers and patients blinded?
4. Investigator with a proven track record
 - Success with recruitment
 - Publication record
 - Evidence of clinical conduct

As this was the first time these criteria were presented to a group of researchers, Dr. Welch suggested that conference participants share these criteria and domains with relevant stakeholders. Next steps will include:

- Develop a scoring system and weights
- Convene a working group
- Revise scoring

In addition, the following questions will need to be addressed:

- Can generalist physicians or clinical epidemiologists evaluate protocols?
- Why health plans should focus on selected randomized trials: Public health benefit to
- reducing costs
- When we get a result, what do we do with it and what effect does it have on cost?
 - Employers don't understand this very well either. The emphasis should not be which therapy is most cost-effective, but what is the best thing to do given cost and quality. There's misunderstanding and skepticism over what's cost-effective based on findings, and cost-effectiveness takes a back seat to "scientifically interesting" findings.
- Focus on cancer because that's where the political heat is.
- Return on investment for transplants
 - Example is bone marrow transplantation for metastatic breast cancer - this can be looked at as a public policy issue - first investigators, then randomization, then standard vs. new therapy.

April 4

CONCURRENT SESSION I A

Prevention Priorities in Practice

Session Chair: Blake Caldwell, MD, MPH, Centers for Disease Control and Prevention
Speakers: Mike Maciosek, PhD, HealthPartners Research Foundation
Carol Friedman, MD, Centers for Disease Control and Prevention
Faruque Ahmed, MD, PhD, Centers for Disease Control and Prevention

Prioritize A and B Services in Guide to Clinical Preventive Services - with Partnership for Prevention

Mike Maciosek - Partnership for Prevention

The purpose of prioritizing the Guide to Clinical Preventive Services is to move beyond "effective" versus "not effective" and to produce a ranking of these services.

The ranking was achieved by using the following formula:

Preventable Burden (PB) - burden of disease prevented by service in usual practice
Cost Effectiveness (CE)

$PB = (\text{burden of disease}) \times (\text{effectiveness})$

5 Principles for PB consistency:

1. Morbidity prevented must be included

Quality Adjusted Life Years (QALYs) saved = years of life saved (deaths prevented X life expectancy at death) + years of illness prevented

2. Burden and effectiveness estimates must match scope of burden
3. Adherence must be considered for every type of service
 - Screening, counseling, immunizations and chemoprophylaxis
4. Time horizon must be consistent across services (Leif Solberg principle)
5. Effect of current delivery rates must be accounted for consistently across services
 - Additional burden prevented given current delivery rates

Compares costs of services to health and financial impacts.

3 principles of CE consistency:

1. CE must follow intent of reference cases of panel on cost-effectiveness in health and medicine
2. Time horizon must be consistent across services
3. CE must be based on current estimates

Ranking can't be better than the underlying data
When evaluating, be careful in local delivery

Carol Friedman

Carol presented a practical application of the Clinical Priorities Project at a corporation.

Executives at General Motors (GM) read an article about CDC linking the outbreak of Hepatitis A in Michigan schoolchildren to contaminated strawberries. This led the executives to apply similar outbreak investigative techniques to tracking and monitoring of warranty claims. GM saved \$1.6 billion by applying these techniques, and the success story was published in the Wall Street Journal. GM was so impressed by the savings experienced by using this approach that they came back to CDC for other areas to collaborate.

The result was a new partnership between CDC and GM, "Partnering with Employers for Prevention" (PEP). The objectives of this partnership were to increase the use of priority clinical preventive services, improve overall health status of working Americans, increase worker productivity, and ultimately to decrease health care costs.

GM is the largest private provider of health insurance in the US with 1.25 million enrollees. GM contracts with over 120 health maintenance organizations (HMOs) and 80 fee-for-service (FFS) carriers, with an equal number of preferred provider organizations (PPOs). The company employs over 300,000 employees, and 3/4 of their employees are hourly workers. Health Plan distribution among active enrollees is 42% in traditional FFS plans, 31% in HMO plans, and 27% in PPOs. Among retirees, 80% of retirees are in traditional FFS, 18% in HMOs, and 8% in PPOs.

The average age of GM employees is 50, and there are 1.25 employees for every active retiree. GM has an at-risk workforce for many diseases, and their workers are allowed to smoke on assembly line while assembling cars.

In 1999, GM spent \$3.5 billion on healthcare, which is more than the operating budget for CDC. This comes out to \$1200 per vehicle, which is more than GM spends on the price of steel for that vehicle. If CDC was able to help GM save over a billion dollars in the area of manufacturing, perhaps they could help them with healthcare too. This project is the foundation of the work CDC is doing with GM.

CDC analyzed data on mammography and pap smears in the GM enrolled populations. The objective was to improve the delivery and use of preventive services with GM, and to develop a model that can apply to other employers as well. The "hook" to getting GM interested in this was "cost-effectiveness".

CDC set out to: identify use of services by plan type; identify and implement interventions to increase use of these services; and to evaluate effectiveness of interventions. GM was extremely generous in providing data. The company has a data warehouse that maintains claims on FFS and PPO enrollees. They don't yet have a data warehouse setup for HMOs. GM linked the health claims data with personnel records for sociodemographic information, in addition to claims data. They were able to assemble a substantial study population with over 33,000 records for mammography and over 90,000 records for Pap tests. A stratified analysis was conducted for salary and hourly employees.

GM linked the health claims data to personnel records and found that the primary enrollee (women) enrollees were more likely to get preventive services (mammograms) than the spouse of an enrollee or retired enrollee.

Hourly employees in Flint were more likely to get mammograms. The effect of insurance on use of service was evident - enrollees in the PPO were more likely to obtain mammograms than enrollees in traditional insurance. They found the same effect with Pap Smears. Hourly enrollees in FFS don't have a covered office visit. Hourly and salaried employees in PPOs do have a covered office visit. This presented a barrier for hourly enrollees in FFS from obtaining services. Initially GM thought of adding covered office visits, but now they're talking about incentives for encouraging hourly employees in FFS to move into managed care, which they consider to be higher quality.

Next steps will include obtaining HMO data for comparison. A letter was sent to the 10 largest HMOs with whom GM contracts. In addition, CDC is in the process of identifying, implementing, and evaluating interventions with GM employees.

Additionally, CDC will explore the use of other priority preventive services at GM. The corporation has chlamydia data that are under analysis, and they're about to make colorectal cancer screening data available as well.

CDC found that the Partnership for Prevention Clinical Priorities is a useful tool to working with GM. The objective to order services based on value fits well with GM's goals to improve health care quality and also to improve the health status of over 1 million working Americans.

Faruque Ahmed

Rating HMO Performance on Prevention Using HEDIS Data

Applying Clinical Preventive Services project results to HMOs

Dr. Tom Vogt at Kaiser Hawaii is currently studying an approach of drawing a single sample to look at priority preventive services. This differs from the HEDIS approach of drawing separate samples for each measure (mammography, cervical cancer, etc.)

Assessing HMO performance on prevention using HEDIS data

Methodological Issues:

- HMO report cards are inconsistent - US News and World Report, Newsweek, Consumer Reports
- Looking at 4 different methodological approaches
 - Weighting categories
 - Missing values
- Difficult to assign/calculate weights
- In order to prioritize use of resources it is important to focus on where the use of resources should be

Methods: Computed an overall prevention score for each HMO; converted score to weighting categories; assessed concordance between the rating categories produced by the different methods using percent agreement and Kappa. HEDIS 1998 data were used to look at mammography, Pap smears and childhood immunizations. Plans with missing information on any of the measures were excluded, and so were plans with samples less than 100 on any of the measures. The number of HMOs with complete data was 242.

CONCURRENT SESSION I B

Research with Children

Session Chair: Andrew Nelson, MPH, HealthPartners Research Foundation
Speakers: Lisa Simpson, MB, BCh, MPH, Agency for Healthcare Research and Quality

Lisa Simpson

Lisa Simpson began the session with a discussion of Children's Health Services Research (CHSR). Much of the research to date concerning pediatric care has been biomedical and classical clinical pediatric research. The emphasis in CHSR is informing – research that aids managers in deciding on ways to “improve *health systems for children and adolescents*” and “improve child and adolescent *health* at the level of both individuals and populations.”

Aspects that differentiate research with children from research on adult populations (the “Four D’s”):

- Developmental change – need to incorporate developmental change
- Dependency – unit of analysis? Child? Family? Child is dependent on family, school environment, etc.
- Differential epidemiology – not a lot of high cost, high prevalence physical conditions (asthma has been heavily studied, some depression, ADHD, diabetes)
- Demographic patterns – children are a disproportionately poor population (20%), much of their healthcare financed by public health systems – all affect data, studies

An area of CHSR that has not been heavily studied is relationships between high volume providers and associated outcome measures (*Dudley et al, JAMA, March 2000*). There is some preliminary evidence indicating a relationship – e.g. “6 of 7 [pediatric studies] showed high volume hospitals had statistically significantly better outcomes.” This raises questions about when children with chronic illnesses are not seeing pediatric subspecialists.

Categories of research relating to quality:

- Underuse (e.g., immunization)
- Overuse (not as many studies in this area)
- Misuse (relates to IOM study on medical errors – medication errors, etc.)

Essentials for translating research into practice:

- Methods – stem from Four D’s mentioned above
- Measures – developing quality measures continues to be a challenge
- Databases – lack of a central database similar to Medicare is a major impediment
- Networks – help to resolve the “N” problem (number of children for studies)
- Training

AHRQ would like to pursue funding studies that promote intervention – concerned with how to implement research findings. For Integrated Delivery Systems (IDS) Research Networks there is currently a master task order contract (3 years, option to renew for 2 more) of approximately \$3.9 million (\$2 million for 2 option years). Final proposals are due May 8, 2000 and awards will be made June 5, 2000.

Major CHSR Funders: Federal Agencies (AHRQ, CDC, HCFA, HRSA/MCHB, NIH, SAMHSA), Foundations (Commonwealth, Kaiser, RWJ, States), Health Plans. Recent AHRQ grants relating to children's health amounted in FY1999 to over \$9 million in new grants. Along with the name change to AHRQ, children are now specifically named as a priority population in the mandate for AHRQ. Additionally, beginning in 2003 there will be two important national reports prepared by AHRQ that also relate to children – one on the quality of healthcare in America and one on disparities. For 2001, emphasis will be placed on responding to the IOM report concerning medical errors and patient safety and also on informatics applications.

For further information Ms. Simpson suggested visiting AHRQ's homepage: <http://www.AHRQ.gov> or contacting her by email: lsimpson@ahrq.gov.

Andrew Nelson

Andrew Nelson, from HealthPartners Research Foundation and also Chair of the HMO Research Network, continued the session with a discussion on the lack of research within managed care with respect to children.

Within the HMO Research Network there are approximately 3 million children that are served – children for whom there are claims and pharmaceutical records, and for whom there is the opportunity to alter the type of healthcare they receive. The capacity is there for research. However, results from a survey of 140 investigators from managed care organizations involved with research shows that pediatrics is near the bottom of research areas in which they are interested.

There are many issues that relate to an ongoing research study on children – community issues, data issues, family issues, and issues with the children themselves. These issues were discussed as they related to a specific study on chronic illness and disability in children. The goal of the study was to develop a community and health systems approach to improving care for chronically ill children. The impetus for the study was two pediatricians who highlighted the difficulties that families face in procuring care for their chronically ill children. Predominant are difficulties due to the interaction of school systems, the various healthcare delivery locations, and the various funding entities (federal government, state government, health insurance).

In looking at ways to redesign healthcare within communities for children with chronic illness and disabilities several questions arose:

- Can the cases be identified? Many are not cared for by managed care.
- Can cost and utilization be identified and analyzed?
- Can community factors be identified?

An advisory group was formed to address the above issues, to formulate a redesign of health services in a community for these children, and also to discuss what can be done internally in a system to better coordinate care. The study began with a patient base of approximately 300,000. The children with the most chronic diseases were identified (specifically eight categories) – these numbered 410 children. These children cost the healthplan approximately \$15,000 per child in 1997. Most of the expense was hospital care.

As Lisa Simpson discussed, the model for a research study with children is much broader than with adults. The child exists within a family. Additionally there are influences from the healthcare providers and the community at large (e.g., the school system). Identification of the healthplan's expenses was comparatively easy, however there were six other sources of expenses, to include the family's out-of-pocket expenses that were not easily identifiable. The study also illuminated how families are adversely affected by managing healthcare services for their children. In many cases, the managing of services is almost a full-time job for one of the parents. Case coordinators were in actuality often just gatekeepers, and not a resource for families.

Other impediments to providing healthcare for children highlighted by the study:

- Benefit packages are designed for adults – do not include language problems, hearing disabilities, etc.
- Data collection – often there are two working parents who are claiming a child on two different policies
- Out-of-plan specialists – not able to collect data

When conducting research with children, there is a need to understand the context of the community. Researchers need to be able to go beyond the sphere of their healthcare organizations. Funding must incorporate this aspect. Many pediatric physicians feel they have inadequate resources to provide proper care for chronically ill children. There is a need for research that focuses on effective methods of incorporating all community healthcare providers.

Session discussion with the audience included:

- Using money spent on case coordinators for health care services and hire, instead, personnel who work for the family
- Collaborations with the Departments of Education and Justice – Education departments often provide mental health services for children identified by schools
- NIH grants must now include children in the patient population or if not, an explanation as to why children are not included
- Whether there is a need for special training for researchers who study children populations

CONCURRENT SESSION I C

**Research Administration Track:
The Relationship Between Research Centers and IRBs – How Close is Too Close?**

Session Chair: Joyce Gilbert, MPH, Kaiser Permanente, Center for Health Research - Hawaii
Speakers: J. Marc Rosen, MD, MPH, Kaiser Permanente, Center for Health Research - Hawaii
Dennis Tolsma, MPH, Kaiser Permanente Georgia

J. Marc Rosen

Background (Two years since Government released report criticizing IRBs):

- IRBs are getting too close to the parent company, which may lead to organizational and/or political pressure being placed on them. IRB is supposed to be making independent decisions.
- Recent changes and increased scrutiny by federal agencies on IRB performance.

Remedies needed:

- Need oversight balanced with independence.
- IRBs need to exist, although past experience found it was hard to recruit volunteer members. Solution was to shift the IRB from the hospital to the research center at Kaiser. Improved knowledge of the research and oversight, however some increased risk due to closer proximity to those with a vested interest in the research projects.
- Keys to success of an IRB:
 - oversight and proper administration of the government regulations
 - remain as independent as possible from the vested interests of the research organization (e.g. Kaiser's IRB reports to the Permanente Medical Association.)

Dennis Tolsma

Research Organization and IRB must be in partnership-Advantages/Pitfalls:

- Need well defined but reasonably close relationship with research organization in order to protect subjects of research and therefore the organization. Not appropriately protecting subjects leads to public relations debacles, often from failing to document protections that were in place and accordingly complying with federal regulations.
- IRB must have sufficient resources from parent organization and be well staffed to carry out its duties
- Each partner (Institution, Research Org. & IRB) has separate functions and these must be based on a clear and sound working relationship

Variety of models exist for research organizations in managed care:

- Foundations

- Quasi-freestanding research centers
- Joint appointment medical school and research arm (e.g. Harvard Pilgrim)
- Department of research housed within Quality Improvement
- Kaiser process in GA:
 - a. Research Committee reviews all proposed projects against specific criteria for appropriateness to KP Georgia: scientific value and compatibility with organizational goals.
 - b. If accepted, the IRB does periodic reviews for human subject concerns.
 - c. Historical background of KP-GA IRB:
 - Dennis sat on the IRB in 1992 when he was with CDC. He became the Chair, and was subsequently hired by KP-GA to form their research center. At end of 1st term as IRB Chair, he was urged by the IRB members to serve a 2nd term.
 - Concerned that to the outside world there would appear to be a conflict of interest. In three situations, he had to remove himself from decision-making on study protocol. Currently, the chair of KP-GA's IRB is an outside member. In the current environment, this seems to make the most sense.
 - However, the Research Director should be a member of the IRB in order to answer specific questions about the research.

Things to keep in mind when setting up and running an IRB:

- Need to ensure adequate funds to cover IRB expenses.
- Documentation must be scrupulous; proof of compliance with regulations; OPRR expects documentation of what was approved to have actually been implemented (e.g. approved version of consent form.)
- IRBs are expected to validate that its decisions were actually followed, which is difficult to do. Kaiser plans to go one-on-one with its researchers during administration of the informed consent form to evaluate its use and whether it was fully voluntary.
- Increased attention to privacy and confidentiality legislation, which is going to be burdensome to enforce.

PLENARY II

Bridging the Gap Between Research and Practice – Opportunities and Lessons

Session Chair: Leif I. Solberg, MD, HealthPartners Research Foundation
Speakers: Carolyn Clancy, MD, Agency for Healthcare Research and Quality
Patrick O'Connor, MD, MPH, HealthPartners Research Foundation

Carolyn Clancy

Bridging the Gap Between Research and Practice

Examine unanticipated outcomes

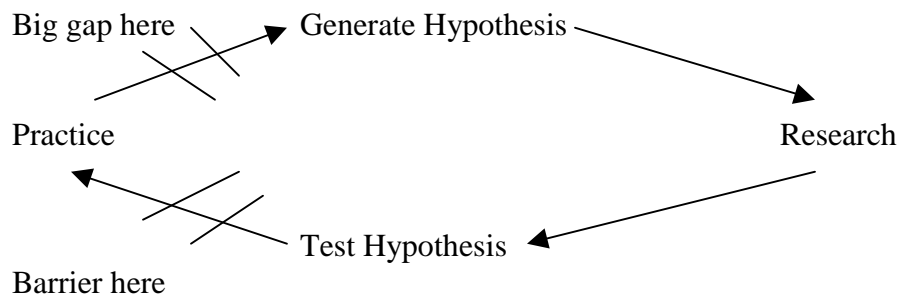
- Overcoming the "not invented here" (NIH) syndrome
- Clearer definition of continuous quality improvement (CQI) as an intervention
- Fine structure of data feedback: personal or anonymous
- Engaging senior leadership

Build a bridge between Quality Improvement and Research

- Generalizable dimensions
- Production of evidence should be linked to use of it

Patrick O'Connor

Bridges Between Practice and Research



There is a huge amount of variation in process and outcomes of care.

Carve-out Disease Management:

- Widespread appeal
- Panic over quality
- Need to do something
- Risk-sharing; cost control

- Venture capital/ pharmaceutical marketing

Small evidence base:

- Impact on costs
- Quality
- "Penetration" of population
- Continuity of care
- Opportunity costs

Same-Day Access

This concept is an example of a system change that is sweeping the country and has had a profound impact on care. Only a tiny amount of research was involved. Would the FDA/NCI approve it? Same-day access had a short time-line and rapid rollout. Some questions to ask when looking at the institutionalization of same-day access into everyday practice are:

- Does satisfaction equal quality?
- How does same-day access impact on chronic disease patients?

Example: Clinical Guidelines

- Typology
- Format
- 55 pounds of evidence
- Where is the value?
- Do we know how to implement?
- Value is as important as evidence, if not more

The quality game:

- Is HEDIS now a barrier to QI?
- Disease a month improvement approaches
- Is improvement a zero-sum game?
- Adherence to ineffective improvement strategies
- Rational allocation of resources

Provider behavior:

- Need to pay more attention to this
- How do providers make decisions?
- Patient archetypes

Population health - is evidence enough?

- Moving from evidence to value
- How to measure and maximize value
- Ethical dimensions

Research methodology:

- Well-defined populations and large databases

Taking advantage of natural experiments:

- Identify opportunities promptly
- Develop surveillance systems
- Group randomized trials

Two examples –Kaiser and HealthPartners:

- Joe Selby of Kaiser Southern California looked at disease management premised on information in the office
 - Capital to put it in place is lacking – what’s the evidence for that?
 - What’s the evidence for using electronic systems/medical records?
 - Experiences with automated medical records – “I’ve been using it for a year and would never go back” – users like it.
- HealthPartners
 - Site with automated records
 - Not doing better with LDL levels than sites without

What is being done to make educational efforts part of practice?

JAMA – Steve Wolf article – re: moving evidence to value

Two cultures – the world in which senior leaders live and our world

AHRQ – request for contracts with integrated delivery systems

- task orders to capitalize on opportunities

RESEARCH ADMINISTRATION TRACK

Management of Multi-Center Studies – The CRN Experience

Session Chair: Tim O’Bar, Kaiser Permanente, Center for Health Research - Northwest
Speakers: Romayne Zanchi, Group Health Cooperative
Sarah Greene, MPH, Group Health Cooperative – Center for Health Studies

The CRN was defined as a collaboration of 10 non-profit HMOs committed to the conduct of high quality, public domain research in cancer control. The following goals for the session were given:

1. Share ideas about how the CRN can better communicate with its members.
2. To be able to answer auditors when they ask, “What have you done to monitor sub-recipients?” We will be able to offer documentation from this meeting. In particular, they want to know how we are monitoring expenditures.

Issues and challenges in administering a multi-site collaboration:

- All tasks take longer; every delay has a cascading effect. Trying to build in more lead-time to improve and be more proactive on administrative and scientific flow.
- Gathering administrative process information (cheat sheets) of each participating organization up front is a good idea e.g. IRB, budget development, sign-off requirements etc.
- A handout on the CRN Administration Cycle describing key dates and key activities was discussed and distributed.
- It is critical to know the budget cycle of each CRN participating organization to ensure meeting the carry-forward budget and justifications. The actual carry-forward is easier to report than an estimated carry forward budget. Note that all sites must submit a carry-forward budget or the process is delayed for everyone.
- The variation in research center administrative staff in terms of resources and experience in preparing budgets and justifications contributes to the problem. There is also variation in the amount of scientific knowledge among the administrative staff.
- It is difficult to predict metrics (e.g. cost of chart abstraction in various sites.) The key is to estimate costs accurately.
- Discussion of cross-site support; collaboration on administrative issues is important (e.g. how to handle honorariums.) Overall support is quite good in terms of sharing administrative questions and answers. However, sites are very independently operated organizations. Need to ask sponsoring site for expectations on a request for data or information such as year 2 budget. Organizations from CRN are encouraged to contact each other.

Summary of CRN Facts:

- 18 million dollar budget
- 9 million member population

- 13 consultants (10 on external advisory committee)
- 7 expert advisory teams
- 3 initial studies
- 4 administrative supplements to NCI for additional funding
- 5002 page visits to CRN web site (hope to add frequently asked Q & A section)
- 174 team members listed on the web site
- 822 pages in the original application to NCI

Summary of question and answer topics:

- Discussion of how others (non-Group Health plans) develop budgets and how to improve the process.
 - How do you combine the budgets from different sites which may all look different because the work is done differently? May be beneficial to look for the best practices when comparing these budgets.
 - There may not be one best way to develop a budget; there may be 10 best ways.
 - We can't be too concerned if some sites cost more than others; need to build in flexibility, trust and tolerance for differences in ways the work is done at various sites and at various costs.
 - It would be helpful however, to understand the framework and practices of each organization when interpreting a budget. For example what are the indirects devoted to? What kind of institutional support does each organization contribute? How does each determine FTEs?
- Diversity of organizational culture in a multi-center study would make an interesting research topic. It would be a great contribution to the published literature.
- The suggestion was made to hold conference calls among the CRNs to discuss administrative issues in addition to the e-mail communications.
- A poll was taken to see who had access to the web site. Nearly everyone did, so it was decided to use it to list contacts and to provide clarification on requests for information/data on budgets and administrative supplements. The handout also included contact information.

Lessons learned from the CRN experience:

- Staff with experts; people with administrative and scientific experience.
- Early and frequent communication is critical; maximize all avenues (e.g. list serves.) Need to have a current list of site administrators in addition to governing board.
- Don't underestimate administrative time in the budget.
- Rapid Cycle Research requires involvement of PI (no proposal, no budget required during initial submission). There is competition to get the opportunity to respond to task orders. After award is made, then the proposal is written. Various components needed for RFP:
 - Describe levels of staff and their salary ranges based on market ranges for various FTEs
 - Need a sheet of representations and certifications
 - Need a small disadvantaged business plan showing historical data on past vendor purchasing awards

April 5

PLENARY III

Ethical Issues and Informed Consent

Session Chair: Mary Durham, Kaiser Permanente, Center for Health Research – Northwest
Speakers: Lawrence Miike, MD, JD, President’s National Bioethics Advisory Commission

Lawrence Miike

“The common rule” – subscribing/signing on to this is voluntary

Only 9 out of 17 agencies have agreed to sign on.

“Why can’t the President just order agencies to sign on?”

Issues regarding IRBs differing in what is acceptable

The real issue for IRBs should be risks and benefits of participants in studies, NOT the word-smithing of consent forms.

Clinical ethics vs. clinical research

- It is clinical research done in an ethical manner.

The most rigorous informed consent process is in Haiti. Patients are given a test that they must pass prior to signing a consent form.

The Federal Common Rule – designed to develop or contribute to generalizable knowledge.

Human Subject:

- Someone who is living
- Data through intervention or interaction with individual, or
- Identifiable private information

Private Information:

- Information that a person never expected to be used for other reasons than the purpose for what it was collected.

Look at record at time of biopsy – you should “refresh” consent if you want to go back to look at the patient’s medical record in the future.

Exempt Activities:

- Involve educational tests
- Research involving collection or study of existing data that are publicly available

- Expedited Review
- Minimal risk
- From specific list of research categories – does risk involve confidentiality, breach, physical or psychological harm?
- Probability and magnitude of harm or discomfort anticipated in the research or not greater in and of themselves

Uninformed consent – “you can use my tissue for research” buried in surgical consent form

Waiver of consent – If the IRB determines original consent document is inadequate and risk is minimal, but research is important enough to waive consent requirements.

OPRR is limited to paper reviews.

Common compliance problems:

- Expedited review requires minimal risk AND specific research categories
- Apply exemption to activities involving prospective data collection
- Individuals from the Office of Research or Grants Support have a conflict of interest and should NOT be voting members of an IRB

Decision Areas:

- Should the Common Rule be extended to non-federally funded research activities?
*criteria for journal publication
- Proposal for new regulatory system
- New criteria for definitions of “research”, “human subject” and “vulnerable subject”
- Proposals for reviewing various types of research
- How assessment of risk should influence the review

Leans toward clinical research – investigating applications to other types of research

Recognizing that IRBs need resources to operate effectively, there are opportunities for them to address accreditation, best practices and consistency. It’s necessary for a comprehensive educational program, including education of the public.

- Does the activity get funds from outside the institution?
- Do you plan to publish?
- Do autonomy and/or consent problems exist?
- Potential for conflict
- Safety issues
- Privacy & confidentiality issues

Collaborate with communities to do research – as with HIV – the research designs were better.

Breast cancer studies – opposition in Massachusetts – little opposition on the West Coast.

The ultimate goal is to revise research design to meet objectives and still conduct research.

Mary Durham

Issue of identifiable versus anonymous data

- Stripping of identifiers does not necessarily make the data anonymous.
- Best left to IRBs, instead of a hard and fast rule, to make judgment at a local level to determine what's anonymous

If there is an identifier somewhere, even if the investigator does not have access to it, the data are NOT anonymous.

Comments from:

- Mark Hornbrook – Kaiser Northwest
 - Preserve rights of researchers in secure organizations, governed by IRBs.
 - Put IRB review at both ends – review the safety of data both at the time of collection and at the time of use.
 - The source institution should get assurances from the recipient institution.
- Katie Irwin – CDC
 - Monitor appropriate execution of studies to ensure human subjects' protections
 - Consistency, best practices
 - It's not just a review function, but a resource allocation issue as well.
- Steve Taplin – Group Health
 - Low-risk observational studies – get out of conflict
 - In a small organization there's a limited pool of individuals to pick to sit on IRBs – be wary of a global statement regarding composition of the IRB
 - The process should include checks and balances
 - There needs to be an evaluation of the entire IRB system

April 5

PLENARY IV LUNCHEON

State of the HMO Research Network Address

Speakers: Andrew Nelson, MPH, HealthPartners Research Foundation

Andy Nelson

“Next Year in Seattle”

- Data privacy issues
- Translation of “so what”
- Look out for and mentor new investigators

- Annual governing board meeting
- New Chair appointed in May
- Application to join – United Health Care, Prudential

An upcoming meeting schedule for the HMO Research Network was presented:

2002 Long Beach – Kaiser Southern California
2003 Denver
2004 Detroit
2005 Colorado
2006 Albuquerque

April 5

PLENARY IV LUNCHEON

Lessons Learned from Collaborations in Network

Speakers: Rich Platt, MD, Harvard Pilgrim Health Care
Ed Wagner, MD, MPH, Group Health Cooperative of Puget Sound

Ed Wagner

Dr. Wagner discussed two major collaborative activities in the HMO Research Network.

Cancer Research Network (CRN)

- Future of understanding of healthcare dependent on what's going on in practice
- Increase effectiveness of cancer services in health plans

Population laboratory:

- Use laboratory to study and improve effectiveness
- Increase size of laboratory by adding sites
- Evaluate quality and extent of collaboration amongst sites – needs to be regularly monitored and improved
- Create an infrastructure that fosters collaboration
- Site the Principal Investigator (PI) in every site
- Added a “new proposals” facilitation committee building capacity to do new research, led by Ann Geiger
- Communications Committee – Cheri Rolnick
- CRN Coordinating Center
- Facilitate understanding of data system to be in a position to develop new projects
- Site data manager in every one of the ten HMOs
- Area of continuous learning for all
- Formal evaluation conducted annually

Issues in Collaboration:

- Can't underestimate fears in sharing data
- Junior investigators are more threatened/worried about role in a massive enterprise
- Different budgeting priorities and approaches among HMOs create real or perceived inequities – Better understand each other
- Data collection difficulty/costs vary across HMOs
- Project administration and coordination needs are high – collaboration takes time and resources.
- Additional demands on project leadership – need to train PI for those roles

Rich Platt

Dr. Platt used a post-marketing safety study of Alendronate and gastroduodenal perforation ulcer and bleeding to illustrate lessons learned from collaboration. When identifying who was treated with drugs, researchers found that in 8 HMOs there were 70 drug benefit programs.

What are people treated with?

- More than 20,000 unique formulary entries – just for the study participants, just for 3 years.
- 90% could be linked to National Drug Codes (NDCs)
- Working with multi-HMO drug data is a new skill
- Less is probably more
- Merging entire formularies should not be a priority
- The chronic disease score works across HMOs
- It required hand coding of thousands of NDCs
- Reusable resource for numerous network activities
- Creating a merged data set
- There's a need for common search logic and common file structures
- Common codes are better than a common workplan

The application of new knowledge in the case of Alendronate and GI bleeding was that, yes, there's more bleeding, but not caused by Alendronate.

- Fracture and GI bleeding – excess result of bleeding
- Diagnostic codes for GI bleeding
- Stairs and fracture – database allows case-control study
- Statins protect – useful information that came quick

Cancer Research Network – Expert team (X-Team)

- Androgen suppression for prostate cancer
- Pharmepi collaborative (would be CERT)
- Diabetes and liver failure
- Pediatric antibiotic use
- Management of CHF
- Drug copayments and diabetes control

Anticipatory management

- Concerned about putting intellectual material on the table
- Safe environment to bring early ideas to the table

Need time to create a research agenda for the CERTS

Measure of function of data coordinating center:

- Collection of information/facts – such as 8 HMOs have 70 different drug benefits
- “Megadata” – repository for those facts

CONCURRENT SESSION II A

Research and Performance Measurement: The Interface

Speakers: Diana Petitti, MD, MPH, Kaiser Permanente Southern CA
Arne Beck, PhD, Kaiser Permanente Colorado
Margaret Gunter, PhD, Lovelace Clinic

Data Reliability

- “Data crud” problem – changed method for collecting data for HgA1C – had an error in lab data.
- When you don’t feed back data to clinicians they don’t stay fixed.
- How do you define the case? Is it too narrow?
- Gap in medication
- What technical help is available for programming complexity? None outside of Kaiser
- If we’re going to do complex measure development – be prepared for training at a much higher level

Race/ethnicity Data

- Lack of race/ethnicity information on health plan enrollees (perceived discrimination)
- Concerns about how to collect information in a non-discriminatory manner
- Method to get SES information on anyone who had an encounter
- CAHPS survey has information on race and ethnicity
- At the aggregate level – geo-code data – take address/zip code and turn into census block
- Coding at the aggregate level is very good – for predictive value at individual level – it’s poor
- What is the sample size at which aggregate geo-coded data has validity so that you can use it?
- People assume we can get at some of these data

Political Issues

- Showing large disparities in minority populations – “How will I look?” problem
- “My measure” problem – people become highly invested down to the specification of the measure
- Measures reviewed on a periodic basis

Accreditation vs. Quality

- Try demonstration projects to see what the quality is of race data
- Issue – data sources – many systems/plans not collecting or recording information for measurement
- Decide if we’re doing a poor job of care and research that needs to make a change if plans have changed
- Opportunity costs – often chasing measures – taking time away from tasks that need help

- Is any given measure a measure that you'd want to invest resources in?

Fiscal issues

- Low prevalence of condition – how to come up with performance measures
- Quality of Life – common measure
- People with seizures – what to do to monitor in a cost-effective way

Look at surveys of health-related Quality of life – using these for performance measurement

- “Worse gets better more” – get up to 80-95% on measures
- Hypothesis-generating process
- Feasibility of research is questionable for measure – does it make a difference?
- What are the characteristics of the people who aren't coming in at all for preventive services (mammograms, Pap smears, immunizations, etc)?
- There's an incredible opportunity to collaborate across health plans with HEDIS/standardized measures
- Do measures actually reflect performance? Work on building in a feedback loop.

April 5

CONCURRENT SESSION II B

Collaborative Economic Research in HMOs

Session Chair: Paul Fishman, PhD, Group Health Cooperative of Puget Sound
Speakers: Richard T. Meenan, PhD, MPH, Kaiser Permanente, Center for Health Research -- Northwest
Jennifer Elston-Lafata, PhD, Henry Ford Health System

Introduction

Paul Fishman opened the session by introducing the panel. The goal of the session was to discuss ongoing collaborative economic research and proposed research. Panel members focused on issues common to members of the HMO Research Network and Cancer Research Network.

Managed care is an economic relationship. Economics is a science of decisionmaking. There is an opportunity in managed care to improve care and business systems through economic research.

Types of economic research:

- Cost effectiveness, cost benefit, cost outcomes studies
- Burden and cost of illness analysis, including both direct and indirect cost analyses
Organization and structure of delivery systems
- Effect of financial incentives on both providers and consumers
- Risk assessment and risk adjustment looking at finance and reimbursement issues

Economic research in the HMO Research Network:

In recent years there has been a trend amongst HMO Research Network members to include economic analysis in the research agenda. There are economic researchers in Group Health Cooperative, HealthPartners, Henry Ford Health System, KP Colorado, KP Georgia, KP Hawaii, KP Northern California, and KP Northwest.

Production Function

Jennifer Elston-Lafata followed Paul Fishman with a discussion of proposed economic research in the Network.

Objective:

Define a cost function for evaluating primary care practices applicable in both fee-for-service and managed care environments. This work may be turned into a proposal for the Cancer Research Network.

Cost function analysis:

- Level and mix of input (physician, other staff)
- Level and mix of output
- Historically used in hospital and other institutional settings where data were available. Data availability is a barrier in other settings.

- Multi-product nature of output
- Case-mix adjustment

Managed care environment has some differences with fee-for-services:

- Deliberate integration of financing and care delivery
- Responsibility for a population of patients (bundling of care)
- Provide care for both the sick and well patients
- Efficiency depends on an appropriate mix of a wide range of care and services

Questions to answer in development of a cost function:

1. What do primary care packages produce?
Health is being produced. (Reductions in the burden of illness.) This area is complex because many things impact health besides healthcare. (Genetics, lifestyle choices.)
2. How do we account for quality differences?
Dynamic tension between cost and quality. Criteria are intermediate health outcome measures. Multiple primary care components: Prevention, health promotion.
3. What are the inputs used in production?
Physician and staff time (traditional), managed care bundling of goods and services (Inpatient and outpatient care, prevention services, pharmacy utilization, etc.)
4. How do you control for case mix?

Dr. Elston-Lafata described a model designed to answer these questions.

Cost Effectiveness Analysis (CEA)

Richard Meenan explained that managed care data have three sources of variation which impact on production and cost functions used to develop standardized cost effectiveness analysis:

1. Care system variation. True difference in treatment between health care organizations
2. Costing method variation. Methods of assigning cost differ
3. Coding system variation

Focus is on health plan liability - the direct health care cost of an intervention, relative cost of treatment. Multi-site studies provide generalizability at the expense of internal (site) validity.

Methodology:

1. Identify the production function
2. Patients' interaction with the intervention
3. Resources consumed during implementation - microcost
4. Expected treatment and - gross cost

Quantity consumed over a period of time divided by unit cost...

Opportunity cost: Value of the resource in its best alternative use.

Focal question:

What is the marginal incremental cost of treating an extra patient or generating an extra unit of outcome? Use average variable cost.

Managed care data generally available from several sources:

- Eligibility, claims, utilization, encounters, billing, financial accounting, clinical information systems
- Pool these data sources into a usable format. This is challenging because data systems are generally set up for health plan operations and administration, not for research

Controlling variation:

There are three types of variation which must be controlled in managed care economic research...

- Care system variation. (Differences in the input mix.) May be controlled through the protocol. Control is resource intensive over longer periods of time
- Costing method variation. Some organizations use claims to capture all care provided and some use claims only for externally provided care. Differences in submitted, allowed, denied and paid claims. Utilization data systems are usually a compilation of inpatient, outpatient, lab, and pharmacy data
- Coding system variation. Local coding systems developed at departmental level are difficult to map. Network providers may code differently than internal providers. Fee-for-service providers have a financial incentive to code correctly (contrasted by capitated provider systems which do not have financial incentive for accurate coding)

What is the effect of this variation in a multi-site cost effectiveness analysis? What is the effect of the intervention on the incremental cost effectiveness ratio?

1. Weighted average of individual site ratios, weighted by population
2. Relative comparisons should be valid
3. Validity is lost when making absolute cost comparisons between interventions if variability has not been correctly accounted for

CONCURRENT SESSION II C

Research Administration Track: Getting the Buck for the Bang –How to Successfully Develop and Negotiate Budgets for Industry-Sponsored Clinical Trials

Session Chair: Nancy King, Kaiser Foundation Research Institute

Speakers: Steve Stoller, PhD, MPH, Kaiser Foundation Research Institute

Background:

- Kaiser suspected that they were 20-50% under-budgeting their clinical research trials.
- Steve Stoller, Health Care Economist was hired to create a methodology for developing future budgets.

The Clinical Trial:

- Clinical trials are a vital step in the drug development process.
- The sponsor, pharmaceutical companies, are for-profit. Their shareholders demand a high level of profitability. They depend on a continual flow of new drugs.
- Pharmaceutical companies get tax credits for their R & D spending.

The Economics of a Clinical Trial:

- Clinical trials are a business decision. The pharmaceutical company's goal is to drive down their costs as far as possible i.e. get the trial done with the lowest outlay on their part. Trend is to outsource some clinical trials off shore especially to India.
- Kaiser was seen as a low cost site because KP had historically developed budgets that didn't cover their full costs.

The Pharmaceutical Company View:

- PICAs is a database used by all pharmaceutical companies for cost comparison purposes on clinical trials. The better institutions know their costs, the less threatened they are. Proactive pricing-means the drug company sets what they feel is the legitimate price they will pay.

The Health Plan View:

- Industry attitude is "let the health plan pay." Traditionally routine development costs have been passed on to payers/consumers.
- Kaiser is a large participant in drug trials. However, the budgets are negotiated one-by-one, at each site.
- Capturing the full costs of a clinical trial is easy in theory, but very hard to determine in a large organization due to size, overhead, and allocation of internal costs.

The Cultural Barrier:

- Physicians don't think like economists and take the view that "the organization will pay." Financial concerns take a back seat to the scientific and medical care aspects of the clinical trial.
- Kaiser is refocusing on capturing the full costs of clinical trials.

The Coding System:

- The basis being used is from the Current Procedural Terminology (CPT) system of identifying codes for reporting medical services and procedures.
- The Relative Benefits Relative Value System (RBRVS) assigns a relative value per CPT code, to capture the intensity of resources allocated. This system was developed by Harvard for HCFA. HCFA assigned regional dollar weightings to RBRVS.
- Kaiser creates such a fee schedule to charge external payers for non-members. Using this same fee schedule, Kaiser Foundation Research Institute can develop clinical trial budgets for pharmaceutical companies.
 - Step 1: translate a study into CPT codes.
 - Step 2: attach a fee schedule to the CPT codes to come up with a budget.
- "Standard of care" is a critical definition. If a health plan such as Kaiser is generous in its standard of care, it will reduce its ability to charge for non-standard care. Need to ask the sponsor to define standard of care and compare Kaiser's internal definition for same care. The key is to negotiate.

Barriers to change:

- Habitual attitudes about payment on both sides of the industry
- Expectations about motives concerning scientific and patient well-being
- "The health plan will pay."

General budget issues:

- Kaiser is trying to move toward a standard contract (e.g. 25% indirect costs on all direct costs in a clinical trial.)
- Kaiser is trying to match cash flow to timetable of work performed.
- Kaiser is trying to get non-refundable up-front payments for start-up expenses & risk of terminations for screening failures or patients who drop out of the study protocol. Also trying to get lump sum payments for explicit expenses like FDA audits, IRB initiation fee, and pharmacy set up fee, in addition to indirects.
- "Negotiating the art of the possible." Win-win remains the guiding principle. "When you want the frame, negotiate for the picture."