

# Practice-Based Research Networks in the 21st Century

## *The Pearls of Research*



Proceedings from  
the Conference  
Convened by the  
AAFP Task Force to  
Enhance Family  
Practice Research  
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## *The Pearls of Research*

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# Foreword

**F**or two days in September 1998, some of the top experts in family practice and family practice research assembled in Leesburg, Va., to assist the American Academy of Family Physicians (AAFP) in charting the course for family practice research networks into the next millennium. Hosted by the AAFP Task Force to Enhance Family Practice Research, the conference was an important component in the Academy's plan to bolster the capabilities of the discipline to undertake research that will improve the care of patients and demonstrate the worth of family practice.

This bold plan to enhance family practice research was initiated at the 1997 Annual Scientific Assembly in Chicago, Ill. The AAFP Board of Directors placed before the Congress of Delegates a plan written in response to the actions of the 1996 Congress. These actions endorsed the call of then AAFP President Douglas E. Henley, M.D., and then AAFP President-Elect Patrick B. Harr, M.D., that the AAFP create programs to assist and develop family practice research opportunities.

The Board has since allocated \$7.72 million over five years to fund research to demonstrate and document what family physicians do every day, the range of

conditions and problems they see and treat, and the complex struggles they face. While most research has been conducted on small subsets of the population, family physicians have a tremendous base of patients — and thus a tremendous potential for research.

Upon approval by the 1997 AAFP Congress, the Chair of the Board appointed a seven member task force to implement the plan. The Task Force to Enhance Family Practice Research initiated an aggressive program to implement the five-year plan.

Based on consideration of the lead-time required to see measurable success for each grant component in the plan, and the need to gather crucial information on the current state of family practice research, the Task Force established the fielding of the Family Practice Research Center Program as the highest priority, followed by advanced research training, practice-based research networks, and joint family practice-managed care organization programs.

The Task Force recognized the unique and crucial role of practice-based research networks (PBRNs) in family practice research. For the first two years of the plan, the Academy provided core support for the Ambulatory Sentinel Practice Network (ASPN). In the last three years of the plan, funds are available for continuing support of PBRNs.

As the Task Force continued to develop the plan in regards to PBRNs, it found it had many unanswered questions about the various models of PBRNs, including the relative advantages and disadvantages of a national versus regional approach; the relative state of the art for PBRNs; technical support for PBRNs and other related issues.

The Task Force explored the possibility of linking PBRNs to other resources such as MCOs, research centers and the pharmaceutical industry. Because the Task Force did not feel it had sufficient information to initiate any funding program, it convened the conference on *Practice-Based Research Networks in the 21st Century*.

A subcommittee of the Task Force, led by Drs. Barbara Yawn, Larry Culpepper and Paul Frame, planned the conference with the goal of determining the current status of PBRNs and their strengths and weaknesses to assist in their further development and direction of PBRNs over the next 10 years. This meeting brought together key stakeholders in the practice-based research community who provided reports on the current successes and challenges for PBRNs. The wealth of information gathered from the conference will assist the Task Force in developing its plan to further secure the specialty of family medicine for now and in the future.

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## Opening Remarks

JOSEPH E. SCHERGER, M.D., M.P.H.  
*Chair of the Task Force*

**T**his conference is a problem-solving meeting that has a very specific purpose: to help the Task Force and all of you take stock of where we are with practice-based research and where we should be going. The Academy has invested \$7.72 million in a research initiative that has five components. First, the launching of the Family Practice Research Center Program. Second, the granting of funds for advanced research training. Third, the support of practice-based research networks.

Fourth, the investment in research projects based in managed care centers. And finally, advocacy to get more money for research.

This meeting will also help the Task Force and the Academy decipher what is the best way to use our financial resources to support and enhance practice-based research. We are here today because the leadership of the Academy appreciate the critical importance of family practice research.

This initiative started with Drs. Doug Henley and Pat Harr, and the torch has been carried by Dr. Neil Brooks, last year's president, and our new president, Dr. Lanny Copeland. It is my pleasure to introduce you to our new president.

LANNY R. COPELAND, M.D.  
*1998-99 President, American Academy of Family Physicians*

**T**he Academy has had great successes over the past few years and this has brought additional financial resources to our disposal. The leadership of our organization contemplated the best use of these additional funds. We looked at what we

could do to secure the specialty of family medicine for now and the future, and we noticed there was little support of family practice research. I believe the \$7.72 million that has been allocated to family practice research is extremely important to the success of family medicine. It will further define the specialty as it continues to develop and change.

Family physicians have a tremendous base of patients and this is a tremendous research potential — and a tremendous

education potential. Research and education go hand in hand. Without education you cannot research. And without research, you cannot educate.

The leadership of the Academy is excited with the actions of the Task Force and the

development of the research plan. We believe this will reap tremendous dividends for our membership and ultimately for the patients we serve. I congratulate you and tell you that we are extremely proud of what you are doing and what is going to be done.

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## Charge to the Conference

BARBARA P. YAWN, M.D., M.Sc.  
*Task Force Member and Conference Chair*

**R**esearchers, policy makers and physicians agree that patients are an important source of information regarding medical care and medical practice. Our pharmaceutical and subspecialty colleagues provide us data from clinical trials using very select groups of patients in carefully controlled circumstances that suggest new treatment and procedures may be beneficial, that they are efficacious. But it is the effectiveness studies done with unselected groups of patients, often primary care patients, that confirm or deny the potential benefits.

Everyone is familiar with the most common source of information for the efficacy studies, academic settings and subspecialty clinics. Researchers, policy makers and even primary care physicians may be less familiar with sources of information for the effectiveness studies that allow us to translate research data into practice. Practice-based research networks are designed to collect and evaluate data on patients as they initially present to the health care community, following them through the diagnostic process including referrals or hospitalization when necessary. These networks represent a large,

almost untapped fountain of data, the type of data necessary to understand the entire spectrum and natural history of disease, the factors that modify efficacy as it is translated into effectiveness and the public's and patients' acceptance of health care and health care services.

Practice-based research does not come without problems. Until recently, only randomized controlled trials based in university centers or other subspecialty-based centers of excellence were recognized as valuable. Even our classification scheme for evidence-based medicine ranks the RCT on the A list despite the potential short comings of lack of generalizability to the population at large and to the entire spectrum of disease. Recently, the importance of other types of work have been touted as on the B list and necessary if not sufficient to understand the disease process and its therapy. It is practice-based networks that can provide the laboratory for some of the RCT that will be generalizable to the population of primary care patients and facilitate the completion of many of the epidemiology and natural history studies that will facilitate new approaches to diagnosis, treatment and enhance patient's participation and acceptance in the health care process.

Today we have come together to discuss what PBRNs have accomplished, what they

hope to accomplish and what they may be able to accomplish in the future. While we will celebrate successes, we must also review failures. We will identify challenges to ourselves, to the practicing physicians who collaborate with us, to statisticians who develop new methods to help us analyze our data and to the visionaries who push all of us beyond our current limits. We believe PBRNs are integral to the fundamentals of science-based medical practice and primary care.

I ask you to participate in this program by always asking what more could we have said, what more can we do, what is the next question we should ask, and where and how should we seek the next answer.

For the next day and a half we are going to do some very extensive work. By the end of this conference, we will have done the following:

- Define the agenda necessary to establish practice-based research as an important

and widely accepted research modality. The “important” half may not be quite as difficult as the “widely accepted” half of that statement.

- Define the scope of research best accomplished in PBRNs.
- Define the strengths and weaknesses of practice-based research evidence obtained from various research modalities, such as randomized control trials, cohort and case-control studies. What is the strength and weakness of research done in a practice base as opposed to the places where this research is usually done and funded — such as tertiary care practices or in very specialized populations.
- Help the AAFP determine how to best facilitate the growth and maturation of practice-based research.

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# Acknowledgments

**T**he Task Force acknowledges the staff of the AAFP, the Board of Directors, and the members of the AAFP for their enthusiastic support of this effort.

Many people have worked to bring us here together today. I would like to acknowledge just a few of them. First, my fellow subcommittee members, Drs. Larry Culpepper and Paul Frame. Their knowledge and commitment to family practice research are well known and their wisdom and enthusiasm are an inspiration.

Dr. Herbert Young and his staff at the AAFP made a daunting task an achievable goal through their diligence, persistence and hard work. Tom Stewart and Carol Tierney deserve special recognition. The publication of these proceedings is possible through the work of the Publications Division staff of the AAFP.

Thank you to everyone who participated in the conference.

— BARBARA P. YAWN, M.D., M.Sc.

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# Section 1

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## **What is the state of the art of practice-based research networks in family medicine?**

The History of PBRNs, LARRY A. GREEN, M.D.

The Scope of PBRNs

Ambulatory Sentinel Practice Network, PAUL A. NUTTING, M.D.

Dartmouth COOP Project, JOHN H. WASSON, M.D.

Kaiser Permanente-Northern California, JOE V. SELBY, M.D.

A Reaction, LARRY A. GREEN, M.D.

Panel and Full Group Discussion/Question and Answer

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# The History of PBRNs

## The Establishment of Practice-Based Primary Care Research Networks in the United States

LARRY A. GREEN, M.D.

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A practice-based research network is a group of practices devoted principally to the care of patients. These practices are affiliated with each other, and perhaps with academic or governmental enterprises, to investigate the phenomena of clinical practice as it occurs in communities.

A primary care network is distinguished by its ongoing commitment to understanding primary care. Such networks are characterized by an organizational structure that transcends a single study, enduring through time to address multiple or recurrent questions.<sup>1</sup> The feasibility of these networks has been established.<sup>2,3</sup> They offer an important laboratory for the scientific investigation of primary care.<sup>4</sup>

### **The modern saints of practice-based research**

Before there were research institutes or networks of practices, there were individual practitioners who studied their patients' problems with scientific rigor. Among these were five general practitioners who have

been recognized for their seminal work during the past 125 years. They are James Mackenzie, Will Pickles, John Fry, F.J.A. Huygen and Curtis G. Hames. Each of these pioneers demonstrated that important new knowledge could be discovered by practicing family physicians. And this is far from an accepted principle in the United States. These doctors all wondered about their patients' problems and they developed a means of gathering and recording data on their patients.

**James Mackenzie.** James Mackenzie attended medical school in Edinburgh in the late 1800s and practiced in Burnley, England. He wrote, "I had not been long in the practice when I discovered how defective was my knowledge. I left college under the impression that every patient's condition could be diagnosed ... for some years I thought that this inability to diagnose my patients' complaints was due to personal defects. But gradually, through consultations and other ways, I came to recognise that the kind of information I wanted did not exist."<sup>5</sup>

Although known throughout the world for his work concerning the heart, Mackenzie never intended to specialize. He never grew tired of expounding on his belief in the unequalled importance of the ordinary general practitioner. In retrospect, many classify Mackenzie as a consultant, a specialist, and



more specifically, a cardiologist. But his biographer noted that Mackenzie's concern for the background of each patient — the whole person in his or her total environment — gives us the answer: Mackenzie was a general practitioner who had a special interest in heart disease.

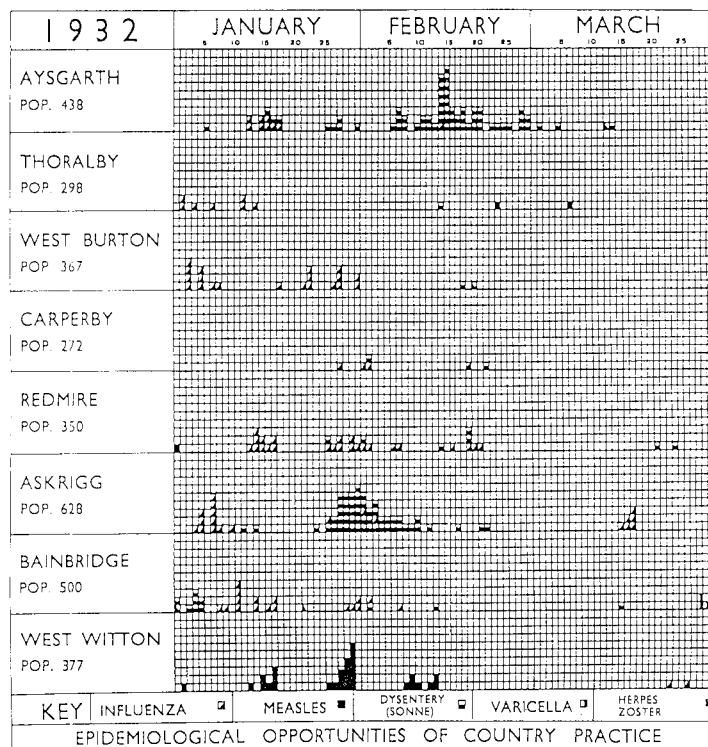
He thirsted for better knowledge and displayed critical attention to clinical details and was an astute observer. He used information from any source he could find, acquired and developed scientific instrumentation to use in practice, and persisted to follow-up with patients to determine answers to clinically important questions. He was knighted for his work, and Sir James Mackenzie indeed demonstrated the power of practice-based research before this century began.

**Will Pickles.** Will Pickles served his patients in Wensleydale for 50 years, and it was from this practice that he conducted

detailed epidemiological research over some 30 years. His book "Epidemiology in Country Practice" describes various epidemic illnesses, such as infectious hepatitis.

*Figure 1* shows an example of his meticulous paper-and-pencil methods that permitted him to discover new diseases, understand incubation periods and the transmission of diseases.<sup>6</sup> He was recognized for his efforts by being elected the first president of the College of General Practitioners in England, and being the first recipient of the James Mackenzie Medal in 1955. Anyone claiming that there is no important research to be done in primary care practice need only review Will Pickles' work to realize his or her error.

**John Fry.** I had the very good fortune to see John Fry in action at his office in Beckenham, England, during the summer of 1991. Fry knew his patients well; as they came and visited with him, he first listened



**FIGURE 1.** Will Pickles's paper-and-pencil methods

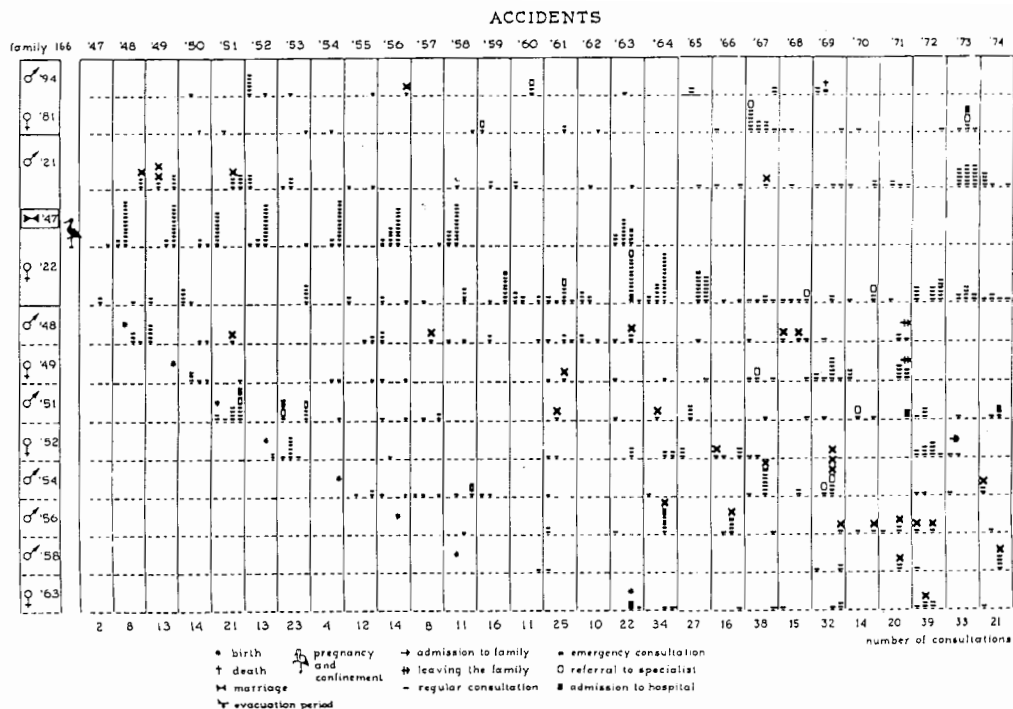
carefully without being diverted. Soon I noticed he made notes in a notebook about this visit, collecting the elements he had selected to record as the consultation continued. In only a few minutes, the patient's concern was addressed and Fry's "minimum data set" had been collected. Because of this meticulous reporting — discreet from the medical record — he was able to declare what was contained in his practice and calculate the rates of illnesses, diseases and services — tasks that are not often achieved by even the most computerized family doctor today.

Fry wrote in the preface to the second edition of his book "Common Diseases: Their Nature, Incidence and Care" that he hoped "... this book will demonstrate once again the tremendous scope and opportunities that family physicians (general practitioners) have to observe, study, analyse and research their patients and the problems and

the diseases from which they suffer. The medical world has been deprived too long of this vital information. The medical world is waiting for more such analyses."<sup>7</sup>

**F.J.A. Huygen.** As Pickles examined infectious diseases, F.J.A. Huygen focused with similar painstaking detail on the complexities of family life and health in his practice in the 1940s. He practiced in an area of the Netherlands that had little migration, and the population relied on his practice as the only general practice in its area. *Figure 2* is an example of the recording system he developed to permit examination of family patterns of illness.<sup>8</sup>

His book, "Family Medicine: The Medical Life History of Families," reveals a multigenerational biopsychosocial understanding of persons within their families. He used the case history method to characterize families (e.g., young family, older family, family with a father who has a chronic



**FIGURE 2.** F.J.A. Huygen's recording system used to examine family patterns of illness

illness, family with a disabled child). He was recognized in North America in 1997 with the Maurice Wood Award for providing another framework for understanding the evolution of disease and the work of family doctors.

**Curtis G. Hames.** Curtis G. Hames had an irrepressible curiosity during his lifelong practice in Claxton, Ga. This led him to an array of research enterprises throughout the world. Among them are the famous Evans County Cardiovascular Studies. In his introductory article in the *Archives of Internal Medicine* in 1971, Curtis wrote that the studies were developed "... from the clinical observation that coronary heart disease appeared to occur less frequently among blacks than whites, even though hypertension was obviously more common in blacks and they consumed a higher animal fat diet."<sup>9</sup>

He elegantly detailed his study site, noting, for example, that there were 2,174 households, including 324 one-person households; and for those 14 years of age or older in Evans County, 3,300 were married, 486 widowed, 129 divorced and 1,199 never married. He characterized the terrain as composed of red clay or sandy soil, covered by pine forests harvested for pulpwood, turpentine and lumber. The breadth of this view is what Hames refers to as "the total approach" to understanding the basis of health and disease.

His collaborator, John Cassel, credited the excellent rapport between Curtis and the population of Evans County for their astonishing 92 percent success rate in a study designed to include every adult resident in the county over the age of 40, and 50 percent of those 15 to 39 years of age.<sup>10</sup> These individuals underwent a standard medical examination and a battery of laboratory tests, and they continue to be tracked. I was privileged to visit Hame's practice and see his basement freezers containing soil, water, butter beans and other environmental substances labeled by time and location, as well as clinical specimens and data derived from the individuals

from Evans County. As individual clinicians can be labeled "sentinel physicians" and selected practices labeled "sentinel practices," Hame's county can be labeled a "sentinel county."

### **The neglect of primary care**

Each of these research pioneers provide inspiration for the development of practice-based, primary care research networks because each demonstrated that important new knowledge could be discovered by the practicing family doctor. They each wondered about their patients, developed means of gathering and recording data, and found collaborators and support from their staff and local communities. Unfortunately, they practiced in an era that was over-committed to specialism. Research focused on molecular mechanisms of disease. The rush to specialization by the medical community and the linking of research to specialists resulted in decades of neglect of primary care and virtually no recognition of the need to investigate care in the primary care setting.

Instead, the common wisdom viewed primary care practices as relatively boring places that could be potential sites of application of the fruits of research done elsewhere in research laboratories, hospitals and institutes. In this mind-set, family doctors were a "problem" and were often referred to as "inept" by the faculty of medical schools. It was not until the rebirth of general practice as family practice in the 1960s that an alternative viewpoint would emerge in the United States.

Once the new specialty of family practice was launched in 1969, educational programs could be implemented that were designed to train family physicians. Systems to describe family practice were immediately proposed.<sup>11</sup> Systematic descriptions of family practice<sup>12</sup> and primary care<sup>13</sup> were established based on data developed and shared among practices selected at random or because of availability. These early descriptions illuminated the content and complexity of the work being undertaken by family doctors and stimulated

the fledgling family medicine academic community to experiment with data collection systems. Specific studies (e.g., assessment of prophylaxis treatment for acute otitis media) concluded that important research could be done in community practices.<sup>14</sup> These developments inspired the first regional practice-based research networks.

#### **Early regional PBRNs in the United States**

Among the early regional networks started in the 1970s were the Family Medicine Information System in Colorado (FMIS)<sup>15</sup> and the Cooperative Information Project.<sup>16,17</sup> These regional networks learned from each other and succeeded in conducting studies focused on what was happening in primary care. They attracted funding from medical schools, national philanthropic foundations and federal programs such as Health for Underserved Rural Areas.

As the 1970s closed, these early networks enjoyed sufficient success to stimulate debate about the next steps in the context of the microcomputer's development. Among them was a small group convened by Gene Farley in Denver in 1978 to consider establishing a national sentinel practice system. It was this idea that led to the Ambulatory Sentinel Practice Network and provided in retrospect what appears to have been a nidus for the establishment of primary care PBRNs in the United States.

#### **The development of the first national primary care research network**

In 1978, sentinel practices were functioning in other countries as part of disease surveillance systems, occasionally expanding their efforts to explore a topic in some depth. The following year, Farley proposed to the North American Primary Care Research Group (NAPCRG) that it was time to launch a nationwide system of primary care practices to continuously report on problems seen in primary care. As researchers are known to do, the members of NAPCRG expressed disagreement and pessimism about the feasibility and utility of such a system that collected

data without carefully constructed questions to guide data collection. After much discussion, the idea was relegated to a small group of optimists who agreed to serve as a steering committee for further consideration. The members of this initial steering committee were Lorne Becker, Larry Culpepper, Eugene Farley, Jack Froom, Rick Kirkwood, Jack Medalie, Walter Rosser, Alan Shapiro, Kerr White, Maurice Wood, David Yens and me. I agreed to chair the committee and the all-volunteer sentinel practice group scattered across the continent to clarify the issues involved in establishing a national primary care research network. By July of 1980, an international search identified several examples of sentinel practice-like endeavors in various stages of maturation.

**Birmingham, England.** Some 14,500 patients were monitored for contacts with their general practitioners via a computer-based weekly batching system overseen by K.W. Cross. (The Royal College of General Practitioners conducted major morbidity surveys from time to time, e.g. 1955-56, 1970-71.)

**Sydney, Australia.** A.I. Adams, working in the Health Commission of New South Wales, indicated there were many family physicians in Australia interested in sentinel systems including practitioners in Darlinghurst, Sydney, Adelaide and Tasmania.

**V. Babuskaas.** V. Babuskaas, while working in the division of noncommunicable diseases at the World Health Organization, collaborated with I.S. Glasunov and K. Westlund to establish a new community-based system to monitor and control noncommunicable diseases. Instead of a single disease orientation, they envisioned a system incorporating several diseases and problems (which was discussed as early as 1957 but was thwarted by medical tradition and inclinations of fund-raisers toward specific issues).

**T. Strasser.** T. Strasser studied hypertension and knew of a comprehensive cardiovascular community control program being

tested in what was then Yugoslavia. Documents were obtained from 1973 and 1975 expressing an unmet need for hard data from the community, including reference information for comparisons.

**Ottawa, Canada.** Walt Rosser was involved in testing a computerized system with 150 Canadian physicians. He reported impediments associated with differing objectives, lack of funding and defining minimum data sets.

**The Canadian Influenza and Surveillance System.** The Canadian Influenza and Surveillance System, partially based on the Miller and Lee studies of influenza in Britain from 1967 to 1968, was envisioned as an early warning system and not an epidemiological survey.<sup>18</sup> It demonstrated that family doctors could generate reliable and useful nationwide data on health problems of public concern. (This project evolved as NaReS [National Recording System] and also continues in the form of the Viral Watch Project overseen by Michael Tarrant and others associated with the College of Family Physicians of Canada).

**Oxford, England.** J.A. Baldwin conducted the Oxford Record Linkage Study, which was partially described in the 1974 Royal Society of Health monograph, "Community Health Information Systems." He suggested that medicine needed new systems of information to know the behavior of health care systems and to gather extensive knowledge of the populations served. He pointed out that information systems based in primary care were technologically and economically feasible and held sufficient promise to warrant their development with attention to their limitations. He lamented that, with a few exceptions, monitoring of primary care was almost nonexistent. He noted that their system developed ways of acquiring data as a bi-product of the basic clinical operation.

**Australia.** In 1979, C. Bridges-Webb recalled the 1962-63 Australian National Morbidity Survey that was based on 85 volunteer general practitioners throughout Australia. He reported a more recent

pharmaceutical company sponsored, six-year reporting exercise by 50 full-time recorders and many other part-time recorders. Over one million contacts were recorded. The basic means of reporting was a triplicate prescription. He suggested this type of recording might reflect the habits of doctors more than community morbidity.

**The Netherlands.** The Sentinel Stations of the Netherlands began reporting in 1970 and traced its roots to the late 1960s, when the first department of general practice was established at Utrecht. The Dutch government provided a permanent grant to establish the Netherlands Institute for General Practice in 1965 and encouraged a group of pioneers to start a set of cooperative studies about general practice. With some prior positive experiences in Rotterdam, The Hague and Amsterdam in mind, the new Institute created a national network of sentinel stations to gain insight into the morbidity patterns of the Dutch population.

The structure of the health system permitted stratification of the sentinel general practices to include 1 percent of the population and be representative of the entire population in terms of age, sex and urbanization. These sentinel stations used a data collection form called the "weekly return" that permitted a variety of problems to be monitored and studied, with changes in topics occurring annually.

In addition to the regular weekly reporting, longitudinal studies among patients with particular disorders were carried out. At the time this information search was conducted, the Sentinel Stations of the Netherlands were directed by H.J.A. Collette and had reported on 30 issues as varied as attempted suicide, skull trauma in traffic, suspicion of a battered child and prescriptions for the morning-after pill. The Dutch system blended surveillance and research.

#### **The results of the information search**

This international information search provided insight about the potential and the challenges involved in setting up networks of

primary care clinicians to do surveillance and research, and, overall, suggested that important work could be done if networks could be created and sustained. As this international survey was being conducted, the NAPCRG Sentinel Practice Steering Committee formed several working committees and recruited other members of NAPCRG to examine some of the critical issues that required resolution before proceeding with implementation. These subcommittees had input from some 60 individuals as they conducted their work from their own offices and prepared written reports addressing the following questions:

- What are the questions that justify the creation of a sentinel practice network?
- What are the validity and reliability issues?
- What are the privacy, security and confidentiality issues?
- What denominators are required for a U.S. network?
- Why would practitioners want to be part of a sentinel practice network, and what will they need to participate for long periods of time?

Approximately 35 individuals interested in sentinel practice networks convened at the April 16, 1980 NAPCRG meeting in Lancaster, Penn. After a lively exchange focused on the work of the steering committee, this ad hoc group concluded that a sentinel practice network across Canada and the United States was possible, important and consistent with NAPCRG's objective to promote primary care research. The steering committee recommended that NAPCRG support the development of a North American sentinel practice network by formally charging the steering committee to develop a pilot project, oversee the selection of practices for a network and seek funding. The membership endorsed these recommendations, and approved an initial budget of approximately \$1,200.

### **Getting the ideas straight**

The working groups prepared written reports and correspondence that I incorporated into an unpublished concept paper. Kerr White participated in this exercise and arranged for a meeting at the Tufts Center in Talloire, France, where a number of the protagonists for various national sentinel systems gathered for the 1981 Ives Baraud conference. I represented the sentinel practice steering committee and presented the paper, "A North American Sentinel Practice System: Progress, Problems and Potential."

Later in 1981, the steering committee submitted a proposal to begin the North American Sentinel Practice System to the Rockefeller Foundation. Kerr White — in his role as vice president of the foundation — approved the first of three annual grants-in-aid of \$25,000. The ad hoc steering committee was revised and formalized to oversee what was named The Ambulatory Sentinel Practice Project of North America (ASPPN). As of November 1, 1981, this new steering committee was composed of Lorne Becker, Gene Farley, Bill Freeman, Jack Froom, Curtis Hames, Walt Rosser, Milton Seifert, Maurice Wood and me.

At the 1982 annual meeting of NAPCRG, we took formal actions to define the purpose of ASPPN and to establish policies and procedures for governance and operations. We initiated conversation with the Influenza Branch of the Centers for Disease Control and Prevention, and appointed an advisory committee, the first 38 sentinel practices and the support staff (Linda Niebauer at half time and me as a volunteer principal investigator). The steering committee also defined the requirements for the practices, including a registration data set and age/sex reports, established the weekly return as the core data collection tool (*Figure 3*), and approved publication and confidentiality policies.

The steering committee decided that the first ASPPN studies would concern headache, pelvic inflammatory disease and

[illegible][illegible]

miscarriage. After piloting the studies, ASPPN initiated data collection in all practices in November 1982. Some four and a half years after Dr. Farley proposed such a network to NAPCRG, the first national primary care PBRN came into being with practices in Canada and the United States. The following year, at the suggestion of Milton Seifert, ASPPN dropped the word "project" from its title to reflect the intention of the steering committee for it to endure as an important infrastructure for family practice and primary care research. ASPPN became the Ambulatory Sentinel Practice Network (ASPN).

first full-time staff member, Linda Niebauer, was hired. Also, an event occurred that later became known as the Peaceful Valley Massacre. This event merits explanation.

Additional funding permitted the first ASPN Convocation, a meeting of the practices, the steering committee, investigators and leaders from various interested organizations. This meeting occurred in the rustic surroundings of Peaceful Valley, Colo. Three experienced researchers proposed a new study of chest pain to the practitioners, who proceeded to demolish the proposal, preferring other approaches and topics. This event established a fundamental principle that has served ASPN and other networks well ever since: The practices are in charge.

PRACTICE-BASED RESEARCH NETWORKS IN THE 21ST CENTURY

realization of the early decision to establish ASPN as an entity independent of any particular university or governmental agency. In 1986, ASPN was incorporated with a board of directors with majority representation by practicing physicians. A supplemental Kellogg grant awarded in 1985 permitted Jack Froom and Larry Culpepper to bring to life the International Primary Care Network (IPCN),<sup>20</sup> which emulated the policies and procedures of ASPN. IPCN conducted its first study involving nine countries, discovering significant international variation in the treatment of acute otitis media.<sup>21</sup>

*Table 1* shows some of the performance characteristics of ASPN from its beginning

through 1991, confirming the ability of a group of volunteer primary care clinicians to sustain their research efforts as a network for an extended period of time, addressing a variety of relevant questions.

#### Other national networks

As NAPCRG embraced all the primary care disciplines, so did the Cooperative Information Project (COOP), ASPPN and ASPN, resulting in the inclusion of nurse practitioners, physician assistants, internists, pediatricians and a few other clinicians into the early networks. As these networks matured, they attracted attention by other entities with similar aspirations, such as the

**TABLE 1. ASPN performance characteristics, 1983-1991 (as of September 1 each year)**

	1983	1984	1985	1986	1987
Number of practices	38	46	47	52	64
Percent rural	63%	63%	65%	60%	62%
Number of clinicians	78	138	145	183	190
Mean age	38	37	40	39	38
Number of doctors	66	117	125	158	167
Number of residents	0	0	0	0	0
Availability of practices' doctors to respond to patients					
Least	63% (Sun. aft.)	69% (Sun. aft.)	65% (Sat. eve.)	65% (Sat. eve.)	68% (Sun. aft.)
Most	98% (Mon. aft.)	96% (Tues. aft.)	94% (Tues. aft.)	98% (Tues. aft.)	95% (Tues. a.m.)
Evenings	70-75%	70-78%	64-72%	65-76%	69-76%
Coverage by practice 52 weeks a year	69%	70%	70%	78%	77%
Reporting rate		89%	86-93%	93-95%	95-98%
Age/sex reports*					
Number submitted by year's end	30	31	41	38	54
Number completely enumerated	7	11	21	30	48
Total patients	114,889	106,402	200,686	166,509	222,430
Percent female	56%	55%	57%	57%	56%
Estimated active population	145,529	157,882	230,056	227,857	263,620
Average encounters per practice each week	160	167	156	177	191

\* Age/sex registers are reported for the previous two-year period (e.g., 1982-83 age/sex registers are collected in 1984).



American College of Physicians (ACP) and the American Academy of Pediatrics (AAP).

During the 1980s, ACP repeatedly considered primary care research network development, and it collaborated with COOP in a study of the COOP functional charts. ASPN repeatedly responded to requests from the ACP for information and invited collaboration, but ACP's interest waned as time went on. The AAP, however, pursued network development with vigor. Cross-fertilization between ASPN and what became PROS (Pediatric Research in Office Settings) occurred through shared board members, shared policies and procedures, and joint projects. PROS, launched in 1986,

became the second national PBRN, under the auspices of the American Academy of Pediatrics, which provided it with a stabilizing framework. Bob Haggerty, Evan Charney and Barbara Starfield provided critical leadership in the establishment of PROS, and Mort Wasserman was just the sort of director that was necessary. PROS and ASPN quickly learned to collaborate and support each other, rather than compete to their detriment. PROS refuted the notion that ASPN was just a one-time aberration.

In 1987, the American Board of Family Practice cooperated with Health Learning Systems Inc. of Lyndhurst, N.J., to launch a national network of diplomates named

**TABLE 1. (Continued)**

	1988	1989	1990	1991**
Number of practices	71	76	75	71
Percent rural	59%	59%	53%	54%
Number of clinicians	216	213	314	334
Mean age	39	38	39	39
Number of doctors	188	182	264	284
Number of residents	0	15	94	130
Availability				
Least	70% (Sun. eve.)	70% (Sun. aft.)	72% (Sun. aft.)	73% (Sun. eve.)
Most	97% (Tues. a.m.)	96% (Tues. a.m.)	98% (Fri. a.m.)	98% (Tues. aft.)
Evenings	70-82%	70-85%	72-86%	73-87%
Coverage by practice 52 weeks a year	76%	76%	80%	78%
Reporting rate	89-97%	94%	92%	87%
Age/sex reports*				
Number submitted by year's end	61	46	67	62
Number completely enumerated	49	44	63	53
Total patients	266,198	297,923	309,925	303,752
Percent female	56%	56%	56%	55%
Estimated active population	309,838	327,013	346,933	347,843
Average encounters per practice each week	195	184	195	173

\* Age/sex registers are reported for the previous two-year period (e.g., 1982-83 age/sex registers are collected in 1984). \*\* This column represents data gathered through August 1, 1990.

The Clinical Experience Network. Their first study focused on managing hypertension in family practice. It took a real-world approach and specifically sought information about quality of life and cost/benefit measures. The study was overseen by an independent editorial board and 20 regional survey coordinators. Participating diplo-mates were compensated for their time and selected patient services through an educa-tional grant from G.D. Searle and Co.

The Practice Partner Research Network (PPRNet) also took on a national scope. This network, composed of practices using the same electronic medical record, included some 57 practices by the mid-1990s. Each month the practices extract data from their records using a program designed to collect information regarding patient-specific reasons for visits, diagnoses, medications, laboratory and radiology tests, and some outside records such as consultation reports. These are linked to a patient-specific code in the central database in a way that cannot be linked to an individual patient or provider, but permits investigation of questions across the entire system.

#### **Regional practice-based research networks in the United States**

In 1994, the *Journal of Family Practice* published a special issue on practice-based research. A survey indicated the existence of 28 active networks in North America.<sup>22</sup>

Among them were three regional networks launched in the 1980s that exemplify the work of these networks reported by John Hickner at the second AHCPR-sponsored primary care research conference in 1991.<sup>4</sup>

#### **The Pediatric Practice Research Group.**

Established in 1984, this network is affiliated with Children's Memorial Hospital in Chicago, Ill., and focused on the epidemiology, natural history and diagnosis of common ambulatory pediatric problems. Its attention to rigor and successful publication of its results provided another positive example of the value of primary care PBRNs.

#### **The Wisconsin Research Network**

(WReN). Established in 1987, this network demonstrated the synergy that could be attained through cooperation of the Wisconsin Academy of Family Physicians and the University of Wisconsin Department of Family Medicine. Its tenacity and advocacy for engagement of the American Academy of Family Physicians in network development provided another locus of leadership that benefited all other networks.

#### **The Upper Peninsula Research Network**

(UPRNet). Established in 1988, this network is affiliated with Michigan State University and adopted dual objectives of research and research training. It had a rural focus, and its leadership overlapped with the ASPN Board, providing opportunities to better understand the type of work that needs a national network rather than a local network.

The other regional networks listed in the *Journal of Family Practice* survey have contributed to the establishment of the value of practice-based research by networks. For example, the Research Association of Practicing Physicians (RAPP) in Ohio conducted the direct observation of primary care study directed by Kurt Stange and was the basis of an entire issue of the *Journal of Family Practice* in the spring of 1998. And regional networks in Michigan, Minnesota and Pennsylvania were contributors of original clinical research in a 1994 special issue of the *Journal of Family Practice*.

These regional networks have provided further evidence of interest, feasibility and importance of networks as a key infrastructure for family practice and primary care research. Further evidence is found in replication of these ideas in other quarters. For example, in 1998 a national neurological network called "CISNet" was reported. It was established to contend with the observations that some patients are hospitalized unnecessarily with neurological disorders and that expensive tests of little value are ordered by family doctors.<sup>23</sup> Another example is some 65 volunteer chiropractors and their staffs in ambulatory settings in the United States and

Canada who united into a practice-based research program to collect data on patients in their practices, seeking to understand utilization and outcomes.<sup>24</sup> The rapid multiplication and continued evolution of practice-based research networks in Europe was reviewed at the World Organization of Family Doctor's meeting in the summer of 1998, and a taxonomy of the various types of networks was subsequently published.<sup>25</sup>

## Conclusion

After 25 years, it is clear that primary care PBRNs are feasible and that they represent a useful infrastructure for the scientific discovery of family practice and primary care. Experience to date points out the great advantages enjoyed by those with enduring, core financial support — such as the Dutch with their early national commitment to primary care and their willingness to invest in primary care research. It is also obvious that these networks require collaboration, cooperation and a spirit of sharing and trust.

These networks are now at once both a place and a concept. As a place, they are a laboratory for surveillance and research. As a concept, they express the still unmet need for practicing primary care clinicians to accept responsibility to improve frontline clinical care by understanding what is happening in their practices. Successes to date have been sufficient to incite the Institute of Medicine's 1994 committee studying the future of primary care to recommend support to stabilize and expand practice-based primary care research networks.<sup>26</sup>

Recognition of the need for the type of research done in these networks has appeared outside the primary care literature, such as the report published in the August 1998 *New England Journal of Medicine* by the PURSUIT Trial Investigators. They studied the inhibition of platelet glycoprotein IIb/IIIa with eptifibatide in patients with acute coronary syndromes.<sup>27</sup> These investigators argued that their study had merit because, "unlike other studies of patients with unstable angina, in which the highly

selected nature of the study populations forced clinicians to extrapolate results to the broader range of patients seen in clinical practice, our trial was designed so that the circumstance of treatment closely resembled clinical practice."

It seems likely that practice-based primary care research networks are here to stay, but they await their full emergence as an infrastructure for the discovery of primary care. How these networks will unite with computer and web technology pleads for the attention of some of primary care's best and brightest minds. Much remains to be done to stabilize and enhance these networks and their successors.

Within the United States there remains great confusion about the nature, role and value of primary care. Much more work must be done to put in place a foundation of primary care for all people throughout the United States. Without such a foundation it is difficult to imagine how PBRNs and other primary care research efforts will be sustained, much less enlarged, to address the vast opportunities for improving health through primary care that now are lying in neglect, in the shadow of efforts to enlarge the traditional medical research enterprises.

I am reminded of comments made to the ASPN Board of Directors by Curtis Hames in 1989 concerning people as they set out to explore new worlds. He quoted Walt Whitman: "Sail forth – steer for the deep waters only, reckless O Soul, exploring, I with thee, and thou with me, for we are bound where mariner has not yet dared to go, and we will risk the ship, ourselves and all."

And that is where we are. In the history and evolution of primary care PBRNs in the United States, it is time to sail forth.

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# A Case Study of the Ambulatory Sentinel Practice Network

**Editor's note:** The Ambulatory Sentinel Practice Network (ASPN), a practice-based research corporation, received a great amount of recognition during the conference for its successes in practice-based research. Shortly thereafter, ASPN experienced significant financial difficulties. The ASPN Board of Directors decided on May 4, 1999, to complete its research projects and dissolve the corporation. Its Denver office will close by late December 1999.

ASPN's 750 practitioners include about 700 family physicians in some 125 practices in the United States and Canada. ASPN has conducted research since 1982 and has provided coordination for about 20 local and regional family practice research networks with about 3,000 members.

In a May 6 message to ASPN practitioners, the ASPN board noted ASPN's "enormously successful history," showing that practice-based research can force the rewriting of medical textbooks. The board recognized "the need for a stable organizational infrastructure beyond ASPN's current means to support the further development of practice-based network research in family medicine."

The proceedings of the conference have not been altered in light of these recent developments, and this book stands as a record of the presentations and the dialogue that took place.

PAUL A. NUTTING, M.D., M.S.P.H.  
*Executive Director, ASPN*

**T**he Ambulatory Sentinel Practice Network (ASPN) was established in 1978 to conduct practice-relevant research on the common problems faced by practicing family physicians. ASPN was conceived as a unique laboratory that capitalized on the wisdom, experience and insight of practicing family physicians to identify and frame research questions. The answers to these questions would be directly translated into their daily practices. In this way, ASPN

took on the challenge of reuniting practice and research, as well as uniting practicing family physicians and researchers. ASPN has attempted to base its research agenda, specific research projects and interpretation of results on the wisdom, experience and insight that comes from the frontlines of medicine.

Our mission statement affirms: "The Ambulatory Sentinel Practice Network is an international network of family physicians and other primary care clinicians dedicated to practice-based research. ASPN research promotes high-quality, cost-effective health care services by expanding knowledge about patients and their care. Our goal is to

improve health care outcomes for individuals, families, communities and the population as a whole.”

### **Structure**

ASPN is composed of approximately 725 clinicians from 148 practices in 40 American states and six Canadian provinces. Most ASPN clinicians are physicians, of which over 90 percent are family physicians. The active network also includes nurse practitioners and physician assistants, together comprising 15 percent of the network clinicians. Recruitment efforts are underway to increase the network membership, with an emphasis on practices that serve racial and ethnic minority populations, as well as practices in relatively under-represented regions of the United States and Canada.

A recent study of enrolled consecutive patients in ASPN practices yielded a total of 14.3 percent of visits by African-American patients. And 48 percent of the 148 practices (or 38 percent of participating clinicians) are in rural settings.

ASPN collects and maintains data in three areas of network operations. First, all ASPN practices regularly provide data that updates the characteristics of the ASPN practices and individual clinicians. This permits not only an accurate description of the network and its practitioners, but also the identification and tracking of relevant trends over time.

Second, beginning in 1991, ASPN has replicated the National Ambulatory Medical Care Survey (NAMCS) in all practices, and requires the NAMCS data collection in all practices joining the network. Although a number of specific analyses are still underway, an initial report suggests that the patients and problems seen in ASPN practices are similar to those of the general U.S. population seeking care from family physicians.<sup>1</sup> More recent analyses have also examined clinician behavior and suggests that there are no discernable differences between family physicians in ASPN and those participating in the national NAMCS.

Third, ASPN practices routinely report the total number of patient encounters for each participating clinician. This permits careful “denomination” of studies that attempt to describe the frequency with which certain phenomena are seen in primary care practices.

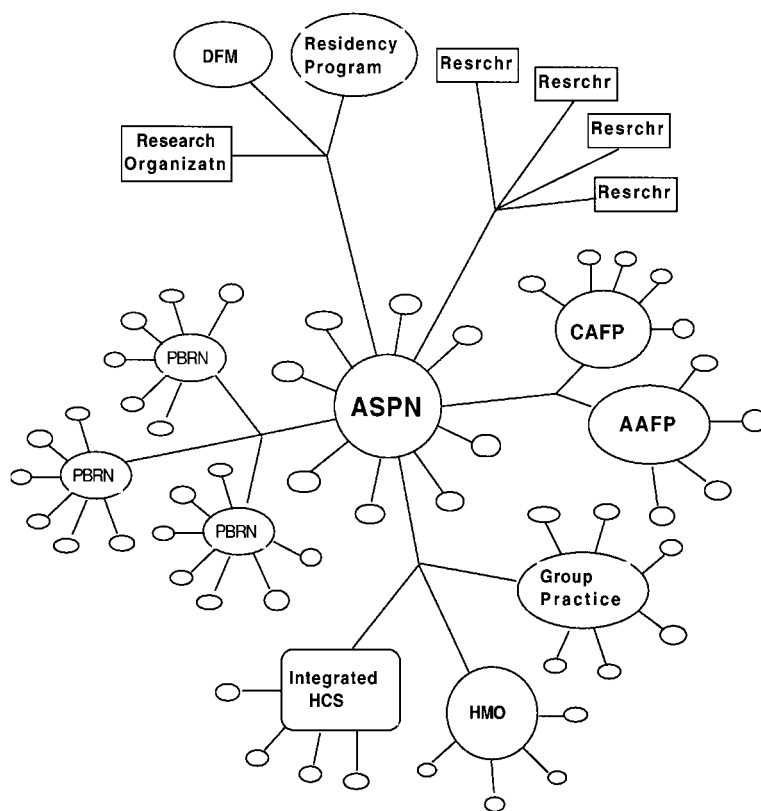
### **ASPN infrastructure**

ASPN has a rapidly maturing infrastructure to support its research activities which includes the following components:

- An experienced and capable central office. The central staff consists of 12 individuals experienced with practice-based research methods, linked by a local-area computer network (LAN) and supported by the full range of personal computer hardware and software required for planning, proposing and managing research projects, as well as World Wide Web and desktop publishing capacity for disseminating results. ASPN also has a close affiliation with the Biostatistics Center of the AMC Cancer Center (where ASPN occupies office space), who provides ASPN staff access to excellent biostatistics support.

- A growing network of researchers. ASPN is active in recruiting the best and brightest family medicine researchers to work on projects in their areas of interest and expertise. Twenty-two family practice and primary care researchers have accepted academic appointments with ASPN. Negotiations are underway with five academic units of family medicine (as described below). ASPN is clearly a public resource to family practice. It doesn’t belong to Denver. It doesn’t belong to Colorado. It belongs to family practice and the nation. We tend to think of ASPN as a virtual research organization. (See *Figure 1: ASPN as a virtual research organization*, on the next page.)

- Demonstrated ability to assemble a high-quality research team and develop research proposals that will be granted funding. Over the past five years, we have had six research projects funded by four agencies of the U.S. Public Health Service and another



**FIGURE 1. ASPN as a virtual research organization**

seven projects funded by five private foundations.

- Experience and expertise in implementing complex research projects. In several recent studies, ASPN has enrolled 960 children in the United States with otitis media; evaluated over 5,000 children in a study of behavioral problems; screened approximately 10,000 adults to detect and enroll 480 patients with major depression; and has recruited more than 200 family physicians to enroll 6,000 patients in a study of referrals. For most of the large and complex studies, ASPN has collaborated with other family practice networks, as well as recruiting participating practices from the larger community of practicing family physicians.

- Administrative expertise in managing the financial, personnel and other federal regulations pertaining to National Institute of Health research grants. ASPN has successfully managed six federal research grants from four agencies of the U.S. Public Health Service, and has successfully completed two federally required A133 audits.

- Effective mechanisms for communicating with practicing family physicians. This is accomplished through the annual meeting, an active ListServ (ASPNet) that supports ongoing discussion of research ideas and results, a recently redesigned and upgraded website that supports both discussion among ASPN members and an untapped potential for dissemination of results, and a regular newsletter.

### **Current activities and projects**

ASPN has extensive experience in conducting high-quality investigations in community-based primary care practice settings. ASPN has conducted over 50 studies spanning a broad spectrum of clinical and health services research that inform both clinical practice and health care policy.<sup>2</sup> ASPN studies have investigated the diagnosis and management of such diverse problems as major depression, otitis media, consultation and referral, carpal tunnel syndrome, depression, low-risk obstetrical delivery, headache, pelvic inflammatory disease, miscarriage, chest pain, accidental falls, acute low back pain, mammographic screening, asthma, cough in children, use of digitalis in congestive heart failure, clinical spectrum of HIV infection and HIB seroprevalence.

These studies have required varying levels of participation by clinicians and patients, with study duration ranging generally from three months to three years. While participation in any given study has always been optional, experience from previous studies indicates that 75 percent of ASPN network practices will agree to participate in any given study, and well over 90 percent participating practices will complete the study.<sup>3</sup>

ASPN practices report data on pocket-sized "study cards." This mechanism permits capture of two types of denominator information: proportion of the week in which the practice was available to its patients, and the total number of patients seen during the week. At any given time, the study card also captures data on one or two specific topics that are under study by the network. Some studies have used the study card to capture data from physicians at the time of each patient encounter.<sup>4</sup> The study card is often used to enroll patients for subsequent follow-up by the physician, by telephone or mail from the ASPN office, or by a patient self-administered questionnaire provided at the time of the visit.

A study of data quality done in conjunction with a study of spontaneous abortion

concluded that data collected by physicians at the time of the visit achieved an error rate of less than 5 percent.<sup>5</sup> Accuracy and appropriateness of ASPN data are periodically assessed by comparing information reported with information recorded in the medical records of patients receiving care in ASPN practices. ASPN has been collecting cross-sectional data since 1982 using the study card (or "card study") system. Response rates have consistently been 86 to 97 percent. Once practices have committed to participate in a study, fewer than 10 percent drop out of a study.

Card studies are considered very important to the success of ASPN research. They have moved from being a primary strategy for conducting studies to being a primary strategy for initial projects that help researchers develop ideas more fully. Card studies are one way for us to act quickly on the good ideas that come from ASPN practicing physicians.

Over the past five years, ASPN has complemented its traditional card studies with several large and complex studies. In 1993, ASPN received its first federal grant for a pilot study of low back pain, followed by major grants to study otitis media (AHCPR), behavioral problems in children (NIMH), a randomized trial to examine the effectiveness of depression guidelines (NIMH), a series of studies on laboratory testing in primary care (CDC), and a large descriptive study of consultation and referral (AHCPR). A summary of 14 current ASPN projects is summarized in the box on the next page.

ASPN's research agenda can be categorized in five areas: (1) research on managing common problems in family practice, (2) the family physician and patient in a changing health care environment, (3) behavioral health, (4) prevention and early detection of chronic disease, and (5) improving the quality of family practice:

1. Research on managing common problems in family practice. ASPN has conducted more than 50 studies of common conditions and challenges to family physicians. ASPN



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### ASPN's current projects

1. Managed Care and the Primary-Specialty Care Interface (Funded by: AHCPR)
2. Depression Guidelines: Outcomes and Costs of Care (Funded by: NIMH)
3. Brief Physician Intervention with Problem Drinkers in Primary Care (Funded by: Alcoholic Beverage Medical Research Foundation)
4. The Feasibility of the AHCPR Depression Guidelines: What lies in the gap between the Guidelines and best possible practice? (Funded by: The John T. and Katherine D. MacArthur Foundation)
5. Consultation and Referral for Major Depression (Funded by: The John T. and Katherine D. MacArthur Foundation)
6. Managed Care and the Quality of Primary Care
7. Physician Office Laboratory Studies (Funded by: CDC)
  - Physician Office Laboratory Survey
  - Laboratory Test Problems Study
  - Laboratory Test Ordering Study
  - Physician and Patient Understanding
  - Satisfaction with the Quality of Laboratory Testing
8. Exploring the Impact of Health Care Plans: Physician and Patient Perspectives on the Reimbursement Incentives Embedded in Health Care Plans (Funded by: AAFP/F)
9. The Effect Of Health Care Plan Characteristics On Physician And Patient Satisfaction With Referrals (Funded by: AAFP/F)

established in 1997 the North American Respiratory Infection Study Group (NARIS) to develop a coordinated agenda of research in respiratory infections for ASPN and other collaborating research networks. New projects in this area include a placebo-controlled, randomized, controlled trial (RCT) of macrolide antibiotics and beta-agonists in the management of acute bronchitis, the value of early detection of cognitive impairment, and management of heart failure.

2. The family physician and patient in a changing health care environment. ASPN established its Managed Care Task Force in 1995 to provide direction to its research in this area. The task force provided oversight for the development and implementation of several studies, including patient judgments of managed care, descriptive study of consultation and referral, "occult care" study (care provided to others in the family in addition to the patient on a given visit), direct-to-

consumer advertising of medications, and patient awareness and perceptions of the effects of health plan incentives on their physicians. A study is under development to focus on outcomes associated with mental health referrals.

3. Behavioral health. Recent work in this area includes studies of stress and illness; physician knowledge, attitudes and beliefs about depression; child behavior; brief interventions for problem drinking; and the effectiveness and feasibility of the AHCPR guidelines on treatment of depression. Two new studies have been submitted for funding that would test the outcomes associated with integration of mental health personnel into family practice, and a strategy for patient activation and chronic disease management for type 2 diabetes.

4. Prevention and early detection of chronic disease. Recent studies in this area include detection of cognitive impairment in

the elderly, mammography, PSA screening and cancer detection in primary care. Two new placebo-controlled RCTs are under development that will examine chemoprophylaxis in well populations with selenium, and collaboration in a trial of breast cancer prevention with raloxifene.

5. Improving quality of care. This area of research and development has been under discussion at ASPN for some time and is relatively new on the ASPN agenda. Previous studies have examined barriers to improved care for major depression, frequency and characteristics of errors in laboratory testing, and patient perceptions and expectations of laboratory testing. Under development is a study of physician-directed disease management, and an outcomes study of type 2 diabetes management in primary care settings.

#### **Affiliation with AAFP**

Beginning June 1, 1992, ASPN and the American Academy of Family Physicians (AAFP) initiated a cooperative agreement that unites us conceptually and financially, while sustaining the network's independence. In the spirit of this relationship, ASPN has assumed a leadership role in coordinating and promoting collaboration in research among the 10 local and regional research networks in family practice that have developed across the nation over the last five years. In this role, ASPN works with a "network of networks" that includes nearly 5,000 physicians.

ASPN has enjoyed wider exposure to the Academy's corporate partners; many are interested in exploring areas of mutual research interests. Within the past year, ASPN developed relationships with three corporate partners with whom opportunities for collaborative research appear bright. Broader partnerships with the industry could provide important diversity to ASPN's revenue stream, as well as new areas of potentially fruitful research.

#### **ASPN as a leader**

ASPN has played a leadership role for a

number of years in developing the capacity for practice-based research in family practice. We are continuing this pattern of leadership in developing partnerships with five other key groups.

1. Network of networks. For several years ASPN has provided leadership to a growing number of local and regional practice-based research networks in family practice. Within the past year, ASPN has developed formal affiliation agreements with 10 of the most active and mature networks (called the "ASPN Associates") and has facilitated the development of, and provided an administrative home for, the Federation of Practice-Based Research Networks (FPBRN).

The advantages of collaboration across networks is very apparent to those of us in ASPN. Individual networks lack the horsepower to do large, complex research projects. We can increase the power of the collective wisdom, experience and curiosity of our member physicians by linking them in ongoing discussions and ways to be discovered.

The infusion of clinicians from other networks allows a richer and more diverse set of ideas to be expressed. Letting our practicing physicians talk to each other in more efficient ways is incredibly important. It increases the opportunities for studies. We all know that a particular study in a particular practice may have one kind of a match with regard to interest and another kind of a match with regard to capacity to actually do the study. Having opportunities to match ideas with participants at the design stage, implementation stage or the interpretation level is critically important.

I believe it is very important for the networks to collaborate in order to do studies that truly matter and to share infrastructure costs. In my view there simply isn't enough money right now in circulation — despite the important work of the AAFP — to support the infrastructures of a large number of networks attempting to do this kind of work independently.

2. Large physician organizations. With the increase in the average size of family

practices and the trend toward affiliation with larger health care organizations, the small physician office that has been the traditional participating member of ASPN may become less typical of family practice. ASPN has been active in exploring relationships with larger physician organizations and health maintenance organizations in order to discover the range of family practice settings in which ASPN studies can be implemented and to expand both the physician and patient bases for studies. One formal affiliation has been accomplished, and another three are in serious negotiations. ASPN is also collaborating with the Medical Group Management Association (MGMA) and many of their large group practice members.

3. Network of researchers. ASPN has been successful in transforming the need for information identified by its practicing family physicians into funded research projects. This success is due in large part to the ability to assemble the best possible research teams

from a national pool of family practice and primary care researchers. These researchers have a tremendous knowledge of the complex ways in which studies should and should not be implemented.

Our national scope and independent nature permits us to draw the best and the brightest researchers and to put together top-notch research teams. We have demonstrated the ability to do that, to work across time and space, and have discovered over the last few years that is called “virtual knowledge teams.” We didn’t know that 10 or 15 years ago. But we are beginning to better understand some of the human dynamics and some of the technological issues that allow us to do that better.

ASPN now offers academic appointments to a growing network of researchers who are kept abreast of, and involved with, ASPN study idea development. These researchers are offered opportunities to serve on one or more research teams. ASPN has



**FIGURE 2. ASPN practice sites**

collaborated and is negotiating more formal agreements with other freestanding research organizations in the managed care community.

4. Academic units of family medicine. ASPN currently has or is negotiating formal affiliation agreements with five academic programs in family medicine. The agreements make provisions for collaboration in research activities for faculty, as well as providing training opportunities for fellows, residents and medical students.

ASPN has about 25 practices that have training residents as part of their mission statements. These practices are excellent and highly productive members of the network. We have agonized over how to exploit the opportunity to expose family physicians in training to lifelong patterns of systematic inquiry. We are working with our residency practices to increase the research emphasis in their programs and to provide an efficient

#### **ASPN strengths**

- ASPN is an active and dedicated group of practicing family physicians who have identified a large number of potential studies.
- ASPN has a strong working relationship with 10 of the most active family practice research networks (the ASPN Associates).
- ASPN has access to the best and brightest investigators in family practice and primary care.
- ASPN has important and growing experience in working with federal grant funds to implement large and complex studies of great importance to family practice.
- ASPN's credibility as a research organization gives us the capacity to design, obtain funding and successfully implement complex projects.
- ASPN has an experienced and stable central office staff.
- ASPN's affiliation with the AAFP provides critical core funding, credibility with practicing family physicians both internal and external to ASPN, and contact with AAFP corporate partners.

way for their faculty and residents to gain experience by working with ASPN.

5. The AAFP and state academies. ASPN has a formal affiliation agreement with the AAFP and with the Colorado Academy of Family Physicians. Discussions are underway for collaborative relationships with other state academies as well. ASPN believes these affiliations are critical to maintaining access to practicing family physicians and their wisdom, experience and insight into the challenges they face and those that will benefit from further knowledge. Affiliation with family practice organizations also provides opportunities for disseminating important research results and other opportunities that have not yet been fully exploited.

#### **Enhancing capacity for practice-based research**

With its traditional focus on practicing family physicians, ASPN has been successful in enhancing the understanding of basic concepts of research among a large number of practicing family physicians, both through seminars at its annual meeting and through direct exposure to ASPN research studies.

ASPN has proposed (but has not received funding for) a mini-fellowship that would permit practicing physicians with an interest in expanding their research skills to participate in a combination of distance-learning and hands-on experience with ASPN research. ASPN has acted on its commitment to assist its member practices involved in residency training to provide a better and more practice-relevant experience in research. In 1997, ASPN established its Task Force on Residency Research to develop and provide oversight for an expanded set of activities in this area. A working group of the task force is currently developing a curriculum for residency research.

#### **Summary**

ASPN has a solid track record of publishing its findings in the peer-reviewed literature, both within and beyond family medicine. With the current agenda of large and more

## Challenges and opportunities

<i>Challenges</i>	<i>Opportunities</i>
Finding sustained funding for infrastructure.	<p>Diversify revenue streams.</p> <p>Explore new ways to provide value to the AAFP for core funding.</p> <p>Develop partnerships with industry contacts.</p> <p>Collaborate with and share infrastructure across networks (e.g., ASPN Associates).</p>
<p>Addressing the rapid changes in the structure and functioning of the family physicians' office settings, such as:</p> <ul style="list-style-type: none"> <li>• Family practices are becoming components of large integrated health care delivery systems.</li> <li>• Family physicians (as salaried employees) have less autonomy to commit time and staff resources to ASPN projects.</li> </ul>	<p>Develop institutional memberships and collaborate with large physician organizations.</p>
<p>Addressing the problems of less time for family practice researchers in academic settings to pursue their research interests, even when they can obtain funding, due to pressure to teach and generate clinical revenue.</p>	<p>Develop organizational capacity to provide efficiencies for investigators in proposal development and project implementation.</p>
<p>Continue to demonstrate PBRNs' value by conducting studies that matter.</p>	<p>Collaborate with ASPN Associates to develop and implement the challenging projects that will "change the way we practice."</p>
<p>Maintaining effective teamwork and communication with research teams and project sites scattered across North America.</p>	<p>Develop ASPN more fully as a "virtual research center," with the capacity to enhance effectiveness of distributed work teams, enhance communication across project teams and effectively disseminate information to the larger community of family physicians.</p>
<p>Disseminating research findings.</p>	<p>Expand access to and readership of:</p> <ul style="list-style-type: none"> <li>• ASPNet</li> <li>• The ASPN website</li> <li>• <i>The Journal of Family Practice</i></li> </ul>

complex studies, ASPN has seven manuscripts under consideration in peer-reviewed journals, thus accelerating even further the publication pace of study results.

ASPN also hosts the editorial offices of *The Journal of Family Practice* and, with the support of the journal's publisher, is beginning to emphasize original work (and eventually other features) from practice-based research. ASPN's website is under development and will disseminate research results of interest to practicing family physicians. The emphasis on expanding relationships with state academies will increase the options for innovative ways to disseminate practice-relevant results of research from ASPN and other networks.

ASPN has a growing experience in communicating with practicing family physicians about practice-relevant research ideas, assembling research teams from the best investigators in the country, obtaining funding for research proposals, and implementing the protocols in a variety of family practice settings. ASPN has developed low-cost strategies for providing rapid feedback of study results (prior to formal publication) to all member practices. With its collaborative relationships of a dozen active family practice research networks and recent developments in electronic communication and transfer of data, ASPN is in many respects a "virtual research center."

ASPN has made great strides in developing a new and important strategy for expanding the knowledge of family practice research. ASPN demonstrated a capacity to conduct research of great importance to family practice and to successfully transition from simple descriptive projects to large complex studies that employ a range of designs and methods. The development and emergence of practice-based research has been a uniquely family practice innovation and one that is consistent with the values and needs of family physicians. ASPN is proud to have provided leadership for this important progress.

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# The Dartmouth Cooperative Primary Care Research Network

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**T**he Dartmouth Cooperative Primary Care Research Network (“The COOP”) is one of the first primary care research networks in the United States. Our membership comprises clinicians who have participated in a COOP research project within the previous five years, have attended a COOP annual meeting, or have precepted house staff and medical students.

The COOP avoids unnecessary costs and time by having an unrestricted and fluid membership that utilizes innovative methods when developing research ideas and gathering data, and avoiding the maintenance of a core patient database.

The COOP is a loose affiliation of altruistic clinicians who use a few core processes to develop ideas for generating fundable research, changing clinical practice and disseminating information. In the past five years, we have conducted research among 300 clinicians (internists, family physicians and pediatricians) and 15,000 patients in Arkansas, California, Colorado, Florida, Maine, Massachusetts, New Hampshire, New Mexico, Pennsylvania and Vermont.

The objectives of this presentation are to (1) summarize the experiences of the COOP, (2) emphasize COOP’s experiences and insights that might be useful to future practice-based research networks (PBRNs) and (3) challenge our thinking about PBRNs.

There is one issue that I believe is obvious to all of us and I want to briefly touch on it: When discussing PBRNs, we are talking about the clinician or clinical side of health care. It is important to remember that we are just a small part of delivering well-being to our patients. Therefore, our network — just like all the others — is struggling and sometimes reaching out for population-based improvements.

## Experiences

The experiences of the COOP can be efficiently addressed by reviewing several published reports. The first article of note was published in 1981. “The Cooperative Information Project: A Sentinel Practice Network for Service and Research in Primary Care” affirmed its position as a cooperative project (hence the abbreviated name, “The COOP”). The article explained that the COOP was a PBRN focused on primary care.

The COOP has also been interested in informatics, decision-making, and education (i.e., how staff teaching and training, as well as medical student teaching and training, is

taking place in community practices).

These attributes of the COOP are similar to those of many other PBRNs. However, the COOP began to differentiate a vision of itself. It focused on patients by asking, "What is the patient perspective of needs that matter to them?" Once we did that, we no longer said we were a family practice, or pediatric or internal medicine PBRN. We began to say that we are a patient-oriented organization focused on the needs of patients as expressed by patients.

The adoption of a patient focus forces an organization to confront measurement and quality improvement processes in the real world. The real-world impediments to change were bothersome. Nevertheless, by 1996 the COOP had a sizable number of accomplishments. We were conducting research in both urban and rural sites in 11 states, and we published 50 articles and the COOP charts. And we have done it with virtually had no infrastructure support; we have always depended on our research funding. However, Dartmouth has given us space, but that is it. This has been both a blessing and a problem.

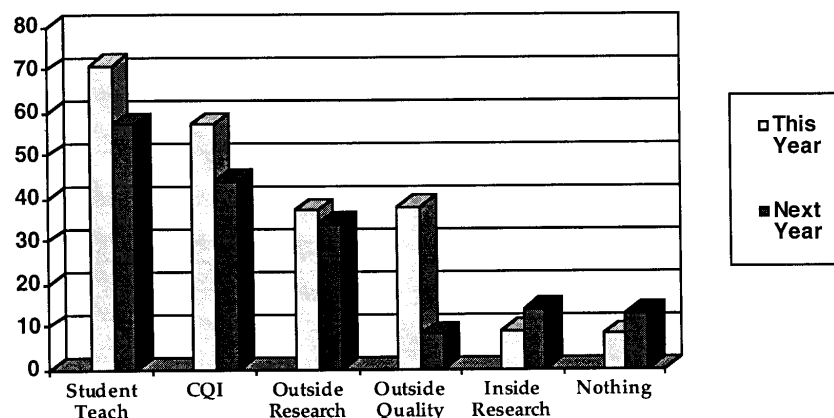
As the COOP moved down the path toward patient-focused research, it performed more controlled trials and quality improvement research.

### Insights

The real-world impediments to change are always bothersome. Nevertheless, by 1996 the COOP had a sizable number of accomplishments. We were conducting research in both urban and rural sites in 11 states, and we published 50 articles. The COOP charts were adapted for use world wide.

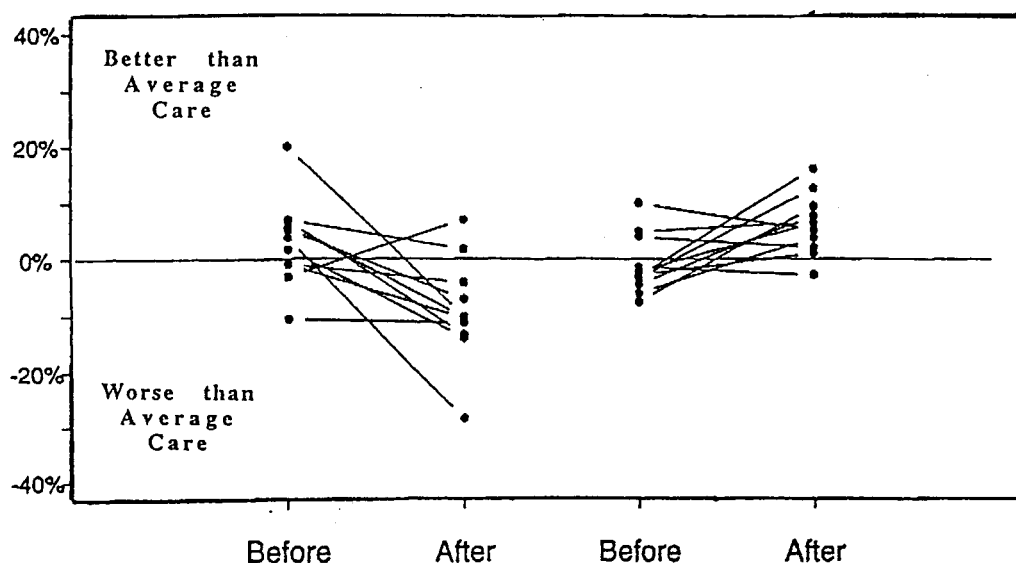
As you try to improve patient care from the perspective of the patients, you have to make it efficient. You have to develop "off-the-shelf-tools." This is the direction we have been forced to take as we look at the medical marketplace.

The medical marketplace is a mess that is not getting much better as far as we are concerned. It is demanding unprecedented change. A study conducted by Kaiser and published in 1998 in *U.S. News and World Report* concluded that 66 percent of the U.S. population felt that quality of health care could worsen in the future.



**FIGURE 1. How COOP affiliates spend their time**





**FIGURE 2. Patients' assessments of change in overall care quality over two years**

In a 1997 survey of about 200 primary care physicians and COOP affiliates, we asked "What are you doing this year and what do you hope to do next year?" (See *Figure 1*.) If you particularly look at "outside quality" — which means dealing with those asking for your HEDIS criteria — most providers are clearly saying that they have done enough already. And this is in turn affecting how much can be done in other areas.

An alternative to fitting research and education into a difficult practice environment is to design increasingly efficient approaches for fitting research and education into everyday work — providing information management with feedback to both providers and patients.

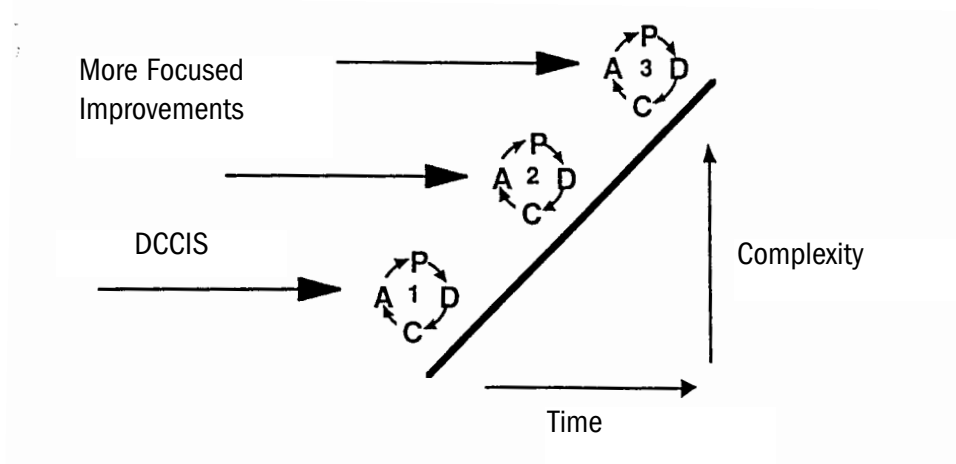
This approach is called the Dartmouth COOP Clinical Improvement Systems (DCCIS). The DCCIS were designed and proven to strengthen patient/health care provider relationships while generating clinical performance data and research questions as useful byproducts. They include a standard database of clinical, preventive and functional measures; provide actionable

feedback/education to patients and providers; and generate research and quality improvement hypotheses.

A controlled trial of DCCIS shows that this approach improves patient outcomes particularly when it is reinforced by health care providers (*Figure 2*). We took 11 intervention and 11 usual care practices involving 45 physicians and 1600 patients over two years. On the left-hand side is usual care, and on the right-hand side is the intervention group. As you can see the intervention group just did better.

In a recent AHCPR-funded pilot study, Tim Ahes and his colleagues have used the DCCIS as a foundation for improving the management of pain in primary care practices. Our intent was merely to take an approach "off the shelf" that would immediately generate needed data and feedback for most pain patients so that we could devote more effort (and money) toward the patients who needed a more potent intervention.

We asked all the practices to give us their list of patients and we mailed out a quick one-page COOP chart asking the patients to check-off how much pain they had.



**FIGURE 3. Levels of complexity**

Any patients with pain in primary care were randomized to the intervention or control group.

The results indicate the DCCIS had the predictable and desirable impact (at the first level), which allowed us to develop, test and improve a more sophisticated intervention (at the second level). (*Figure 3* illustrates these levels.) This allowed us to move up the ramp of complexity very quickly and efficiently.

The DCCIS illustrates one path forward into the future for PBRNs. It exemplifies an off-the-shelf innovation to efficiently meet the demands for convergence of objectives

(research, education and improvement), and development of “small replicable units” (efficient/effective approaches).

#### Looking to the future

Two competing visions for the future of PBRNs are compared in *Table 1*. The PBRN “wish list” is the situation in which most of PBRNs could operate comfortably. On the other hand, there is likely to be another less stable future.

Infrastructure efficiencies are needed. The outcomes are multiple. What we do to become efficient will require networks to think broadly about the outcomes. Networks

**TABLE 1. A vision for PBRNs**

	<i>PBRN Wish List</i>	<i>Another Vision</i>
Environment	Stable	Less stable
Infrastructure	Supportive	Efficiency dependent
Outcomes	Single or at least discrete	Multiple
Applicability	Health services	Population care

### Strength of approaches used in PBRNs

<i>Approach</i>	<i>Measurement Intensity</i>	<i>Hypothesis Generation</i>	<i>Answering Clinical Questions</i>
Chat rooms, annual meetings or focus groups	+	+++	+
Problem solving surveys, administrative data	+	++	++
Codman cards with follow-up	++	+	+++
Quality improvement with before and after outcomes	variable	+	variable
DCCIS with follow-up	+++	++	++
Randomized clinical trial	++++	+	+++++

will have to transcend our tools and approaches to the population outside clinical walls.

If this alternative vision is the better bet, PBRNs may need to operate quite differently from typical academic research organizations of the recent past. For example, PBRNs risk becoming pieceworkers if they contract for dollars only as dictated by the exigencies of outside sources of revenue. Pieceworkers often lack distinguishable expertise, compete for similar work and have a very low margin. They can't innovate easily. They cannot support infrastructure from piecework alone. PBRNs should avoid becoming pieceworker organizations.

For its part, the COOP is trying to maintain a mix of "piecework" and "product work." From a "product point-of-view" PBRN work is measurement, hypothesis generation and answering clinical questions.

There are many tools we can use such as chat rooms on the Internet. We find them very helpful in the COOP. Annual meetings and other convocations are a great way to

generate hypotheses and focus groups, but are not particularly good for answering questions. With this approach, the measurement intensity is low, but it has some inefficiencies. You can use problem-solving surveys: You send out a standardized patient case to all providers and ask them how they would handle the patient. Another option is to use administrative data such as Medicare claims data.

Hypothesis generation often involves a little more measurement and sometimes answers clinical questions in a little greater depth. The Codman cards and the ASPN cards are wonderful tools good at answering clinical questions. But they have a little more measurement intensity. Deciding on how much measurement you are going to do is still an art form. It is highly variable and is not ideally suitable for hypothesis generation. Randomized clinical trials are usually highly intensive for measurement. We believe in and have done them a lot for years, but again they have limited utility in certain areas.

There is a risk that if an organization's future is locked to a product that becomes obsolete, it will be ruined. A possible lesson for a PBRN: If it chooses to "productize" an approach, it should remain as diversified as much as possible.

In summary, the COOP's patient-centered approach has forced it to think long and hard about efficiency and changes in the practice environment.

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# Kaiser Permanente-Northern California: Conducting Research With Data From Clinical Practice

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**I** will begin by making it clear that I do not work in a practice-based research network (PBRN). Well, then, just what in the world I am doing here? There are some commonalities between what I do in Kaiser Permanente's research division and PBRNs. I access practice data from more than 3,000 physicians who work in our large, integrated health maintenance organization (HMO). Kaiser has been able to put together the capital to develop a remarkable clinical information system used in the delivery and generation of health care. We pull the information from this system to conduct our research.

## **Data accessible in databases**

Our information system has several databases that we work with on a daily basis. These include the following:

- Monthly membership. This database gives us population denominators.
- Hospital discharge diagnoses and procedures.
- Outpatient diagnoses. This database is generated from a set of encounter forms.
- Pharmacy records. This database

captures more than 90 percent of all prescriptions issued to our patients.

- Laboratory and lab results.
- Utilization and costs.

Resources that are not exactly electronic databases but are certainly useful include the following: medical charts, pathology, specimens and x-rays. With a little extra research, we've developed a number of special registries, such as cancer, HIV and diabetes. We also have databases that include physician data, such as their demographics, board certifications, panel sizes and number of hours worked.

Why does this not seem to be a research network? I believe the answer is because there is no process. We don't have to go through the painful process that PBRNs go through of recruiting physicians to participate. Every physician who works in our organization is a de facto participant in our research. They are not researchers. They are clinicians.

We can discuss the benefits that accrue from having these clinicians actively involved in research, which is not to say that in any project we undertake there are not a number of interested clinicians. In fact, many of our projects are inspired by interested clinicians. We do have some clinician involvement. However, we do not require physician

involvement to mine the data. I believe what we have in common is the clinical data resources.

#### **Advantages of these data**

I see a number of advantages to this kind of data. First, the data are collected in a standardized fashion, whether it is a pharmacist, lab technician, office clerk or physician who enters data on a standardized computer screen. I would argue that this actually makes the data probably of higher quality than that which was entered by people hired as part of a research project to abstract it since it comes directly from the patient. This standardized data collection is largely integrated into care delivery.

Another advantage is that the data input, except for diagnosis, is not dependent on physicians directly. Our experiences tell us that physicians tend to not be the best data collectors.

The various databases are readily linked by each patient's medical record number. We access a large population of 2.7 million patients who see 3,000 physicians (of which about 1,200 to 1,300 are primary care physicians, and about 300 family physicians).

It would not be that useful to talk about the advantages of these data in great depth. Instead, I believe it is more important to discuss some of the drawbacks of clinical data and some of the strategies that can be used to overcome these drawbacks.

#### **Strategies for addressing the drawbacks of clinical data**

I call the first drawback "incomplete or inaccurate identification of cases." Systems based on encounter forms will not capture all the cases of any one condition. So we do not put ourselves forward as being able to describe to the world the actual population incidents or prevalence of a particular condition. We believe this does not hurt us much. Our strategy is to look at what we call "relative prevalence," or "relative incidents." In other words, how does the appearance of particular conditions in our database change over

time, across medical centers, or how do different conditions ascertained in the same incomplete way compare with each other.

A second strategy is to use multiple sources. Since we have these automated clinical databases we can sometimes identify patients using multiple sources. This increases our confidence that we have true cases in our database. And finally, there is always the opportunity in your setting, and in ours, to judiciously use chart review and patient interview to validate both the accuracy of our diagnosis and the sensitivity of our retrieval methods.

The second set of drawbacks is that of missing data. And here I am not talking about prescriptions that just did not get into the database, but instead recognizing that clinicians are not always epidemiologists. They are not thinking in terms that their 30 patients a day are in our epidemiologic cohort. Rather, they are gathering data when they feel it is relevant. For example, our clinicians see 100,000 patients with diabetes and administer a particular test to only 75 percent them. Although this is often quoted as a real drawback of clinical databases, you write your grant and then the reviewer comes back and says, "you know you haven't really gathered data routinely, the way you need to do for this epidemiologic study."

Finally, there is little patient-reported data. The answer here is fairly simple, although it does cost money. There is tremendous value in linking the clinical database to a strategically planned patient survey or physician survey. For example, we use prevalence data or case identification data to look at the relative prevalence or the relative cost.

We are very curious in finding out what, in our HMO, were the leading conditions in terms of costs? We put together the 25 conditions and determined their prevalence by a very standardized method across conditions. Yes, we probably missed a few, but we ascertained them in the same way. There is less concern that we missed them differentially.

We determined the independent cost

**TABLE 1. Top ten most costly conditions in 1996**

	Prevalence (%)	Adjusted Costs per Person (\$)	Percent of Total Health Plan Costs
Trauma (injury and poisoning)	9.8	1,934	11.5
Ischemic heart disease	2.2	5,169	6.8
Hypertension	9.4	1,022	5.7
Pregnancy	2.5	3,448	5.3
Pneumonia	0.8	9,499	4.4
Congestive heart failure	0.9	7,176	4.0
Depression	3.3	1,898	3.9
Diabetes	3.8	1,647	3.7
Lower back pain	7.6	651	3.1
Asthma	4.0	1,009	2.5

Source: Kaiser Permanente.

contribution from each one of these conditions and we calculated the percent of total health plan cost. (*Table 1.*) I do not know how it strikes you, but trauma (injury and poisoning, although mostly injury by virtue of its high prevalence) turned out to be the single condition costing the most in our entire HMO. Even if you combine ischemic heart disease and congestive heart failure, heart disease did not come out to be as costly as trauma.

Using the notion that you can use multiple data resources to identify cases, we built a diabetes registry beginning in 1993. We access a number of sources of information for this registry (such as outpatient diagnosis, pharmacy records for insulin, oral hypoglycemic prescriptions, and abnormal Hgb A1c). We also use hospitalizations and emergency department visit records from earlier years before we had outpatient diagnosis and member surveys (*Table 2*). The three main contributors each contribute about 84 to 90 percent of patients. In the right column, if you add those up, less than 5 percent of patients in the entire registry are identified from a single source.

Whereas one outpatient diagnosis of diabetes may well be inaccurate, or one pharmacy prescription for insulin may have been for the person's spouse (and that happens a fair amount of the time), one Hgb A1c test may be wrong if you use a low cut-off. Ninety-five percent of the patients in our registry have been identified by multiple methods. This is an argument you can often use if you have access to several ways of identifying data. It just gets better over time, particularly for chronic diseases, as you are using this data over time. The overlap particularly improves.

For another example, we studied new onset angina pectoris over a period of 18 months. We identified by a variety of methods those patients who appeared for the first time with angina pectoris. We used angiography without accompanying diagnosis that suggested it was for valvular heart disease or other congenital heart disease. We used outpatient diagnosis of angina, discharge diagnosis from hospitalizations of angina, and more than one nitroglycerine prescription (one nitroglycerine would not get you in, and more than one did) (*Figure 1*).

**TABLE 2. Constructing a registry from automated databases. Sources of notification of KP diabetes registry as of January 1, 1998.**

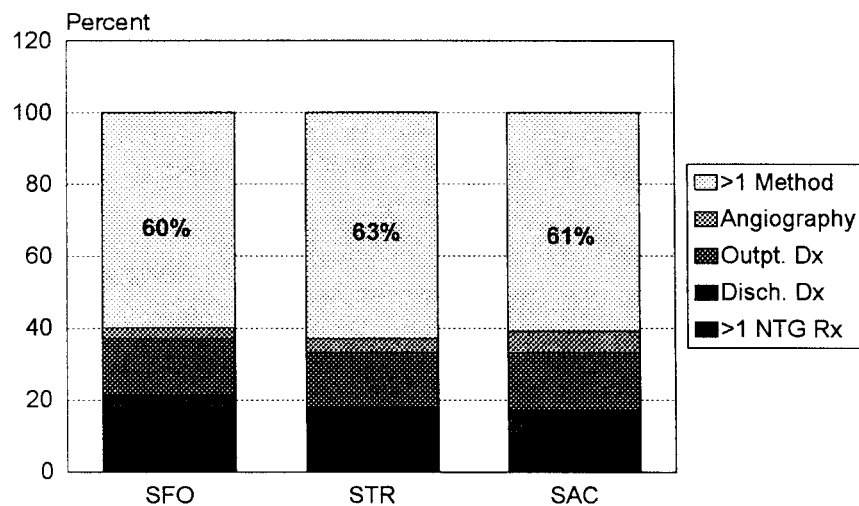
<i>Data Source (Years)</i>	<i>Number Identified from this Source</i>		<i>Number Identified Solely from Source</i>	
Outpatient diagnoses (1995-1997)	91,629	90%	1,390	1.4%
Pharmacy records (1994-1997)	84,923	84%	452	0.4%
Abnormal Hgb A1C (1991-1997)	88,923	87%	1,896	1.9%
Hospitalizations (1971-1997)	35,539	35%	494	0.5%
ED visits (1991-1995)	2,088	2.1%	11	0.01%
Member surveys (1990, 1993, 1996)	1,826	1.8%	4,267	4.2%
<b>TOTAL</b>	<b>101,698</b>		<b>4,267</b>	

Source: Kaiser Permanente.

The good news to us is that even in this relatively short period, over 60 percent of the cases were identified by multiple methods. The second piece of good news was that across the three areas, the pattern of identification was really quite similar. We can argue

that this cohort of angina (it is a tough cohort to nail down) looks like it was ascertained quite similarly across the three areas. We can now begin to compare outcome for this cohort.

Now to the issue of missing patients.



**FIGURE 1. Sources of identification of incident cases of angina pectoris**  
(n=10,627) Source: Kaiser Permanente.



**TABLE 3. Short-term predictors of macro/microvascular complications in patients with diabetes mellitus**

Predictor	Odds ratio	p-value
Hgb A1C (%)		
<7 (reference)	1.00	–
7-8	1.11	0.29
8.1-9.9	1.33	0.001
>10	1.7	0
Missing	1.22	0.03
Albuminuria/microalbuminuria		
Absent (reference)	1.00	–
Present	1.25	0
Missing	1.24	0

Source: Kaiser Permanente.

This study is a prospective analysis in about 75,000 patients with diabetes (*Table 3*). We used data from 1994 through 1995 to predict who would have a microvascular or macrovascular complication in 1996. About 25 percent of patients were missing; they did not have Hgb A1c drawn during that two year period. We took the continuous distribution of Hgb A1c and chopped it into categories. One category is missing (shaded area of graph).

In terms of being able to predict short-term risks for micro- and macrovascular complications, Hgb A1c strongly related to risk. Having a missing Hgb A1c is also a predictor. We found it interesting that patients who do not have the test are at some increase in risk. Now several explanations follow, and one might be that their physicians are not tuned in to the management of diabetes. It may be that these are noncompliant patients who do not come in to get their tests. Or it may be that the patients are so sick that the physicians do not order the test and instead concentrate on other things. Missing this goes from being a problem to being an interesting finding.

#### **The effect of specialty training on the practice of primary care**

We conducted a study where we used a lot of automated clinical data from automated databases and combined it with a survey. This study was funded by the Agency for Health Care Policy and Research (AHCPR). We have over 200 family physicians in our HMO. Most primary care is delivered by general internists, and there is also a fair amount delivered by subspecialty internist. We asked within this single group model HMO, with a strong 50 year culture, if we see differences in practice style between family physicians, general internists and subspecialty internists with respect to quality of primary care; prevention practices; patient satisfaction; outpatient visit rates; specialty referral rates; use of laboratory, pharmacy and diagnostic testing; and costs of care.

We had a lot of outcomes. Quality of primary care as reported by patients, prevention practices as reported by patients, and patient satisfaction are the top three outcomes that we gathered from the patient surveys. But the last four, and the four that I am going to show you today, are outpatient visit

rates; specialty referral rates; use of laboratory, pharmacy, and diagnostic testing; and costs of care.

Our sampling strategy included 13 facilities where we have two types of specialists providing primary care; seven of the 13 facilities compared family physicians to general internists, and the remaining six facilities compared general internists to subspecialty internists. In regards to the family physicians vs. general internists mix, there were 60 family physicians in these seven facilities and a portion of 245 general internists. We sampled them such that there would be an equal number of patients from each physician group. We came up with a sample of 16,098 primary patients ages 35 and above, all impaneled to physicians. We could look at the utilization and cost data for this group of patients.

We quickly saw that the patients of general internists were slightly older and somewhat sicker than the patients of family physicians, even within these same sites. One could say that we needed survey data in order to adjust for the differential disease, severity and core morbidity. We actually have the survey data, but we used our outpatient diagnoses and linked them to ambulatory care groups.

#### **Ambulatory care group case-mix adjustment**

These three boxes may be a bit outdated in the sense that I believe the new version of the software to study ambulatory care groups (ACGs) is now much more complex, but the

**Outpatient ICD-9 Codes for 9 months  
grouped into 34 Ambulatory Diagnostic  
Groups (ADGs)**

**Further grouped into 25 mutually  
exclusive Major Ambulatory Categories  
(MACs)**

**25 MACs divided on basis of age,  
sex, number of ADGs into 51  
Ambulatory Care Groups  
(ACGs)**

version that we use grouped all ICD-9 outpatient diagnoses into 34 ambulatory diagnostic groups (ADGs). There is similar severity and predicted utilization. These were then dropped into 25 mutually exclusive major ambulatory categories (MACs), again predicting varying levels of utilization but are mutually exclusive. These 25 MACs were then divided into 51 ACGs on the basis of age and sex. Those are put into regression models and used to adjust for differences essentially in the burden of disease group of patients.

How well do these ADGs help to adjust cost comparisons? We tried to predict outpatient care costs, pharmacy costs and total costs (*Table 4*). The three columns are varying levels of adjustments, and the numbers in the boxes are the r-squares from the model — the percent of the variation in total costs that we are explaining.

**TABLE 4. How well do ADGs help adjust cost comparisons?**  
Model r-squares from regressions comparing costs for FPs and GIMs.

<i>Adjustments</i>	<i>Outpatient</i>	<i>Pharmacy</i>	<i>Total Costs</i>
Demographics	0.03	0.03	0.03
Demographics + SF-12	0.10	0.09	0.10
Demographics + ADGs	0.18	0.14	0.15
Demographics + ADGs + SF-12	0.20	0.17	0.17

*Source: Kaiser Permanente.*

For each type of cost category, demographics alone (i.e., each patient's age, sex, race and socioeconomic status) explain extremely little of the variation in cost. When we looked at the 70 percent of patients who responded to the survey and added the SF-12, the r-squares went up to about 10 percent. If you just add ADGs and forget the SF-12, ADGs do substantially better for each category of costs than the SF-12. If you combine ADGs and then add SF-12, you don't improve that much over ADGs, alone. This told us we could feel fairly comfortable using the large 16,000 patient sample. The ADGs explained most of the variability that could be due to burden of disease. We did not gain more by adding the patient reported SF-12, or at least, not much more.

*Table 5* compares family physicians and general internists. The two numbers to the

left are the crude visit ratio at crude costs, and then the column on the right is the adjusted rate ratios (ratio of family physicians to general internists). This is adjusted for age and sex of patients and physician demographics in the automated databases and for ADGs.

The family physicians hospitalize less, but after you adjust for their milder case mix the ratio is not significantly different. It is the same story in terms of outpatient utilization: Family physicians saw patients at slightly lower rates, but when you adjust for the case mix, the ratio is not different.

We had hypothesized family physicians would make fewer referrals to some specialties and sub-specialties, particularly to orthopedics, dermatologists, gynecologists and psychiatrists. If you total these — even after case mix adjustment — family physicians made 14 percent fewer referrals to

**TABLE 5. One year utilization and costs of care, family physicians versus general internists**

		<i>Crude Visit Rates or Costs</i>		<i>Adjusted Rate Ratio</i>
		<i>FP</i>	<i>GIM</i>	
Hospital Utilization	Hospital Admissions	74.2	107.8	0.95
	Hospital Days	275.2	380.4	1.01
Outpatient Utilization	Primary Care	1.4	1.7	0.95
	Urg. Care	0.99	0.85	1.19***
	ED Care	0.19	0.25	0.91
	Specialty: Ortho	0.31	0.34	0.92
	Derm	0.23	0.32	0.82*
	Gyn	0.58	0.61	0.9
	Psych	0.25	0.31	0.76*
	Total For Specialties	1.1	1.3	0.86**
	Med. Subspecialties	0.35	0.47	0.99
	All Other Specialties	0.7	0.65	1.13
Costs	Lab	50	60	0.99
	Radiology	70	75	1.07
	Pharmacy	158	203	0.89*

*Rate Ratio (FP/GIM); Model 1: adj. for demographics; Model 2: also adjusted for ADGs.*  
*Source: Kaiser Permanente.*

these four specialties. We found a countervailing trend that patients of family physicians showed up more now in urgent care.

Urgent care in this setting is same-day appointments to physicians other than your primary care physician. Patients of family physicians were using urgent care 19 percent more than patients of general internists. It turned out that family physicians had larger panel sizes because the powers that be had decided that since they had younger, less sick patients, they should have more. Family physicians were seeing more patients per unit or per day. Yet, when we asked patients in the survey about availability of their physicians, patients of family physicians reported their physician was less available.

It looks as if we have a setting where the expectations in terms of work load are pretty similar between the internist and family physicians. The family physicians are trying to practice more comprehensively as their training would suggest they do. And they actually appear to be succeeding. But the payoff is less access/less availability.

Overall total costs did not differ between the family physicians and general internists. We saw an interesting paradox in that family physicians practice more comprehensively, but their patients had more trouble getting in to see them.

### **Conclusion**

What do we research? We research a lot of things, and a lot of them — like John

Wasson referred to — have to do with the health of the entire population. We try to take advantage of practice variations between patients, and this is the exact same thing you would do in a PBRN: Compare how patients respond to one treatment versus another.

I believe it is the strength of a network when you look at the outcomes of a group of patients cared for by one physician, or one physician group compared to another. You get away from some biases that trouble you in observational studies at the individual level, or between groups of physicians, between medical centers, or between specialties. We concentrate on studies of the relative importance (prevalence or costs) of various conditions and we are beginning to get involved with randomized trial research.

I believe that data collected in the course of practice can be highly useful either alone or when linked with relatively small amounts of primary data (e.g., from practice surveys, patient surveys, chart reviews). Outcomes assessed at the practice level can provide a less biased approach to assessing treatment in the “real world” than individual-level observational studies. Multiple means of ascertainment can help to reduce the “noise” in data that arise from differences in clinical practice or data recording style between physicians and practices. And finally, remember that missing data are not always a drawback.

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# Observational Comments and Questions and Answers

## A reaction

**Dr. Larry Green:** After listening to these presentations, I believe there are three areas that warrant attention. First, we are in a chaotic practice environment. Physicians are aggregated differently now than they were when practice-based research was conceived and launched. Physicians are no longer in charge. Efficiency is critical. Excess dollars are being wrung out of the systems to Wall Street and tax returns, and this is inherently messy. The practice environment is messy. It always was, it is, and it will be.

Second, we need to do studies that matter. These three presenters stated they do studies that matter to them. I would argue we need to expand that assertion to include patients, doctors and to payers.

I am organizing the third area into what I call “wrestling with the right devils.” I heard eight of these devils:

1. The right size. Being a small network for the sake of being small is stupid, and being a large network for the sake of being large is also stupid. You want to be the right size in order to answer the questions that matter to you and to patients, doctors and payers.

2. Virtual systems.

3. Compatibilities. You have to link your important questions to capable primary investigators and use the right methods in the laboratory.

4. Data. The quality and use of different data types must be better understood.

5. Delivery of services while researching. How do you do practice-based research within whatever structures are invented to deliver services?

6. Productive linkages. How can you have productive linkages among primary care physicians, pediatricians, general internists and family doctors?

7. Variations. Finding variations and understanding them — rather than stamping them out — provides a rich opportunity to comprehend clinical practice problems.

8. Enough funding. I am convinced that too much funding is a disaster. I am also convinced that John Wasson is not quite right: Dartmouth gave the COOP, in my opinion, much more than just space. Although infrastructure costs have been exaggerated and distorted by the established research enterprises in a way that we should not replicate, there are some real costs. I argue that the right devil around funding is the word “enough.”

I believe that the most important thing is the purpose to which this enterprise is directed, and Dr. Mackenzie had it right. The purpose of this enterprise is to solve the problem that the knowledge we need to take care of our patients best does not yet exist. If the people sitting in this room cannot figure out how to produce that knowledge, then I

do not know who is going to do it within our lifetimes.

PBRNs are not the problem; they are a solution. They are a means to solving the problem that we do not have the knowledge we need to take the best care of our patients, and we can no longer rely on someone else to produce it for us.

**Panel and full group question and answer/discussion**

**Dr. Lanny Copeland:** Today there are rapid changes in the way family physicians work. The practice environment is changing very dramatically. Family physicians are becoming components of large integrated health care systems, and as such, they are often salaried with less autonomy. That has become a major challenge for us. We also find that family practice researchers in the academic setting are facing great pressures to teach and generate clinical revenue.

As a result, a lot of our senior family physicians simply are facing heavy demands from their own academic institutions for their clinical skills. I am very concerned about the ability of our best and brightest researchers to do research. I believe the challenge is that we have shown our feasibility and value in much of what Dr. Green presented and what brought us into the modern times. I think the current challenge we face is that we have got to move forward aggressively and do studies that really matter. We've got to start doing POEMs (Patient-Oriented Evidence that Matters) and doing studies that say "here is what we do, but here is what we can also do better." I believe that will move us into new classes of studies, and introduce some methods challenges. Another challenge is to get better at working with distributed knowledge teams. It is unlikely that we are ever going to have a critical mass of researchers in one time, space and location. I think that is true of all the networks. We need to think a lot about disseminating research findings.

**Dr. David Hahn:** I am a full-time family physician, the director for research project development for the Wisconsin Research Network, and a shareholder in the largest physician-owned medical group in the United States with its own HMO. I am aware of the managed care environment because I practice in it. I am a clinical researcher and I have a master's degree in practice. I am doing some research, which is really sort of my second career.

When I talk to people I realize how heterogeneous our practice situations are. I recognize the origins of practice-based research. I think Paul Nutting has already eluded to my view, which is that PBRNs came out of the tradition of the solo/rural or independent practitioners in North America. But things are changing. It is time to start thinking about using the research network as a tool. All of the PBRNs will have to evolve with the times. I believe the affiliation with MCOs — convincing MCOs like mine to join in this enterprise — is a crucial factor. If you or I could convince my organization to get involved, then it would be tremendous. But I do not see it happening. I do not know how I can do that. At least among physician-owned-and-operated organizations there is a huge barrier to getting involved in these kinds of research enterprises. It may not be quite so much of a barrier for nonprofit. As we go forward as a network, we should affiliate with those who are trying to answer the same kind of patient-oriented, clinically-relevant questions.

**Dr. Peter Franks to Dr. Paul Nutting:** I have a question about what seems to be a tension (or contrast) between ad hoc networks (where the physician is sort of a passive participant) and networks directed by an autonomous practitioner. This is sort of what Dr. Selby described. Is there tension between the physician needing to be in control versus (on a broad basis) the need to get funding, and the funding perspective of having a top-down approach to it? If so, how

does it get managed in a network that is not ad hoc?

**Dr. Nutting to Dr. Franks:** I am not sure it is tension, but it is a contrast. If I understand, what you are saying is that the contrast is becoming less clear. Tell me if I am missing a couple of your notions, but one of them I heard was that it is important to have participants and their input into the studies from a lot of different systems, and I think that we are trying to do that.

The notion that all of our studies are done just in our membership is no longer true. Half of our referral study participants were not members of our networks at the time we recruited them. Many of them may become members afterward. We were working with organizations at the recruitment level as well. The lines are blurring a lot. They are being driven by pragmatics and by the need to address an important question. And this will take us into new forums that we have not yet invented.

**Dr. Paul Frame:** I just had a couple of thoughts. First, I was delighted that Dr. Green started his presentation with a definition of PBRNs because that was sort of troubling me. I think his definition was good, and I could not have improved on it. But the key element is that practitioners are doing research — presumably — as a secondary part of their job. And I add to that the administrative structure that is permanent in some form. In that sense, I believe Dr. Selby — claiming that he does not have a PBRN — actually does. There are multiple models for PBRNs to follow, and Dr. Selby clearly has a PBRN.

The second issue that really struck me, especially from Dr. Wasson's presentation, is the specialization versus diversity dilemma. He mentioned productizing what you do, in other words, create a process and then replicate it, which will allow you to do multiple studies for multiple questions. This is exactly what bench researchers do all the time. They set up a model for studying a disease and

then do variations ad nauseam on that same model. It is an excellent point and it raises the issue that is always a dilemma in family practice: Do you specialize to do research or do you try to remain diverse?

I am a firm believer that you must specialize to do research. You can use a specialized technique or tool that you developed, to look at multiple questions, or even specialize in a particular area of interest. I think PBRNs will have to specialize in terms of not trying to do everything. They will have to decide what they can do and not take on just any research question that comes down the line.

The third issue that jumped out at me is the value of geographic diversity. Geographic diversity clearly is expensive. For certain types of questions it may be critical and have tremendous value. For other types of questions it may just be an excess cost. I believe we really need to think hard about that.

**Dr. Nutting:** I think Dr. Frame made a good point about specialization. But I believe it is a bit more complicated than just that. I clearly agree that a research team needs to have some focus in order to develop expertise over time. There is some real risk in a network specializing, and it has to do with the interest of the clinicians and the diversity of their ideas. In ASPN we are trying to understand some important themes that we emphasize while developing research teams. These research teams have sustained interest in a commitment to focused questions. In some ways the issue of network specialization is not quite the same as the issue of specialization at the research/team level. Some of our larger networks can easily accommodate both.

**Dr. John Wasson:** We are in a bit of a semantic bind here. What I was talking about was not specialization as a medical career. When we think of specialization, we think of a urologist. Rather, I was stating we specialize in a research process in our service industry, and that is quite different.

**Dr. Frame:** I meant in the sense that you can specialize in a tool ... you can use the same tool to address multiple questions. In other words, specialize in the sense of having the tool. Actually, Dr. Selby is doing the same kind of thing. But if you look at the multiple data input and multiple sources, I presume that you have now learned to manage this collection of data input to more efficiently and quickly look at multiple kinds of questions. The specializing can either be in terms of a particular tool that you use over and over, or it could be in terms of a particular content area. That was my point in terms of a need for specialist. It does not have to be, and Dr. Nutting's rebuttal is well taken. I believe that is one of the real issues we need to talk about.

**Dr. George Isham:** I have an observation as an outsider of this culture. I noticed Dr. Selby's reaction was at first he had to figure out what PBRNs are. That was my reaction as well. I was struggling with this deep dark secret. My training is with primary care and internal medicine. I became aware of John Frey back in the 1970s and I just recently rediscovered his work. But I had not heard a lot about PBRNs. I spent the first 15 years of my clinical life as a primary care physician trained in clinical medicine, and concerned with the health delivery system, HealthPartners, etc., during the past 10 years. PBRNs are the best kept secret. They are very relevant to a delivery system with a predominance of family physicians. But apparently that may be dividing some cultural lines. It would be interesting to think about that.

**Dr. Jim Mold:** Just some thought: Who learns the most from practice-based research? The practitioners who participate? The researchers? Or family physicians in general? I think it is the practitioners who participate.

Is there greater value in the process or in the outcome of practice-based research? My opinion is the process, which is contrary to what Dr. Green said, which to some degree was the purpose.

**Dr. William Phillips:** I hear a mismatch between the values that we hold in practice-based research and the results seen. If, as we are told today, and as we believe, that the purpose of this enterprise is for practitioners to create the knowledge they need to take care of their patients, and if we organize ourselves in such a way that these practitioners have a big ownership stake in the leadership of the networks themselves, then how can both of those things be true at the same time that we have so few POEMs?

**Dr. Green:** My favorite way of coping with your excellent point is that it is amazing to me how we underestimate how much work it takes to change practice on the basis of evidence. Every now and then we talk about these wonderful new things that can happen. But to the extent that you really want to nail it down, it can take a while. The other part of it is that we also underestimate how little time is actually available to a practicing physician to do this. The rest of the research enterprise isolates people from their work, protects them and lets them go work full-time on a question. We do not do that. That is not where we have been, and I am not sure we want to get there. It is another tension, and I do not know what to do about it.

Let me give you a quick story from Friday afternoon at my work. I am part of a committee that is reviewing our area health education centers. They distribute information about AIDS. Now, our AIDS program says "Get off of my turf. I do AIDS education and I will teach the people in the Rocky Mountain region how to do AIDS education." But they come to us anyway.



We looked at the budget for the last 10 years and it is flat, except for the incremental funding received to do AIDS education. We looked at the AIDS budget and found that they have gone from a budget of zero for an AIDS research center at the University of Colorado in 1989, to \$11 million —

which is more than the entire of the Department of Family Medicine at age 25. That is the difference. You have to be able to have enough funding to have some people who can ask and answer important questions.



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# Section 2

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## **What is the current science of PBRNs?**

Methodologies Used by PBRNs, DONALD C. IVERSON, M.D.

Success and Failure in Practice-Based Research: A view from three networks

WReN, JOHN W. BEASLEY, M.D.

UPRNet, JOHN HICKNER, M.D., M.S.

PPRNet, STEVE ORNSTEIN, M.D.

Panel and Full Group Discussion/Question and Answer

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# Methodologies Used by PBRNs

DONALD C. IVERSON, PH.D.  
*Clinical Professor, Department of Family  
Medicine, University of Colorado School of  
Medicine, Denver*

**T**o give you an idea of where we are in terms of network-based research, I looked at 73 papers that have been published or were under review by different PBRNs. These represent just some of the research conducted by PBRNs (*Table 1*).

When looking at the four research approaches, we notice that a lot of the papers — 66 percent of those 73 — use a cross sectional survey approach to describe what is currently happening in primary care practice. This might reflect what Dr. Green said in his presentation that, a lot of the time, we really do not know what is happening in primary care.

Cohort studies — where you take a group of patients and track them with follow-up measures — occur about 16 percent of the time. Cohort studies are occurring with greater frequency now than before. Some networks tend to use one method more than another in experimental studies. This reflects practice from the beginning of PBRNs; I did not look at just the last few years.

I asked a few questions: What is the focus of these studies, and are they really in an area in which we are trying to make a difference? Do they have a clinical focus? About 41 percent had a clinical focus: specifically, a direct clinical focus on patient issues as defined by the physician or another group.

I found that three percent dealt with economic issues and four percent dealt with measurement. If we do not increase the percentage for measurement, I believe this could be a deadly area. We cannot do good studies unless we have good measurement tools, and four percent of studies is not adequate.

## **Value of large numbers**

I took a look at the value of large numbers in practice-based research — for example, the number of patients in a study and the number of specimens collected. The ability to use large numbers is one of the strengths of PBRNs. A few examples include the following:

- ASPN looked at laboratory problems that included 167,000 patient visits and was able to create a visit rate based on this incredible number.

- The HIV serology prevalence study had almost 22,000 specimens collected. Researchers were able to calculate a prevalence rate.

- WReN's problem drinking study — a difficult issue to study — had data on almost

18,000 patients. WReN came up with about 2,500 positives to work with. Again, an incredibly large number.

- A secondary sexual characteristic study included 17,000 young patients.

- An asthma prevalence study conducted by WREN screened almost 14,000 patients. Researchers were able to determine numbers and rates of diagnosed and undiagnosed asthma.

- The asthma study Dr. Larry Green directed utilized almost 26,000 patient visits to 83 physicians.

- UPRNet's obesity study looked at the prevalence of obesity among 5,000 patients.

Cancer is one area where studies typically use smaller numbers. It is typical for cancer studies to use 100 to 200 patients. We can get into tremendous problems because patient characteristics often change any significance that the statistics bring to the table. Large numbers help make a study more important. You will not get into patient characteristic selections to the same extent as with smaller numbers.

#### **The varied contributions of network research**

I made some value judgments based on two questions. What do these studies mean? Have they done anything from the methods point

of view? I divided the value judgments into four areas: (1) understanding family practice, (2) clinical practice, (3) research methods and (4) public policies.

**1. Understanding family practice.** Here are four studies conducted by PBRNs that help us understand family practice. The results are changing because of managed care. The RAPP Study contributed a lot in the last few years, but it left out the complexity theory. The study identified new ways of looking at how we may want to change physician behavior.

The consultation and referral process study that Neon did helped us understand the nature of a referral in the residency pattern. The context and content of family practice study described the whole nature of the black box. RAPP's development of a practice genogram took a look at how we can characterize interaction within a practice to know why one research group had a different set of outcomes than another. These studies have made tremendous contributions, all helping us understand research in the family practice setting.

**2. Clinical practice.** In this group, the research deals with issues that have a direct relevance to clinical practice. For example, the acute otitis media in adults study by the

**TABLE 1. Analysis of 73 research papers**

	<i>Characteristic</i>	<i>Number</i>	<i>Percent</i>
Research approach	Cross-sectional	48	66
	Prospective cohort	12	16
	Quasi-experimental	3	4
	Experimental	10	14
Focus	Clinical	30	41
	Economic	2	3
	Measurement	3	4
	MD behavior change	5	7
	Policy: clinical	16	22
	Policy: other	17	23

International Primary Care Network (IPCN) found that if you do not use medications, you get better outcomes. That is an interesting finding.

The COOP's program of adopting an office-based system, which Dr. John Wasson described, has implications for clinical medicines when you bring systems in that have been shown to work. WReN's study of diagnosed and undiagnosed asthma and the difference between adult onset and non-adult onset is another example.

The University of California at San Francisco/CRN studied reasons for physician recommendations for revisits. The urinary incontinence study, which I believe is one of the more fascinating studies, documented the lack of discussion between the physician and his or her patient. If patients cannot talk about these critical issues with physicians, then with whom can they talk? That was an important study from a clinical perspective.

Cancer prevention studies include Steve McPhee's, which I believe represents superb methodology.

A study not yet published is the quality of care for heart failure patients in the upper New York area, which looked at family physicians adhering to quality control standards. Reducing alcohol problems was a study conducted by WReN using interventions.

**3. Research methods.** I think PBRNs have made important contributions in terms of research methods. The development of a primary care index — the components of primary care — is an important advance in measurement that can be refined, if needed. The HIV seroprevalence study that Dr. Larry Green did represented a really unusual approach to collecting data on a sensitive and difficult problem with many legal ramifications. Again, an advance in methodology.

The practice/patient generalized study tried to compare patient and practice characteristics — a methodology showing that you can do this. RAPP looked at ways of recruiting practices for research. An important item to remember is that you can take the core research project and add important

components all around it. You can continue to take advantage of an opportunity to build on.

Looking at the use of medical records and patient questionnaires for patient profiling demonstrates that if you look at the primary care record — depending on what you are looking for — the record may be better than a questionnaire.

**4. Public policies.** In terms of public policies, or studies that have public policy implications, I found the Neon study, which looked at the economic analysis of family practice residencies. Another study looked at the impact of different insurance types on the delivery of primary care. It found that different insurance types do not affect what the primary care physician does.

The models of delegation in rural primary care study looked at nurse practitioners and how they practice with family doctors. The results of this unpublished study could have important policy implications. The secondary sexual characteristics study did a lot of work with school health programs to decide when we should deal with issues concerning sexuality and sexual development. This has an important priority.

#### **Increasing the return on network research**

The issue that arose earlier was why do we not know what is happening in primary care. Well, I took those 73 papers and found that almost half were published in the *Journal of Family Practice* (Table 2). If you do not read family medicine literature then the practice-based research will be unknown. This is where we tend to publish. Most family physicians do not read the family medicine research journals.

I am beginning to think in the terms of where do we go with practice-based research while increasing its return. There are four issues that I suggest we focus on. First, we should focus on important and costly problems seen in primary care. Second, we should recruit large numbers of practices, physicians and patients. Third, we should consider cost implications. And fourth, we

**TABLE 2. Percentage of papers published in medical journals**

<i>Journal</i>	<i>Percent</i>
<i>Journal of Family Practice</i>	46
<i>Family Medicine</i>	9
<i>Archives of Family Medicine</i>	8
<i>JAMA</i>	8
<i>Pediatrics</i>	5
<i>Journal of the American Board of Family Practice</i>	3
<i>Medical Care</i>	3
Other	6
Unpublished articles	12

need to develop large projects that can address multiple issues.

Dr. Larry Culpepper and I were at a meeting where we heard health care is now a trillion dollar industry. With that in mind, I think the large numbers of patients, physicians and practices utilized in research studies become increasingly important. The concept of combining different PBRNs into one makes a difference to achieve this.

The USNCI released a report that examines the way it does clinical trials. The report states that they have to change their procedures for the future, and some of their solutions will be virtual network trials using the Internet. We cannot do trials or studies any more without looking at cost implications. I think if we do not look at costs, we will make a huge mistake. The one value that is consistent across America is the U.S. dollar, and it is the one value everyone shares one way or another.

We have to develop large projects that address multiple issues. By that I mean taking a look at the COOP's depression study and finding a central core of it to add pieces. We gradually gain not only a greater understanding in the breadth but in the depth of it.

### **Conclusion**

I want to make three other comments that

relate to the presentations in section one of this conference. First, I have a concern that the current funding for the National Institutes of Health (NIH) will make our situation worse in primary care research. NIH's research will become more specialized. It is almost to the point now where you are in trouble as a researcher if you dare to go beyond the cell surface and deal with an organ. Researchers are becoming more and more irrelevant to the NIH's focus. This means that the kind of research we are doing could become less appealing to the NIH research community. Unless we can develop another screen through the AHCPR, I believe we are in trouble.

Second, I just finished my last term as chairman of the AHCPR study section. Over the seven years that I served, I talked with several people who served on review panels. They have some interesting concerns. For example, where do you get funding for a project. And who is assigned to review your proposal. I could predict with almost certainty who is going to get funded, based upon the reviewer assigned to it.

If a certain reviewer was fair and thought the research proposal was presented in an enthusiastic way, was focused on the positives, and mentioned the negatives but in a way that demonstrated they could be overcome, then I could almost guarantee the

research project would be funded. But if it came to someone else on the panel, I could almost guarantee that — irrespective of its quality — the research project would not get funded solely because of the way the project was presented.

I have also noticed that family medicine applications have done better because their writers paid more attention to detail. Those that did not get approved usually had good ideas, but they got hammered on the details. Grant proposals are starting to be very competitive because of the focus on details.

Finally, I am concerned about the problem with indirect cost. I am in the

process of trying to merge two 5401C3 scientific organizations. These organizations deal with the prevention of cancer from cellular levels and all the way up. What has been interesting is that in doing cost modeling — to break even with an NIH model of funding where you live and die on indirects — we must have 31 funded scientists at 70 percent funded to break even. I think the NIH model is incredible in terms of its independent organization. But how far do you have to go to really break even? I believe it is becoming increasingly more difficult with peculiarities of funding. And that is a big challenge.



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# Success and Failure in Practice-Based Research: WReN

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**T**he Wisconsin Academy of Family Physicians (WAFP) founded the Wisconsin Research Network (WReN) in 1987 to promote practice-based primary care research. Supported by the WAFP, the University of Wisconsin Department of Family Medicine and the Wisconsin Institute of Family Medicine (WIFM), WReN has three goals:

1. To support the personal research interests of physicians in community practices.
2. To facilitate collaborative research among practicing physicians.
3. To provide a resource for academically-based external investigators who need access to community practices.

WReN is really a mailing list of physicians and others with some interest in research. We are a loosely knit research organization. There is no way that the steering committee of WReN can ask 695 physicians to jump and then expect them to ask "How high?". We run into major recruitment

problems when we try to get physicians involved in a study. We are entry level. We try to get people involved in the process and hope they do find some of the research questions interesting and appropriate in the care of their patients.

We often get credit for projects and publications that we probably should not take. In reality, some studies are done within the University of Wisconsin. We provide some help, but not an overwhelming amount.

To prepare for this meeting, I went to our membership and asked two questions. First, what do you see as the greatest success and failure of WReN? Second, what made these successes succeed and the failures fail? Based on this kind of mini-study of our own membership, I can say that most of our members did not talk about specific research projects. Rather, they talk about cultural change, about getting involved in research, and some of the strengths and weaknesses that we have.

We looked at the successes and failures in a rather broad way. First, it looks like there are many possible definitions of success and failure. Demonstrated impact on patient care could be the gold standard. However, grant funding is good if one wants to stay in business. That is very important in the university setting. Did work get published? Publications are the "sine qua non" of success in the

academic world. Did the network stimulate interest and involvement? For our members, stimulating interest and involvement (also critical for network function) is important. Did network activities develop the discipline? Did the work help us receive credibility among other colleagues in the medical world? For our parent organization (the Wisconsin Academy of Family Physicians), the development of the discipline and credibility are critical measures of success. Does it feel good to the physicians who participate? For the individual member, simply feeling good about the whole thing may be important. Did we survive? Someone mentioned that point earlier. In this business, mere survival is not bad. If you look at the track records of survival among research networks, there is about a 60 to 70 percent mortality rate in the first two years.

To break things down a bit, I will talk about successes and failures in five different dimensions. These dimensions overlap, but nonetheless, form a useful breakdown. These dimensions are:

1. Research projects
  - A. External/supported
  - B. Internal/network-wide
  - C. Individual
2. Survival/developing network support
3. Creating the culture
4. Helping new and “little r” researchers
5. Supporting “big R” researchers

You should notice that there are three major categories of research projects which reflect our goals. The first category is large “macro-scale” funded projects that often originate within academia and are funded by large extramural funders. The next category is collaborative projects originating from within the network, which are generally minimally funded. The final category of research projects includes those where WReN has supported an individual clinician’s scholarly interest.

#### **Research projects: external/supported**

One of WReN’s goals has been to provide a resource for academically-based investigators

who need access to community practices. Three highly successful academic research groups have used WReN support in grant writing and in recruiting sites for their projects: the first on primary care prevention topics, the second on heart disease prevention in clinical practice, and the third on the early intervention for problem drinkers. All three of these studies have resulted in multiple publications.

The success of these studies can be attributed to having very skilled, National Institutes of Health (NIH) level principle investigators (PIs) and associated staff who asked a question important to the practitioners and achieved major federal or other funding that enabled them to provide intensive support to recruitment efforts and to provide considerable support to the practices.

The PIs felt that we were successful in helping to get the grants, somewhat useful in recruiting physicians, and in providing a mechanism to handle money (e.g., staff lunches) that was separate from the University of Wisconsin’s administrative hassles. On the other hand, there were grave concerns: “WReN was not that helpful for recruiting practices. Follow-through during recruitment was very disappointing. WReN chose not to be around or to be a member of the research teams.”

Other limitations were also noted by these experienced investigators: “... not sure if WReN will be helpful to my research program in future studies. I am more likely to use a health care system.” “WReN does not have access to health care data, claims data or costs.” “WReN is strictly a volunteer group.” “WReN has had minimal impact on the care of patients or changing the U.S. health care system. We have mixed feelings about WReN in the future of serious family medicine research.” “WReN provides little scientific expertise to its members, since the leadership of WReN is not made up of senior NIH level researchers.” The leadership is primarily well-meaning doctors who have an interest in encouraging research.”

## Keys to success and failure

<i>Success</i>	<i>Failure</i>
Well-funded projects	Inadequate funding
Skilled and dedicated PIs and staff	Remote PIs
Important questions	Poor or uninteresting questions
Excellent support to clinics by PIs	Design not applicable to community practices

One external, or contractual, project that was clearly a failure from WReN's perspective was the Digitalis Investigation Group (DIG) Study designed and supported by the National Heart, Lung, and Blood Institute. While the question was an excellent one ("What is the impact of digitalis use on mortality?"), the study was designed by people naive in the ways of the practice world. As a result, the design was not applicable to community practices. In addition, the PIs were remote (in Bethesda, Md.) and the funding to WReN and the practices inadequate. Despite great effort on the part of all, WReN could only recruit three participating practices and they had a very limited number of patients.

WReN has become a bit more experienced since that debacle and thus avoided a project with a Centers for Disease Control and Prevention (CDC) sponsored study of urinary tract infections. The question, methodology and funding were all inappropriate. We learned that all potential network studies must actively involve network representatives in the design stages of the project.

### **Research projects: internal/network-wide**

A goal of WReN is to facilitate collaborative research among practicing physicians. These studies involve multiple sites in WReN with a collaborate project initiated by a WReN member and supported primarily by WReN staff. An example is an epidemiologic study of adult-onset asthma designed as the beginning of an exploration of a set of hypothesis

regarding a possible infectious etiology for some asthma. The study was designed, "PI'd" and published by a physician in private practice with considerable support from WReN and a series of small grants (none of which provided any funds for WReN). This project was a success because of the importance of the question, a very dedicated and skilled PI, some funding for "out-of-pocket" expenses, and a chance to compete in the future for large-scale NIH funding.

A failed collaborative project (at least at the present) is a proposed study on the comprehensiveness of care in community practices — an exploration of the number of problems managed at each visit versus the number of problems billed for. This has been a failure simply in that after about 18 months of discussion, nothing happened. The project is still on the back burner. The reasons for the failure include PIs with other major academic and community-oriented activities, and the lack of dedicated infrastructure to support this project.

We have not adequately developed project level infrastructure or funding for internal/network-wide projects. Recruitment has been difficult. While we have made efforts to develop research training for our members to support the projects, it has not been something we have been able to do well.

Regarding collaborative internal projects, our members commented on our success: "Enrolling more than 14,000 patients in an asthma epidemiology study that also compared practice demographics with the

National Ambulatory Medical Care Survey (NAMCS). The research projects I have participated in require very little time on my part.”

However, there were also comments on our failures: “WReN has not realized the potential of a ‘network’ (i.e., real time queries to a whole series of research questions). It has not stimulated the development of projects conceived and led by community physicians.”

#### **Research projects: individual**

The third type of project is related to WReN’s goal of supporting the personal research interests of physicians in community practices. An example of a successful study is the one done by a rural physician and his Certified Nurse Midwife (CNMW) spouse who explored the relationship between maternal birthing position and perineal injury, a study which was presented at a plenary session of North American Primary Care Research Group (NAPCRG). The success of this study hinged on a supportive practice environment, two interested and organized PIs, and the support by WReN which provided a summer research extern and technical help with the presentation.

The failed individual study was one done by a retiring physician who received a small grant from WReN to ask the question, “Does an egg a day improve the nutritional status of nursing home residents?” While the study was complete and presented at the WReN meeting, the numbers were so small they made any real analysis impossible. The failure was due to an inexperienced PI and WReN not “riding herd” closely enough on the project to ensure the numbers were adequate.

Regarding these individual projects, our members commented: “What is important for me is the role-modeling, particularly in developing a theme for a research agenda. Physician intervention research has been especially useful for me to think about, as with the blastomycosis research, there are always more questions to ask. WReN has also

been a very useful deadline for me. I always know I need to get things done during the summer for WReN (in time for the fall meeting). The research stimulation grants have been helpful.”

Other respondents were not as enthusiastic about WReN’s ability to support individual researchers: “There is a lack of resources to really tap into the creative energy of these researchers and the patient population cared for by the WReN doctors. You need a bigger core staff (and more director time) to get the grunt work done and resources to pay for the researcher’s time. I do not know how to tap into the resources.”

If we look at the ingredients of the successes and failures, I think the successes have been characterized by champions at both the organizational level and at the project level. One controversial challenge will be the conflict between the big, sophisticated fundable projects versus the small, individual-interest projects. Yes, there is a conflict.

#### **Research we cannot (or should not) do**

We should not be involved in research that is underfunded in terms of its support for either the infrastructure of WReN or for the involved practices. The exception, probably, is some entry level and pilot studies. In addition, our own focus group work with physicians showed very strongly that we cannot engage in projects that disrupt the flow of practices too much. These physicians reminded us that patient care comes first.

There are several other types of research we should not even attempt. Some of that is research better done with other populations and that revolves around subspecialty diseases and in-hospital problems. There is also some research that is better and more easily done at a single site or with the large data sets that MCOs and insurance carriers have access to. The network probably offers little in these cases. We need to avoid research where the underlying question is poor or which is impractical in the community setting. In every case, especially where the network is involved in external or “contract”

research, it is essential that network representatives be involved in the planning of the research project from the outset if we are to be successful.

As I pointed out earlier, MCOs have access to a type of data we do not have and can do some research non-MCO networks cannot. They certainly have a great coherence that a series of practices spread across two dozen health care systems cannot begin to approach. What they lose in a generalizability and community richness may well be made up for by other forms of precision.

Should WReN engage only in research that will change primary care practice? There has been discussion this morning about POEMs (patient-oriented evidence that matters). Does WReN need to come out with POEMs? It would be helpful, but to insist that all network research is going to change our practices may be overly demanding. How much research comes out of a cell membrane lab that actually changes clinical practice radically?

Enormous amounts of research work are done to achieve any useful results — and the results that are clinically useful are the tip of a huge iceberg. I do not believe we need to be ashamed of that fact. We have a very large iceberg with only a little tip that is visible. That is probably okay, because if you do not have the iceberg, you are not going to have any tip. We need to take pride in the general enterprise and not worry if not all of the research results in POEMs.

### **Survival/developing network support**

In the family of PBRNs, there have been a very high rate of early network mortality. A number of years ago I reviewed a list of research networks that was at the time about five years old. The mortality rate appeared to be about 75 percent. One of our members commented that simply to survive was a measure of success. We attribute our success in this dimension to the skilled and dedicated staff infrastructure; to stable WAFP funding for our base support; to the University of Wisconsin Department of Family Medicine's

support in the form of 0.2 FTE time for the director, office space, etc.; and the ability to become involved in financially-sustaining trials organized by academicians, ASPN and others.

We have had failures that impaired our ability to be successful. Although the WAFP and University of Wisconsin have provided stable support for the WReN infrastructure, it is still far less than what is provided to other traditional biomedical research infrastructures.

The chronic infrastructure funding problem arises in part due to the difficulty of articulating the argument for primary care research in a way that has general appeal. As one member said, "We need a poster child." The lack of this poster child has led to a failure to garner major philanthropic and industrial support, and a general inability to adequately support practices (i.e., make research part of the revenue stream). This lack of infrastructure and practice support funding has led to WReN having had problems meeting its contractual obligations.

### **Creating the culture**

It appears that WReN has had a substantial role in articulating the need for primary care research, in involving a wide range of clinicians in the process, and in supporting cultural change. The most marked change of culture is reflected in the recent strategic planning process of the WAFP wherein WReN received the second highest priority in the organization. The annual meeting is seen as a very important event.

Highlighting our successes, the members commented: "The annual meeting involved many students and residents in research — the environment there is exciting, positive and comfortable. The WReN meeting is a common ground for the academic folks and the practicing physicians in the pursuit of research. It has been a stimulus for all of us and a focus for getting physicians together to discuss research in practice; it has stimulated a lot of practicing physicians. WReN has defined many of the elements of practice-

based research. It contributes greatly to the family practice environment in Wisconsin. We in the front lines have an input into what research is needed. WReN gives us a voice.”

On the other hand, our successes within the academic environment, especially residencies, have been less impressive. Our members noted: “There is a lack of embracement by academics. Whereas a handful of faculty see the value of WReN, I am afraid most do not. You have not successfully communicated the values (of research) to faculty and residents.”

#### **Helping new and “little r” researchers**

WReN has had considerable success helping new and “little r” researchers — those physicians who do small, minimally funded projects and for whom research is not the focus of their careers. We have done this through Summer Research Externships for medical students, supporting some resident research, providing (or brokering) technical help, and providing the WReN meeting for presentation, and publishing the meeting’s proceedings. At the same time, we have lacked sufficient funding to provide extensive staff support to many researchers, have lacked some internal expertise (e.g., statistical, health services) and we have not had internal funds allowing us to provide much project support (including salary) for clinicians.

It is in this area that the members had the most positive comments: “WReN has provided students and residents an introduction to primary care research. The meeting gives them a chance to present to experienced researchers in a nonintimidating forum. “Getting the abstracts in the *Wisconsin Medical Journal* is a real plus.” “I learned through WReN more about qualitative research and have since embarked on a couple of projects.” “WReN gave me the encouragement to move ahead with the project; the networking that occurred at the annual meeting allowed me to find participants. WReN’s handling of the finances freed the PI from having to deal with that aspect of the project.” “I have benefited from the

research stimulation grants given to medical students and residents. This has been beneficial to the students who have received modest support for short-term projects and it has enabled us to complete projects, which have lead to publication.” “I can relate to having a support system for ‘clinic-based’ research. I would not be doing my doctoral research in primary care if it was not for WReN.”

Nonetheless, there was a continuing concern: “The infrastructure is not sufficiently funded or expanded.”

#### **Supporting “big R” researchers**

Perhaps WReN’s largest contribution to the “big R” researchers has been in the grant application process where demonstrated access to a wide range of practices has helped to show that the grant plans are realistic. We have also, in reality, created to some extent a “culture of participating” and thus have been able to give some, if not entirely adequate, help in practice recruitment. However, the problems have been substantial. WReN has not always been consulted adequately during the design phase of projects (sometimes the question is not even an appropriate one), and we have not solved the recruitment problem. WReN has tended to fail to ask for sufficient funds to ensure success in major recruitment efforts — both funds for the infrastructure and funds sufficient to make the projects attractive to practices.

#### **Success and failure: the ingredients**

It seems that success overall hinges on the presence of committed and skilled champions — both for the organization and for the individual projects. Their task is impossible, however, without equally skilled and dedicated staff, and a stable base of financial and in-kind support. There needs to be ties to academia for expertise in asking fundable questions, in getting grants, and in executing complex projects. No success is possible without adequate infrastructure.

#### **Future success and failure**

Our members brought up a number of

issues that do not fit neatly within a list of successes and failures. These include the following:

- “There is a balancing act of setting a research agenda (coherent goals, fundable projects) versus the personal interests of curious practitioners.”
- “I think research targeted to nonphysician providers within the primary care setting deserves more emphasis from WReN.”
- “Nonacademic research is not very popular among some researchers. Can we talk about scholarly clinicians? Can we close the gap between ‘real life’ and ‘academia?’”
- “We need better research. Perhaps members should be allowed to make mistakes at the beginning of their research endeavors to allow them to take small steps and progress. However, we should not allow that to happen in the area of methodology. It does us no service, nor does it promote primary care as a discipline to produce studies which are inaccurate. We need to be credible even if entry level.”

- “Is WReN a recruiter? Academics and ASPN view WReN as a tool for recruitment. If that is what we want to be, we need to pay more attention to it so we can be successful. If not, we need to be more clear. We should firm up the process, write a recruiter into grants and develop a better system where someone gets paid actual money to recruit.”

#### **Another type of success?**

Finally, a view from a rural physician: “I attach most of WReN’s significance to more personal issues. Primary care research is important to me. Without WReN, I would have no way to maintain my enthusiasm and fulfill my personal goals. It is important to get people of like minds together at the annual meeting to reinforce one’s philosophies. Do not get discouraged if the answers to your questions do not all emphasize ‘research agendas’ and ‘national goals.’ For many, like me, it is much more personal.”

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# The Best and the Worst Studies of the Upper Peninsula Research Network

JOHN HICKNER, M.D.  
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I will focus much of my presentation on the specific studies we have done and some of the lessons we have learned. First, a little about myself and the Upper Peninsula Research Network (UPRNet). I consider myself to be a family doctor first and a researcher second. I have been involved with practice-based research for more than 17 years on several levels. I have been an Ambulatory Sentinel Practice Network (ASPEN) clinician since 1982, an ASPEN board member since 1993, and ASPEN's president since 1997.

I cofounded the Michigan Research Network (MiRNet) in 1984. It was a regional network. In 1988 I founded UPRNet, which is a group of practices in the upper northern parts — a very rural network. The network is both a research and teaching network. Interestingly enough, however, we have done more research than teaching. UPRNet is a program of Michigan State University College of Human Medicine's Upper Peninsula campus, from which we receive infrastructure support including about 10

percent of my salary and 1.5 FTE staff support. However, UPRNet is governed by a steering committee (just as ASPEN). We have learned many things from ASPEN and have modeled a few aspects of UPRNet after ASPEN.

Our steering committee comprises UPRNet doctors, nurses, coordinators and local community faculty. We have 15 practices, 21 sites and about 70 clinicians — of which about 95 percent are family practice. UPRNet is designed to maximize the input of both clinicians and support staff. We have two meetings a year, because — unlike WReN — we have a very tightly knit group. The doctors and nurses and their support staffs know that they are in UPRNet, and therefore most UPRNet practices participate in most UPRNet studies.

We have a very different model from ASPEN and WReN because we are, after all, a small, regional, highly committed group. We often have, for example, receptionists come to our biannual meetings because we recognize that they are one of the main links in the data collection process.

## The best studies

**1. Do gastrointestinal symptoms accompanying sore throat predict streptococcal pharyngitis?**<sup>1</sup> Although there is a slight association of gastrointestinal symptoms



with streptococcal pharyngitis, it is not strong enough to make a difference in diagnosis. Why did I pick this one out as one of our better studies?

The question arose from the daily work of a network clinician — in this case, from a physician assistant — who noticed this phenomenon. He wondered if the association of GI symptoms with strep throat was really true. Therefore, it was a well defined, answerable question. And it is a common problem. We see strep throat a lot. If the association panned out, it would be quite important if gastrointestinal symptoms did provide some predictive value to the diagnosis of strep throat. The study ran very smoothly and efficiently. We had a very high participation rate and we had our analysis planned ahead of time.

#### ***Reasons for success***

- The question arose from the daily work of a network clinician.
- The study addressed a well-defined, answerable question.
- The study revolved around a common problem of clinical importance and interest to the clinicians.
- The gathering instruments were tested thoroughly and were user-friendly.
- The study duration was short.
- The database was excellent.
- The participation rate was high.
- The analysis plan was finished ahead of schedule.

#### **2. Accuracy of on-site data entry in a rural primary care research network.<sup>2</sup>**

We thought this study centered around an important method issue for PBRNs. We asked ourselves if our practices are able to accurately enter data. This issue was a side-line of a description alcoholism study we conducted via questionnaires. We entered all of the data twice to compare accuracy.

First, we had the nurses or receptionists enter the data from the questionnaires and then ship us the questionnaires. The central office staff then entered the data again. We

computed the error rate of the staff in the practices who did the data entry. We found these untrained office personnel had error rates that were similar to industrial standards. They averaged one error per 5,000 keystrokes. That tells us it is possible to have people in these practices do very accurate data entry.

**3. The high prevalence of obesity in rural northern Michigan primary care practices: an UPRNet Study.<sup>3</sup>** The bottom line of this study was that our patients were, on average, much heavier in weight than the prevailing norms for our state. Why do our patients weigh more than others in the state? It is a real interesting question to grapple with.

This was a good study because it illustrates the difference between practice-based epidemiology and population-based epidemiology. This is something we debate with our colleagues in public health. I believe it makes sense for us to study our patients. They are the people we care for — day in and day out — as family physicians.

The data was very easy to gather, and we gathered a lot of it. We had data on more than 4,000 adults and more than 2,000 children and adolescents. This study led to an on-going research theme for our network, obesity. The network is now interested in obesity, and society seems to be interested in it as well. The study has led to collaboration with another network, the Practice Partners Research Network (PPRNet). We examined heights and weights in the very large PPRNet database to confirm our suspicions.

#### ***Reasons for success***

- The study taught us that practice-based epidemiology is dramatically different from population-based epidemiology.
- The study was a basic descriptive study.
- The study question was raised by an academic/clinical nutritionist.
- The study had very low cost.
- The study produced an ongoing research theme for the network.

**4. The clinical epidemiology of diagnosis and treatment of respiratory infections in primary care practices.**<sup>4</sup> We looked at the frequency of whether or not antibiotics were prescribed by diagnosis, age, sex, clinician, etc. We also looked at the frequency of prescribing by symptoms as reported by patients. Then we developed a logistic regression model to determine what factors were independently associated with prescribing antibiotics for upper respiratory infections. In this case we limited diagnoses to upper respiratory infections, acute bronchitis and acute sinusitis.

I believe this was a good study because of its prospective nature. We were able to gather data prospectively, by patient encounter, and enrolled nearly 1,000 patients. We gave questionnaires to the patients, physicians and nurses. We had prospective data and we were able to look at the clinical epidemiology of how it fell out from there, because that is how patients come in. They do not come in with the diagnosis. This study approach allowed us to look at the phenomenon by starting with the patient's presenting complaint.

There are obvious advantages and disadvantages to different data collection systems. This type of collection took a network of dedicated clinicians. We gathered this data on 1,000 encounters in three months. There was no complaining from our clinics. We had excellent data. These practices have been doing studies for 10 years. Everybody in the practices know their roles. There is a lot of enthusiasm within the network.

#### ***Reasons for success***

- We gathered data prospectively on the basis of presenting complaint rather than secondary analysis of diagnosis-based data, enabling a fresh look at the issues involved in antibiotic over-prescribing for acute respiratory tract infections.
- The question was of great interest to the network clinicians.

- There was a short duration of data gathering.
- There were high participation rates. Everyone knew their role.
- The topic became a research theme for UPRNet.

#### **The worst studies**

**1. A randomized trial of phone management of dysuria.** This study has an outside investigator. He is within Michigan State, but is not in our network. We made a gross overestimation of participation. The recruitment method we used in this randomized trial of phone management of dysuria turned out to be a huge hurdle. We are in a fee-for-service environment, so the doctors were accustomed to bringing patients into their offices.

There was probably a poor fit between the requirements of the study and the capabilities of the network practices. For example, the receptionists in these busy offices were the first contact. They had to remember to refer all phone calls from patients with dysuria to a particular nurse to triage and check enrollment criteria. This process did not duplicate the practice system. I believe in another setting this particular study would have worked great, such as in a single large outpatient clinic or in a managed care situation.

#### ***Reasons for failure***

- Outside investigator who was not familiar with local practice patterns
- Gross overestimation of participation
- Difficult method for recruiting participants
- A poor fit between the requirements of the study and the capabilities of the network practices

**2. Attitudes and beliefs of family physicians toward treatment of hyperlipidemia in the elderly.** We surveyed elderly patients and then we surveyed their physicians. It was a good question when we asked it three

years ago. We presented doctors with six scenarios at baseline, and then a follow-up at six months, to see if they would manage these patients consistent with the National Cholesterol Education Program (NCEP) guidelines. We found that they were pretty close. The problem was that it took us too long to analyze the data. The question was bounded by time. Once we analyzed the data, the question was out of date and our analyses were of no use.

We had several new studies in the pipeline and they distracted us from this one. We did not publish in a timely fashion. We could not push this one out the door.

**3. Are tattoos a marker of sexual abuse in women?** This was a fascinating study. One of our local social workers noticed that a lot of women in jail had tattoos. He wondered if these women were sexually abused. He asked them and found out that many of them were. We thought that tattoos — particularly those on the hands — were somehow related to the emotional feelings tied to being sexually abused.

I do not know if this question would work anyway these days, because lots of people have tattoos for social reasons. This was another time-bound question. However, it was an interesting study. It had a lot of informed consent issues: If you are identifying people who have been sexually abused, what is your obligation to legally report those who did the abusing? We met with the local prosecutor to get these issues settled. We could not get published. We could not motivate the investigator. He had no motivation himself to publish it.

### ***Reasons for failure***

- Informed consent issues
- Could not get the investigator to finish writing the study and to submit for publication

- No motivation for publication
- Time-bound question

### **Lessons learned**

When I look at our successful studies, we followed general principles of excellent clinical research. We also asked appropriate questions. Because of the demands of clinical practice and limited financial resources, general principles of research are necessary but not sufficient.

We have to consider the constraints of clinical practice in every study. Our research network is very different from others. We are a very circumscribed network in a circumscribed geographic area. I personally think there is great value in these small intimate kinds of networks, as they provide intellectual support to the clinicians in the networks. It really brings something new and exciting to them because it provides some stimulus for them to think critically about their practices. Finally, I believe the lessons that we have learned from conducting our research can provide lessons to other family doctors around the country.

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# The Practice Partner Research Network: Successes and Failures

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**T**he Department of Family Medicine at the Medical University of South Carolina (MUSC) and IMS America (a medical information services company) collaborated with Physician Micro Systems Inc. (PMSI) in May of 1995 to create the Practice Partner Research Network (PPRNet).<sup>1,2</sup> PMSI is the developer of the electronic medical records (EMR) software called "Practice Partner Patient Records." The Department of Family Medicine at MUSC had used this software since 1991. Faculty and staff were actively involved in research evaluating the clinical benefits of EMRs. IMS America provided financial support for PPRNet's infrastructure.

In the summer of 1995, PPRNet recruited a staff and an advisory board of physicians from across the United States who use the Patient Records software. Practice recruitment began concurrently. PPRNet recruits member practices from lists of Patient Records users supplied by PMSI.

Our membership comprises 64 practices in 24 states, with 364 physicians and 380,000 patients. About 90 percent of these physicians are family physicians. This is a little misleading because we have seven family practice residencies, so the proportion of sites is not really 90 percent family practice. We also have several general internal medicine sites as well.

## **Electronic medical records**

EMR systems are powerful tools for clinical practice. Less appreciated is the role that EMR systems can play in practice-based research activities, both to generate new knowledge and to improve the quality of care. EMR systems are uniquely able to implement interventions designed to improve quality and measure outcomes, and can demonstrate the benefit of such interventions. As such, practices that use EMRs are able to participate in research activities that would be impossible for practices that use traditional paper-based record systems.

These activities have two major benefits for practice-based clinicians. First, they provide a relatively simple means to participate in research, which has traditionally been confined to the academic medical centers. Such participation provides intellectual stimulation and appeals to many physicians' sense of altruism through contributing to



improving health care beyond the confines of their particular practice. Second, the specific research activities suitable in practices that use EMRs are often directly relevant to the needs of participating physicians. Interventions found to be effective in research projects can be readily continued in participating practices.

Although individual practices can independently conduct research using their EMR systems, synergies that evolve through the collaboration of many practices can enhance the types of studies performed and the external validity of the findings. I will describe and discuss the strengths and weaknesses of PPRNet.

#### **PPRNet data collection and analyses**

We began data collection in November 1995. It took a year to enter the data and all the rest. We did not have our first database until the beginning of 1997, and then we were able to start doing studies. In early 1998 we received funding from three different sources for studies on congestive heart failure, resource allocation and antidepressants.

Each month the practices run a computer program (developed and maintained by PMSI) to extract patient-level data from the Patient Records software. The first time the program runs, all existing data is extracted in subsequent months and only the new data is extracted. To protect patient confidentiality, the extract program assigns a unique anonymous numerical identifier to each patient. The data is copied to diskettes and mailed to IMS America.

At IMS, the data is aggregated and undergoes rigorous quality control. Coded data elements are bridged to standard data dictionaries. Data tapes are sent quarterly to the PPRNet office at the MUSC Center for

Health Care Research (CHCR). The tapes are converted to statistical analysis system (SAS) data sets on a UNIX computer. PPRNet staff perform all subsequent analyses using microcomputers and standard database statistical software.

The PPRNet database currently has information on more than 380,000 patients, including 2.3 million patient visits, 6.6 million diagnoses, 2.7 million prescriptions, 370,000 allergies, 7.8 million vital signs, 8.6 million laboratory records, and 771,000 preventive services. Several research projects are underway using these data (*Table 1*). Project investigators include PPRNet staff, clinicians in participating practices, and others interested in using PPRNet data for their research.

#### **PPRNet member benefits**

In addition to the opportunity to participate in research, PPRNet members receive two other major benefits: quarterly practice reports about their individual practice volume and adherence with the U.S. Preventive Services Task Force's recommendations and a number of quality care markers for chronic disease, and discounted fees to PPRNet-sponsored continuing medical education (CME) meetings.

#### **Successes and failures**

The nature of PPRNet itself and the data it obtains leads to predictable strengths and weaknesses in its research endeavors. Instead of focusing on one successful and one unsuccessful project, I will identify these strengths and weaknesses and illustrate their impacts on several studies.

#### **PPRNet strengths and impact on research**

Breadth. The breadth of data and the

**TABLE 1. Study designs and goals of research projects from PPRNet**

<i>Study Design</i>	<i>Project</i>	<i>Project Goal</i>
Survey	Use of EMR	Assess the extent to which practices used the features of their EMR system
Qualitative	EMR impact	Evaluate the organizational and economical impact of EMRs
Case Series	Redux for obesity	Assess the effectiveness of Redux
	Depression	Assess the diagnostic and treatment patterns for depression
Cross-sectional	Childhood obesity	Determine the prevalence of childhood obesity
	Heart failure and thyroid disease	Study the association between thyroid disease and heart failure
	Quality of care for chronic illness	Determine adherence with practice guidelines and clinical outcomes for coronary disease, hypertension, diabetes, and other chronic illnesses
	Preventive services delivery	Assess practice adherence with commonly accepted recommendations for preventive services
	Lab monitoring with non-steroidal anti-inflammatory drug (NSAID) use	Assess whether specialty-based guidelines for laboratory monitoring for patients on NSAIDs are followed in primary care practices
Cohort	Antibiotic use for upper respiratory infection (URI)	Determine the impact of antibiotic prescriptions for URI on resource utilization.
	Recurrent otitis media	Assess whether more expensive antibiotics are more effective for recurrent otitis media
Clinical trial	Anti-depressant compliance	Determine whether patient reminders will improve compliance

potential subjects available in the PPRNet database permits a variety of research projects. Examples of data include: diagnoses, medications, vital signs and laboratory results. PPRNet data has been available for less than two years, but investigators have already, or are currently, exploring a wide range of subject areas. These include common problems, chronic disease, prevention and mental health.

**Existing data.** The presence of an existing database, which is updated regularly, greatly speeds the process of data analysis and allows more projects in a given period of time. We have been able to study the body

mass index of 30,446 children; antidepressant medication use by 1,171 adults; and adherence with practice guidelines for 11,027 asthmatics, 11,789 diabetics, 35,237 hypertensives, 7,004 coronary disease patients, and 4,003 heart failure patients.

**Network/database structures.** The presence of both a network of practices and a database of clinical information from these practices permits great flexibility in the types of studies possible (*Table 1*). Some studies, including the survey of members' EMR use, qualitative study of the EMRs' impact on practice, and clinical trial to enhance antidepressant use, required active participation of

our members. On the other hand, the case series, cross-sectional studies, and cohort studies were done using the PPRNet database, without additional member participation.

**Large databases.** The large number of patients in the PPRNet database permits the study of uncommon problems. In the recurrent otitis media study, the objective was to determine whether children with a prior episode of treatment resistant otitis media had fewer follow-up visits for treatment-resistant episodes if they were treated with a second-line antibiotic. Since most episodes of otitis media are not treatment-resistant, and many children never develop a second episode, a large initial sample of children with otitis media was needed to address the study question. Indeed, of the initial otitis media episodes, only 18 percent were initially treatment resistant. Only 24 percent of these children had another episode. Nevertheless, the database was large enough to provide 343 children for the analysis of interest.

**Multiple perspectives.** The scope of the information in the PPRNet database allows examination of subjects from several perspectives and may create unique insights. The initial goal of the depression study was to examine treatment patterns, with particular emphasis on the use of antidepressant therapy. Traditional studies of this type would have focused on review of records of patients diagnosed with depression, the initial approach we used as well. However, when we studied the PPRNet medication file, we realized that more than 40 percent of antidepressant prescriptions were written for patients without the diagnosis of depression. This finding brought to light numerous other questions concerning the treatment of depression and the use of antidepressants in clinical practice.

#### **PPRNet weaknesses and impact on research**

Uncertain data validity. Ultimately, the value of research done using the PPRNet database depends on the validity of the data. Problems

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#### **PPRNet strengths**

- Breadth of data and potential subjects provides many opportunities.
  - Existing data speeds analysis
  - Network/database structures permit various designs
  - Large databases permit study of uncommon problems
  - Multiple perspectives allow unique insights
- 

with the validity of clinical databases<sup>3</sup> and clinical records<sup>4</sup> upon which they are based have been discussed for years. With respect to research, this problem is often termed the “garbage in, garbage out” phenomenon. A well-known family medicine researcher and editor of a prominent periodical in the field declined to publish a paper from the PPRNet URI study, citing concerns about the validity of the diagnoses in the database.

**Incomplete data.** Data derived from clinical records reflect the reality of medical practice in which clinical measurements are often made and recorded inconsistently. In the Redux study, nearly 20 percent of adults treated with Redux did not have a height measurement recorded in the record, obviating the possibility of calculating body-mass indices. Additionally, 40 percent of the patients had no follow-up weight recorded, and the effectiveness of Redux for them could not be determined. In the preventive services studies, it became clear that many practices inconsistently used the “health maintenance” section of the EMR. For example, some practices would record immunizations in the medication section of the record, others in a separate text section, and others in the health maintenance section. These inconsistencies greatly complicated analyses.

**Limited data.** Due to issues of patient confidentiality and data volume, free text records (progress notes, reports, consultation notes, and discharge summaries) are not included in the PPRNet database. These

**TABLE 2. Comparison of PPRNet and traditional PBRNs**

<i>Dimension</i>	<i>PPRNet</i>	<i>Traditional PBRN</i>
MD involvement	Limited	Active
Data collection	Longitudinal: data gathered every month, new data reports every quarter	Intermittent: depends on individual studies
Study samples	Large	Small
Strengths	Breadth of topics we can study	Depths in which a particular question can be looked at

limitations preclude the possibility of corroborating diagnoses or studying variables that may be included in the free text sections of the record. As discussed earlier, we could not substantiate the validity of respiratory diagnoses in the URI study. In the depression study, we could not determine whether many of the patients given antidepressants without a mental health diagnosis actually met the criteria for mental illness. Clinicians may have purposely given an alternative diagnosis for reimbursement purposes or concerns about patient stigma.

**Disinterested members.** Participation in PPRNet requires no more than the willingness of a practice to run an automated extraction program monthly and put data diskettes in a postage-paid mailer. Although this process does allow PPRNet to receive data from practices that might not participate if more effort were regularly required, it does create the possibility of inadequate enthusiasm for projects that need practice participation. Fifteen percent of practices refused to participate in a simple survey concerning their EMR use<sup>2</sup>. Less than half of PPRNet practices elected to participate in the antidepressant clinical trial. Only one-third of PPRNet practices send a representative to the expenses-paid annual member meeting, at which ongoing and future research projects are discussed.

**Financial support.** Financial support is the last major issue causing limitations in

PPRNet research. The initial support agreement with IMS America prevented PPRNet from receiving pharmaceutical company funding or from conducting any clinical trial that might alter prescribing habits. Since intervention studies are a critical component of primary care research, this prohibition was serious, but was a necessary compromise to receive infrastructure funding. Quite recently, IMS has decided to end its collaboration with PPRNet. While this decision will remove prohibitions about the types of studies that PPRNet can perform, the loss of infrastructure funding may be a critical blow to the continued existence of the network.

### **Summary and conclusion**

We have successfully developed an EMR-based primary care research network. PPRNet members, with little additional effort, can contribute to the national need for practice-based research. The unique

### **PPRNet weaknesses**

- Uncertain data validity
- Incomplete data
- Limited data
- Disinterested members
- Financial support



nature of PPRNet leads to predictable strengths and weaknesses in its research endeavors. We believe that PPRNet is a useful model for other PBRNs.

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## Observational Comments and Questions and Answers

**Dr. Joe Scherger:** Research from the PBRNs is published mostly in research journals. It appears that many family physicians do not read the research journals. The *Journal of Family Practice*, the *Archives of Family Practice* and the *Journal of the American Board of Family Practice* are not financially stable. Reader surveys tell us the readers do not read most of each issue — if the readers even read them at all. Family physicians are reading *American Family Physician* — which is a clinical review journal — and *Medical Economics* instead of the research journals.

I was wondering if the broad participation by family physicians in research networks — for example, 695 Wisconsin physicians involved with WReN — increased the readership of research journals? Do PBRN members read the *Journal of Family Practice* at all? I am estimating there are about 4,000 doctors nationwide participating in research networks. This should be about 10 percent of our practicing physicians. Do you think these physicians will start reading the journals? These physicians should be reading the research journals. And if more family physicians do not start reading the research journals, the whole program of PBRNs could die due to the lack of interest of those family physicians and primary care providers who do not read research-based journals or are intrigued at all by practice-based research.

**Dr. Joe Selby:** In direct response, some physicians do not know they are members of a research network because their office managers signed them up, and they wonder “What is this stuff that I keep having to throw away every couple of months.” I think the short answer is probably that they are not reading the research journals at all, and it grieves me to say that. You can actually turn that into an interesting challenge of how do we build *JFP* or some other journal into part of the equation. Part of what physicians get for participating in this knowledge-generating endeavor should hopefully be interest stimulation. Does that sort of force an issue that should be forced? Yes.

**Dr. John Beasley:** I have two answers to this problem. The first one is that we will write for those journals that physicians do read. The other answer is that we are at a stage where information (especially in the future) is not going to be disseminated via print journals. Physicians need information at the point of patient care to help in making decisions. They do not need magazines that they are going to read at home on the couch only to end up trying to remember what it said when they are taking care of patients.

**Dr. Steven Ornstein:** This battle has to be won in the medical schools. I believe that

departments of family medicine have started training students in evidence-based medicine. This then carries into their residencies and then out into their practices. Twenty years from now the culture of family medicine will be very different. Junior students are now much more sophisticated so that when I teach them research design principles, I am able to quickly take them to the next step.

**Dr. George Isham:** I appreciated the information about the journals and the percentages of studies each publishes. Now I know why I do not know much about this subject because I do not read those journals as a non-family practice physician. The journals I do read have just a few studies published in them. So, if I as a system-level person — who is very much concerned with primary care and many of the issues that have been raised here — need to know some of these things, then I wonder if the communication strategies need to be something other than those journals. I think we have sort of talked about that a little, that is, if you want to reach an audience that is me and others like me. That is one comment.

Another comment is about what I am hearing in the examples of these research networks. I wonder whether we are expecting every family physician to be a researcher, and how realistic is that? If we are not expecting that, then what is the relationship of the research skills and research activity to the general concern of doctors — whether they are family physicians, internists or pediatricians — who are interested in delivering quality care and getting through the days. That thought has caused me to wonder whether or not we need to sort of instill something between formal research and systematic observation on a more wide-spread scale in terms of those who want to contribute to their knowledge, but do not need to necessarily be formally trained along the lines of some of the John Frye work and others that I am more familiar with.

It is not becoming clear to me in these

discussions. If you are thinking about these kinds of concepts and can help me to understand these things, your response would be appreciated.

**Dr. John Hickner:** I would like to respond directly. The answer to that is one in 10 because of the students I teach — and I have been teaching medical students for about 20 years now — one in 10 catches the research bug. If you look at our UPRNet publications we have many students who have been coauthors on studies. It is about one in 10 who I think will be interested and become significant collaborators. Yes, the others we would like to raise their skill level to the level that they will at least have a passing interest and agree to gather data in their practices for the network. And then there are the others that are in between. But one in 10 is the answer.

**Dr. Mary Croughan-Minihane:** This will sound totally different from what the rest of you have been talking about, but I think this is probably the only forum in which I can air this major concern. I think, in fact, this concern has probably a bigger impact on practice-based research than a lot of the issues that have been brought out. I am the only PhD-trained epidemiologist in this room, and one of the few non-family physicians. When I go to NAPCRG I can name two other people who are there who are PhDs with primary appointments in family medicine departments. When I go to the epidemiology meetings I do not see anyone else who has an appointment in a family medicine department. I do not know if they do not go or what happens in terms of meetings they attend.

It has been amazing to me after 11 years of sitting in a family medicine department and directing a network at the lack of methodologic expertise that is out there for family physicians to rely on. I think that is really one of the biggest problems. Who are family physicians going to turn to when they are interested in obtaining research training? There are not enough family physicians who

are well trained in research methodology. Family physicians cannot be expected to train themselves. There just are not enough people who have strong methodologic training out there in the field for them to have access to. Even if you have five people in the whole country, that is just not enough people to pull it off. Not that I think the AAFP money should go in that direction, but something has to happen about visibility to getting family medicine research as a priority for the general field of people who are out there trained and doing methodologic research.

**Dr. Don Iverson:** I want to take exception to that, because I think that it is a narrow view. I have reviewed grants for seven years and I do not know how many I have seen from family physicians and where they come from around the country. But they are not lacking methodologically. They tend to look for people in other departments and sometimes those departments may be in psychology, for example, and the statistician might be from a biostat or education or research department. But I have not seen the lack of methodological expertise on the grants that have been submitted, and some of them have been extremely complex grants.

There may be fewer people in the departments, but what I have seen from the grants is departments reaching out to bring in people who have that expertise and they have not had any trouble finding it. Certainly in the applications they have reached out and brought in good statisticians, good epidemiologists, good psychometricians and good psychologists. I have yet to see any applications go down for lack of content in that area.

**Dr. Croughan-Minihane:** I think what happens is the result of the lack of subject matter expertise specific to family medicine. When you are not in the environment on a daily basis, it is the same as it is for any other field. Unless you have been acculturated to the environment where you think of yourself

first as doing primary care research instead of first being an epidemiologic expert. It is different.

**Dr. Iverson:** The mind set is different, I agree. I guess that all I am saying is that people around the country have obviously been able to entice enough colleagues where there seems to have been some osmotic diffusion here in terms of mind set, because the applications certainly reflect an understanding, at least as I look at them, an understanding of family medicine.

**Dr. Mark Ebell:** I have a comment about POEMs. Several people have mentioned POEMs. POEMs focus on three things, and the presenters have talked about just one: does it change practice? This is what the "M" stands for ("does it Matter?"). There can be very good studies that show that some things should not change practice. That may not be a POEM, but it is still important. I think we are more likely to do POEM-type research in our work here in PBRNs than in the NIH where we are at the cellular level.

The other two sides of a POEM are, first, is it common or important to our patients? In other words, is it a problem we deal with? Again, PBRNs are more likely to do that kind of work. Second, does it measure patient-oriented outcomes? That is the hard part and is maybe why we do not see as many POEMs as we would like. It is a lot harder to measure those kinds of important patient-oriented outcomes like morbidity and mortality and quality of life than it is to measure blood pressure and Hgb A1C. We need those large, long-term studies to try and answer these questions and our practices are the place to do them.

**Dr. Lee Green:** I have been sitting here thinking about what studies I have seen out of the PBRNs that have made a real impact on things either in practice or in policy outside of the small circle of PBRNs or family medicine researchers. The example that springs most readily to mind for me is

Dr. Mike Klinkman's study of chest pain in MiRNet. That study had considerable impact and changed the course of the AHCPR's unstable angina guidelines. It also affected the thinking of the ACC and the AHA and their work with MI and unstable angina and so forth. The study had a widespread impact outside of our discipline. And I try to think about the features of studies that people presented here that follow that sort of pattern and that allow that kind of impact. What springs to mind is a little bit more of an elaboration of the notion that we ought to be going after the questions that are important and costly.

I do not want to discount the idea that we should be doing the things that the physicians in office are fired-up about. But if we really want to get outside of doing research that just talks to ourselves, I think we need to go toward the important and costly questions, and a little beyond that. What I think we can do that will really make a difference, that will attract enough attention outside our own discipline to maybe attract some funding, and to put PBRNs more on the radar screen in the outside world, is to study problems that are not only important and costly, but that focus on things where primary care is different. We should focus on ideas that are current and prevalent in the research literature, in the huge multi-center trials, etc. We should focus on really good ideas that probably ought to work, but are not practical in primary care. And this, I believe, we have seen in one of the studies where the system for the study just was not the same as the system in the office.

I think we can pick on an awful lot of things that are proven effective, if you will, in large prospective multi-center trials (where the doctors spend 30 minutes with each patient and they have a specialized study nurse, and that sort of thing) but that clearly will not translate into 15 minutes with the patient who has three problems to address. That's the kind of application research that a PBRN can do that will make a difference. Or, focusing on good ideas — maybe even

practical ideas — but ideas that miss the problem.

One of the things that we can do in primary care research is to demonstrate that the question was framed incorrectly. The answer may be wonderful, but the question is not framed correctly and that is one of the things that I am looking at with asthma. A number of the questions have been framed incorrectly in the treatment of asthma.

I think if we want to go after it — if we want to get outside of ourselves and talk to the wider world — we've got to take on those sorts of questions where things are important and costly, but what's out there doesn't fit. We need to hammer on the point that it doesn't fit. Because the research networks are the laboratory. I will say that again and emphasize "the laboratory" in health care where that fit can be assessed and where effectiveness — as opposed to efficacy — research can really be done. I believe that is our selling point.

**Dr. Jim Mold:** I agree. I think we need to remember the purpose of research — at least in my mind — is to influence practice. If we do not have an impact on practice, or at least on primary care researchers, I do not think that other purposes of research (such as tenure, promotion and self aggrandizement) are in the running as a main reason to do it. Dissemination is the biggest problem affecting practice-based research, not the research itself.

While I do agree with Dr. (Lee) Green, there are ways of influencing practice through policy decisions that are made in regulations and that sort of thing. I think the main way to influence practice has to do with dissemination. The most effective way to disseminate information is through opinion leaders. I think we have a unique opportunity in PBRNs to influence opinion leaders. I recognize this does not even involve publishing in *JAMA*. It is a matter of including opinion leaders in the formulation of questions, in collecting the data, and analyzing the data and using it. I think we should

not lose sight of the tremendous opportunity we have, which is a different sort of a paradigm from the way we usually look at research, and incorporate the most important aspect into our research, which is changing practice behavior.

**Dr. Paul Nutting:** I am fascinated by this discussion. I have the privilege of sitting in a spot that lets me watch a couple of things. One is the collaboration of the networks and their combined power, not only as a research engine, but also as a potential strategy for dissemination.

I think when we have 10 percent of all practicing family physicians in one or more of these networks, that is significant. I think it is very clear that publishing is going to be different in 10 years than it is now. I do not think we know quite what it is going to look like, but as Dr. Ornstein said, it is not going to be just hard copy journals piling up in your To Do Box.

I can imagine that in time, family practice will become truly a learning discipline because of where we are and the opportunities that we have with the questions that are asked and answered in our networks, diffused back through that 10 percent that may or may not be the opinion leaders. And perhaps coupled with electronic and other ways of disseminating information so that you have information in your palm at the time you need it, when you are seeing patients. And linked to programs (e.g., the AAFP Annual Clinical Focus) where we engage the process by which we continue as a discipline to learn over and over again.

**Unidentified:** One thing that I have been impressed with this morning is the great diversity in the huge numbers of studies that are being conducted. Most of these studies are not the kinds that many of us would like to do, for example, the best evidence studies. If you had money, you might want to do one study at a time. Take a very important question that will affect the whole health care system — not just family doctors — and see

if you can really answer that question. I think that people would pay attention to it. I think the danger from some of these networks is that they are doing so many studies that they do not have the time to do the big studies.

**Dr. Beasley:** There is an additional dilemma that I think we get into with family medicine research. Some topics like diabetes are relatively easy to define — for example, in terms of micro-albuminuria or retinopathy — if you are going to be asked if yes it works or no it does not. But if you ask how did you feel, how did you do with your diabetes and how did you function, then it may be that some people are going to function much better with one type of care and others much better with other types of care. Some people may do better with loose control, other people may do better with tight control. If you look at their global functioning and beyond the biological markers, I think your end-points get pretty fuzzy. This is dealing with individuals rather than just biochemical parameters. I really do not know how to deal with that.

**Dr. Michael Fleming:** A question for Drs. Beasley and Hickner. Assume that you get some money to support your network, for example, \$500,000 a year for 10 years. What would you do differently with your network? What would you do with the money?

**Dr. Hickner:** I would have to think a bit, but things that come to mind quickly are including skilled methodologists in our research teams, and being able to pay skilled methodologists some money for their expertise. And giving some money to the practices. It is becoming increasingly difficult, as Dr. Nutting pointed out, because doctors no longer run their own practices. We need to go to the practices with some money, although not necessarily a lot.

I would also use some of the money to train a small number of the doctors in research methods. These doctors are the ones

who can ask the research questions. I would do mini fellowships — like the AAFP is doing for my folks — in order to get these doctors up to speed so that they could better participate in and contribute to the network. Those are a few ideas.

**Dr. Beasley:** A fair chunk of it would go to building enough infrastructure at the practice level so that when a good study came from, say an academic center, we can say yes we can deliver and then really do. I mean having a very rapid turnaround where we would have people online in the practices, on retainers, and be able to offer enough additional funding to really bring the practices in. I agree with what Dr. Hickner said about bringing in the expert methodologists. I would love to have people whom we are paying give us some thought about what else could we do epidemiologically, and what else could we do, in a whole series of research arenas where we really do not have the moxie at our level, nor the energy to do it.

**Dr. Bernard Ewigman:** I would like to respond to the question about what would one do if he or she received \$500,000 for 10 years. There is a model for this. For six years I was on the data safety monitoring committee of the National Institute for Child and Human Development Maternal Fetal Medicine Network. I believe we need to acknowledge that we have not invented practice-based research, although it is not the kind of practice we think about. For pediatric oncologists, 75 percent of their patients are enrolled in protocols. Five percent of all patients of adult oncologists are enrolled in protocols. The Maternal Fetal Medicine Network, I believe, provides an accountable and scientifically valid way of doing what the basic lab researchers have been doing for many years. Simply put, they have a lab, the support staff, the infrastructure, the training programs and the investigators.

The model is that every five years they open up a competition for their research centers, and in this case it is for maternal

fetal medicine specialists. It could equally be family practice researchers in our model. Our laboratory is our outpatient practices, for the most part, and their laboratory is high-risk inpatient obstetrical services. The successful centers (and generally there are 10, 12 or 15) get core support for the PIs and other items you need to run an operation. Protocols then bubble up from participants in the network, just as we have been talking about this morning. The difference is that they do not do it simply because it is a good idea, or someone feels good about it. They go through a systematic peer review process both internally and externally. I was on one of the external bodies that evaluated the scientific merit and the protection of patient safety.

Those studies that survive the peer review process are the ones that get funded by this network. They are then paid on a capitated basis on the number of patients enrolled. So it provides a mechanism, first, for generating the ideas and, second, for providing peer review. I think peer review is an essential process that we need to encourage and adopt. The model also provides infrastructure support without saying, “Look, you are the practice-based network so we are going to keep dumping money into you, and you are going to buy experts to try and do this.” Rather, the model makes you keep competing for this infrastructure support. Some of these centers have been successful for two or three rounds, and have been doing their research for 15 years. But others that do not perform get dropped out. It is a healthy and vigorous process by which you can support success and innovation that is sound, but also weed out nonproductive organizations.

One of the things I would like to encourage us to think about in this conference is that a million dollars a year is really not very much. There are single studies that cost that much to do. We need funding. I have great admiration for groups like the Dartmouth COOP, and others who are in this room, who have made this happen just on the basis

of sheer willpower. On the other hand, if we expect to lead in this country, we are not going to do it using the sheer willpower of a few extraordinary people. We are going to do it the same way that other research communities have done it. Take the National Cancer Institute, for example. Their budget is a billion dollars a year. Most of the funding in this country for cancer research comes from the NIH and the pharmaceutical industry. We need to tap into that, and I believe we can do it. I believe we have a lot to offer.

I would like to make one more point. I often hear people say that we do not have a disease that we can sort of tout out to Congress or whomever. I believe you have to think about how long it has taken the cancer community to convince the public that they ought to study things that the public has never seen. Most of the research that is actually done is much more difficult to communicate than what we do. I suggest that we simply have not made the effort to tell our stories in a way that is convincing, and I am not convinced that it is any more difficult. I think the people who have been advocating for cancer and other kinds of diseases have simply tried harder. I believe we need to start doing that.

**Dr. Lee Green:** The comments that you made Dr. Ewigman about peer review have really kind of resonated because that is one of the things that we have explicitly designed into the consortium that we are doing. I suspect that you probably have, as well, when projects came before your center as a suggestion that there is an organized peer review mechanism. That has not been present, I think, from the sort of concept, paper and development stages, in general, in the research that we have done. I want to encourage folks in the network practices to consider using the centers as a mechanism to accomplish that. I think that is one way of getting the quality of product we are sending out for funding improved, and not only directly improving our funding success, but improving the lens through which our sub-

missions are viewed.

More generally, the issue of what the PBRNs can contribute is something that I am having a tough time pulling a focus out of all of the research and ideas that were presented. I think what might help me get a better handle on what our focus is would be to define what it is that we do not do. So far I have not heard anyone say anything about what kinds of projects might come to a network, what kinds of ideas might come up from the ranks of a network, or from the outside that we would say, "No, that is really not what we are about." And I do not just mean badly designed projects or badly conceived ones, but rather projects that we would say is not what we are about. I think the perception of the research networks would be easier to pick up on for folks outside of our community if it were better focused. I would like to challenge the panel to tell more pre-operationally what it is that the PBRNs need to do to get that focus. What is it that the PBRNs are not?

**Dr. Hickner:** Well I can tell you from the opinions of the doctors in our network, because at the end of each of our conferences we rate the studies on the plate in terms of interest. The studies that tend to emerge are those that are of common problems, not surprisingly. We have not had any particular interest in studying any rare diseases. They have all been outpatient problems. We have not had any studies that have involved enrolling patients who are hospitalized, for example. They have tended to focus on prevention too. So common problems and prevention, not esoteric diseases nor hospital-associated illnesses. Those are the things that have percolated to the top in our network.

**Dr. Beasley:** Again it depends on which level you are talking about. If it is an external project, the criteria might be very different from, say, if we are simply supporting one member who has some little pet project he or she wants to do. Externally, we have not



done much in the way of pharmaceutical stuff; not so much by design, but partly we were so badly tarnished by a NHLBI study (well, not tarnished by it, but we didn't deliver). We have had ones where the event trapping problems we were looking at were simply too rare, say DVT, to do any kind of reliable event trapping when it occurs. We would not do something that was strictly for money, or contractual stuff where we did not jointly own the data. We are now talking to one pharmaceutical firm about a study where we will jointly own the data with them and we can publish even if it shows a product is of no good for the proposed indication. Beyond that, again, it would be other things where it simply does not meet member interest, and I have trouble being real specific. We sort of look at anything, but it would be our research committee of the Academy that would decide.

**Dr. Paul Frame:** I have a very specific question for Dr. Beasley. You mentioned a project you are working on in which you felt that you lacked the expertise, so you went to ASPN and they helped you considerably, I presume, in writing the grant. Could you take a few minutes to be a whole lot more specific on exactly what the blocks were and exactly how they helped you.

**Dr. Beasley:** Actually, the better person to talk to about that is Dr. Hahn who is functioning as the PI on that study.

**Dr. David Hahn:** I met Dr. Nutting a few years ago at one of the WReN meetings. Now before that I was at a NAPCRG meeting during which I had this bizarre hallucination that asthma might be an infectious disease. I think it was not taken very seriously by anyone at that point. However, over the years there has been a lot of developing information suggesting that, in fact, this may be another *Helicobacter pylori* story.

In 1991, I did a practice-based microbiologic study of chlamydia pneumonia in a network of physicians in my own group

practice. (This was not like the networks that we have been talking about.) I stumbled on an association of chlamydia-asthma, which you are probably a little familiar with. Well, this led directly to a multinational randomized trial of macrolide, which is going to be unblinded in December 1998. I do not know the results, but the original screening criteria to get into the study were some fairly high levels of antibodies that suggests potential chronic infection. About 60 percent of the population screened in Australia, New Zealand and Argentina met that criteria. We do not know whether the treatment is going to work.

I want to again work on that basis and design a randomized trial in this country. I have basically designed the scientific part of it, for example the methodology and protocols. I realized I had naively thought that the protocol was the most important part of the enterprise for getting funding. Well, it is not. The budget justification and the very complex interrelationships of project management are actually going to be a bigger part of our proposal, in terms of inches of text, than the science itself.

We had absolutely no experience in writing grants. So, we went to Dr. Nutting for two reasons, not just so they could help us write the grant, but because part of this protocol — I think and am not certain — should be done in a primary care network. And that is how it is being designed— to look at the differences of asthma characteristics in three different community-based settings where asthma is being cared for: allergy, pulmonology and family practice. So it seems like a good fit. Dr. Nutting has been very helpful in working with us. ASPN has the fire power, the right grants, and has done this enough times that it helped us tremendously. I do not think, in retrospect, we could have done it. It might have taken us two or three years to stumble and fall, but ASPN did it for us in two weeks.

The answer, briefly, is that substantial amounts of the mechanics of writing a research grant must be well thought out, and

that very substantial amounts of expertise must be documented to prove that you have to do this study in this particular way and not other ways. I believe WReN has historically relied on that.

**Dr. Beasley:** Regarding the funding issue, one of the things I believe has happened in Britain is that about four years ago there was a report before the House of Commons that resulted in them reallocating some portion — not a very large portion — of a huge pot of money of the National House Service Budget to primary care research. It was a major initiative under the report that looked both at supporting individual physicians in their practices, and developing research consortia and networks. I believe the first three-year cycle is coming to an end. So, how it is going to play out? I am not sure. What was really needed is that they started realizing they were spending a whole bunch of money in this arena, they did not have the foggiest notion of what was going on, and they wanted to see what could develop if they gave it some capital funding in order to get them to a point where they could be competitive. Others here may know more about where that initiative stands now, as I am not sure.

**Dr. Larry Culpepper:** I would like the panel to answer the following question: What are the critical methods questions facing you in doing practice-based network research?

**Dr. Hickner:** I still think the biggest methods problems for me is first having access to the expertise so that we get the study designs done properly. Second, having sufficient financial support in order to get the studies done in the practices, recognizing that there is some cost that has to be borne that we have not really touched on.

**Dr. Beasley:** I would add to that, to a small extent, the issue of enough ongoing support for some sort of core infrastructure that can write the grants and develop liaisons, and people and expertise. I would slightly qualify

what you had on the experts and say that you really need expertise that knows and understands the family medicine and primary care environments. For example, you have statisticians who just get pale and sweaty when you talk about the realities of practice.

The second issue is also what Dr. Hickner said about being able to give enough support to the practices so that we really can do a good job of recruitment and not wind up with too much selection bias nor get only the true believers involved. When we come to them with a project, they should be able to say, “Yes, that actually helps.” Or when we go to the managed care organizations and say we want 40 of your doctors to participate, they reply, “When would you like them to start?” rather than, “You got to be kidding.”

**Dr. Iverson:** I would say the biggest challenge is to try the two or three network research models that allow for a great deal of interaction between the practitioners (nurses, doctors, assistants, etc.) and the research communities, and are sustainable over a long period of time. I think that the models that are going to work and are going to be sustainable because of costs will not be U.S. models. The cost of research in this country is obscene. For example, a billion dollars for women’s health is crazy.

**Dr. Ornstein:** I do not have anything to add to what the others have said.

**Dr. Beasley:** Something came to mind, which has been a dream of ASPN and to some extent of WReN, that has never quite come to fruition is developing some means (or more organization than scientific methodology) for defining and translating important practice questions into fundable research projects. We have at times gone to members and said, “What would you like to study?” And I would say, “I want to study patient compliance, or I want to study obstetrics.” How does that translate into

something that becomes a fundable project and a definable question? There is a gap.

**Dr. Larry Green:** I am observing a couple of things. First, what a wonderful set of problems to have. We need to make sure that we stay oriented here about where we are in time. We have gone through an entire century of neglect of primary care with the misunderstanding that because it was so simple, anyone could do it, and it really does not matter very much. We have arrived at a time where we recognize that we need to talk about the intersection of two of the most complex human enterprises known. One is primary care and the other is research. There is not going to be a tidy, simple intersection here. What the conversation has revealed,

over the last couple of hours, is there is going to have to be a buffet of methods and approaches that are to be required to understand primary care and improve it.

The task that the AAFP and others face in deciding what to do with this, in my view, is not to come up with the right answer. The task is to continue to formulate the right questions for where we currently are. We must not let ourselves become confused, distracted or discouraged by not knowing the answer to all of these questions. The questions are so much better now than they were 10 years ago. Ten years ago they were better than they were 20 years before that. This is progress. You can see the progress, you can hear it in the quality of the discourse. I just wanted to express appreciation for that.



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# Section 3

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## **What are the organizational issues faced by PBRNs? Who are the customers and what are their needs?**

The Internal Environment: Crucial Functions in Conducting Network Research, LARRY CULPEPPER, M.D., M.P.H.

The Structure, Function, and Use of PBRNs: Three Perspectives  
Principle Investigator, MICHAEL FLEMING, M.D., M.P.H.  
Executive Director, MARY CROUGHAN-MINIHADE, PH.D.  
Practitioner, DAVID L. HAHN, M.D., M.S.

Panel and Full Group Discussion/Question and Answer

The External Environment: Funding, Policy, Relationships and Communication Results, PAUL NUTTING, M.D., M.S.P.H.

The View from “The Outside”  
Government, CAROLYN M. CLANCY, M.D.  
Industry, HUGH H. TILSON, M.D.  
Managed Care Organization, GEORGE ISHAM, M.D.

Panel and Full Group Discussion/Question and Answer

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# The Internal Environment: Critical Functions in Conducting Network Research

LARRY CULPEPPER, M.D., M.P.H.  
*Department of Family Medicine, Boston  
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**I** will create the context for our discussion of the internal operation of networks and network management. The network directors present will have much to contribute. Let me paint the broad brush strokes, and then have our panel fill in the details.

## **Key functions**

Key functions include network infrastructure maintenance (particularly project development including sustaining relationships with principal investigators, academic collaborators and funders; recruitment and retention of participating physicians; staff management and governance groups) and research project specific activities such as piloting methods and study materials, human subjects review, data management and quality control. As we discuss the research project specific functions, I approach them from the perspective of both their impact on the validity of study results and on the efficiency of the research process.

## **Key components of research networks**

Practitioners, principle investigators (PIs), network staff, and network governance (leadership) are key components. We need each of these components to make networks operate. What makes networks successful is the enthusiastic collaboration of practitioners, experienced PIs, and competent and responsive leadership and support staff. Like with some functional diseases, we can have all of the components and still not have success if they do not work well together.

## **Critical characteristics of successful**

**PIs.** One is being experienced with all aspects of the research cycle from initial idea development to final publication, including obtaining funding. At the same time, a PI must understand the realities of practice and be able to include this perspective in all aspects of research projects from data collection, to analysis through publication. The ability and willingness to negotiate the final conceptualization of research questions, the analysis of data, and the interpretation of the results with the participating practicing physicians, are also critical characteristics.

Another critical characteristic is the ability of the PI to actually work with the different participants in the research projects. This is easy to say, but I think there is another level of meaning in this, and that is really

believing, understanding and valuing the interaction he or she has with everyone involved in a research project.

It takes a long time for network research to go through piloting and development to funding. Successful accomplishment of a project will frequently take a lot longer in a network environment than other research environments. So the ability to hang in there with a project through completion is critical. It is not uncommon for a network project to take five to seven years from conceptualization through completion, and this requires someone with stability in career direction. Given that, it usually requires someone who is well on their way to senior faculty status; if a junior faculty is depending on network project publications for promotion, this might become a source of tension.

### **Voluntary practitioners**

This information is readily apparent but needs to be stated. The objectives of research networks include helping participating physicians maintain excitement about their practices, as well as involving them in developing the research questions, getting the study questions right and ensuring that the answers will be relevant to their practices. This requires attention to developing and maintaining the volunteer physician group.

As I have helped develop networks internationally, I found that endorsement of a professional society is very helpful in getting a network off the ground. WReN emulates this experience in terms of the value of chapter endorsement. Our experience, validated by discussions with other network leaders, is that 25 to 30 percent of physicians who start a network, or jump into an existing network, drop out. They never really follow through with participating in network studies. They find it is not feasible or does not match their interest and time expectations. The ability to maintain and/or replace physicians over time then becomes a critical network function.

The following approaches are helpful in maintaining voluntary practitioners in a network: having the participants share a sense of ownership; communicating frequently; having periodic face-to-face meetings; involving the participants in choosing and piloting projects; acknowledging the critical role of practice staff; and involving key practice staff members in annual meetings. Participating practices' staff have a major role not only for individual studies, but also in the ongoing life of a network and its research activities, and must be nurtured and included in network discussions.

The better the experience the initial physicians have with a new network, the less

### **Practical issues in conducting a study**

- Physicians are willing to put in the time it takes to collect information, but lose patience very quickly if unnecessary information is being obtained, or the study question may not be answered.
- Keep data to be collected to a minimum, and data elements should be universally obtainable by participating physicians.
- The amount of time physicians must devote to the project is often best thought of in time per patient enrolled.
- A reasonable limit is two minutes of physician time per patient from whom data is to be collected.
- If possible, tasks should be delegated to office staff.
- It is fatal to limit the data so severely that the study question cannot be answered appropriately.

important dropout becomes. The experience of the initial physicians establishes the network's reputation.

Physicians must feel that studies are answering important questions in a way that is applicable to their practices. Ongoing communication during study development and data analysis intervals, with recognition in publications, is crucial in terms of the long-term maintenance of a network. Obviously, resources required for participation (including physician and staff time) cannot be too onerous. Supporting a

network's practicing physician leadership to attend larger national research meetings, such as NAPCRG, is helpful to maintaining a network.

#### **Network grant development**

There are several network administrative tasks requiring funding. Project grant development is one for which major up-front investment is required. Generally seeking network funding requires an experienced PI to be successful, and there is an investment-yield trade-off regarding the investment of

**TABLE 1. Network grant development financial model**

<i>Model</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
Average annual budget	\$500,000	\$500,000	\$300,000	\$300,000
Indirect rate	50%	50%	50%	50%
Annual total indirect	\$250,000	\$250,000	\$150,000	\$150,000
Indirect retention at network	60%	30%	60%	30%
Annual network indirect	\$150,000	\$75,000	\$90,000	\$45,000
Success rate	25%	25%	25%	25%
Project duration (years)	4	4	4	4
Annual network indirect yield per annual grant development start	\$150,000	\$75,000	\$90,000	\$45,000
Annual grant development starts for \$100,000 base	0.67	1.3	1.1	2.2
Resubmissions per year	0.67	1.3	1.1	2.2
Annual grant development cost @ \$50,000 per initial and \$30,000 per resubmission	\$53,333	\$106,667	\$88,889	\$177,778
Project starts per year	0.17	0.33	0.28	0.56
Grant starts for \$450,000 base	3.0	6.0	5.0	10.0
Resubmissions per year	3.0	6.0	5.0	10.0
Annual grant development cost	\$240,000	\$480,000	\$400,000	\$800,000
Project starts per year	0.75	1.5	1.25	2.5



time and resources to write grants. This relates to access to and allocation of “indirect” grant revenue.

I have constructed a spreadsheet model to demonstrate the issues involved (see *Table 1*). The assumptions built into this are:

- Indirect rate of 50 percent.
- Retention of indirect funds by network: retention rates of 30 and 60 percent are both modeled. Federal and many foundation grants have a fixed percentage (the indirect rate) of the total amount of funding required to do the study (the “direct” funds”) added

for administrative infrastructure costs. The indirect rate is determined using specific accounting criteria. For major subcontracts, the grant recipient organization does not itself receive the indirect. Therefore, the percent of the total indirect that the network retains — as opposed to being distributed as required by subcontract terms — will depend on the work done by the network directly or subcontracted to other organizations. Thus, if the PI is at another organization, or if data management or laboratory work is done at another organization, it is

**TABLE 1. (Continued)**

<i>Model</i>	5	6	7	8
Average annual budget	\$500,000	\$500,000	\$300,000	\$300,000
Indirect rate	50%	50%	50%	50%
Annual total indirect	\$250,000	\$250,000	\$150,000	\$150,000
Indirect retention at network	60%	30%	60%	30%
Annual network indirect	\$150,000	\$75,000	\$90,000	\$45,000
Success rate	15%	15%	15%	15%
Project duration (years)	3	3	3	3
Annual network indirect yield per annual grant development start	\$67,500	\$33,750	\$40,500	\$20,250
Annual grant development starts for \$100,000 base	1.5	3.0	2.5	4.9
Resubmissions per year	1.5	3.0	2.5	4.9
Annual grant development cost @ \$50,000 per initial and \$30,000 per resubmission	\$118,519	\$237,037	\$197,531	\$395,062
Project starts per year	0.37	0.74	0.62	1.23
Grant starts for \$450,000 base	6.7	13.3	11.1	22.2
Resubmissions per year	6.7	13.3	11.1	22.2
Annual grant development cost	\$533,333	\$1,066,667	\$888,889	\$1,777,778
Project starts per year	1.67	3.33	2.78	5.56

not unreasonable to assume that the network will retain between 30 percent and 60 percent of indirect funds. A 30 percent retention reflects a project that has been developed externally with the network participating primarily in data collection. A 60 percent retention of indirects would occur when the network is taking a much greater role in actually developing and writing a proposal, and conducting most project activities.

- Success rate of 25 percent and 15 percent in getting grants funded. Of every new start (as opposed to a resubmission of a revised grant), one in four (25 percent), or one in six (15 percent) get funded. Again, this is not out of step with national experiences.

- One resubmission per funded

application. I'm assuming that we resubmit an average of one time per application before funding is obtained, and after that second resubmission we either get funded, or, give up.

- Project duration: three and four years. I have modeled two different project durations.

- Grant development cost: \$50,000 initial and \$30,000 resubmission. These costs are estimates based on discussions with various PIs and their estimates of the time required to develop a grant that has a chance of success.

Model 1 assumes a network targets a grant that is \$500,000 each year for four years, or a \$2 million total direct application. With an indirect rate of 50 percent, that

**TABLE 2. Influence of network characteristics on validity and efficiency**

Key functions	Efficiency	Validity	National Network	Regional Network	Local Network
Practice & physician selection	++	+	High diversity	Diversity available	Relatively homogeneous
IRB functions	++		Complex	Moderate	Simple
Physician/office staff training	++++	++++	\$\$\$\$	\$\$	\$
Physician/staff TLC and maintenance	+++	++++	Weak	Moderate	Strong
Subject enrollment monitoring	+	++++	Difficult	Moderate ability	Moderate to strong ability
Timely subject follow-up	++	+++	Difficult	Moderate ability	Strong ability
Forms development & distribution	++	+	Difficult	Easy	Easy
Data collection & quality control	++++	+++	\$\$\$ Difficult	\$\$ Moderate	\$ Easy
Data management	++	++	Difficult	Moderate	Easy
Data analysis and interpretation	+	++	Physician input requires major effort	Moderate effort	Easy

+ Low efficiency or validity; ++++ High efficiency or validity. \$ Low cost; \$\$\$\$ High cost.

gives us a \$250,000 a year indirect yield. If we calculate that the network retains 60 percent of its indirects, the network retains \$150,000 a year. Now, assuming a success rate of 25 percent, we will get one project in four funded. If a network develops one new grant submission (grant start) a year, and gets one funded every four years, this will yield indirects of \$150,000 a year on average. The table displays how many grants a network would need to develop each year to maintain a \$100,000 and a \$450,000 annual indirect base. Also displayed in the table is the number of new projects that a network actually would be fielding each year.

A network writing \$2 million (\$500,000 four times a year) in applications needs to get one funded every four years to maintain \$100,000 in average annual indirect base. That is very optimistic. I created some other scenarios in the table. For instance, Model 4 displays a \$300,000 application developed by a PI friend of the network, whose own institution expects 70 percent of the indirects (network receives 30 percent); then the network gets only \$45,000 a year in indirects from the project. In this model, to maintain a \$100,000 infrastructure on indirects, the network needs to collaborate on 2.2 new grant starts a year. This begins to be a fairly major grant writing demand to maintain a \$100,000 base.

In Model 7 the network undertakes an average size research project, \$300,000 for three years, retaining 60 percent of indirects (with the network likely to be primarily responsible for having put in the development work to write it); to maintain a \$100,000 base, the network will need to start 2.5 such new grants a year at the 60 percent indirect retention rate, or (Model 8) collaborate on five grants a year (new ideas, new grants) at the 30 percent retention rate to keep a \$100,000 base. To keep a \$450,000 base, the network would need to write 22 new grants every year.

These figures are sobering regarding the challenge of maintaining a network's infrastructure solely on the basis of grant

indirects. It will be very difficult for networks to maintain substantial internal indirect-based funding. Therefore, networks require a subsidy from somewhere. We either have to provide support from academia, from industry, from federal or state sources, from practitioners, or from somewhere else. This requires significant negotiation of scientific control and assurance of deliverables.

Once a network gets into multiple projects, all of its other administrative functions become enormously more complex and it also leads to the need for large numbers of physician participants.

### **Network maintenance**

Let me briefly introduce the concept of network maintenance, or network care. I looked at three straw-man networks: first, a national network that requires airfare to get people together and has a high overhead related to meeting time; second, a regional network; and third, a local network (see *Table 2*).

In terms of practicing physician selection, the national network certainly has the most diverse pool to draw from. The local

### **Key functions of network maintenance**

- Network development
  - Physician/practice recruitment
  - Training and maintenance
- Communications
- Project development and selection
- Research networking
- Funding development
  - Infrastructure support
  - Project specific
- Administrative
  - Personnel
  - Finance
  - Information systems
  - Facilities

network may be very homogenous in terms of its exposure to consultants and opinion-leaders regarding practice behaviors and so forth. Institutional Review Board (IRB) functions are another key network issue. Practices that have been bought now have to go through the employer of the physician to obtain IRB clearance. In a national network — which must deal with the idiosyncrasies of multiple institutions and multiple organizations — this can be quite complex. Regional network PIs can at least drive and meet with the IRB committees. Local networks generally have one committee.

Office staff training, which is a key factor in terms of efficiency and validity of projects, and staff maintenance for national networks are very expensive if face-to-face contact is required. If the network can develop other methods of physician-office staff training, then costs go down. Obviously there is a similar scale of costs in terms of the tender loving care it takes to maintain

high compliance with study procedure after you have enrolled the 20th patient and are trying to get to the 25th patient in your practice. This is a key factor. For local and some regional networks, in which the network staff and PI are seeing the physicians every week because they are in the same local environment, it is much easier to maintain enthusiasm than when working at the national network level.

Three points become obvious: First, we need to match projects to the smallest networks that can do them well. Second, we should develop the internal functions of all networks to create efficiencies and improve validity in our national and regional environments. Third, even when large projects require numerous practices or geographic diversity, getting several regional networks to collaborate might be more efficient than using a large national network. This is a challenge for the future.

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# The Structure, Function and Use of PBRNs: The View From the Principle Investigator

MICHAEL FLEMING, M.D., M.P.H.  
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I was asked to respond to the question why anyone would want to be a principle investigator (PI). Let me begin by saying I had no research training prior to my first faculty position at the University of North Carolina in Chapel Hill. This was in 1981. In 1986 I moved to the University of Wisconsin where I was able to secure a research position with 50 percent protected time. I think this is the minimum effort required to develop a research career.

I have had 18 extramural grants over the last 12 years. These included seven NIH grants — four R01s, one R25, one R21 and one training grant. As a result of these successful grant applications I have become an insider. One of my major points in this talk is that the specialty of family medicine needs to get family physicians inside the NIH research community as respected scientists.

I was promoted to associate professor with tenure in 1991 and to full professor in 1998. I am the first family physician at the University of Wisconsin to be promoted to professor for research. I also became director of the University of Wisconsin

Center for Addiction Research and Education (CARE) in 1994. We have 40 scientists educators and clinicians who are members of the center. As a family physician, it is exciting to link basic scientists and health services researchers together in order to develop better clinical tools.

I would like to talk about three different ways I have done research. One is in my practice when I practiced in a small town. The second is in residency programs. The third is through practice-based networks.

## **Small town practice research**

The first study I did was in 1978 when I was in practice in Hancock, Mich. I was interested in looking at the side effects of reserpine. The practice I inherited from a retiring general practitioner had nearly 100 patients with hypertension on reserpine.

In residency I was taught not to use this medication due to increased rates of depression and sexual problems, so I switched most of these patients to a beta blocker or methyldopa. Within a couple of months many of these patients became depressed and impotent. That was the opposite of what I had been taught about reserpine and beta blockers. What was going on here? So I did a study of the 100 or so hypertensive patients in my practice and found similar rates of depression and impotence with beta blockers,

methyldopa and reserpine.

I learned a great deal from this research and it changed my practice. The research study was a lot of fun and it was easy. My nurse and I thought about the project and said let's do it. So we did. That is all it took. We interviewed patients and had them fill out questionnaires for about a year. We did the study with no IRB or any other committees.

What are the negative aspects to such an approach? First there is obvious selection and measurement bias. The research is not generalizable. I paid for the study out of my patient care revenues. I was in a solo fee-for-service practice at the time. It was hard to get the study published. However I learned a great deal and I became very interested in research.

#### **Residency program research**

I have done a fair amount of research in teaching clinics both in Chapel Hill and Madison. I conducted a number of studies that examined the psychometric properties of alcohol screening tests. This area of work led to a number of collaborative projects with other researchers on the University of Wisconsin campus.

The research was inexpensive but had limited generalizability. Residency teaching clinics are difficult settings in which to conduct research. The clerical and nursing staff are often very resistant, patients are often low income with limited resources and the resident and faculty are part-time and not in the clinic on a daily basis.

#### **Community based research settings**

I have conducted two large trials in community practices. These studies focused on physician treatment of problem drinkers. These trials were NIH funded and very expensive. The cost for both trials exceeded \$2 million. There are a number of advantages about working in community practices. The results are more generalizable. One can conduct research that meets the criteria for a POEM (Patient-Oriented Evidence that

Matters). Such studies can answer the big questions. One is able to attract large federal funding for these studies. Practice networks allows one access to large patient populations. The populations are stable and follow-up rates for treatment trials are often very high. We can answer questions that can only be answered in these settings.

#### **Drawbacks and challenges**

Some of the drawbacks in working in these settings include problems with quality control. There is so much going on in these practices that it is difficult to know if the research procedures are being followed and whether the nurses and physicians are doing what they are supposed to be doing. Claims data is another issue when one is working in a fee-for-service practice or one that has multiple HMO contracts. Multiple insurance companies complicate cost benefit research.

#### **Answers to questions on the agenda**

First, I think it is important for family physicians to get inside the NIH at many levels. We need to get FPs invited to scientific review seminars. The institutes will often convene 10 or 20 scientists in order to review the current state of the art. RFPs are frequently developed from these reviews.

Second, we need to identify the agenda of the leaders of the various institutes. I have gotten to know all the major leaders in the alcohol institute (NIAAA) and their various interests and areas of expertise. I have been able to link up my ideas with those of various leaders at the alcohol institute. This increases my chance of funding.

Third, it is important for family medicine researchers to become friends with the leaders of the institute of their choice. Get to know the person in charge of press releases and communication. Send any important articles to the director and the division chiefs so they can promote your work around the NIH. We need to develop these connections with as many institutes as possible.

Fourth, we need to push ourselves to answer those questions of importance to the

U.S. health care system. It is important not to limit our research to questions that are only of interest to family medicine. We can answer the big questions that can improve patient care for all physicians.

Finally, we need to submit grants. It is an old story, if you don't ask you will never know. Unless you send in the grant, you have zero chance of getting funded. There are three NIH cycles per year and more for special RFAs. I am currently writing a grant for October 1. I try to write at least three NIH grants per year. If family medicine sent in 100 grants for every cycle the NIH would begin to pay attention. Every department of family medicine should have at least one family physician faculty member who is capable of writing an NIH grant. Each department should send in at least five NIH grants per year.

#### **Define the scope of research best accomplished by PBRNs**

I think one can use PBRNs to answer questions focused on the prevalence or frequency of a topic, disease or event. Incidence studies are more difficult in these settings as people move around too much or change their health care insurance. Another area of work is the development and testing of research instruments such as measuring quality of life. Efficacy studies can also be conducted in these settings and may provide the best setting for medication and behavioral treatment methods. Effectiveness studies are also best conducted in PBRNs. Academic medical

centers and VA hospitals are often atypical and do not provide representative samples of patients or systems of care.

#### **What can the AAFP do to facilitate the growth of practice-based research?**

Provide money. Provide the intellectual and philosophical support. Let family physicians know it is okay to specialize in an area of work. That it is okay to be an alcohol expert and to also be a family physician. The AAFP should work with deans of medical schools and graduate schools to support FP research salaries and start up packages. One of the new heads of perinatal medicine at UW Madison received a start-up package of \$200,000 for her lab and 60 percent protected time for five years. Family physician should get the same thing. There is no reason why other faculty should receive this kind of support and not us. I believe the academy can play a major role in this.

The academy should link with HMOs, the NIH RWJ, AHCPR and other federal agencies. The next time we have a meeting like this you need to invite members of the NIH. We need senior researchers from the NIH in order for them to understand what we can offer the NIH. I have always been supported by the NIH.

If anything, being a family doctor has been an advantage. Yes, peer review is tough and I often feel beat up — the process improves my research and my contributions to the field.

# The Structure, Function and Use of PBRNs: The View From the Executive Director

MARY CROUGHAN-MINIHADE, PH.D.  
*Director, University of California San Francisco/Stanford Collaborative Research Network, and Associate Professor, Departments of Family and Community Medicine, Epidemiology and Biostatistics, and Obstetrics, Gynecology and Reproductive Sciences*

**F**or those people who don't know me, I will let you know a little more about who I am. I trained in Epidemiology at Johns Hopkins University and was recruited to UCSF to be the Director of the University of California San Francisco (UCSF) Collaborative Research Network in 1987. The network was started in 1984, and it covers the area from San Luis Obispo and the Central Valley of California to the northern California border. In 1997, we merged with the Stanford Research Network to form a contiguous network in northern California.

Given the large geographical area that we cover, we are a regional network. The clinicians, practices, and patients in our network are quite diverse and reflective of the population of California.

## **Organizational issues faced by PBRNs**

**Infrastructure support needs.** The most critical problem faced by most networks is funding for infrastructure support. It is often feasible to receive funding for a specific project. However, it is nearly impossible to secure funding for maintaining a central office, recruiting additional members, holding membership meetings, or for nurturing the research interests of network members.

We have been very successful at UCSF in receiving grants for the establishment of the Department of Family Medicine through the Health Services Resource Administration (HRSA). These grants have provided the minimal infrastructure support necessary for maintaining the central office. Specifically, these grants have partially funded my salary as Network Director, as well as a part-time project assistant. On occasion, these funds have been sufficient to support pilot projects or small-scale research projects.

Through the years, I found it is very easy for people to come up with great research questions to address in a practice setting. However, it is difficult for network members to generate research ideas, communicate those ideas, or follow through with them if there is no funding for the network infrastructure. Once an idea is generated, we often find the funding and sufficient



volunteerism to actually begin the study and collect the data. However, this is followed by insufficient or non-existent support for analyzing the data and writing manuscripts. As a result, the productivity of the network is compromised.

I think there are several functions of the network office that are necessary for a network to remain viable. The office should have sufficient infrastructure support (i.e., money and staff) to conduct at least the following activities:

- Regular meetings of central office staff with network members in their practices
- Regular meetings of network members with each other
- Soliciting research ideas from network members
- Exploratory studies of research ideas generated by network members
- Study design and grant preparation
- Data collection and quality assurance
- Data analysis and manuscript preparation
- Maintenance of a network member database
- Collaborative arrangements with other networks

I have found through the years that making collaborative arrangements with other networks is the single most difficult activity to achieve without infrastructure support, because it is hard to know who else is out there. Many of the network directors felt like we were working on islands, not because of geographic disparity, but because we could not find others who were doing work similar to our own. So we developed the Federation of Practice-Based Research Networks, which you've heard mentioned. The Federation has largely overcome that single barrier for collaboration between the networks, and this has resulted in collaborative grant applications and collegiality.

**The need for nurturing family physicians' research interests.** There are basic things outside of infrastructure support that are needed to maintain a network. Two of these are interrelated problems. One is that

most networks have very low rates of network physician participation in research study conceptualization and planning. This is usually the result of insufficient training in research methodology, even for those physicians interested in research. Few physicians have done research, or had the opportunity to do so, at any point in their medical education (medical school or residency), and a very small number have done fellowships. This lack of training in research methodology results in an inability to even serve as a partner in developing research questions and designing studies.

The second problem is the low participation rate of network physicians in specific research studies. It is critical to have the network physicians actually generating the research ideas if you want them to be interested in participating in a given study. If the impact of research participation is made minimal, the lack of research training does not impair most physicians' abilities to participate in the conduct of studies (i.e., patient recruitment, etc.). However, participation in specific studies appears to be dependent upon "buy-in" to the research question at hand, interest in the general topic, and the effect of competing demands upon physician time. Buy-in and interest in the research question are enhanced significantly when the physician has participated in generating the research ideas and study designs being explored by the network.

To address these problems, I undertook a survey of our network physicians. The number one reason doctors gave for their lack of participation, both in terms of doing research studies and actually conceptualizing research questions, was their lack of research training. That was cited by 68 percent of our network physicians. More than 75 percent of our network physicians had been in research studies, but their participation typically consisted of recruiting patients for pharmaceutical company clinical trials. So it was not that they did not have hands-on experience in enrolling patients, but they had no experience in how to actually ask a research

question, how to develop it, how to design a data collection instrument, how to analyze data, or how to write a manuscript. Now, that probably does not come as any surprise. The part that came as a surprise to me was that 92 percent of the doctors said they were interested in going through a research training session to learn how to do research.

The overall effect of lack of network member input is that network member physicians are not sufficiently invested in the network to make it an optimally effective vehicle for collaborative practice-based research. Networks generally need to consider structural changes to overcome these problems. These structural changes include (1) developing a collaborative network, (2) developing a practice-centered network, and (3) educating the network members in research. A truly collaborative network is one that is structured from the ground up, rather than from the top down. A practice-centered network is one where the staff in the entire practice buy into the study. When one introduces the study and asks for a letter of support signed by every person in the practice, the need to educate network members in research is a pivotal need.

#### **Our efforts at UCSF**

To increase the involvement and the productivity of the practices in the UCSF Collaborative Research Network, we had to develop a new organizational structure. Until 1994, we had an advisory committee that was predominantly community-based physicians who met once a quarter. We had a newsletter that went out to all the network members. And the research questions addressed by the network were those which were suggested by the advisory committee or individual members. Research questions were not specifically solicited from network members.

In order to change the structure for network member input and collaboration, we developed the Collaborative Research Development Program (CRDP) for the network. We obtained infrastructure support by

writing two HRSA grants for the "Establishment of Departments of Family Medicine."

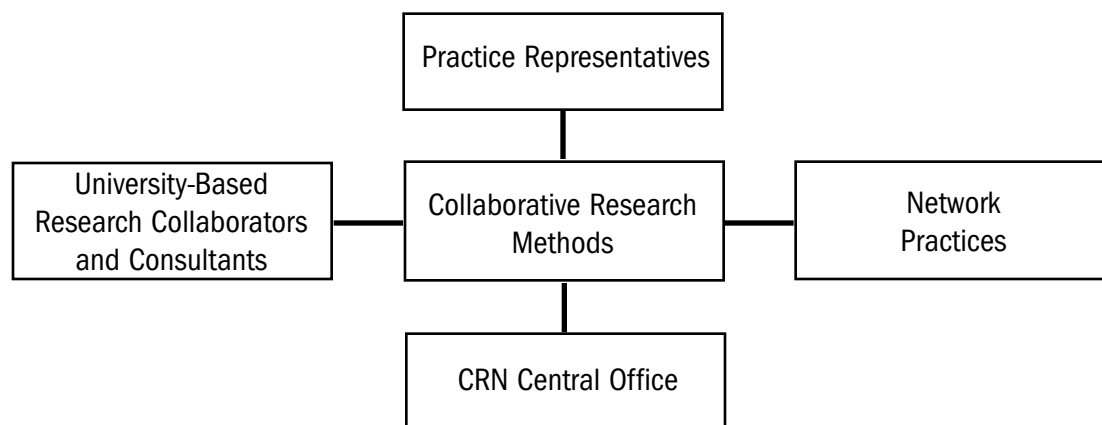
The goal of the first grant was to increase the involvement and productivity of community physicians in the CRN by establishing the new organizational structure, the comprehensive CRDP, and improved infrastructure support. The goal of the second grant was to increase the productivity of the CRN through improved infrastructure support and hiring a project director.

The new organizational structure was based on active community physician involvement. We gathered preliminary data on the strengths and shortcomings of our own network structure through member surveys and discussions. We supplemented this by reviewing organizational structures that had been successful in other networks, as well as general literature on organizational structure and faculty development. The CRN membership approved the new organizational structure proposed in the Department Grant. The network organizational structure contains four elements (see *Figure 1*).

1. Representatives of community-based physicians, called "Practice Representatives," include the community-based physician members of the network who are elected by fellow network members or volunteer to serve as representatives to the CRDP. Each person represents other network members with similar practice characteristics and concerns from a geographically-defined area. These practice representatives assume primary responsibility for developing and overseeing CRN research activities.

2. The network practices are the community practice-based physician members of the network. We have encouraged the participation of all physicians and staff within each practice in order to enhance collaboration and to improve the quality of research.

3. University-based research collaborators and consultants consist of network members and non-members who serve the network through teaching, mentoring, and advising/consulting.



**FIGURE 1. Organization of the Collaborative Research Development Program**

4. The CRN Central Office comprises the network director, two FP associate directors, an FP assistant director, a project director, and a part-time administrative assistant. The CRN Central Office is responsible for all administrative activities necessary for developing, maintaining and nurturing the network.

The strategies for active involvement of community physicians in the generation of research ideas and study designs for the CRN is encompassed in the comprehensive CRDP. The CRDP has the following general objectives:

1. To provide an ongoing mechanism for integrally involving community-based physicians in the organizational development and governance of the CRN.

2. To prepare community-based physicians with both the research and organizational skills to participate as full partners in practice-based research.

3. To produce a minimum of two large-scale funding applications.

The strategies used to accomplish the above objectives have included:

1. Conducting annual one-day network conferences of the total CRN membership, including a reflective practitioner exercise to generate research ideas.

2. Mailing research ideas from the conference to the general membership to determine interest in specific research areas and specific research questions.

3. Obtaining CME credit for all CRN activities.

4. Negotiating release time for residents to attend CRN activities.

5. Negotiating volunteer faculty “teaching credit” for CRN activities.

6. Holding eight sessions for practice representatives. The first four sessions are on basic research methods and the last four sessions are on advanced research methods.

#### **Practice Representative Sessions**

The first session concentrates on generating ideas for research and relies on the principles of “reflecting on practice” developed by Donald Schon (author of “Educating the Reflective Practitioner” [Jossey-Bass Publishers, 1988]). This process encourages clinicians to step back and look at the way they make decisions around individual cases. Participants are expected to keep diaries and bring brief descriptions of cases seen in their practices during the preceeding week. Small group discussions help participants identify common patient-based clinical problems. Practice representatives are given

instructions on using this process to help their practice partners generate research ideas.

The second session concentrates on prioritizing the research ideas generated in the first session. Criteria considered in this prioritization include the relevance to participating practices, generalizability, feasibility, and originality. These questions are presented by the practice representatives to their practice groups. A workshop on MEDLINE searching and critical review of medical literature is presented at this session as well.

The third session begins with the presentation of critical literature reviews by practice representatives of articles sent to them after the second session. Participants are expected to critique the selected articles on these subjects. As a result of the critique process, participants begin to develop a knowledge base of the issues regarding a specific research question as well as the skills necessary for critical appraisal of medical journal literature. Following the literature review, participants work together to map a general research design for addressing the question at hand. The design focuses on developing the null hypothesis and determining which study design is the most advantageous for addressing it. Participants are encouraged to consider various designs (e.g., descriptive, cohort, case-control, clinical trial, qualitative studies) and various design issues (e.g., eligibility and exclusion criteria, data collection methods, sample-size). Practice representatives are expected to discuss these potential projects at practice-based sessions with their practice partners subsequent to this session.

The fourth session concentrates on developing details of the study design for one project. A pilot study plan is prepared. The fifth session focuses on the logistics of conducting a research study. Using the study proposal developed in the fourth session by the practice representatives, the elements necessary for conducting a pilot study are finalized. Such elements include development of actual data collection instruments;

methods for pilot testing data collection instruments; methods for enhancing study subject recruitment, participation and follow-up; and methods for enhancing data quality, confidentiality and data entry. Following this session, practice representatives obtain input from other physicians, office staff, patients, and appropriate consultants on both the study design and data collection instrument(s).

The sixth session concentrates on finalizing the study design and data collection instrument(s). Methods for incorporating practice representatives into the data collection process are determined and finalized. This includes writing letters or making phone calls to CRN members to increase participation rates, having practice representatives administer interviews, and other appropriate activities. Prior to the next session, the instrument is administered and data entered by the CRN administrative assistant.

The seventh session involves collecting data in the pilot study to illustrate data analysis techniques. Practice representatives are provided a brief didactic session on preliminary data analysis as well as appropriate methodologies and assumptions for more sophisticated analyses. Such methodologies include examination of frequencies and distributions, hypotheses tests (chi-squared, t-tests, ANOVA, linear regression and logistic regression) and measures of association (odds ratios, relative risk, confidence intervals, and attributable risk). Each practice representative has his or her own computer to work on in the UCSF library containing the dataset, appropriate analytic software with a printed tutorial guide to using the software, and faculty available for consultation. At the end of this session, practice representatives are responsible for developing the tables to be included in the "results" section of a manuscript.

The eighth and final session concentrates on developing the elements of a manuscript from our pilot study. Using the format and curriculum currently used for the

department course on "Writing for Journals," the practice representatives are expected to write a paper containing an abstract, introduction, methods, results and discussion section. At the completion of this session, the practice representatives are responsible for summarizing the findings in an article for the network newsletter and for presenting the findings at the next CRN conference.

### **Evaluation of the CRDP**

We have held these sessions for two years and are in our third year. We have recruited more network members by mailing to all volunteer clinical faculty, particularly newly-appointed faculty. Practice representatives have also recruited additional network members from their colleagues, friends and family. (We increased membership by 109 members in the first 18 months of the new program structure for a total of 220 network members.) We have had 12 physicians participate as practice representatives. Two of these physicians were so inspired that they took year-long fellowships in clinical research methodology as well. We just recruited an additional 13 network members at a recent conference.

Although the CRDP was designed to end at the completion of the first four sessions on basic research methodology, the consensus among participants was that they did not want to quit. Thus, the advanced series was developed and has continued. Practice representatives now serve as senior advisors to the more junior participants.

New practice representatives are recruited and given didactic sessions on research methodology; however, much of the training now is obtained through the "hands-on" process of actually doing research with more senior practice representatives.

Two studies have been completed by the practice representatives to date. Both are being presented at NAPCRG by the practice representatives and are being written for publication. The results of each study are being used as preliminary data for submission of two large-scale NIH applications.

The practice representatives are taking the lead in determining the direction and methodology used in each study, as well as writing the grant applications. Unfortunately, they do not have enough experience to be listed as PIs, but they will be listed as co-investigators with protected, paid time.

We found that the practice representative sessions have worked best when they are held at a family-friendly center that provides good food and a scenic setting. The practice representatives have benefited personally and the productivity of the sessions has been enhanced when homework is provided between sessions. If we convey clear expectations and provide assistance (at least encouragement and support), the practice representatives stay actively engaged. If we convey high expectations, the practice representatives rise to the occasion.

Practice representatives appreciate the camaraderie and ability to interact with others interested in research and in different practice settings. Probably the strongest indicator of enthusiasm for the program can be seen in the scheduling of the practice representative sessions. The sessions in the first two years went from Friday night to Sunday afternoon every six to eight weeks. This obviously required significant commitment and the participants worried about taking away time from their families. Subsequently, the practice representatives asked to schedule the sessions for a single day during the week, despite the fact that it took them away from their practices. I believe this is particularly significant given the managed care environment in California and the pressures for high productivity.

What can we improve? We need to increase the number and percentage of physicians who attend the annual network conference, and we need to speed up the process for selecting research ideas for the next investigation.

### **Summary**

The development and nurturing of a PBRN is dependent upon adequate funding to

support all activities necessary for the research network to exist and be productive. Such activities include having sufficient staff and support for involving and nurturing network members in all aspects of research. It is not appropriate for network members to serve merely as “research fodder” for the

conduct of research of interest to others (i.e., academicians, pharmaceutical companies). Rather, community physicians need to be supported in developing and conducting research in a collaborative manner through their network participation.

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# The Structure, Function and Use of PBRNs: The View From the Practitioner

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**L**et me first apologize in advance for giving a very scattered presentation. I wear many hats so my comments reflect different points of view. I have performed research in a single practice (my own), within a group of practices (my partners) and within a network (the Wisconsin Research Network, or WReN). I have a position as the Director of Research Project Development for WReN and an academic title as Clinical Professor of Family Medicine at the University of Wisconsin. But first and foremost, I earn all my money from seeing patients full-time in a non-academic setting.

My group practice offers no direct incentives or support at this time for research, but on the other hand, does not interfere with my chosen avocation as long as clinical duties are fulfilled. So I am going to focus on what it feels like to be doing clinical research outside of an academic setting and offer my perspectives on the importance of PBRNs.

## **What types of studies are best done by PBRNs?**

I think that service delivery and evaluation studies are what come to mind most often when this question is considered. Obviously, structure, function and outcomes in clinical settings cannot be studied anywhere else and the benefit of using PBRNs to improve generalizability needs no elaboration here.

My impression is that large funders think that health services research (i.e., dredging large administrative or clinical databases) is all there is to primary care research. Those of us in the trenches know this is not the case: primary care research that informs and changes practice for the better involves direct participation of practitioners in the conduct of the research. As examples, I cite the studies of Dr. Mike Fleming ("Brief Intervention with Problem Drinkers") and Dr. David Katzelnick ("Identification and Treatment of Depression in High Utilizers of Medical Care").

Both investigators posed a directly relevant clinical question and involved practicing physicians in the conduct of the intervention. Those of us who participated in these studies learned a new clinical skill that we now use successfully in our practices,

long before the confirmatory articles were published. I am working on a study to document this observation for the case of unrecognized depression.

So, I believe that successful primary care service delivery and evaluation research is not just doing research “on” primary care (traditional health services research) but is more importantly doing research “with” primary care to improve practice directly (often in the context of PBRNs).

Health service delivery research is not the only kind of research that is important to do in primary care: the potential to contribute to etiologic research is underestimated in my opinion. I’m a great fan of unique clinical observations generated by practicing physicians that lead to breakthroughs in clinical medicine. In the modern era, Barry Marshall’s discovery of bacteria in the stomach of ulcer patients comes to mind. A pathologist rather than a clinician, nevertheless Marshall’s observation introduced a paradigm — the “outsider” who ultimately prevailed against academic dogma — to which we can relate. His work has certainly made it easier for me to gain an audience that will at least consider a new paradigm in asthma that was first suggested by observations in practice.

Which leads me to quote from the following anonymous editorial from the *Lancet* entitled, “Should We Case Control?” The following words encapsulate for me the excitement of making initial discoveries in practice: “...real creativity in medicine lies in the hands of the world community of innovative investigators who together carry out hundreds of thousands of small research studies; confirmatory large randomized controlled trials (RCTs) become the task of burnt-out leaders who are only fit enough for administration and organization.”<sup>1</sup> As I am in the process of becoming burnt out, I increasingly cherish the feeling of excitement that practice-based research has brought me and want to remind other clinicians that participation in PBRNs can provide the same experience for them.

Doing etiologic research on initial causes of chronic disease that may be obscured by chronicity will require collaboration with biomedical scientists and this will be a good thing for PBRNs. First, PBRNs are in a unique position to encounter chronic diseases in the earliest stages ... long before the disease presents to academic medical centers. Second, many scientists are eagerly seeking to collaborate with primary physicians because these scientists recognize the value of interdisciplinary work and their dependence on primary care as a source.

As examples, I can think of scientists who are studying infectious agents that may cause type 1 diabetes and arthritis. These infections can be detected only during the early stages of disease, often only during the first few months after illness onset. I must say that some of these scientists with whom I am acquainted have been disappointed in the lack of successful collaboration with the average practicing physician; formal collaboration with PBRNs would probably be more successful. These kinds of relationships are important and have not been sufficiently cultivated, in my opinion.

My own area of interest in etiologic research is obstructive airways disease. The final answer is not in yet, but it is possible that observations made in a practice-based study I conducted 10 years ago may radically alter our view of the etiology of asthma. Conclusive proof depends on results from RCTs. I think PBRNs are in a position to do these RCTs but the feasibility of doing RCTs in PBRNs hasn’t been demonstrated yet. WReN is about to begin an RCT feasibility trial now with the support of the AAFP.

#### **What motivates physicians to participate in PBRNs?**

I want to address the questions of what motivates physicians to participate and what amount of clinician involvement is appropriate. Very briefly, Dr. John Beasley has performed focus groups indicating that willingness to participate depends on at least two factors: the research has to be perceived



as relevant and it must be designed so as not to disrupt practice. Beyond that is the question of why some physicians are interested and others couldn't care less. Is interest in research some type of deviant behavior or the result of a recessive mutation, perhaps? Whatever the underlying biology, I want to offer my personal classification of the various levels of interest and participation.

I don't know what to say about the "Inactive" group except that it is probably large. I wonder how many of this group could be converted to "Passive" participation in PBRNs. We performed a successful asthma prevalence study in 60 WReN practices by asking the RN or MA to collect data while taking vital signs. This strategy worked well to accumulate a database on more than 15,000 patients; the physician was not directly involved and only had to give passive acceptance. "Active" participants I would classify as physicians willing to do card studies. "Fully active" physicians design the card studies, etc. There is another category I would refer to as "Hyperactive" — that is composed only of non-academic clinicians in full-time practice who do research as a hobby.

The majority of PIs are in academia and actually get paid to do what they do, and do not suffer the consequences of doing research as an avocation: they just have to sit through committee meetings. Should "Hyperactive" researchers be institutionalized? Most of them already have been. A lot of you in this room probably started out in practice like I did, but now you are all in an institution.

On a more serious note, I believe that the AAFP has to weigh the risks and benefits of promoting research by clinicians like me in community practice. So I want to present a "risk-benefit" assessment based on my personal experience with doing research in private practice.

I have already touched on the benefits, including quality of care issues and discoveries. The primary mission of community practice is patient care, not research, and

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#### **What amount of clinician involvement is appropriate to network research?**

- Inactive
  - Passive (will open practice, minimal participation)
  - Active (will open practice and collect data)
  - Fully active (designs and implements research)
  - Hyperactive
- 

frequent lack of support from community practices can lead to social isolation, loss of income, time pressures and ultimately an incentive to join academia. I believe this is unfortunate since I see community practices as Sutter's Fort in 1848: lots of gold nuggets lying around waiting to be mined.

Nurturing community-based researchers will require a major restructuring of incentives. This restructuring is becoming increasingly unlikely in an era of contracting resources: the same forces that are squeezing clinical research in academic centers are also affecting PBRNs and community-based research. I see little hope of restructuring incentives to reward research within

#### **Benefits and risks of practitioner research**

1. Benefits: self-fulfillment, improved quality of care, professional recognition, important discoveries (maybe).
2. Risks: social isolation, loss of income and other opportunity costs, a university career.
3. Optimization of benefit/risk: community-university liaison (including PBRN affiliation), restructured incentives (within community practice, between university and community, at funding agencies).

physician-owned group practices such as mine. MCOs understand the value of evidence-based practice and accountability but are, with some exceptions, mostly unwilling to fund large research organizations. This is particularly true in MCOs without an established research tradition. The NIH won't fund PBRNs until a track record has been established. So I view the AAFP research initiative as a very important step toward developing research credibility for PBRNs and primary care research. From a practitioner's viewpoint, I urge the AAFP to devote some of the initiative dollars to support practicing clinicians.

### **Conclusion**

As a clinical researcher, my perspective on why I have chosen to remain in practice relates to the paradox surrounding the "My Lai" syndrome: "I had to leave practice in order to study it." When I went to medical

school I had an interest in research but got turned off by the academic scene and turned on by primary care practice. So I told myself I would practice, learn what was relevant, and then do research. This plan seems to be succeeding, but at a slow pace. I think the AAFP recognizes the value of supporting this kind of career track. Participation in PBRNs offers the best hope, I think, of producing a cadre of clinician-researchers that can contribute to a more rational health care system. Collaboration between PBRNs, primary care researchers and other health care scientists (biomedical and biopsychosocial) will mark a developmental milestone indicating the passage of U.S. primary care research from adolescence to maturity.

### **Reference**

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# Observational Comments and Questions and Answers

## A reaction

**Dr. Paul Frame:** These have all been wonderful presentations. A lot of things came up. One thought that I had was practitioner interaction and involvement have become so important that maybe, again, we should be go back to Dr. Larry Green's definition of a PBRN to add a sentence that it is not a PBRN unless the practitioners are required to actively participate. This does change the definition a little bit, in terms of the types of things Dr. Steve Ornstein and Dr. Joe Selby were talking about — and those may indeed be a data collection system, but not really PBRNs. That is just one thought I had through all of this.

Dr. Larry Culpepper gave us a wonderful introduction that was perhaps depressing, but pointed out that research networks are expensive to maintain. The bottom line of what Larry was saying was that you're not going to maintain a research network for very long independent of some exterior funding, whether it comes from a supportive institution, from the AAFP, or from a charitable foundation. But, just from the mechanics of applying and getting grants, it is very difficult — if not impossible — for a network to remain viable unless it is sort of a seat-of-the-pants kind of network that does everything in terms of volunteer work, and, by nature, has to limit itself to taking on those very small, feasibly easy projects.

Dr. Mary Croughan-Minihane re-emphasized that in her talk about the difficulty of maintaining infrastructure and the costs of maintaining an infrastructure, which is not an easy thing to do. Mary also talked about collaboration from the ground up, and involving the entire practice — not just the physicians. This perhaps ties in with some of the things that Dr. David Hahn said (I will get to that later).

In this environment we have the PI, and my take from Dr. Michael Fleming's talk, among other things, is that the PI is out hunting to get his project completed. He has an idea. He wants to see something to fruition. He doesn't really care what tools he uses to get it done. So, he will look at networks, he will look at systems, he will look at a local — any way that he can get it done cheapest and best — that is how he is going to go. Therefore, the challenge PBRNs have is to be the vehicle that will make it easiest and best for the PI. This gets back to looking at what types of questions the network is really an asset for, and what types of questions the network is just an hindrance for. It is not going to be the same answer for every question.

The practitioner, as David eloquently stated, has a lot of idealism and self-satisfaction. This is what gets practitioners involved in networks. I think it is true, and it is a very real thing that the practitioners who are

really interested in this do not remain practitioners. They go on to really fulfill this, if that is indeed a major driving interest in their careers. So how do we maintain some kind of balance? The people who stay in practice are the people who want to practice and don't necessarily care about doing the research. Let somebody else do it. An innate curiosity is something that all practitioners should have. Ideas of how to get practitioners more involved (Mary's discussion of how to nurture them) need to be centered around how to get them to a much more excitable level, if you will. Mary, I know it was through some fairly intensive and time-consuming efforts. What you did was not easy. It is really fascinating.

The last thing about practitioners that I want to speak to directly (because actually I am — now that I found out I am — a practitioner involved with networks) is the institutional support issue that David mentioned. It is really true, and as I look at my career, I have had lots of institutional support. Nobody has given me money, but the other guys in the group have let me take time off, and my secretarial staff have spent numerous hours doing things that did not relate to the productivity of the practice. So, in a sense, I have had institutional support in-kind, if you will. Many of us in this room are in the positions to influence the institutions within which we work. We work for managed care organizations, for practices, and universities, so there has to be institutional support if you're going to get practitioners involved. It doesn't necessarily have to be dollars. There are other ways to do that. We need to be more creative in terms of looking at those type of things.

#### **Questions and Answers**

**Dr. Lanny Copeland:** I would like to ask Mary about the comment you made about CME. I assume you are talking about the difficulty getting CME through the Academy?

**Dr. Mary Croughan-Minihane:** This is the problem with not being a family physician.

I didn't know there were differences until last year. So Shelly Rodriguez from the California Academy said that what these guys really want is not the CME that you are offering through the UCSF ... they want the CME that we offer. So, it wasn't until this last year that we got it through the Academy.

For the first two years, we just had it through UCSF. What was really difficult was that clinical research, either learning how to do it or actually doing it, is not considered a CME activity. However, if the physicians went to a lecture or course where they were hearing the results of clinical research, then the CME office would approve it. So, it actually took me six months and about probably five meetings with the CME office to tell them that teaching people how to do research was important.

One of the other hats I wear is directing epidemiology and biostatistics required courses for the first-year medical students. It is 40 hours on how to do clinical research. That was the final plug. I said, if the first-year medical student is required to take 40 hours of curriculum that is a required course to learn to do clinical research, you cannot tell me that somebody in practice doesn't need the same kind of training. That is what finally did it. By the way, they get an hour lecture on how to do practice-based research as first-year medical students.

**Dr. Joe Selby:** I came here this morning professing to be not at all certain that I belonged in a meeting with practice-based researchers, but now that you are trying to kick me out, I'm going to resent that. (Laughter)

I said this morning and I say it again, I have heard several people say that it takes involvement of the practitioners in the research process to make it PBRN. I have not really heard the explanation of why that is the case. To put it another way, what is the ultimate aim of the PBRN? Is the primary aim to get research done in real world settings, or is it to get more and more family physicians involved in research? Or to put it yet another way, when you write your grant,

what good does it do you to say that every physician in the network is involved in conceiving the research, or conceiving some research projects, but not this one.

**Dr. Croughan-Minihane:** I can answer that to some degree. I think one would be when you actually train people in the process of asking the research questions, and teach them how to do it, the results become much more applicable to patient care than they ever were when we asked the questions out of the department of family medicine with a bunch of academicians — even in practice. So I think the quality of the questions is enhanced dramatically. We just completed a study on treatment of chronic non-malignant pain with opioids. I can guarantee that question would not have been asked out of UCSF, which has its own pain center.

**Dr. Selby:** But, Mary, for example, we have at Kaiser a large number of primary care physicians, and we probably have that one in 10 ratio — might even be a little higher in Kaiser — one in five ratio of practitioners who are research-inclined. That small group generates more than enough good questions for us to address in a lifetime, so I still don't see the benefit of having every network member be a junior researcher.

**Dr. Croughan-Minihane:** We don't have everybody. But everybody gets taught how to ask the questions at least.

**Dr. Frame:** I am not sure they need to be junior researchers, but I think if you are talking about experimental trials as contrasted to just observational trials — where you are asking people to collect significantly extra data from what they need to get their job done — or you are asking them to intervene slightly different for specific population. Those types of studies clearly need practitioner involvement and will fail without it.

**Dr. George Isham:** Practice-based research should be done not only in family practice

or primary care, but also in managed care organizations and any other organization that has the appropriate population to answer a specific question. To me it doesn't matter what the history was. I simply think there is a track record of some excellent research being done in a few managed care groups. Kaiser and Group Health are two of them. There are a lot of other managed care groups like my own that have a rich patient population and data sources where I think the barriers to doing research are greater than they are in our own research networks. I think we ought to broaden the definition rather than restrict it.

**Dr. Paul Nutting:** I want to pick up on a couple of threads and make a pitch again for family practice as a learning discipline. I am picking up on a thread regarding Academy CME. Some of the purposes of networks, above and beyond producing research, and the notion of what kind of training might be appropriate for network participants .... I think at ASPN we have grappled with this for years in terms of training, and what our practicing doctors want to know about research. We've given everything from design workshops at the annual meeting, to a variety of other things. The thing that we keep seeing in the evaluations of whatever it is that we've tried in the most recent year, is a lot of clinicians saying I want to know and what I want to learn at the next research workshop about how to better participate in the ASPN process of asking and answering questions in practice. I don't think we have quite figured out how to do that. I don't think we've quite figured out what it means.

But I think if we can figure out what it means, we will have identified some activities, and we can perhaps enhance the ability of practicing doctors to act on their curiosity. Hopefully the Academy will figure out a way to reward and recognize people who do that. Straight CME credit for participation and research is on the right track, but not quite on target. It becomes, I think, another purpose of participating in a research

network. One of creating motion, and creating energy in our discipline, to push back the frontiers of our knowledge of about how to take care of patients. I would like for us, in a decade or so, to be known as the specialty that does that very deeply into our specialties — and not just the academics, the researchers and a few networks. It is something that the entire discipline participates in.

Again, I hark back to the fact that 10 percent of practicing family physicians, plus Dr. Paul Frame, are involved in networks. That is a pretty sizable chunk of our universe. I would like for us to think a bit more aggressively about what that means, and how we can enhance it and recognize it with some sort of CME-like recognition that goes to the practitioners. It is the crux of what we are all about. We don't have it quite right yet.

**Dr. Kevin Peterson:** I would like to just reinforce that a little bit. We have been talking about how to integrate research into clinical care. One of the things that, as you mentioned Larry, we don't do is to recognize the research efforts that our volunteers in the networks actually do. We do reward the time that they sit and listen to us talk. And we do give them credit for writing articles, or co-authoring, or a number of other activities. But, we rely on their volunteerism to do hours of work. If we could devise a way that would reward that volunteerism, in the honest investigation of their own practices, I think that helps the networks in participation. It might even help integrate the research into the thought process of clinical care.

**Dr. Croughan-Minihan:** If I could respond a little on the incentives. We survey our doctors every year. Partly because as an epidemiologist I care about the denominator issues. So I want to survey the network every year, as well, for those people who aren't interested any longer. We don't have to worry about dropping our response rates lower than they should otherwise be.

The incentive that came up number one

year after year is CME. Now CME is really expensive in California, I don't know. But, they actually care a lot that it costs them nothing other than mileage to get to a CME-approved activity that they find exciting and they are not paying for airfare to come back to Washington, D.C., and taking four days away from their practices. So they keep talking about the cost-effectiveness of their practice-based research activities.

The other things that we give them is a Medline account with the University. They have access to all the University resources that any other faculty member would have. They have a volunteer clinical faculty appointment. The fact they get excused from their teacher activities for the family medicine department during the time period that they are active in network research is really significant. These are again people in managed care environments who are out there trying to precept medical students. If you tell them you are preceptorship for the following year because you participated in this clinical trial, they're thrilled.

We have offered them money, and that is not what they wanted. So, again it may be geographic specific, but I have done studies where I have budgeted for \$200 or \$500 reimbursement to the practices, and they have always written back saying use that for something else for the network.

**Dr. Bernard Ewigman:** Actually I've heard a number of issues that I felt I would like to respond to, but just let me pick a few. One is that I would repeat Dr. Larry Green's point earlier that there are a lot of great ideas, and there is not one way to do it whether you are institutionalized or not.

I would also like to repeat what Dr. Michael Fleming said earlier about the NIH. Because of all the ideas we are talking about here, and all of the intense efforts and resources it requires to do this, the NIH is really a very deep well.

I want to mention that I represented the Academy at one of the focus groups for the medical specialty societies. There are ten

focus groups leading towards this clinical research summit that the AAMC and the AMA are sponsoring. We need to be at that table because I was shocked. There were 20 of us in the room, each representing our specialty society, and I was expecting to be the lone voice talking about health services, epidemiology, behavioral science, and practice-based research. That was not the case at all.

To the person, people supported that very broad definition of clinical research, and not just the traditional patients in a university hospital (we'll get some blood tests and some enzyme tests). There was a very strong consensus among the clinical research community — if this group was at all representative of the value of the kind of research we are talking about — that we can do it in practice-based research. But if we're not at the table, the kind of language and the kind of priorities and the kind of infiltration that we need to have in all the federal agencies and the various institutes are not going to happen. I just want to put a plug in for those of you who have the opportunity to get to the table, and to influence the political process. Clinical research is, I think, the current word that enables us to come under that umbrella with our interest.

**Dr. Michael Fleming:** When we're talking about practitioners, I think we should talk about the PIs and how we can celebrate their success. When I get an NIH grant, no one ever knows about it except for me and a couple of other people. One would think the Academy would celebrate that achievement by making a big deal of it in a press release. I hope the Academy will think about how they could do that, because it is a big accomplishment for those of us who put in all those hours and years.

Another comment I have builds on what Bernie was saying. We talked about the women's health initiative costing a billion dollars. How do you think that happened? That's been 20 years of work on the part of women's groups and organizations. It didn't

just happen. There is no reason that this cannot happen for us in that we cannot give \$50 million or \$100 million or whatever it takes to develop the model that Bernie talked about.

If we get eight or 10 centers with good, solid funding for 10 to 20 years, it will really help us achieve this. It can happen, but only if we start dialoguing with the NIH — talking to the right people — and getting the support of institute directors.

**Dr. Peter Franks:** I would like to get back to Joe's question, because I don't think it has been adequately addressed, and I would like to link it to what Larry talked about earlier. He sort of framed networks from a national to a very local level. I think it would be useful to add to that matrix a dimension of active to passive involvement of practitioners. It seems to be where Larry started from, which is the purpose of networks, is not so there can be networks and we can all have something to do, but to answer the questions that practitioners need answered in primary care. It seems to me the key question that we should be addressing is what is the most efficient locus to address that question — both in the dimension of is there a reason to have active practitioner networks because it is clearly a lot more expensive in the passive mode? And is there a reason to do it nationally versus locally because it is clearly a lot easier to do it locally?

So, the best, in terms of most efficient, if it can be done, is local/passive. The most expensive is national/active. And why should it be localizing the national active level if it can be done in the other levels? I think the key questions that we need to address are, first, what is the rationale for localizing those questions? And, second, what do the practitioners need to know in an environment where there are active physicians? This really gets back to Joe's question. Why do we need active practitioners?

**Dr. Larry Culpepper:** Let me just comment on that. I think there is sort of a swarm or a

constellation that goes together here, that has come up today. I think what you are eluding to involves matching not only the right research project, but the right research effort with the right locus of engagement. Dr. Fleming demonstrated something elegantly for us that is not simply a research project being linked to the right sized network, or the right characteristic network — in terms of active, passive or electronic. More importantly, the idea of linking a research career to a network environment.

What we have seen from Dr. Fleming's brief history of his career is an ability to harvest practice information, and do that in a variety of ways fairly consistently in his local regional practice environment, and that out of that he has in essence created a network that shares his interest in substance abuse. I think that, to me, is critical.

One of the reasons for choosing a network is its cache in helping to get a grant funded. No one has heard about the Brownsville Research Network — and I don't know if it exists — but the lack of recognition and the lack of a track record, certainly impedes major grant funding. Whereas, an experienced network that has a track record of accomplishment is going to aide in getting grants funded. The problem when that supercedes the issues of validity and efficiency in dictating the linkage of PI and the network.

**Dr. John Beasley:** Just briefly, one of the themes that one sees at a number of levels is a valuing of the research. I mean whether the Academy is valuing it in terms of saying this is a "CME-able" activity. Whether the practice environments or the corporations value it as a legitimate part of, if you would, productivity — which they don't. Even where I come from, and as Dr. David Hahn would like to say "academentia," there is not necessarily a valuing or even in some ways a decrease valuing on research as opposed to "clinical productivity." One of the challenges to the Academy is to highlight this at a whole

variety of levels to say that this is important.

**Dr. Larry Green:** Follow this logic for just a second. Let's assume that primary care is different from secondary and tertiary care, and the rest of the health care system. Then it would seem likely that primary care research might be different. Now maybe that is just that the questions are different, but there is also the very real possibility that those different questions will require different methods.

If that is so, then it seems quite likely that the approach to doing primary care research may need to be different. Just as 25 years ago, people said we need a different kind of laboratory from the laboratories that existed. What this discussion reveals to me is the need for creative thinking. For a little bit of rebelliousness on the part of the primary care research community. There is nothing wrong with taking full advantage of every tool you have at your disposal to ask and answer your research question. But if the systems in place in this country are not sufficient, we should reveal that and be prepared to invent other systems.

What would be wrong with establishing a research ethic that said you will stay in practice three days a week and do research two days a week. Your publication curve, instead of expecting it to be six to 10 publications a year will be six to 10 per decade. This is a non-trivial question in my view because of the belief I have. I believe that primary care is fundamentally a relationship. And if we establish a research enterprise in this country that divorces the researchers from their patients, we will have to go back and reinvent it with our great-grandchildren.

The fundamental essence of primary care continues to reside in care among friends and people who know each other. If we destroy this relationship to produce our research enterprise, we will rule the day. I would challenge the group to think very seriously above what it would take to have very successful clinician researchers. It goes back to what Paul was saying.



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# Practice-Based Research and the External Environment: A Construct for Thinking Strategically

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**T**he Practice-Based Research Networks (PBRNs) in family practice operate in a very challenging environment even in the best of times. The many confusing trends in the current health care system have profound impacts not only on family physicians who represent both our practices and our researchers, but profound impacts on the organizational structures of our PBRNs as well. The ability to analyze the challenges and opportunities presented by forces in the external environment may be critical to survival and ultimate success of PBRNs in family practice over the next decade.

ASPN has devoted a considerable effort to strategic planning for organizational survival and growth of our research program over the next decade. Some of the approaches we have used might be useful for other networks and I would like to describe strategies for identifying and characterizing the critical features of the environment in which our PBRNs exist, analyzing the challenges and opportunities they present, and

developing strategies to cope with (and occasionally even capitalize on) those features of the environment.

Attempting to describe and deal with the environment in which we operate can be an overwhelming task. The current health care environment, for example, is extremely complex and presents a bewildering array of features that directly impact our research, even more features that effect our research networks, and an even larger number of features that may merely represent “background noise.” Thus a useful working definition of the external environment is that set of forces around us, over which we have little or no control, but which influence (in either a positive or negative manner) what we can achieve. The challenge is to identify, analyze, and focus on those features that are critical while avoiding distraction by those features that are less relevant. I believe that this task is made easier by adopting a strategic perspective on the external environment and asking ourselves three questions: What are the resources we need? What are the environments in which our resources reside and what are the important trends in those environments? And what opportunities do those trends suggest to advance our work?

## **What are the resources we need?**

First, it is useful to identify the resources that

are critical to our success. In ASPN, we have found it helpful to ask ourselves, “what are the things that we need to conduct our work and accomplish our goals?” and “who are the other players in the environment on whom we depend for our success? I have found it helpful to think of our external resources in five categories, including the practicing family physicians who are members of our networks, our collaborators including our research colleagues and the other PBRNs, those who advocate for practice-based research in the policy world, our potential sources of funding, avenues for dissemination of research results, and finally our patients. These are summarized in *Table 1*.

Perhaps most importantly, we count on practicing family physicians to bring into this research enterprise a strong sense of what their information needs are — what they need to know and what kinds of problems the patients bring to them. Increasingly, we need to be hearing from them about the changing environment in which they work, both because it suggests further questions to address and informs us of their changing capacity for research in their practices.

We need collaborators. The life blood of ASPN is our network of collaborators, including both individual researchers and other networks. I spend at least half of my time recruiting the best and the brightest researchers, and trying to match them to our research questions, so that they will be effective investigators with the special qualities they need for working with a network. They are absolutely critical and among the most important of our friends.

Another critical resource is the advocates for practice-based research who work in the policy environment. Probably the most important reason the policy environment is important is that it's where the people are who are either advocating for us, or advocating for something else that is competing with us. Among the issues discussed in the policy environment, probably none are more important than the development of funding for our research and our research infrastructure.

Clearly, another important resource is our sources of funding. The profile of funding agencies will vary by network aspirations and the circle of contacts that have been

**TABLE 1. Resources needed for PBRNs to be successful**

Practicing Family Physicians	<ul style="list-style-type: none"> <li>• Foundation of a PBRN</li> <li>• Provide clinically relevant researchable questions</li> </ul>
Collaborators: <ul style="list-style-type: none"> <li>• Research colleagues</li> <li>• Collaborating PBRNs</li> </ul>	<ul style="list-style-type: none"> <li>• Provide the research expertise</li> <li>• Collaboration among networks affords opportunities for critical mass and shared resources</li> </ul>
Funding Agencies	<ul style="list-style-type: none"> <li>• Provides resources for our research activities</li> </ul>
Advocates for practice-based research	
Avenues for dissemination of research results	<ul style="list-style-type: none"> <li>• Provide the vehicle for feedback of research activities to member physicians</li> <li>• Provide vehicle for dissemination of new information to practicing family physicians</li> <li>• New technology may offer opportunities for two-way communication with network members</li> </ul>
Patients	<ul style="list-style-type: none"> <li>• Patient problems represent the central focus of our research</li> </ul>

formed over the years. In ASPN we try to think very broadly about our funding sources and nurture a balance that includes federal, private, and industry partners. Each has their own set of advantages and disadvantages for network research.

We require resources for publications or dissemination of our work, both back to our practicing physician membership and to the larger community of practicing physicians as well. We need to think very broadly about dissemination as well, something we have not done particularly well in PBRNs. Our thinking about this should extend well beyond medical journals and include a variety of ways of communicating what we have learned that helps family doctors take care of patients.

Finally, I would consider our patients to be an important resource. It is after all, their health problems and the challenges they bring to family physicians that drives our research agenda. Several years ago Bill Phillips invited some of his patients to attend the NAPCRG meeting. This was a bold idea and one we are considering for ASPN. I believe we have just begun to explore the myriad possibilities for partnering with our patients in the network research enterprise.

#### **What are the environments in which our resources reside and what are the trends in those environments?**

So, we must ask what are the environments in which our friends exist? What is going on in those environments? What are the forces that are determining their ability to participate in and support our research programs? Some of the important environmental forces are shown in *Table 2*.

Our practicing physicians are living in a practice environment that is undergoing very rapid and dramatic change. Most of our member practices in ASPN have become part of larger groups over the last five years. Many of our physicians have become salaried employees of larger physician organizations and are no longer in charge of (or

invested in) their offices. Many find that they have less time for network research and many find that they have opportunities to engage in analytic activities within their own organization and may have less need to participate in network research as their major intellectual activity. Most of our physicians still seek opportunities to think and act in ways to improve care, but these opportunities will increasingly be available in their own organizations. Many practices are under increasing pressure to show evidence of quality assurance activities and the possibility of formal accreditation of physician offices looms large.

Finally, many practice environments are increasingly using computers for a variety of practice activities and the availability of computer technology and access to the Internet certainly increase computer applications in family practice. Although progressing slowly, we will eventually see sophisticated clinical data systems in most practices.

Our research colleagues are experiencing a rapidly changing academic environment as well. First, there appear to be fewer new researchers in the pipeline and many of our academic researchers are under increased pressure to teach and see patients. There is difficulty in recruiting new faculty and in engaging them seriously in a successful research track. Many of our mid-career researchers are experiencing difficulty in advancing from small projects with local funding to the larger projects requiring funding from more competitive sources.

Finally, many of our mature family physician researchers are being recruited to industry. The net effect is a decrease in the availability of academic researchers with time and energy to devote to network research. I am seeing evidence of this from both the ASPN perspective and the perspective of a journal editor. I have had a number of senior researchers in our field say to me, "I don't think I am going to be able to do much research this year. I'm being eaten alive back in my academic department. I am

50 percent funded for research, but that doesn't make any difference."

Most of our colleagues in other PBRNs live in either an academic environment or within a state academy. Many are subject to the same trends in the academic departments as described above for our research colleagues. Given these constraints, it is unreasonable to expect academic departments to provide more than the important in-kind contributions they have traditionally made to their research networks. Across all other sources of financial support for PBRNs, resources for infrastructure support is sparse at best, with no reason for great optimism over the next few years. The major

resource that many of the networks have is their collaboration with each other, and the growth of the Federation of Practice-Based Research Networks (FPBRN) offers hope of a more efficient bootstrap opportunity for many networks.

Important trends act on our potential advocates in the policy environment as well. The annual crisis of Title VII funding (while extremely important) continues to present a regular distraction from efforts to expand resources available for our research. We are also seeing a serious backlash against primary care in the literature with flawed research suggesting that subspecialists do a better job taking care of a given disease than

**TABLE 2. Important trends in the practice environment**

<i>Resource and the environment in which the resource exists</i>	<i>Important trends in the environment</i>
The <u>family physician</u> members of our networks work in a rapidly changing <u>practice environment</u>	<p>Practicing family physicians are:</p> <ul style="list-style-type: none"> <li>• Becoming part of larger groups that engage in analytic activities; may have less need to participate in PBRNs as their only intellectual activity</li> <li>• Increasingly salaried; not in charge of (invested in) their offices; have less time</li> <li>• Becoming more computer literate and likely to be on the Internet</li> <li>• Under increasing pressure to show evidence of quality assurance activities. Physician offices may go through an accreditation process through the AMA or AAFP</li> <li>• Still seeking opportunities to think and act in ways to improve care, but these opportunities will increasingly be available in their own organizations</li> </ul>
Our <u>research colleagues</u> largely work in <u>academic departments</u>	<ul style="list-style-type: none"> <li>• Increased pressure on academics to teach and see patients. This decreases the supply of academic-based researchers for our networks</li> <li>• Difficulty in recruiting new faculty and in engaging them seriously in a successful research track</li> <li>• Fewer new researchers in the pipeline</li> <li>• Family physician researchers are being recruited to industry at an alarming rate</li> <li>• Continued difficulty for young researchers to move from moderate to big studies</li> </ul>

we do. This appears to be a popular tune and it seems to be playing well in both the medical and the lay literature.

One of the most exciting developments in the policy environment is the AAFP Initiative to Enhance Family Practice Research and the related development of the AAFP Policy Center in Washington, D.C. One of the important features of the initiative is the advocacy support which has the potential to leverage the AAFP research investment to a much larger pool of resources from federal and private sources. Finally, the policy environment is becoming crowded with the many disciplines who have found religion and discovered their primary

care roots and now espouse a unique ability to meet the primary care needs of the population. We are increasingly being required to explain ourselves all over again and defend the many strengths of family practice, even to a growing number of disciplines who have recently invented their own primary care mission.

The environment in which our funding sources exist includes several federal research agencies, foundations, pharmaceutical industry and managed care industry. My own view is that we are not going to see a substantial increase in federal research funding for family practice in the near term. I think that several people have made an important point

**TABLE 2. (Continued)**

<i>Resource and the environment in which the resource exists</i>	<i>Important trends in the environment</i>
Our collaborating PBRNs	<ul style="list-style-type: none"> <li>• Sparse infrastructure funding for 20+ PBRNs in family practice</li> </ul>
Our <u>advocates</u> for practice-based research work in a policy environment that continues to favor traditional biomedical research and continues to misunderstand and/or misrepresent primary care	<ul style="list-style-type: none"> <li>• Continued backlash against primary care by specialists with shoddy studies showing they do better in caring for patients with specific diseases</li> <li>• AAFP Center for Policy Research in Washington, D.C.</li> <li>• AAFP Initiative to enhance family practice research</li> <li>• Continued push for nurses and others to be primary care clinicians</li> </ul>
Our <u>avenues for dissemination</u> of our work consists largely of <u>medical journals</u> , but will rapidly expand to include the new media, including CD-ROM, Cable, and the Internet.	<ul style="list-style-type: none"> <li>• Marked decreases in advertising revenue for journals</li> <li>• Technology for low-cost electronic publishing</li> <li>• Push-pull technology in cable television</li> <li>• NLM open to indexing electronic publications</li> <li>• Discussion of a 'real-time' electronic medical journal at National Library of Medicine</li> </ul>
Our <u>patients</u> live in their <u>home and community</u> , but can also be found in our <u>practices</u>	<ul style="list-style-type: none"> <li>• Large numbers of patients remained uninsured and underinsured</li> <li>• More computer literate patients with greater access to medical information</li> <li>• Patients are baffled by complexity of health care system</li> <li>• Patient trust in the system (and possibly in physicians) is waning</li> <li>• Patient trust in their family physician appears strong</li> </ul>

and there is quite a bit there if we know how to go after it. However, I don't think we should base our strategic planning on any substantial new federal funding. I keep hearing that the forces in the market place will evolve from competition on price to competition on quality. If that ever happens, we may find new interest in the health care industry in some of the research that we conduct in family practice.

Our major avenues for research dissemination have always been the medical journals. An important trend in the journal environment is direct-to-consumer advertising by the pharmaceutical industry and a concurrent decrease in advertising revenue for medical journals. This could have a devastating effect on many of our journals and our ability to disseminate our research through publication in family practice journals is at some risk.

New information and communication technology promises a number of new opportunities for low-cost dissemination of information. Consider the push/pull technology in cable television. This permits the cable provider (who has a great deal of information about you and your family) which permits them to estimate (or perhaps know directly) about your buying patterns and preferences. They will know you are a physician and you may soon turn on your television to hear, "Good morning Dr. Nutting. If you are interested in our new symposium on low back pain, please press the appropriate button on your remote pad. And incidentally, have you tried the new Prince tennis racquet?" That is "push" technology. "Pull" technology would be less intrusive and simply permit you to select the options you want. There is a great deal of money being spent on the push side of cable technology and it's going to happen in a short period of time. With a little imagination, we can easily think of many ways that this could be harnessed to enhance our research programs.

As a journal editor, I'm caught up in the enthusiasm and challenges of electronic publishing. Nearly every medical journal now

has a web site and several are beginning to publish additional material on-line that does not appear in the hard copy journal. I suspect we will see changes over the next decade that make information available to practicing physicians and researchers in ways we can only imagine now. This is an exciting time and one that affords many opportunities for us to think creatively about how we disseminate our research results and provide information services to our member physicians as a value added feature.

Finally, our patients are also resources. I don't have a lot of thoughts here, but I think it is a fertile area for us to be thinking about. Patients are clearly one of our resources and they exist in the home and the community. They exist in our practice. Here are some things I see going on. I think patients are baffled by the complexity of the health care system. I think it is affecting their trust in us. Large numbers of patients remain uninsured. I just put those up as placeholders. I think that this group or somebody that wants to take this on can think of a lot of additional ideas.

#### **What opportunities do those trends afford to advance our work?**

It is useful to consider those strategies that may be appropriate for advancing practice-based research in the context of our resources and the trends in their environments. For this talk, I was asked to discuss the forces in the external environment that affect PBRNs, but I can't resist the opportunity to provide some examples of this last step that I think will have application in many of our PBRNs.

First, there are a number of strategies that may serve us well as we consider the changes in the environment of our family physician members. First, and foremost, we must be prepared to address new research questions that are relevant to the changing practice environment and the new challenges facing family physicians. We must be vigilant to the opportunities to develop projects at the interface of research and quality of care

improvement. This may also provide possibilities for providing CME and/or practice certification credit for participation in practice-based research. We must stay abreast of developments in information technology and explore new strategies for automating data collection, transfer, and management, taking advantage of the growth of information technology in our member practices. At the same time we must expand electronic mechanisms for communicating with practicing physicians, both within our network and among the larger physician community. We must also develop the capacity to manage complex research grants.

ASPN, for example, has benefited a great deal from the ability to directly receive an NIH research grant and enjoy the indirect cost recovery funds; a luxury, however, that has come at great effort. Hopefully, we will be able to exploit this capacity within ASPN for the benefit of other networks. Finally, we must recognize that the unit of participation in our networks may change. For example, ASPN has begun to explore the advantages of institutional memberships, by which the family physicians of large organized medical care systems can participate in ASPN activities in a way that benefits both organizations.

Second, changes in the environments in which our collaborators live suggest several important strategies as well. I am impressed with the potential value in developing a “network of researchers” who are prepared to work with PBRNs on projects of mutual interest. We have begun in ASPN to develop a more formal relationship with about 30 of the best and brightest primary care researchers and we are beginning to see tremendous benefits as they step forward to take the research lead on a number of study ideas that have been languishing within the network for lack of research expertise and leadership.

To make participation with us in our research activities attractive to the researchers, we need to be able to offer our research collaborators a highly efficient opportunity to make the most of their

limited time, to still take on complex projects with the networks now having the capacity to manage a lot of the logistics. In order to take maximal advantage of the capacity of our research collaborators, we must become much more efficient at linking virtual knowledge teams, often scattered geographically and working within their own unique time constraints, for optimal efficiency.

Fortunately, there is a growing body of knowledge about the development and maintenance of virtual knowledge teams of which we should become familiar. We also need to collaborate among the networks at every opportunity. None of the PBRNs has such a secure infrastructure that it will not benefit from sharing resources as much as possible. I have been pleased to be able to foster this collaboration from ASPN and we have certainly benefited immensely from the collaboration.

Finally, I think we should redouble our efforts in the changing policy environment and seize opportunities to support our advocates. The development of the AAFP Policy Center in Washington, D.C., under the direction of Dr. Larry Green, should be seen as a watershed event in the history of our specialty and a unique opportunity to participate in an effective mechanism for supporting and disseminating our research. Larry Green and I have had several discussions over the years — and one fairly recently — about the important capacity to develop rapid turnaround studies that will support the policy discussions in which Larry and others in the policy arena engage. Supporting his ability to bring real data into the discussion could be a very tangible and important strategy for advancing our policy interests.

These are only a few of the strategies we should be thinking creatively about in response to the rapid changes in our external environment. It is my hope that providing this outline of a way to think proactively about our external environment stimulates a great deal of important thought and discussion among the PBRNs in family practice.

### Family practice as a learning discipline

Our PBRNs in family practice offer our specialty a unique opportunity to become a learning discipline. The combined membership of our networks approaches 15 percent of all practicing family physicians in the country. The ability to ask and answer practice relevant questions and efficiently disseminate that information to the larger community of family physicians is a major

strength of our specialty. A health corps of PBRNs, working together, offers us an avenue for reuniting practice and research, experience and science, and the practicing family physician with the academic researcher. With leadership from the AAFP this could transform our specialty into one that continuously learns and improves the care we provide to the American people.

**TABLE 3. What are the challenges to PBRNs in the external environment?**

<i>Resources needed for PBRNs</i>	<i>Environment in which resources exist</i>	<i>Health care trends in the environment</i>	<i>Considerations for strategic action</i>
Practicing family physicians	<ul style="list-style-type: none"><li>• Practice environment</li></ul>	<ul style="list-style-type: none"><li>• Become part of larger group that engages in analytic activities; may have less need to participate in PBRNs as their only intellectual activity.</li><li>• Increasingly salaried; not in charge of (invested in) their offices; have less time.</li><li>• Becoming more computer literate and likely to be on the Internet.</li><li>• Under increasing pressure to show evidence of quality assurance activities. Physician offices may go through an accreditation process through the AMA or AAFP.</li><li>• Will still seek opportunities to think and act in ways to improve care, but these opportunities will increasingly be available in their own organizations.</li></ul>	<ul style="list-style-type: none"><li>• Seek new questions relevant to the changing practice environment.</li><li>• Develop new strategies for organizational participation in PBRN research agenda; institutional memberships.</li><li>• Develop projects at the interface of research and quality of care improvement.</li><li>• Expand electronic mechanisms for communicating with practicing physicians.</li><li>• Explore strategies for automating data collection, transfer, and management.</li></ul>



**TABLE 3. (Continued)**

<i>Resources needed for PBRNs</i>	<i>Environment in which resources exist</i>	<i>Health care trends in the environment</i>	<i>Considerations for strategic action</i>
Collaborating research colleagues	<ul style="list-style-type: none"> <li>• Academic Departments</li> <li>• MCOs</li> </ul>	<ul style="list-style-type: none"> <li>• Increased pressure on academics to teach and see patients. This decreases the supply of academic-based researchers for our networks.</li> <li>• Difficulty in recruiting new faculty and in engaging them seriously in a successful research track.</li> <li>• Fewer new researchers in the pipeline.</li> <li>• Family physician researchers are being recruited to industry.</li> <li>• Continued difficulty for young researchers to move from moderate to big studies.</li> </ul>	<ul style="list-style-type: none"> <li>• Develop and nurture a network of researchers.</li> <li>• Develop very efficient and effective organizational structure and management capacity to administer federal research grants.</li> <li>• Develop capacity for efficient implementation of complex projects.</li> </ul>
Collaborating PBRNs	<ul style="list-style-type: none"> <li>• Academic Departments</li> <li>• State Academies of the AAFP</li> </ul>	<ul style="list-style-type: none"> <li>• Increased pressure on academic departments to teach and see patients. This decreases the supply of academic-based researchers for our networks.</li> <li>• Sparse infrastructure funding for 20+ PBRNs in family practice.</li> </ul>	<ul style="list-style-type: none"> <li>• Lack of critical mass of researchers in PBRNs requires development of very efficient virtual knowledge teams.</li> <li>• Collaborate to share infrastructure resources.</li> <li>• PBRNs must collaborate to achieve adequate infrastructure.</li> <li>• PBRNs must collaborate to achieve critical mass for truly significant studies.</li> </ul>

**TABLE 3. (Continued)**

<i>Resources needed for PBRNs</i>	<i>Environment in which resources exist</i>	<i>Health care trends in the environment</i>	<i>Considerations for strategic action</i>
Advocates for practice-based research	<ul style="list-style-type: none"> <li>• Policy environment</li> </ul>	<ul style="list-style-type: none"> <li>• Continued backlash against primary care specialists.</li> <li>• AAFP initiative to enhance family practice research.</li> <li>• Continued push for nurses and others to be primary care clinicians.</li> </ul>	<ul style="list-style-type: none"> <li>• Continue to find new ways to unite practice and research (and possibly delivery systems).</li> <li>• Develop capacity for rapid turnaround studies of great policy relevance to family practice.</li> <li>• Make generation of new knowledge from practice settings a relevant and regular activity of both trainees and practicing physicians.</li> <li>• Develop commitments to make family practice a learning specialty.</li> </ul>
Avenues for dissemination of research results	<ul style="list-style-type: none"> <li>• Family practice journals</li> <li>• Other medical journals</li> <li>• Electronic and new media (CD, Internet, cable)</li> </ul>	<ul style="list-style-type: none"> <li>• Marked decreases in advertising revenue for journals.</li> <li>• Technology for low-cost electronic publishing.</li> <li>• Push-pull technology in cable television.</li> <li>• NLM open to indexing electronic publications.</li> </ul>	<ul style="list-style-type: none"> <li>• Expand dissemination of PBRN research results through use of electronic media.</li> <li>• Collaborate with <i>JFP</i> in expanding publication of results from PBRNs.</li> </ul>
Patients	<ul style="list-style-type: none"> <li>• Home community practice</li> </ul>	<ul style="list-style-type: none"> <li>• Large numbers of patients remained uninsured and underinsured.</li> <li>• Patients are baffled by complexity of health care system.</li> <li>• Patient trust in the system (and possibly in physicians) is waning.</li> </ul>	<ul style="list-style-type: none"> <li>• Publish selected research results in lay press and periodicals.</li> <li>• Explore strategies for involving patients in PBRN research agendas.</li> </ul>

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# The View From the Outside: Government

CAROLYN M. CLANCY, M.D.  
*Director, Center for Outcomes and  
Effectiveness Research, Agency for Health  
Care Policy and Research*

I am a primary care internist, which Dr. Peter Franks used to tell me in so many words was something like being a bio-medically correct family physician. However, I have had the opportunity to work with and be influenced by many of you in this room, so I don't think that I will say anything too impolite.

I first want to congratulate the Academy and the Task Force for creating this opportunity to look at the successes and opportunities for improvement in practice-based research. This evaluation is something we have been doing a lot of internally at the agency — focusing a bit more effort recently on outcome research, but beginning to do it in primary care research as well.

This sounds like a fairly simple, straightforward exercise, except in this country we don't have really much precedent for evaluating the output of research investments. We have always assumed that publication was a good idea. But, increasingly, the Agency for Health Care Policy and Research (AHCPR) and even the National Institutes of Health (NIH) are under pressure from Congress —

our sponsor — to answer the question of why the taxpayers are better off as a result of this investment. I know a lot of you have mentioned the “poster child” problem today. There is a reason why Arethra Franklin is in town today with other bright, shining stars on behalf of cancer research. So, more and more, the challenge for all of us is to be able to answer the question, “What problem is this research solving?” Not why the research is so good, in and of itself.

## Update on the AHCPR

I want to just give you a couple of brief updates on the AHCPR because people want to know about funding right at the outset. And then I want to tell you about my effort to do sort of an evidence-based assessment of the practice-based research projects that have been reviewed by our study section. Then, I want to conclude by telling what we need from you.

First a brief update on the AHCPR. Many of you may know that we are up for reauthorization, which actually Senator Frist is still trying to push through even though it is not, as you have probably figured out, the most important topic in Washington these days. We would like to think that it is in the top five, but definitely not number one.

If this reauthorization bill goes through, the Agency's name will be changed to the Agency for Health Care Research and

Quality, that is, AHRQ (healthcare is one word, in that case). Right now, it looks like — whether our name changes or not — we are going to have a 17 percent increase in our budget for a new high of \$171 million. That is all good news. In the new reauthorized bill, there is a great deal of emphasis on the Center for Primary Care Research, thanks in no small part to both the Academy as well as Andrew Balas, who worked for Senator Frist this year.

#### **AHCPR review of research projects**

Moving on to an evidence-based assessment of practice-based research projects that have been reviewed by the AHCPR (and acknowledging all the shortcomings of the review process that Dr. Don Iverson mentioned this morning), the first observation is that the stack of summary statements is not that high. While they are double-sided, they are not even an inch high. So what that says to me is that not a great many projects are coming in, and this goes back about 10 years.

Some recurrent themes come up in reviews, regardless of subject matter. The first is how representative are patients and providers. I know a lot of the networks in this room as well as networks in other specialties have been struggling with ways of addressing that question. A second issue relates to selection bias, is there complete ascertainment if you are doing a prospective clinical study? Is there a measurement bias related to when doctors assess outcomes from their own patients? Will important events be missed?

A third methodological issue that has not come up today, and people have gotten a lot smarter about, is what is the right unit of analysis? Are you studying groups or are you studying doctors? Are you studying patients? Are you sometimes doing some of each, and can you be very clear about that in a limited space or on an application?

Another issue that comes up all the time, and that we don't have any good answers for at all, is what are the incentives for

participation? We have been talking about it here today in much more lofty terms such as collegial interaction instead of a learning discipline, and so forth. The issues that comes up before the study section are usually like, "Is \$20 per patient too much? And who ought to get that?" Does that bias people who work in the practice, particularly support staffing, and enroll too many people? To be honest, we do not know the right answers. It seems to be that the collective wisdom in this room might actually be able to review some of the strategies the different networks use, and it would be very helpful to us.

A fifth issue relates to feasibility studies. Sometimes we get projects that strike reviewers as very important and interesting, but there is very little pilot data to support how feasible it is going to be in daily practice.

A sixth issue for which we definitely don't have any good answers for, but we have recently gotten a couple of letters about, relates to informed consent when the subject of the study is actually physician behavior. Now, to some extent, many of you assume that by virtue of the way the networks are established enhances the expectation of practitioner involvement and participation. Do people understand this is what is going on here? Again, I think that your wisdom here could help us quite a bit.

Not mentioned in any review whatsoever is the added value of the unique collaboration between researchers and clinicians. I have heard a number of you assert today that you are quite confident that the results of some of these studies — both by virtue of your participation as well as your having read the results — has led to your improving your quality of care. If you could demonstrate that, I can't overemphasize what an important contribution that would be. Broadly speaking, one of the most important initiatives for the department right now (and certainly obviously for an agency that is going to have its name changed to the Agency for Healthcare Research and Quality) is actually how to translate what we know

from research and practice. We have a mountain of evidence much higher than the pile of summary statements to show that we are not very good at it. By and large, when we look at successes, most of the time, they are hospital-based studies, because once you get all the right people around the table, you actually have a common order sheet. You've got a vehicle to make this happen. How to make this happen in outpatient care — where you have decentralized networks or arrangements of clinicians — is less obvious. So, if you can come up with any evidence that shows the participation in networks improve the quality of care, we need it and we need it now. It is very important.

### **How you can help**

I want to conclude by talking about how you can help us. At the AHCPR, John Eisenberg, our administrator, and I are certain that everybody in the Center for Primary Care Research believes very strongly in the concept of “centers of excellence.” So, when I hear all of you talking about the need for infrastructure support, we're sold. My problem is, I don't exactly know what it looks like.

There's very, very little in the literature for arthritis and cancer centers ... you name the kind of research center. There is very little evidence of what that right constellation of resources and infrastructure support should be to enhance research productivity. Many of those activities, I would suggest, are actually much easier than primary care research. So to the extent that this group, the Task Force or anyone else can help us come up with some of the answers to that question, it would be very helpful. Resources obviously are needed to do that, but right now I don't know what that would be like. So, developing that blueprint, I think, is very important.

A big question that has been eluded to by a number of others, but certainly comes up in the subtext of review group discussions and, frankly, in our own internal conversations as we try to come up with clever

concept ideas while developing future budgets is, “What is the primary purpose of networks?”

Are they used to describe practice? That's easy. I can actually suggest to policy makers that what we need is a Nielsen index for clinical practice in the United States. They can understand that. Or, are they going to be subjects of intervention? There is a real tension there, and I don't think that I have heard people push hard enough on that. Because obviously if you intervene, and are very successful, then you get back to the question of how representative is the group that you are using?

I don't think these are unsolvable questions. I know that the American Psychiatric Association's Practicing Research Network has come up with some clever strategies to sort of replace some practices from a randomly-selected pool, but I think it is that kind of methods question that we need to push much further on.

Some of the other issues that we are struggling with are going to be privacy of data. I know anyone here from Minnesota is acutely aware of this problem. I know Institutional Review Boards (IRBs) are a big, big issue for all of you and it is an issue that we would like to work with you on.

I heard a little bit about dissemination today and I heard that some people's fears, concerns or beliefs are that family physicians don't read. Actually that is probably not so surprising, I mean Dave Sackett is in Britain doing studies showing that people read 10 minutes a week. That is actually the good group. The other questions are, what are the information needs? And if people aren't reading the *JFPR* and other research journals, then where are they getting their information? It seems to me that you do have a critically important resource to help us answer some of those questions. In our Center for Primary Care Research, we imagine that we are supporting research that will have an impact on practitioners and ultimately on patient care and outcomes. But we don't really have any idea about the answer

to that question. Together I think that we need to attack these issues to develop better methods for improving practice.

The other question I have for you is, again thinking about the issue of quality

improvement and ambulatory care, is there one in 10 in your networks who is the opinion leader for practice? I don't know. It is just a question that I would love to have some answers for.

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## The View From the Outside: Industry

HUGH H. TILSON, M.D.  
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Park, N.C.*

I want to say three things to start off. First, I come from North Carolina and I would like to profess that the only good thing that tobacco has ever brought us is tobacco auctioneers who talk faster than I do. It makes me feel a little less bad about it. Second, it turns out that John F. Kennedy used to speak at exactly this rate. The only difference was that he and the tobacco auctioneer had more to say than I do. The third apology here is that I am Hugh Tilson, M.D., Dr.P.H. I am apologizing only to Dr. Mary Croughan-Minihane. I am a recovering epidemiologist. You know that I am a pharmaco-epidemiologist; I practice pharmaco-epidemiology. For those of you who are curious about that, it is correct. That is 20 letters, 10 syllables, 9 vowels and a "y." Pharmaco-epidemiology. There are very few of us because no one can say it that fast.

First a word from my sponsor. You are hearing, of course, from a vested interest in the pharmaceutical industry. Now, I should point out that I am the immediate past president of the American College of Preventive

Medicine (ACPM). They could have been sponsoring me. Dr. Copeland and I were commiserating about how we spend our Sundays as presidents of national/professional societies, and it turns out that it is exhilarating. As Lanny was saying, what an extraordinary day it has been. I told him he is in for a great ride as president of a national society — this one with this agenda is really quite remarkable. But I am not going to talk about the ACPM except to say that preventive medicine is one of America's primary health care specialties. We are partners and friends and have many common interests, particularly starting from the perspective of the community in recognizing that it is made up of individual patients. Primary care research is part and parcel of what the ACPM is interested in.

I am actually speaking from the perspective of chair or immediate past chair of the clinical steering committee of the Pharmaceutical Research and Manufacturers of America (PhARMA), because for the last 15 years I have been practicing public health in the private sector working in a drug company, a large multi-national, co-educational pharmaceutical company with its U.S. headquarters based in Research Triangle Park and its world headquarters based in London.

I guess my first perspective is that what you are doing here today is not a U.S. issue

at all. These issues are global and are shared by our primary health care practitioners and researcher friends all around the world. Some of the most exhilarating research experiences I've had being an international pharmaco-epidemiologist have come from working with the GP Research Database in the U.K. I won't begin to try and tell you all of those tales in the short time that I have. Allan Dean, the progenitor and hero of this saga, ought to be here telling you about it, but he's not. Therefore, I share a little bit of what I've learned working with that database, which is simultaneously a very rich database and electronic medical records based one, like the one that you are hearing about from our Charleston colleague. Also our GP Research Network uses that database and expands and collects further data around it, and so come some very exciting stories in my experience with the pharmaceutical industry.

#### **Pharmaceutical development needs**

It has to be clear to you that no one would speak for the pharmaceutical industry, and I would not presume to do so here or anywhere, but certainly I have a few perspectives from this experience. They are this: The pharmaceutical industry needs evidence in order to be able to develop, market and sell drugs (see *Table 1*). It needs help in order to be able to facilitate its objective, which is not to get new drugs approved, but to get needed, new medicines into practice in an effective way so that people can benefit from their products. I hope that didn't sound like a report from a shill, trying to sell you the pharmaceutical industry. I am scarcely that. What I am is someone, who after working there for 15 years, no longer sees himself as the adversary or enemy. I don't take "drug money." I heard it from the platform even today: "We don't get involved with things like that." Believe me, I used to say the same things, but I think that is wrong-headed and I would like to spend a few minutes telling you why, and why I think, as we've heard today, the pharmaceutical industry

**TABLE 1. Pharmaceutical development needs**

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Pre-Development
• Market characteristics
• Burden of illness
• Drug utilization
• Economics
Development — The Three Phases
• Randomized trials
• Companion data and modeling
• Actual use for projections
• Utilities/Quality of life
Marketing — Phase IV
• Experience
• Utilization
• Effectiveness
• Outcomes
• Post-marketing surveillance

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represents at least one of many, but one very fertile area for support for what you are trying to do, and some financial and substantive help in getting it done.

Does the figure 21 billion dollars get your attention? I don't know if you understand billion, or how that is a lot of zeros. That is how much the U.S.-based, multinational, research-based pharmaceutical industry spends in America every year on developing new drugs. That's a lot of money. It should not surprise you, but just so that you know, that the research budget exceeds 20 percent of the total turnover/profits in the industry. They plow 20 percent back into research and development; that's a lot of percents. Higher than any other sector, that I know of, even the high-tech sectors, even computers. So, there is a lot of money there, and a lot of it gets plowed back into R&D. I particularly remember writing down with interest the comment about not doing randomized trials "because we don't want to be somebody else's data collector." That is fair, but I would point out that at least 29.5 percent of this \$21 billion is spent by the industry in clinical research. So, there is a great deal of money to be had there.



And, I will mention one last statistic. I just noticed that you are evidence-based, and so I thought you would be interested in some of these statistics. I always find them interesting. The pharmaceutical industry spends more on R&D than the National Institutes of Health (NIH), just in case you're interested in going after all those ROIs (federally funded research grants). I hope that I have caught your attention. There is a source of funding for what we (notice the pronoun) primary health care researchers want to do.

I really appreciated the trends analysis, and I couldn't agree with it more strongly. The trends are facing the pharmaceutical industry as well. Here, I am quoting from a document that was published by the Center for Medicines Research last year. It is a U.K.-based group (*Table 2*) that looks at medicine research in general. It is a confidential document, so I report it with their permission today. I actually called Stuart Walker and asked if I could talk about it because it was a very revealing document.

There is a series of things that follow here that I hope to quote from briefly, but the table reinforces what you have already heard from Dr. Paul Nutting. Namely that the needs in the pharmaceutical industry for information have changed dramatically since you and I went to medical school — long since I went and even since you went to medical school or public health school.

That is to say, it is not just safety, efficacy and risk factors for safety, not just cost of treatment and drug surveillance and quality of life, which we all sort of think is pretty au courant. Doing quality-of-life research in primary care practices, I think, has a lot of promise and a lot of interest for a lot of pharmaceutical companies who are recognizing that people are willing to take medicines for improvement in their quality of life, even if they don't have any specific clinical indicators of improvement — information that can only be gotten from asking a patient in the natural experiences how he or she is doing. So quality-of-life research clearly is a major vector here.

But those are considered established needs. Look over here at the emerging needs. Again, Dr. Carolyn Clancy always talks about patient characteristics, predicting outcome and how you can adjust treatment to ensure that you are optimizing outcomes in the context of a real practice, so-called effectiveness research. Critical for the pharmaceutical industry in an emerging market place where people are demanding effective drugs, not safe and efficacious drugs. "Effectiveness are us"; that is to say, that is what people who understand primary health care research know that we can do and others cannot. That is, we understand how interventions play out in the real world setting. So, it seems to me, here is an enormous possibility for

**TABLE 2. Established and emerging information needs of pharmaceutical research and development**

<i>Established needs in clinical development</i>	<i>Established needs for marketed drugs</i>	<i>Emerging needs</i>
Efficacy	Cost of treatment relative to cost of other treatments	Patient characteristics predicting outcome and individualization of treatment
Safety	Drug surveillance	Impact on the environment
Risk factors for safety in specific groups	Quality of life	<ul style="list-style-type: none"> <li>• Patient acceptability</li> <li>• Provider acceptability</li> <li>• Cost of delivery</li> <li>• Cost effectiveness</li> </ul>

*Adapted with permission from Gabby and Bax.*

you, where the needs of the pharmaceutical industry and contributions of primary health care research intersect. Patient acceptability — only they can tell you, only you can legitimately ask. Provider acceptability, cost of delivery, cost effectiveness — can those be collected in the primary health care setting? I think so. But I would not just turn to that in Phase IV for some clues. Even before a drug enters into development, drug companies have a lot of research to do that you can help with, I think, and they do not do so very well or very extensively. That's not your fault. I think it is a mutual fault — of not looking for and plowing deeply into the opportunities out there in clinical practice for network-based research.

Marketing characteristic research — marketing research is generally done by marketing firms without asking you or bringing you together and putting you in a focus group. Not using the possibility of network, even for an automated-based focus group. Burden of illness — that is epidemiology. Drug utilization — critical to know before you ever develop a drug whether you would be able to sell it and make enough money so that you could pay back the investment.

What does it cost, per drug, to develop a new drug in America today? \$80 million? \$250 million? \$500 million? Sold to the man in the third row. Five hundred million bucks according to the Center for Drug Development at Tufts. Five hundred million dollars ... and it turns out that only three drugs in 10 that make the marketplace will cover that investment. In case you resent blockbuster drugs, which I used to, recognize that only three of 10 are ever going to recoup the average investment, and that is how the drug companies make their money back.

Within development there are three phases: Phase I, Phase II and Phase III. Randomized trials, of course, which you may or may not want to get involved with; there is big money there. But perhaps better done in other settings where you are asking not effectiveness questions but efficacy questions, sort of in the rarefied hot house of

the academic department of clinical pharmacology and departments where there are patients that you don't even know exist. No, they don't smoke; they don't drink; they don't have much sex. They don't have much of a life, as far as I can tell, except to come into medical schools and get drugs tested on them. That's probably not you or your patients.

But what is you is understanding projections on your clinical experience so that one can model actual experience. So that when formulary discussions come up, for example, then what one can talk about is the likely fiscal impact on a group or practitioners. I have already mentioned quality of life. Phase IV is everything else. It is what you can learn from drug experience after a drug is marketed. You all know this by heart, but let me just tell you there is enormous interest in an investment in doing something much better about studying the effectiveness of medications and the link between medication treatment and important outcomes; long-term outcomes and outcomes that cannot be studied in a randomized trial including, of course, safety outcomes. There is a great head of steam about this particularly right now.

Those of you who read the April 1998 issue of *JAMA* know that the pharmaceutical industry, and everyone else, was given a little April fool's surprise in an article that said hospital-associated adverse reactions from drugs are the fourth leading cause of death in hospitalized patients in America today. Is it true? Is it not? Is it a bad study or is it irrelevant? The fact of the matter is that people are nervous about drug-associated adverse reactions following marketing in your practices. Can that be monitored by a physician practice network system? Ah-hah, it sure could. Read the 'net. The Healthy People 2010 objectives are out in their draft form. They are out there for your review and comment. Turn to Section 13, Medication Associated Events; turn to Outcome Objective 1. Twenty million patients will be under surveillance using large automated

population-based multi-purpose database approaches by the year 2010. Is that you? It could be.

### **The GP Research Database experience**

Finally then, a few comments about a wonderful trip that I had in the last 15 years using GP data in the U.K. The GP Research Database in the U.K., about 300 to 400 practices, about 1000 physicians with about 3.5 million covered lives for which there is an electronic medical record available for every patient put together by a group that had a lot of vision, called Vamp Vision, which is what they called themselves. I was there the day they decided to do this. That was an enormously exciting adventure where they gave computers to doctors saying, "This is just to automate your medical records; send us the floppies and we will analyze them every quarter and send it back to you for patient profiles. And we will of course sell the data to the pharmaceutical industry and other possible users for research."

For those of you interested in funding of such ventures, I would point out that Vamp Vision has long since entered bankruptcy. But the database survives, through several iterations bought by Rogers and bought by the National Health Service and the Office of Health Statistics in the U.K. and exists for primary care office-based research. The data are extraordinarily rich — every encounter, every indication, every prescription. Patient bit by an otter; patient having a hard time in her marriage; patient hospitalized. With a referral note, always recorded. GPs just do that. Protocol driven. They just do that. When the notes come back, they always enter the diagnosis and any dispositions. When the patient is hospitalized, ditto. The data are rich and the data are useful. If you want to know whether a new drug is associated with an adverse event that is occurring less frequently than one in 10,000 patients, you've got to have 20,000 to 30,000 persons in that database exposed to that drug — perhaps in circumstances other than those in clinical trials. They are there when you have 3.5

million persons in such a database, as they also are in Dr. Joe Selby's database. As they will be as our nation moves from five to 10 percent electronic medical records-supported primary care to where the visionaries say we will be in 10 years, which is about 50 percent.

I've done about 20 studies using the GP Research Database. Obvious ones: Acyclovir was a product that Burroughs Wellcome developed and was a nucleoside analogue. We didn't know whether it would be associated with major adversity out there. We didn't think it would be from all the clinical trials and so forth. We all know in epidemiology that rare things happen rarely and sometimes they are very bad and sometimes they result in drug recalls and major pharmaceutically-associated epidemics. So, we just contracted with a series of large automated population-based, multi-purpose databases — one of them was the GP Research database — to see if anything adverse was happening.

We looked at every pregnancy exposure and looked at birth defects occurring in the population. Nobody had to do anything here. All they had to do was collect the data, but then if we found something, the GPs who agreed to be research GPs would get in the network mode and would look into the database — they would look into their hospital discharge summary data and would tell us exactly what was in there. So it is a cooperating research enterprise. We actually found a signal in one database. And then we rapidly went to the GP Research Database, where we didn't find it. Therefore, we were relatively assured that it was an anomaly and were able to hold the course and wait until next year. Sure enough, the signal went away and it was just what happens at the right-hand side of a normal distribution every once in a while. You get excesses in things that are not causal, just cluster.

### **The way forward**

So, your uphill battle here has somebody up here, pulling you. Not just somebody down

there saying, don't worry. I would submit to you that it is a good time for us to go back and look together — the pharmaceutical industry and the primary health care research community, at where we can do a better job to harness what we know we can learn in primary practice and what pharmaceutical companies need to know but have

never been terribly creative about finding. There are a lot of accumulated experiences already out there and, therefore, my proposed way forward involves some new partnerships with you for which I think the pharmaceutical industry will be very receptive over the next couple of years.

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# The View From the Outside: Managed Care Organization

GEORGE ISHAM, M.D.  
*Medical Director and Chief Health Officer,  
Health Partners, Minneapolis, Minn.*

**I** will do four things today. One, I will make some comments about trends in managed care, which will be brief because of Dr. Paul Nutting's excellent comments on some of the trends in the environment. Second, I will talk about research from the perspective of managed care and make some observations about that. Third, I will offer you some of my own observations about money and funding, since that is what managed care is purportedly about. Then lastly, I cannot resist the opportunity to offer you some specific advice, since you asked me here as a guest. I won't disappoint you in that.

## **Managed care issues**

At the end of 1995 there were 13,015 registered managed care organizations (MCOs) covering about 151 million Americans. This represents dramatic growth in enrollment. Most of that growth has been in the looser forms of managed care. The independent practice associations (IPAs) form where individual physicians are contracted with preferred provider organizations (PPOs) and

point of service products. The group staff component, which is the original MCO, that goes back to the 1930s and 1940s, has been relatively flat in terms of total enrollment, and have declined to about 10 percent of the total of what is now managed care. The organization that I come from, Health Partners, is one of those group staff organizations, and Dr. Joe Selby talked this morning about Kaiser, which is also one of those organizations. So my first reaction is a little bit of a schizophrenic episode. I am trying to figure out whether I am hurricane George, an external thing that is blowing in and threatening your family PBRN or whether I am threatened too, because of our family physicians and our own research efforts.

First, let me mention some of the key features of managed care that I think are relevant to research. One is a positive proactive enrollment process with members, unlike other forms of health insurance. People sign up, records are created, and you have the opportunity to do health/risk assessment. You know the total denominator of the population you are working with. That has been a marked advance for quality assurance and utilization management because you can get rates per thousand of this and that. But, there are also tremendous advantages when you are looking at total populations of people. Although it is easy to forget, it's key to

remember that knowing the total enrolled population is one of the most important characteristics of MCOs for research.

Second, you have a defined network of providers. You've signed them up and you've contracted with them. It is a fairly fixed network of providers. It is unlike previous insurance arrangements in which just about anybody who sent in a bill, and was licensed, would get paid. That defined network of providers affords the opportunity to develop a relationship and it affords the opportunity to collect transactional data linked to providers and other opportunities.

Third, there are administrative and clinical data systems that didn't really exist before. In other words, you have claims information on the population, and you have the opportunity to develop clinical and other databases for the entire population.

Fourth, something that is not always regarded as an advantage, there is the opportunity for proactive management of what happens to the population. Sometimes that is seen as hassle factor, and sometimes it is seen as an opportunity to improve care.

Now some of the issues, and I will mention these only briefly because Dr. Nutting did such a nice job of bringing some of them to your attention. One is the tremendous shift to group practice and employed status by physicians. This is a larger trend among physicians that I think is just a tremendous influence on what will happen in the future. And so, we're seeing more and more physicians in group practices, in particular in the upper Midwest and Minnesota, which has a high percentage of nonfederal physicians in group practice.

We're seeing that most physicians are in fact employed rather than individual entrepreneurs. I realize that is a regional difference in some. So, for example, in the District of Columbia, and out here on the east coast, physicians are not as aggregated in groups. I do, however, think that it is a trend that is not going to reverse itself. I think in the future more and more physicians will be part of organizations. So the unit of analysis

issues that Dr. Clancy raised, I think, are particularly important for an association such as this with a research network as you have constructed it. Who will be in and who will be out? Is this always going to be just independent physicians, independently constituted, or will your relationship be to those organized forms of group practice?

I am a primary care physician by training, background, emotion and passion. I used to think that the gate-keeper concept, and primary care, was the right and only way that care was to be given. In the last couple of years, I have come to doubt that for a couple of reasons: first, because I think the potential for improving care using technology (either telephone-based technology and the knowledge of specialist applied to individual patients through the Internet or through telephones) will compete substantially with one-to-one visit-based care. I am beginning to doubt whether the future of primary care still involves the gate-keeper, primary care type of network.

Second, the consumer trend that has been mentioned is substantial and profound. I think we need to understand that people who are going to seek care are going to newer forms of information distribution. These patients are going to be more challenging to their physicians and are not going to be the ignorant dependent part of a one-way relationship with someone who is highly trained. The relationship of the future will be more equal. I think that those two trends pose a challenge to primary care physicians of all types and in particular to family physicians. They need to be contemplated as you think about putting together research networks. Are the variables only what happens to the patient, the clinical outcomes and so forth, or indeed are you, the primary care providers, one of the variables that will be manipulated in terms of providing better care?

#### **Managed care and research**

Looking at research and MCOs, the article "The State of Research Within Managed

Care Plans, 1997 Survey” in *Health Affairs* in early 1998 gives some insight into MCO research.<sup>1</sup> The authors looked at the research activities within managed care plans and identified 24 research organizations affiliated with 100 managed care plans. Remember, there are 13,015, so less than a tenth of the MCOs in the country have formal research activities. These represent 29 million members, about 19 percent of the 151 million members that we identified earlier.

There are 158 FTE career researchers, of whom 40 are physicians. I know several who are family physicians. One hundred are Ph.D.s and 18 have other research training. There are 849 FTEs of other research staff. The types of research that are carried on in the 20 centers that responded to the survey include 19 centers with health services research, epidemiology in 15 centers; health economics in 14; clinical trials in 14; applied clinical research in 11; basic research in 4; animal research in 2.

The interests of the researchers included a long list, and they ranged from 68 responses at the top, to 5 at the bottom. I will just read some of these so that you can get a feel for the types of interests that the researchers have. Epidemiology is at the top of the list, 68; chronic disease, 63; disease prevention, 55; women’s health, 45; utilization and cost, 40; and then mental health, clinical guidelines, cardiovascular disease, geriatrics, diabetes mellitus, cancer screening and so forth on down to work force issues for 5.

Funding sources for this group included a total of \$92 million annually; \$70 million of which is external funding from either federal/state, foundations, industry donations or other; \$22 million of which comes from sources internal to the MCOs. This is about 76 percent external funding, 24 percent internal. Internal funding goes to support the core functions of those research centers and reinforce all the comments that have been made about the need for core funding to sustain research activities within networks.

Why would an MCO want to do this?

Well, 14 of 20 of these organizations are not for profit; 6 of 20 are for profit. They often reflect the commitment of the organization to social needs and the growth of medical knowledge as reflected mission statements. They are interested in stimulation and retention of clinicians as a support for their intellectual growth and learning. They are interested in innovation and improvement and care delivery. They are interested in program evaluation in looking at cost and utilization issues to inform decision making. They are interested in leadership and shaping the larger health care world in which these MCOs must function. They are interested in managing requests from outside organizations for access to managed care populations for data and research purposes.

Some barriers, rapid marketplace change and instability in organizations caused by mergers, are disruptive to the research projects. Increased pressure for productivity in terms of efficiency of care delivery is a big problem in these environments, as I know they are in yours. Uncertain and fluctuating funding streams for new, small and developing research organizations are a problem. Cost-cutting makes the research difficult; competition leads to less openness; and confidentiality is a huge concern.

### **Funding**

Here are some concerns and observations about funding. One, an organization that funds care delivery primarily — and that’s what managed care does — cannot fund inefficiencies in care delivery in a competitive market, or it will be driven from the market. You can’t fund out of care delivery funds, either direct and indirect research costs, or education. In the economic sense that ought to be funded out of tax or donations or philanthropy. The research funding that comes from MCOs comes from the bottom line, or from the balance sheet, and represents the commitment of those organizations to fund research. It is only coming from some but not all of the universe of MCOs. So that every dollar that goes into it

is a potential dollar that makes those organizations less competitive in the marketplace and may result in them going out of business. They reflect a "Mission Dividend" for those not-for-profit organizations that represent a substantial commitment of those organizations developing new knowledge.

### **Conclusions and advice**

I think the AAFP should think about collaboration and developing relationships and partnerships. With MCOs, if you have a research project that you have in mind, it will be easier to get MCO cooperation within the context to an existing relationship. I want to reiterate there are two flavors of managed care: the 10 percent that are the integrated delivery systems, and the 90 percent that are not. You need to approach both.

Some cautions: Confidentiality. It is a very serious concern and is one that any group that is thinking about practice-based research needs to be knowledgeable about, needs to be thinking about and needs to be working on. Your strategies must also incorporate those organizational relationships that are group practice and managed care.

I think you need to beware of the Copernican dilemma. Copernicus was the fellow who was concerned with whether the sun moved around the earth or if the earth moved around the sun. Family practice (read internal medicine, read obstetrics and gynecology, read pediatrics) may not be the center of the universe around which all

emotions and questions revolve. You may want to think about the act of delivering excellent primary care. So, I would ask you to beware of the Copernican dilemma and be continuously asking yourself whether the world revolves around your notion of family practice, primary care research networks, or whether you need to be thinking about how you can contribute to better primary care in general.

Communicate. I see the potential here for communication among my colleagues who are less aware of your initiatives than they should be. I know that from attending this day-long process. I am willing to work with your representatives to do what I can to open up communication channels, a lot of which are going to be useful to us and to my constituency.

Finally, be aware of the fact that the world is not necessarily one of science. I have become more and more aware of that fact in working with consumers and the public that the end point may not be just good science. When you turn up with it, the American public may reject that for some other notion of what it wants, and we do need to be aware of that.

### **Reference**

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1. Nelson A, Kwitter E, Solberg L. The state of research within managed care plans, 1997 survey. *Health Affairs* 1998;17(1):24-31.



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## Observational Comments and Questions and Answers

**Dr. David Hahn to Dr. Hugh Tilson:** Could you expand on the general transition of the pharmaceutical industry from focusing on marketing a pill to marketing disease management, and how that could impact research opportunities?

**Dr. Hugh Tilson:** Your question, of course, embodies an answer, which is that the pharmaceutical industry is converting from selling a pill to selling a set of services around pharmacotherapy, called disease management, care management, etc.

But it is not new, is it? In the old days, the oldest days I can remember, the first detail I ever had from a pharmaceutical company representative was when the person helped me understand the disease I was treating, and the reason this drug was better than the other, and what the other drugs were, and so forth. So, it is an old approach, now much more comprehensive because we are learning a lot more about the components of care that matter, and/or the component of care in which good pharmacotherapy can achieve its objectives.

Now, how does that tie back into practice-based research? Well, obviously we're learning more about it because we're looking in practices where it is being put together in different components. And those components are not available in almost all processes

of drug development. There are things that we learn as we look at the way doctors practice. So, I think that is an enormous contribution. First, disease management is here to stay. It is a good thing. It helps us to use drugs better. Second, drug companies are willing to invest in it. Third, it involves an understanding of practice-based experience, which is something that a practice network could contribute to.

**Dr. Hahn to Dr. George Isham:** Would you expand on the six for-profits that are actually spending money on research? I would like to hear about that.

**Dr. Isham to Dr. Hahn:** Are you asking what types of organizations are in that for-profit category?

**Dr. Hahn:** I have been under the impression, based on my experience, that one of those six organizations might actually be mine. Unfortunately, we have been unable to convince our physician-owned group to invest in meaningful clinical research. But if there are five other organizations who have succeeded, I'd like to learn more.

**Dr. Isham:** I can think of the Prudential Center for Research, which reflects corporate, sort of social commitment. I can think

of Loveless, which is owned by Cigna, which is number two. United Health Care, which I know is in the survey, which has a research-based organization, clearly for-profit and stock-owned. I think there are also probably organizations that are like Dean Clinic, which may be more physician governed, who are technically for-profit, where it is not necessarily a stock large ownership. The impetus to be in research is either for research and development (which a number of United Health Care and some of the others, and even the not-for-profits are) or a manifestation of social commitment (that I think is reflected even in some of the for-profits, not very often, and then in the not-for-profits; however, it is not the majority of the not-for-profits, either). So, if that helps you to understand it.

**Dr. Hahn:** The misunderstanding is the for-profits versus the physician-owned organizations.

**Dr. Isham:** There are two different dimensions. You have to say group practice, physician owned and even not-for-profit. You will have more consumer really dominate in terms of boards of directors or you want directed, that's another dimension.

**Dr. Carolyn Clancy:** Can I ask a provocative question? If managed care organizations that invested in research did better on HEDIS scores, would that be an incentive for plans, do you think?

**Dr. Isham:** I would like to think it was. If you notice that most of the organizations who are at the top of the *U.S. News and World Report* list are not-for-profit organizations, and they happen to be there because they are the ones with research. Now, what we know is that some organizations are beginning to buy health benefits based on that ... some, but not very many, particularly the large national purchasers, and from our own marketing staff in Minneapolis. It is a requirement that we report that data to

many of our large accounts. But, I think the major driver is still cost, and it still will be cost. So it is not an all or none kind of thing. It is not totally pessimistic, Carolyn. But the dynamic is still there.

**Dr. Steve Spann:** I wanted to ask Hugh and George what specifically you would suggest in terms of venues for the AAFP to begin conversations with the pharmaceutical industry and the managed care industry about collaborative efforts ... real concrete suggestions about how to get those conversations started.

**Dr. Tilson:** I have a couple that I want to be sure to call to your attention. The basic venue is the Pharmaceutical Research and Manufacturer's of America; they have a Washington, D.C., office, they have a set of standing committees, and they have appointed liaisons across medical specialty areas. We need to be sure that liaison with the AAFP is working because it is much needed. There is one with the American College of Preventive Medicine, I can assure you, and with some other specialty areas as well.

Second, there is a group of friends, colleagues, fellow practitioners and researchers about whom you are probably not aware, at least most of you are not, but you should be. These include the American Academy of Pharmaceutical Physicians. This is a group that was spun off from PhRMA. It was a group of doctors within PhRMA who were interested in quality of medical care, quality medical practice, and medical ethics as they applied within the pharmaceutical area, but who felt that while they were still inside PhRMA, perhaps they could not achieve the sector objectives that they wanted. They formed a separate association or academy, which is actually now a majority membership from academia and practice, and quite active from government as well.

I commend the American Academy of Pharmaceutical Physicians as a second group particularly because they will also be at the triple S meetings, and the AMA where the

AAFP and the pharmaceutical physicians will have some common agendas. For example, the confidentiality agenda is very high on the AAPP list.

The third venue that I would call to your attention, just briefly, is an effort called CDDI. That is the Collaborative Drug Development Initiative, put together by PhRMA, the FDA and academia, led by Georgetown under the leadership of Professor Carl Peck (erstwhile of the FDA, now professor of pharmacology and drug development at Georgetown). This collaboration is looking at ways to make the enterprise more interactive and develop new partnerships. This group's (the AAFP's) efforts need to be called to the attention of that group, quite actively. I will commit personally to doing it, but I suspect that your Washington, D.C., office will. I know they are because I saw them writing it down. We will be sure that you are known to that effort as well.

**Dr. Isham:** I also would be very personally committed to making that connection, because I think it is important. I think there are family practice physicians who are in these research networks, and who are doing this kind of research, and who are in practice, who are investigators that I know are known to you, and need to be connected. Certainly the industry connections are not a great deal in number. I would be very personally committed to making that connection. It is very, very important for us to make that effort.

**Dr. Tilson:** It would be very useful for us to talk, perhaps one-on-one immediately, about the planned forum that is going to happen at AMA in Honolulu in December, which is going to be looking at institutional review boards and confidentiality. Because I think that this network ought to be represented there.

**Dr. Barbara Yawn:** I'll make one quick comment about individuals working with the

pharmaceutical industry. I make this reluctantly because the pharmaceutical industry has been the major support for my research for the last five years, and the only reason I make it reluctantly is that I am not sure that I want everybody else in the act.

The first comment you made about developing the background information; a lot of time this is done by a department of epidemiology within the pharmaceutical firm. People want to know how do you get to work with more Ph.D. epidemiologists? Well, I collaborate with the Ph.D. epidemiologist in the pharmaceutical firm, and we design a study together, hopefully not even knowing what the drug does or if there really ever was a drug. Of course, there always is, but it is way out there somewhere. So, it is a way to do it.

I wanted to ask Carolyn a question: You gave us several charges, which I appreciate very much, but I am going to turn around and ask is there going to be any funding? You asked IOM to do one of these things. Were you going to pay IOM and are you considering funding for some other group to identify this blueprint for the centers of excellence for example?

**Dr. Carolyn Clancy:** We could certainly talk about some support for reviewing the evidence about a variety of dimensions of PBRNs. That would be something we would have to discuss. I would be happy to do that. I also wanted to follow up with two other points. One is, a lot of people here in this room are connected to an international network of researchers. Someone mentioned earlier that United Kingdom has invested a lot in primary care research and so forth. To the extent that there is any evidence from there, I think that would also be a very useful source in terms of what is the return on investment, so to speak.

The second comment was to Dr. Michael Fleming. It is actually fairly surprising how many people that we fund directly don't actually even tell us about their publications. That is sort of a momentary courtesy, and I

think that technically you sign a form somewhere that says you will do that. But more to the point, I mean, the Academy actually calls us — not for the publications — for sound-bites. What they need is information on what it means, and what they can tell a congressional aide if they run into them in the cafeteria line, which means they have about 30 seconds to slam the point home. Now, to be really honest, I think that a lot of researchers actually have trouble distilling it down to that. But boy, if you let me know where it is, and make a start, I've got good dissemination people who can help. And it doesn't even have to be about what AHCPR has funded. If you have got any evidence that the research made a difference, we really need it. But, it is very, very hard for us to find it. It is certainly no easier for us. Because all we can do is to call people up, but it is critically important.

I thought your point was about the fact that some very senior people there carry your publications around is very important. It is true for all funders. RWJ is now spending a ton of money actually trying to do this because their researchers have a hard time doing it.

**Dr. Jim Mold to Dr. Clancy:** As we all know, among ourselves — whether we acknowledge to you all or not — that these are not representative practices that are involved in these networks. The question is, to what degree is that a problem? A lot of the research that is done in other areas you do not demand of other folks, so why are you demanding that of us?

**Dr. Clancy:** The question comes up then, what kinds of questions are uniquely suited and in what ways is the group of people that you are dealing with, both the practitioners and patients, not representative and how far off is it? The issue isn't whether we're demanding it of anybody else, the question then becomes for a funder, what is the most efficient way to answer the question, given that you've identified an important question?

So, for instance, one study that I looked at proposed to look at a very important public health problem through PBRNs. One of the comments was, wouldn't a probability sample survey actually have been a better way to get at this. Those are some of the issues that have to be addressed.

**Dr. Mold:** There is an issue that has to do with electronic medical records and the fact that Great Britain has an advantage over us. They have a national health system. It would be wonderful if I could get all my practitioners in my network to purchase the same electronic medical record software program. I could probably do that if I had some matching money that would say if you buy this product, we'll chip in a thousand bucks toward the cost of that. Wouldn't that be a nice source of data for us? We're spending a fair amount of time trying to access billing data and all of this in different software packages and different companies, and it is a nightmare trying to get data from these practices.

**Dr. Tilson:** Allen Dean isn't here, but if he were he would rise up and say we actually automated our practices despite the NHS, not because of it. That is to say, there was no requirement that they automate. They did so for all the right reasons.

**Dr. Paul Frame:** It has been interesting to me that, and I had written that down a couple of talks ago, aside from Steve's talk which obviously does have a common data network — that is the essence in the whole thing — that the issue has not been mentioned up to this point in the day. It is a little bit surprising, actually. Paul, you're running the biggest, diverse network; do you have any ... I mean obviously that is a wish list that you would love to have. Any thoughts on where that is going, feasibility, how can that be achieved? How do you approach that?

**Dr. Paul Nutting:** Well periodically in its history ASPN has taken a hard look at

whether or not now is the time to automate the network. A bunch of times that decision was no, and I think in each of those cases it was the right decision to avert disaster. The right answer isn't always going to be no. We have an information technology task force looking at that right now for 1998 and beyond. What should we be doing? Clearly, nothing is not the right answer. But it isn't clear exactly what we should do, and how we should do it. I think that every network director here would kill for the kind of data that Steve has, whether or not that would be our primary data source for studies or not. I would love to be able to characterize denominators through our practices for any number of reasons in some useful way.

**Unidentified (1):** (Inaudible question.)

**Dr. Roland Goertz:** This question has some potential application for all on the panel. It would occur to me that the dilemma we have is a bit like the artist. Does the artist pursue his agenda in spite of what the consumers want? The question that I am leading to is, if we could have enough qualified researchers in the areas of mutual interest, for example, George, if we had the researchers that could bring to you an idea or model that could save you money in your delivery systems and they are credible, wouldn't you have an interest in funding it? And Carolyn, if we had researchers that had credibility that would present to you issues of which models the future of the government should fund, that would seem to have interest. And these are the same issues about pharmaceuticals. So, is the issue not having enough? Because when I look at having enough credible researchers that compete with the others from internal medicine or pediatrics, or wherever, when I look at that article, and I see a thousand plus get NIH funding who are internists, and that goes to departments, why can't we access those same things? What is the issue here?

**Dr. Isham:** In terms of managed care funding, I've taken some time to lay out how

there are only 20 research operations, and they are located in group staff organizations, which are a minority of the total managed care organizations. The reason that they exist is because there are defined networks there where the bulk of the service is going on. It is associated with that managed care organization. In other words, it is just like your motivation for doing this.

The investment that is going on there is from the reserves that have been created; the treasure that has been saved out of operations. When the board of directors of those organizations have stated we want to do something that meets our social mission. Let's do it for our community. Let's do it with our clinics. It is no different than motivation.

A lot of people look at managed care as a potential banker or donor. I tried to address that, and my other point by saying that, if you fund research out of patient care dollars, you know the amount of money that flows through that you pay for things, and you create an inefficiency when only a small proportion are actually funding research. You create an economic disadvantage that drives you out of a market that is price competitive. And so, you can't do it.

You fund research out of patient care revenue through taxation. It should come from the government, either state or federal; or it should be a tax on everybody. If you talk about taxation, you don't tax at the level of the insured, but you want to tax at the level of uninsured, of self-funded, of general revenue — in order to meet that social need. If you really look at the numbers and you look at what you're talking about, it is really understandable why Health Partners funds research in its own delivery network. When you think about it and just think about it from that prospective.

**Unidentified (2):** ... inaudible ... We believe in a certain model. If indeed that could be proven to be what is most efficient or has the best outcome, which has yet to be proven, then the money should come somehow. The

money should come in a logical sequence to fund that which needs improvement. But we struggle because we haven't gotten there yet. We don't have the funding yet. Instead, we fund specific diseases.

**Dr. Clancy:** I think that is partly correct. I also think that collectively we probably haven't done a good enough job communicating to people how useful the information could be. You know we've done this much and this is how many problems we have solved, and you know with a greater investment we could do even better. I guess for those of you who are interested, John Wasson's research was recently featured in *Hustler* magazine: a fairly graphic illustration — sort of bringing it right to your attention — of what it might mean to you, a man, if you were to have an orchiectomy that might not be necessary. That really puts it front and center what clinical uncertainty means. There is not too much of that. (Laughter)

**Dr. Tilson:** Barbara, is the research that you did proposed by the drug company or proposed by you?

**Dr. Yawn:** Some of both.

**Dr. Tilson:** It seems to me that your question is right on the money, so to speak. Assuming that you're not asking questions that are irrelevant to the funder, then almost all pharmaceutical companies have established programs for investigator-initiated research that relates to the use of their products and specific practice-based experience. Of which, I would guess, the people in this room take far too little advantage. Those protocols are not just for marketed drugs, they often are to understand the diseases in which the company is clearly moving. All of which are matters of clear public record published by PhRMA, proudly I might add. Where you can read it and say, well I am interested in orchiectomy too. And therefore I have a study that might be of interest to you if you are coming up

with a substitute endocrine product, just for example.

**Dr. William Phillips:** I have appreciation and respect for these comments from all the panel members very much. I wanted to see if we could maybe connect the conversation we had before the break with this one. We were still debating, I think, as an article of faith versus evidence, whether or not we want our network members and perhaps most primary care and family physicians to be, if not research-oriented, at least have organized curiosity. However, if it is true that the trends call for all of us to be salaried in the future, to follow clinical practice guidelines, to be evaluated by the kind of quality measures that employers find easiest to buy, and to prescribe from limited formularies determined by someone else, do we really want thoughtful practitioners that have curiosity, or would we rather just have people who get on with it and who get the job done ... thank you very much, don't ask any questions.

**Dr. Isham:** I think in our setting, we probably have more than 100 family physicians in active practice. And we have two M.D. researchers who are family practice and are devoted to this. One of the reasons that we have the research foundation, the 501 CP3 Corporation, is because most of those in practices aspire or think they might at some point want to do it. In fact, we fund some projects that aren't really research that are more about people who have questions and want them answered. In fact, we make very sure that we put some of our own internal money into stimulating and providing doctors who want to answer questions in their practices with methodologic expertise to do that systematically. That is a tremendous incentive for recruiting and retaining physicians who not only want to practice medicine, but have curiosity about what they do. And for many it is a potential advantage that they do not, unfortunately, often use. But the thought that it is there and they could do that is important to many. Some do and

don't really come up to this level, of really peer review, sort of externally funded research.

That is why I've asked the question several times earlier today. I think that we need to encourage something that is systematic observation of inquiry for the nine out of 10 — I think that was the figure that somebody threw out earlier. I think that you have to have a program for those folks that helps them keep their interest up, that responds to an innate curiosity that I hope every physician maintains right to the end. I know that they all care about what is happening to patients and it gives them the opportunity to respond to that. I don't think that is the kind of research that we have been talking about mostly today, but I think that is something that particularly this kind of association that represents family physicians ought to be thinking about and encouraging too.

**Dr. Tilson:** I think you are asking the wrong question. I hear what you are saying, predicting that practice would be like that, and in some places it is like that, but where it is, the trend seems to be going in the other directions. Thanks to the leadership of people like John Eisenberg and others who are advocating for quality, because some of the corollaries are dynamism, non-monolithic approaches, opportunity for physicians to learn as they practice, not just to be filling out some other chef's recipes.

This certainly is the way that it has been in the United Kingdom. The United Kingdom moved the pendulum and went all the way over to we're going to have one set of clinical practice guidelines with only three drugs of choice for the nation. There will only be three; that's all you can prescribe. Fortunately, then you can sleep through your course in clinical pharmacology and just let the guideline tell you what to do. But the general practitioners in the United Kingdom rose up in righteous indignation and said they could not accept that, and moved the guidelines development process all the way back to the same philosophy you're talking

about with practice-based research. That is to say, the best clinical practice guidelines are those that are developed and applied by the people who are actually in practice, and every practice will be different, although they will have a set of criteria that they use for them. And every guideline will be different, although they will be based upon similar principles, and we will learn incrementally. That is to say, they all will be dynamic. Tom Wally is, I guess, the best spokesperson for this in the United Kingdom, and I am very impressed that they are actually winning the day back from this kind of monolithic and mindless approach that none of us want — I don't want to practice in that type of climate and I assume that you don't either.

**Dr. Frame:** Certainly there is a tension between the two forces. I am a believer, as you, in the pendulum. I think one of George's other hats is on the NCQA, and I must say that at least so far, I have been very frightened but very pleased to see that they have only put things for which there is pretty solid evidence in their sort of grading guidelines. But when I see the list of potential new things that may be coming down the line to be looked at, I get scared.

**Dr. Isham:** We just had one of our annual meetings with the medical groups in terms of what they have achieved in the past year relative to our internal measurement system. Ten of those group practices, not the ones that we own and operate but the ones that we have relationships cross contracts, have achieved a 95 percent level with respect of pediatric immunizations, up from 60 percent five years ago. Four have achieved our internal objectives for Pap smear rates in their practices, and I can't remember the other numbers. We have a couple who have begun to have statistically significant improvement in terms of rates, management of their diabetics and their practice. One because they know them, and two because they are looking at them.

I think those are important results, and I

think that kind of systematic approach, which is not research, that is something different, should have been the topic that we were talking about, quite frankly. I think those are achievable. I see that with my own eyes in some practices, and so I have that sort of anecdotal evidence, convinced at that level that it makes a difference. I know it is the reflection of a lot of hard work by physicians who care a lot about what happens in their practices. These results are achieved by clinical leaders; they use the data and it is not research. This is that systematic approach to looking at what they are doing and measuring it. I think that is a wonderful kind of story.

**Dr. Mary Croughan-Minihane:** Just to respond to some of the questions that Dr. Clancy and Dr. Tilson had about the practices in the U.K. I can't speak for the entire

U.K., but at least in terms of England. I think that Paul Nutting has probably played a large role in getting those PBRNs off the ground as the funding did for the national health service. Because, as far as I can tell, every one of those people came to ASPN for consultation and advise on how to get their network started, and they proceeded to go around the country and visit several of the rest of us to see what we did. The difference is that although they are fairly new, and now doing quite well, they were incredibly well supported to get off the ground. I think that is where it will probably respond to Dr. Clancy more, that once you have enough support, and that comes from a central governmental agency, he can see what can happen in five to 10 years, in contrast to those of us who have been working very hard at this and have been scraping by for significantly longer time periods.



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# Section 4

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## **Brainstorming for the Future: Summation and Group Discussion of Conclusions and Lessons Learned from the Conference**

Previous Day Synthesis, WALTER ROSSER, M.D.

Best Strategies for the Use and Growth of Practice-Based Research:  
Reports From the Breakout Sessions

Family Practice Organization and Service Delivery

Natural History of Disease

Clinical Interventions

Panel and Full Group Discussion/Question and Answer

Closure

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## Previous Day Synthesis

WALTER W. ROSSER, M.D.  
*Professor and Chair, Department of  
Family and Community Medicine,  
University of Toronto, Canada*

**T**rying to summarize yesterday's enormously exciting presentations and discussions is a gargantuan task. I will lead off by saying I have tried to attribute every statement to the correct person. I issue an apology up front: I probably have not made the right attributions all the way through. I tried to consolidate things and took some liberty with interpreting what people said.

I divided the presentations into categories, some of which are posed as questions:

1. Why do we need PBRNs? Can they be justified to the public? (I think these are two very important questions, especially after hearing Dr. Carolyn Clancy talk about the need for research.)

2. What scientific questions are best answered by PBRNs?

3. What are the essential elements needed for a successful PBRN?

4. What elements are needed to sustain PBRNs and what are the barriers to gaining them?

5. Other innovative ideas that have emerged from the discussion.

6. Differences in opinion.

7. Suggestions.

### **Why do we need PBRNs? Can they be justified to the public?**

I have gone back to some pretty ancient studies that I believe we can use to our advantage in justifying what we're doing. The first is the prevalence of illness in the community reported in the Canadian Health Study (*Table 1*). (It does not make much difference whether you look at it in Canada or the United States.) Dr. Paul Nutting stated that practice-based network studies focus on common problems, and this table supports his statement.

The second study is the reason for visits to family physicians. This is the distribution of the workload (*Table 2*). This study is from Virginia and dates back to the 1960s. Now, I added the column on the left, and it is a combination of three research programs. You can look down the column and see that the three research programs have studied almost all of the problems. This reiterates most of what these programs have said. The process started by the AAFP, and the selection of the sites, has hit the nail right on the head because you are dealing with the common problems in practice. I believe these are very

**TABLE 1. Prevalence of illness in the Province of Ontario in 1994**

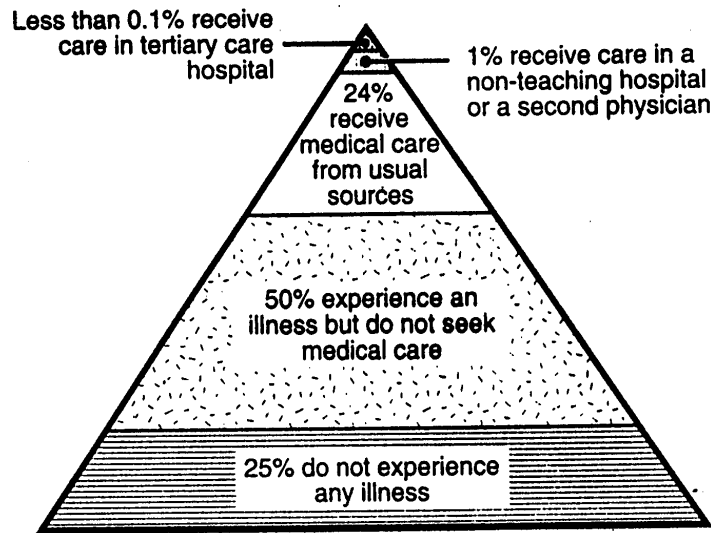
<i>Condition</i>	<i>Percent male</i>	<i>Percent female</i>	<i>Total Percent</i>
1. Seasonal hay fever	15	18	17
2. Pain in joints or muscle	11	16	14
3. Allergies to foods, drugs	7	9	8
4. High blood pressure	7	8	8
5. Low back pain	7	7	7
6. Respiratory problems	6	6	6
7. Gastrointestinal problems	5	5	5
8. Cardiac problems	5	5	5
9. Problems with eyes	2	3	3
10. Diabetes	2	2	2
11. Thyroid problems	1	4	2
12. Cancer	1	2	2

*Source: Hamilton-Wentworth Department of Public Health*

**TABLE 2. Problems recorded as the most common reasons for visits to family physicians in five surveys of Canadian and American practices**

	<i>Condition (ICHPPC Classification)</i>	<i>Percentage of visits</i>
*X	1. Uncomplicated hypertension	11
*	2. Rhinitis (allergic or other)	9
*	3. Pharyngitis (including URI)	7
X	4. Anxiety disorders	3
X	5. Depression	2
*X+	6. Preventive health procedures	2
*	7. Contraceptive advice	11
*+	8. Acute or chronic cough	11
	9. Well-baby check	11
	10. Nutritional advice (obesity)	>1
*	11. Diabetes mellitus	>1
	12. Abdominal pain	>1
	13. Otitis media	>1
	14. Lower urinary tract infection	>1
*X	15. Heart failure	>1

*\* = Michigan Consortium; + = Center for Family Medicine Science; X = Center for the Value of Family Practice.*



**FIGURE 1. Illness in 1,000 persons during a one-month period**

Source: White, et al. 1961.

important points in selling what is going on in family medicine research.

The third study, which I believe is the biggest selling point of all, is Kerr White's famous diagram about meeting the health care needs of a population (*Figure 1*). I imagine everyone in this room is familiar with this diagram. If you look at that 0.1 percent of the population who received their care in tertiary care hospitals, and the 24 percent who received medical care from usual sources, you'll suddenly realize that, yes, these numbers are out of date. My guess is the 0.1 percent is now 0.01 percent. The one percent who received care in a non-teaching hospital or from a second physician is probably now less than one percent. The 24 percent is now bigger, and the 50 percent is also bigger because of the way health care is evolving.

I believe it is even more important to attach research dollars to this figure, which I couldn't do for I don't have the data. I am sure it is in the billions of dollars and less than 0.1 percent. There are probably a few million dollars in the 24 percent area that are

being spent on research, and I believe that is your most compelling argument. The research enterprise is backwards.

If I were the AAFP and had invested more than \$7 million in the research enterprise of family medicine, I'd want to see a return on my money. The return should be somewhere between \$30 million and \$50 million in sustained funding. I believe the most important part of that strategy is sitting right across the room ... Dr. Larry Green. If you have him loose inside the beltway of Washington, D.C., I would guess that is going to have a fair effect on getting some of that money turned into sustained funding.

We heard Dr. Clancy yesterday pleading with this group to give her the data she needs to allow her to argue for that funding. I believe most of the data she asked for was presented here yesterday. So it seems to me the answer to this difficult question was provided yesterday. Dr. Green should have White's diagram on the back of his car and pasted on his briefcase. We should attach the research dollars to it, where we believe the

research dollars should go, and the amount that is going into family medicine compared to other specialties. The numbers we heard yesterday from several presentations are minuscule: millions of dollars versus billions of dollars.

Dr. Green told us yesterday that we just don't have enough information about what is going on in any aspect of the interchange and the work in family practice. The information we do have tells us that the most common reason for visits to family physicians is hypertension, and it represents only 11 percent of the workload. After we deal with the six most common problems, all the remaining problems will be seen less than once per 100 patient visits (once a week or less). This is a compelling argument for the need for research networks.

Dr. Don Iverson told us we need large numbers to demonstrate clinical significance versus statistical significance. You can get these large numbers from PBRNs. This is a huge asset in sorting out many of our problems. These facts suggest that if you were going to study, without networks, any of the 25 most common problems seen in family practice, it would take you a long time to enroll the number of patients you need because of the low frequency, and the low prevalence of the conditions in the community. Research networks address this issue very effectively.

The other important issue that came from Dr. Green was that primary care is fundamentally different. Dr. Barbara Starfield, another one of our giants in the background, figured out that 40 percent of all new problems presenting to a family doctor never evolve into a diagnosis. So if that in fact is true, then it means what we do is completely different from the specialists who deal with specific areas and specific diagnoses. This also means what actually goes on in that 40 percent of the workload is pretty much unknown. Nobody really knows how that works. How do we deal with that? Do we pat people on the shoulder? Do we reassure them? What do we do?

We know very well that most of the research has traditionally been carried out in tertiary care centers with highly selected populations. We also know that much of that research just doesn't generalize to what we do. It's not transferable, even though the *New England Journal of Medicine* would like us to believe that. Networks provide results that are more generalizable (Nutting, Fleming). There is a difference between practice-based data and population-based data (Hickner). The amount of research to better understand how to prevent and manage a problem tends to be inversely related to how common the problem is.

Current trends have rapidly shifted care from hospitals to the community, thus Kerr White's 24 percent of care in the community is less likely to have increased since 1961. The amount of personal care is also less likely to have increased.

PBRNs can produce the best evidence (Fleming). We can address POEMs. We haven't done it very much yet, but it's quite possible and feasible. PBRNs appear to provide a culture in which adoption of new knowledge occurs (Croughan-Minihane, Beasley). This is an exceptionally important point, especially after hearing Dr. Clancy yesterday. She, again, was literally begging this group to give her the evidence that she could transfer. Networks accelerate this transfer of knowledge.

#### **What scientific questions are best answered by PBRNs?**

PBRNs answer the common, relevant problems seen in family practice (Nutting, Beasley). The questions are of interest to most practitioners, and the questions arise from the practitioners' daily work (Wasson, Nutting). The questions allow the data collectors to have input to the choice of questions and study design (Hahn, Green, Nutting). The questions require a short time to gather data. And finally, the data collection required to answer these questions minimally disrupts office functions.

We heard some other interesting ideas,

such as etiology obscured by chronicity (Hahn). I thought that was an interesting concept.

**What are the essential elements needed for a PBRN to be successful?**

First, a dedicated champion. One who is committed, respected, trusted and willing to go the extra mile for the network (Beasley, Hickner). If you don't have somebody who really is committed to his or her network, and willing to go the extra mile, success will not happen.

- You have to have effective communication with and between the network members (Hickner, Culpepper, Croughan-Minihane, Beasley, Nutting). That is a given.

- You need to have face-to-face meetings and build trust.

- You need to have a sense of ownership.

- Practitioners must have a say in the questions and relevance of the work.

- You need skilled senior researchers who are sensitive to family practice and the network to serve as principle investigators (Nutting, Culpepper, Beasley). The role of the PI in a network study is absolutely crucial. You've got to have a very unusual kind of animal to do it: Somebody that is methodologically skilled. There aren't too many of those people floating around. What we heard yesterday about failures of research projects were not the result of bad ideas. They were the result of the individuals involved not quite making things click. The successes always depended on a PI who was knowledgeable and capable. I believe this is a critical point: If we are going to make our research enterprise move, we've got to have some senior researchers that understand what is going on in family practice.

- We need full participation of the office staff in each participating clinic. Everyone who has tried to do one of these studies knows you're in deep trouble if that doesn't happen. The Dartmouth COOP group, in particular, has emphasized that over the years in the work they've done.

- Adequate infrastructure. Quite a few people said we are inadequately funded, we don't have infrastructure, and we need it desperately. This was argued eloquently by a number of people. Then we heard an opposing view, and we'll talk about that a little later.

- We need experienced and solid consultant researchers for methods and analysis (Nutting, Beasley, Hickner, Culpepper). I differentiate the consultants from the PIs, because consultants are easier to come by. They don't have to understand all the sensitivities of the network, not like the PI does.

- Administrative skills. We heard Dr. Beasley say how much Dr. Nutting helped with a grant because he had a group of people in Denver that really knew how to write grants. There isn't a lot of that around, and I think that is another area that needs to be developed.

- Accuracy and validation of data collection (Nutting, Ornstein, Hickner, Selby). One of the points we heard was that networks that do not collect data for research have a fair amount of trouble with their data. On one hand we heard from Dr. Ornstein. On the other hand we heard some very interesting methods of dealing with that problem from Dr. Selby.

- Enthusiasm and interest in the network. And a lot of energy to maintain it. That, in itself, takes a lot of effort. The care and feeding of a network is a major issue.

- You need the ability to communicate effectively and efficiently with the members of a network (Nutting).

- You need a balance between the bottom-up, grassroots organizations, and top-down demands of funders (Beasley, Hickner, Frame). How do you balance that? That is a tough issue, and I don't know that we have the answers. But if this is going to go forward, we are going to need the answers.

- Rapid feedback about studies to maintain practitioner interest (Wasson, Hickner). That is a way of keeping people active, energized and involved.

- Sound and responsive governing structure (Culpepper). Most of us don't like thinking much about governing structures because we don't want to be governed, but if you don't have a good governing structure when things go off the rails, then you're in deep trouble.

- Endorsement from professional society (Culpepper).

- Capacity to accept 25 to 30 percent dropout rate (Culpepper).

- Effective study area of greatest contribution (Fleming).

- Collaboration with other networks and organizations (Fleming).

- Finally, the questions that are best answered by research networks are service delivery, natural history and etiology (Hahn).

#### **What elements are needed to sustain PBRNs and what are the barriers to gaining them?**

Some of the ideas that came forward included partnerships with private enterprise (Tilson, Nutting, Hahn). Others include:

- Stable funding from multiple sources (Ornstein, Nutting). You cannot fund one of these organizations on the back of overhead alone. It just will not survive. You've got to have multiple streams of funding because some things go up and down. The only way the network is going to be stable is to have multiple streams of funding.

- Recognition of value by funding agencies (Tilson, Clancy, Croughan-Minihane). What I heard from Dr. Clancy, again, is that the AHCPR is interested in this research enterprise, but doesn't have the right data to support it financially. They have to be able to convince the politicians that this research enterprise is a good thing to support. So I come back to Kerr White's diagram and Dr. Green carrying it around. What do you do to change the thinking of Congress on this subject? We have to change the thinking, and it will take some kind of gimmick to do it.

- Methods for supporting infrastructure (Nutting, Green, Culpepper, Wasson). We'll

talk more about this later because there is some controversy.

- Focus on the needs of patients (Wasson).

- Sound governing structure (Culpepper).

- Ability to generate funds; need for data to change the funding system (Culpepper, Fleming, Clancy). Dr. Clancy emphasized, again, that she has to go to the politicians and say, "This method they're using is going to change the health care system for the better, and we've got evidence to prove it." I believe the evidence exists, but it just has not been pulled together.

There are a lot of barriers keeping PBRNs from gaining the elements necessary for success. More barriers than there are elements. And the most obvious barrier is lack of funding. We've had a debate here, because not everyone believes that the funding should go to the same place. We'll come back to that in a minute.

I think we need a paradigm shift in the thinking of research funding agencies (White, Ewigman, Fleming, Green). Kerr White's diagram illustrates that remarkably. You are spending, in the United States, billions of dollars on researching molecules and subcellular stuff. But what is being spent on primary care research? A hundred million dollars a year? I doubt if it's that much. Whatever it is, it's backwards. It's upside down. So we have to really push that paradigm shift.

- Inability of most funding agencies to support infrastructure costs (Green). As I understand it, the NIH is to support the kind of infrastructure funding that this organization or these research groups need.

- The larger and more geographically diverse the network, the more expensive it is to maintain (Culpepper).

- The rapid reorganization of medicine from small groups to HMOs, MCOs, etc. (Wasson, Nutting). Doctors are becoming salaried employees, and this and other factors are changing the system and

destabilizing the traditional network where the doctors were volunteering. It's becoming more difficult for academic physicians and salaried physicians to participate on a volunteer basis in research.

- The lack of research training or experienced family physicians makes it difficult to participate effectively in study design (Croughan-Minihane). One of the goals of a network should be to provide education to the participants and to get them to be more sophisticated in conducting research. That has happened in ASPN. The kind of questions ASPN asked back in 1985 were barely descriptive studies. Now ASPN is conducting much more sophisticated studies, and that is because the people working in the network have become much more sophisticated in their understanding of research and the kind of questions that they want to answer. This is a way of elevating the whole discipline.

- Piecework versus productive work: we need a balance (Ornstein).

- Need to assess relevance of products (Wasson).

- Deans of medical schools do not support family practice research (Fleming).

- Lack of links to the NIH (Ewigman, Fleming). Again, this is what Dr. Clancy was talking about. We have "ins" in her agency, but not in the NIH. That should be a strategic issue. How are we going to permeate the committees of the NIH?

- A strong sense of volunteering to participate is needed (Croughan-Minihane, Ornstein). If anything, our networks have depended too much on volunteerism, and that may be one of their weaknesses along with one of their strengths. However, the enthusiasm is so overwhelming. People believe they are getting a lot out of volunteering. We need to maintain that kind of momentum.

- Adequate infrastructure support for communications, science, computerization, etc. Dr. Culpepper demonstrated the impossibility of actually funding a large network off the back of grant overheads. That re-emphasizes this issue. Dr. Nutting talked

about the changing patterns of salaried physicians. Academic family physicians cannot volunteer anymore because they are overloaded. We need infrastructure support to help these doctors.

Barriers include the following:

- Lack of linkage between the university and the community physicians (Hahn).

There is no terribly good reason I can think of why, if you can fund an academic family physician for 50 percent of his time to do research, why can you not fund a family physician in the community for 50 percent of his time to do research? I can see no particular reason except that the guy in the community probably has a higher income and will have higher income expectations.

- There is no prospect for increased funding for family practice research (Nutting).

- Inadequate dissemination of results (Nutting). Big issue. If we don't tell people what we're doing, how can we expect them to get on board with us and give us more funding or more resources?

- The lack of a research career track (Nutting, Fleming). We've agonized over this for years. We have to have the resources so that young people can be family medicine researchers, and there's actually a career track for them. And they will not be cut off from funding or projects after five years. There's a support system. There's infrastructure. You've got to have that or else you're not going to attract the best and the brightest people into family medicine research.

### **Networks and innovative ideas**

Again, Dr. Clancy said if she could go to the funding agencies and say that participating in a PBRN meant that you were improving the quality of your practice, and we have evidence to prove that, it would be a tremendous selling point. We have that evidence to prove it. The Dartmouth COOP group published it. I don't know whether it shows outcomes at the patient level, but I'm sure you could do that. Every network should adopt whatever it takes in quality improvement to



do that. There's a tremendously compelling reason to have PBRNs.

- Adopt "off the shelf" quality improvement packages (Wasson). The issues were raised yesterday as to what you need to do, and it sounds to me like it has already been done. It's just a matter of putting it together in a package that we can sell to Congress (who has to sell it in 30 second sound bites).

- Reorganize participating practices to deliver care more effectively and efficiently (Wasson, Clancy). If you can demonstrate that being in a PBRN actually does that, then it's a very big selling point for a lot of different agencies.

- Use "small replicable models" to design and evaluate practice interventions (Wasson).

- Provide educational workshops and encourage attendance with CME credits for doctors who lack research expertise and find it difficult to participate in study design (Croughan-Minihane).

- Provide other rewards for participating, such as library cards at your university.

- Train physicians in the methods of the reflective practitioner to help generate PBRN research questions (Croughan-Minihane).

- Appoint practice representatives to stimulate the participation of groups of similar practitioners in networks (Croughan-Minihane).

- Use interactive voice-response technology (Hahn).

- Classify practice-based researchers as inactive, passive, fully active, and hyperactive (Hahn).

- Link PBRNs together. This provides a wider choice of studies for the participants in the networks to choose from (Nutting, Beasley).

- Expand to HMOs and other types of practice organizations (Nutting).

- Develop a network of researchers to nurture their skills (Nutting).

- Use standardized data collection techniques for clinical purposes in an integrated system, then triangulate (Selby, Ornstein). If you take diabetes, and then look at it from

four different angles inside an integrated health care delivery system, you can validate the data very effectively. That has been a very exciting breakthrough. We may be able to use data differently in the future.

- Involve residents in studies to generate future interest (Nutting).

- Use missing data to predict outcomes (Selby).

- Convince large integrated systems to get involved (Hahn).

### **Differences in opinion**

- Infrastructure funding. We had Dr. Wasson saying we should be more efficient. If we're more efficient, then we may not need very much infrastructure funding. On the other hand, we heard compelling arguments from Drs. Hickner, Beasley, Nutting and Culpepper on why we need infrastructure funding. It is essential. I believe both arguments are right. Surely you want to be as efficient as you possibly can. Dr. Wasson has come up with some excellent ways to combine two or three things in the cycle that make it very efficient, and thus it requires less infrastructure funding. But you need infrastructure support to continue developing your network beyond its current abilities.

- The need for more epidemiologists committed to family medicine (Croughan-Minihane), versus needing more family physicians to serve as role models for future family physician researchers (Iverson, Nutting). Research grant applications are of good quality because they've been developed by consultants. We need some family physicians to serve as role models who are very well epidemiologically-trained, who have worked in family medicine for a long period of time, and who understand what is going on in family medicine. Without these role models, young people are not going to know how to relate to methodologists, and I think that is where the lack is right now.

- We need two or three network models (Iverson). We need a budget for network models (Green). I'm not sure what the answer should be, but it must be more than

one network model. “There is more than one way to skin a cat,” as the expression goes. Therefore, we need a number.

- Drug companies are a good source of funding (Tilson). Drug companies are a bad source of funding (Anonymous). This argument has gone on for many years. I think that anyone who can work with drug companies has to be very clear up-front with the company as to who is doing what and who owns what. We heard yesterday a very compelling argument that drug companies spend \$22 billion a year on research on molecules. But drug companies are not at the molecular level. They break down at getting the research money out into the field where we are. I keep coming back to Kerr White’s diagram. That is where the action is.

#### **Suggestions**

- Improve the recognition of practitioners and PBRNs.

- Lobby for more funds to support centers of excellence, career awards, fellowships, expertise development, and PI training.

- Infrastructure funding.

- Expand the knowledge of family physicians involved in research.

- Advocate more vigorously for PBRNs at the government and academic levels.

- Focus networks on identified areas of need, and keep that focus very narrow.

- Link with MCOs. We heard some eloquent pleas for that yesterday.

- Work more closely with the pharmaceutical industry.

- Develop multiple income streams for networks.

- Promote networks.

- Put data collection to multiple uses.

- Promote peer review of network proposals.

- Evaluate the impact of the networks on the quality of members’ practices.

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## Full Group Question and Answer/Discussion

**Dr. John Hickner:** There is one other compelling argument that just came to my mind as you were talking. All we're doing is really the same thing that the other disciplines have done within the last 30 or 40 years. The cancer centers across the United States are really networks. Each cancer center has a number of different doctors, private practitioners, etc., who work with them. So we are not doing anything new. We are just developing our laboratories. The networks are the laboratories in which we are going to do family medicine research, so I don't think it's all that innovative of an idea quite frankly.

**Dr. Walt Rosser:** No. The only difference is that you are dealing with a much bigger population than the people being dealt with in cancer centers. They are only a small fraction. You are dealing with a whole population. So in a way, it's the same model, but it's a much more powerful argument — except it hasn't been made very persuasively.

**Dr. Hickner:** It's been a successful model for research for everybody else, so it should be a successful model for us, too.

**Unidentified (1):** Let me just follow along that line of thought with a question. Are PBRNs research laboratories or are they self-contained research enterprises? I believe

there is a difference, and I have heard both sides of the argument.

**Dr. Rosser:** I don't think that is a surprising issue given the debate. It fits into the top-down, bottom-up debate. These are bottom-up, grassroot volunteer organizations, and therefore, they perceive themselves as being autonomous. However, to survive they must attract funding and will have to comply with what some external funder says to do. There is a lot of tension between the two viewpoints and the only conclusion may well be a parting of the ways. It may be that some networks wish to continue on a volunteer bottom-up, grassroots basis. That is great. Why would we argue with that? But if you want to go into the next level of the research enterprise, you will have to give some of that up. You'll probably need more funding and more support to go forward and answer the important questions that need to be answered. It is possible that there will be both. And that is fine. More people can be attracted into an interest in research, and that is surely beneficial to the overall discipline.

**Dr. Michael Fleming:** John, I think what you said is probably not true. I believe the PBRNs that existed before were driven by the PIs and driven by the NIH. We need a place

to do our research. Our networks are coming from a totally different direction: the family doctors and their offices and the Academy. It's like sort of starting from the grassroots and going up. The PBRNs, from what I heard yesterday, give the family physicians a way to do research, a way to train family physicians, a way to get them to use more evidence-based medicine. PBRNs are not being driven by PIs and big research questions.

**Dr. Hickner:** I don't believe that is true. The reason I've become involved in PBRNs is because I wanted to do research and I did not see any good ways for me to do the kind of research I wanted to do — research on common problems in family medicine — without getting a network together. I wrote a little quote that I didn't say earlier. I was taking off on the comment, "It takes a village." Well, it takes a colleague, in this case, to do good research in family medicine. To me it takes a group of colleagues and a network of practices in order to generate the numbers. Now one doesn't have to necessarily have an established network to do that. One can, as Dr. Ewigman did, generate his network on the research question. But the only reason I'm interested in building network infrastructure is that I consider myself an investigator. I wanted a laboratory in which to study things. That is why my network exists today.

**Dr. Fleming:** I'm not discounting that. But I'm saying you were not a senior NIH researcher who said, "I'd like to do this." You started out more as an average family physician who has some research interest and wants to do this.

**Dr. Kurt Stange:** I'm the associate director of a cancer center, and I think that the center analogy works very well. We don't have a disease-specific focus, but all the things that a cancer center does (develop population, basic, and clinical research) is exactly what we want to do with these networks.

The difference is that we don't have a place to go for the necessary funding. The cancer center model works very well, and rather than reinventing the wheel, I think we can argue by analogy to funders. That is something they understand.

We also need basic science research. We're going out and trying to intervene and improve the quality of family practice. And yet we don't know what the core structure is and what the processes are. We need to map the core structure of family practice, look at what the core processes are, and then we'll know how to intervene to improve family practice. We need to take control of the debate on quality of care and redefine it. We lose with the way it's being defined now: how well do we do on narrowly-defined disease-specific process measures. You cannot show the value of a broad patient-centered approach in that way. If we had centers that could actually look at the value of patient visits, that could prioritize this large agenda, and choose the most important research subjects, we would have the most excellent and useful research. If we could only convince funders to support these centers, we could make some really big strides.

**Dr. Steve Ornstein:** I would agree with you. We do need the better descriptors in our studies. I would like to go back to something Dr. Rosser said. Are PBRNs a "research club" or more of a laboratory for high-level NIH researchers? I think PBRNs are both. We need networks at all levels if we are going to be successful. We need to define the questions properly. We need to look at this almost as a capitalistic effort where we do more work with some of our friends in the pharmaceutical industry and the government.

**Dr. Lee Green:** I think you hit the crux of the crisis point, that being the developmental stage where our discipline is at right now. This question about whether our PBRNs are laboratories or self-contained research units strikes at the transition that our discipline

has to make right now. We come out of a counter-culture mentality, and we haven't given up those counter-culture roots. I don't think we should ever completely give them up because they are part of what we are. But if we fail to make the transition, if we fail to sort of go through that growing-up process in order to give up our "adolescent contrariness," if we fail to come together and realize that we each have different strengths and different things to contribute, if we fail to get rid of those big NIH researcher types who want to come in and use us as a laboratory, if we fail to get out of the mind-set that we are just a hobby, we will not matter. We will not matter in the way the research enterprise in this country matters. We will never achieve the ends that we are trying to achieve. We will be ineffective, as we have been in the past with a few very small exceptions.

We have to bring in another thread, this notion of the clinician researcher and needing to be a family physician. I think that portraying it as the network versus the big NIH researcher is a false dichotomy and it inflames what really shouldn't be a debate any longer. I don't think our model is contemplating bringing in the NIH researchers

with questions they want to impose on the PBRN. I think we need family physician researchers and we have them. Practicing family physicians like all of us here this weekend who see patients every week, and who really practice family medicine, and who have research questions and who are able to function as senior researchers working with a network to ask questions.

I think it's unrealistic to portray the researchers who want to use our networks as sort of these big remote NIH researchers. They're not. They're us. It's equally unrealistic for networks to think that family physicians with 0.02 percent of their time spent on research are going to really drive the research enterprise. We've got to get away from the "town versus gown" sort of mentality. We've got to overcome our counter-culture enough to ban together. "In unity there is strength." We do not have the unity, so we will not have the strength. We need to pay very close attention to the question Steve has raised, and all of the questions that have come up this entire weekend. If we did nothing more at this conference than answer that question, I think we would have more than justified our presence here.

# Best Strategies for the Use and Growth of Practice-Based Research: Reports from the Breakouts

## Clinical Intervention Studies

**Dr. Barbara Yawn:** We discussed clinical intervention trials and studies. I will first give a synopsis of our answers, and second, because this is a typical research group, I will tell you the question we refused to answer, and the new question we came up with instead.

### What are the critical issues for practitioners in conducting clinical intervention studies?

We interpreted that to mean people actually in the practices. And these are the top issues we came up with in somewhat of a rank order:

- Time buying and relevance.
- Cost reimbursement payback for the practitioners and their staff.
- Complexity.
- The effect of the intervention on the practice, the staff and their partners.
- The effect of the study on patient satisfaction and family time.
- Concerns about crossover in contamination when you do a study and then randomize patients within the same study.

### What are the solutions to these critical issues? What do we do about these?

- Dollars. Almost everyone agreed most of their practitioners are not particularly

impressed with dollars.

- Rewards. For example, CME. This is a very important issue for some.

- Recognition. Put their names on a paper if they've contributed more than just collected data.

- Selection. We should be very careful about selecting our designs and our methods to make them interfere the least with the practice itself.

- Respect. With the staff and the colleagues, we need to give them respect. We need to ask their opinions.

- Cookies. We need to give them cookies. Buying food is a useful way to get people to attend your meetings and participate. I don't know why cookies attract doctors. But they'll always attend and participate for cookies or doughnuts. I do point out that it's just not the cookies they come for. They, of course, attend because of the respect in asking them to participate.

- Patient issues. We need to think very carefully about patient issues when we design one of these studies and ask a practice to participate. We need to consider the informed consent — how disruptive it is — and we need to be asking patients in these studies “What did this do to their level of satisfaction?”

- Care. We need to take care of the doctors who participate in the networks and

participate above our expectations. We need to take care of each other the same way we care and are concerned about our patients.

**What are the major methods impediments to doing clinical intervention studies in PBRNs?**

We thought the major impediments were patient selection bias, practice selection, and how do you know if you are going to randomize by practice, and how do you know that your practices are comparable?

We may not have good tools for assessing and evaluating whether practices are comparable on important characteristics, and those obviously vary by study. We have problems with the logistics in implementing it across many different kinds of practices. We have problems with participation rates — both with practices and the physicians within them — and then patients.

We also looked at the problems you have fitting the design with the practice. If you've got a group of practices who are all different from each other, how does your study have enough flexibility designed into it to allow the study to work properly? Another problem is cross contamination, which is a real concern if you randomize patients or physicians instead of randomizing whole practices. And another problem is getting the utilization data you need in your study. For example, it can be very difficult if you need cost data, and you have Medicare/Medicaid, Blue Cross/Blue Shield, United Healthcare, HealthPartners, or whoever else, it can be very difficult to get cost data or utilization data from all those people.

**What are the strategies to overcome these impediments?**

The first obvious answer is: Train the staff. I think it was actually train, train, train, train, train, train the staff. You need to be there to properly train the staff. You need to have enough dollars so you, or the PI, or a central coordinator can be there. You need to train people to pay attention to the details that may not be possible in a busy practitioner's life, but are very important in research.

You need to make the incentives appropriate not just for enrollment of patients, and for more than a single one shot intervention for continuation and for completion. People use the examples of payment at the end of a study. It may help to give them a little bit of money in the beginning — or whatever it is you give them — but you should give them a lot more in the middle and at the end.

When you are thinking about an intervention, use focus groups and pilot tests at your intervention. Don't just decide on it because it sounds great, or assume that since it worked in another setting that it is going to work in all settings. Go out there and try it in the practices first.

If we are going to randomize at the practice level, we need to consider developing — or identifying if they are already developed — the tools that allow us to determine comparability across practices. We need to think about using other kinds of technology that will take data collection out of the practice setting so that the practice staff don't have to do all the data collection. We need to take away the data collection from the people that don't have the expertise and are too busy to do it.

**Can national, regional, local PBRNs harvest valid data better than other less expensive approaches?**

We didn't like this question, so we opted not to answer it. Instead, each person wrote a new question and then answered it.

1. Can PBRNs harvest important, unbiased, generalizable data for a reasonable price? The unique feature PBRNs have in answer to this question is that they are able to examine unique features specific to family practice, and the process and organization of family practice care. It is pretty difficult to do this in any other setting.

2. What kinds of questions are best answered by PBRNs? (This question gets repeated a couple of times, as it is the same question that several people came up with.)

- Questions that require a richness of

data about the patient and the physician, and that have to do with the context and interaction that goes on between them — something other than what you could get by just using medical records. The reason that we would be able to do this is because we feel that there would be a higher response rate, and a better buy-in. We believe this because the physicians would have decided this is an important question, and by doing it in this kind of a setting — rather than having somebody from outside come and say “Would you do it there?” — would be lead to better buy in.

- Questions related to co-morbidities. There was a fair amount of discussion on this answer. Why can PBRNs do this better than others? Because they can look at the multiple exposures and outcomes in patients that are different than the patients in a lot of other practice settings. These patients are different than patients in specialty tertiary care centers. Our patients just look different. And perhaps we could take care of multiple co-morbidities, and the interaction of those co-morbidities, instead of having them go from the diabetes specialist to the hypertension specialist to the cardiologist. You could go across several conditions and the settings are different. We also see patients in a broad spectrum of diseases as opposed to a tertiary care setting where they may see them only in the moderate and severe or later end-stages of disease.

- Questions that deal with the whole family.

- Questions that require a large number of subjects with only a minimal data set.

- Questions that deal with rare conditions. Perhaps we can get rare conditions earlier in their process and look at rare conditions in a way that tertiary cannot. But you need a very large group to do that. The direct competitor for many of these would be large single groups. And the answer was, “We’ll just bring them into the PBRNs, too.”

3. What kinds of studies are best conducted by PBRNs?

- Studies of effectiveness with a wide

variation of cross practices.

- Studies in which representative sample is important.

- Studies about behavioral intervention.

- Studies with brief intervention versus a medical, medicine or procedural intervention.

- Studies that test and validate instruments.

These are the kinds of intervention studies best done in PBRNs: efficacy and effectiveness for PBRN diseases (we have now defined a new disease category — PBRN diseases — and they are also the Kerr White’s Virginia Study diseases) and studies where referral bias is a potential confounder.

4. When are regional or national variations important? When they are important in defining the results. You need national if you need large numbers. Regional when there is cultural or geographic issue that you thought might affect the success of the intervention. The example was that people in California may not respond the same way as people in Georgia or Minnesota. There may be all kinds of geographic differences.

### **What are the three major challenges facing family practice investigators and PBRNs in conducting clinical intervention studies?**

We did well defining three issues, that is why there are five listed here. We can’t count. We’re researchers.

1. Securing proper infrastructure.

2. Selecting questions and matching them with skilled investigators, methodologists and PBRNs.

3. Establishing the goals for the PBRN.

4. Doing a better job of selling ourselves.

5. Celebrate our success.

We went around the room and there were three or four people who have done things that have had a major impact on our country and others about changing practice. No one knew about those, and the people who commented on those really hadn’t told too many other people. So we don’t do a very good job of selling what we’ve done or what our goals are. Do we want to be a



laboratory through data collection? Do we want to be —this is my word and they didn't like it to well — a Petri dish where we grow our own culture? Or do we want to change practice? What is our goal?

### Natural History of Disease

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**Dr. Paul Frame:** We took a fairly concrete approach and figured that the best way to run through the process was to start with a list of conditions that might warrant investigation in terms of their natural history, and then pick one or two or three of those and ask some of these questions about how would handle that particular problem. Not surprisingly, the list that was thrown out in terms of what issues might we want to study.

First, just respiratory infections or “snot”, asthma, somatization disorder, fatigue, anxiety, headache, depression family dysfunction, the patient with multiple diseases which could be defined a number of ways, and patients with multiple risk factors. That latched onto our underlying premise in what we're suggesting: What is the prognosis of different reasons for presentation? This is a little bit like asking, “What is the natural history?”

There is a difference between asking the question, “What is the prognosis of someone who presents to a family doctor with ‘X’?” and asking “What is the natural history of ‘X’?” These are two significantly different questions in terms of how you have to go about answering that, and this is depending on the question you want to answer. So with that construct as a premise of what is important in terms of family medicine, what is the prognosis of different reasons for an encounter?

Some of the reasons that fell out were (1) physical pain, (2) mental pain, (3) abdominal pain, (4) nerves, (5) fatigue, (6) depression, (7) allergies, (8) chronic upper respiratory congestion, (9) cancer, and (10) a sort of broad area called disease surveillance

(we didn't try to define that any further). There was also a suggestion that for any of these conditions, given the fact that we are family physicians, you might want to try to strategize your follow-up by family, by family type, by family situation, etc., so that any one of these looks at the influence of the family on this particular condition.

Having created this list, we then narrowed it down to three that we thought maybe were more important or that we just happened to choose: nerves (as a presenting complaint), chronic upper respiratory congestion (chronic snot if you will, which is a condition that lasts for a long time, and this includes allergic rhinitis, vasomotor rhinitis, and a number of other conditions), and abdominal pain.

We spent most of our time looking at how we might conduct a natural history of disease study on the topic of “nerves.” After we looked at nerves, we realized there were a lot of similarities between nerves and the other two subjects. So we didn't go through in detail how you might look at chronic snot and abdominal pain.

There is a lot of commonality in the methods you might use to look at the natural history of disease. We decided that you would be talking about a cohort study with patients being identified by the reason for encounter. We decided that you would probably be talking about adult patients. Then you get into a whole issue of how do you want to frame the question. What is the question that you really want to answer? Are we wanting to look at a cross section of the practice which would obviously include prevalence cases, as well as incident cases? If you do that, it takes less time. You need smaller numbers. Or do we want to look at patients who are new to the practice? And again, this was sort of the conclusion of the group, is that this was the most reasonable approach because it's at the point where a new patient with nerves presents that the physician may be asking “What are the probabilities of different things happening down the road with somebody presenting with this

particular complaint?”

On the other hand, we have to point out that this is different from studying the natural history of the diagnosis of nerves, because if you really want to study the natural history, you have to get the symptom from the first time it presents anywhere and you follow that along, which is a little bit of a different problem and has a little different methodology. So having sort of settled on patients new to the practice with this complaint, then clearly you would need to do some kind of a pilot study. You would enroll 100 to 200 patients over a short period of time to look at how this is going to sort of seem to branch out, to have some kind of ballpark idea of what kind of numbers you might need in a bigger study.

We decided that a bigger study, and this is clearly top of the head because what would need to be generated from the pilot study, would need at least a five year follow-up and would probably need at least a 1,000 patients with that complaint. Again, throwing out numbers, the consensus was you'd need an adult population of somewhere between 30,000 to 50,000 in order to generate 1,000 patients with that complaint. Obviously your pilot study would help you refine that.

Then the question of how do you do it? We decided that you would need some type of network, because doing it all in one practice, even if you had a large practice, would raise the question of maybe there is a bias in terms of practice style, interventions, and how these are handled. You would need a network. We debated for some time on Whether it should be a regional network or a national network. Our consensus was probably a regional network would be the most efficient way to go. The criticism might be, “Well, yes, that’s what happens in Michigan. But you know, Texas is different.” That criticism certainly could come up. The ways to handle that kind of criticism would be either to do a study in Texas and see if there is a difference. Or possibility — in the pilot phase — doing pilots in multiple geographically diverse locations to see if it looks like

there are any differences, and then based on that, decide whether indeed you think you need a regional or a national network.

We looked at problems that would be encountered in doing this kind of research. The first problem was money. Clearly you know money is an issue. And one of the issues that comes up with regards to money is the problem of the way this question has been framed. It’s very family practice oriented. There was some discussion at the very end that to frame the question so it is more palatable to funders changes the question. Would a funder be more interested in looking at a true natural history population-based study of “nerves” as contrasted to how do nerves present in the family doctor’s office?

Practice support was considered to be a major concern similar to what Dr. Yawn talked about, so I won’t go into that. Then we talked about passive versus active methodology, which are two ways to get around the practice. We had some debate and considerable differences of opinion in terms of whether you could effectively do the study on a passive basis (meaning practitioners would have very little direct involvement in the study). The doctors would just go about doing their thing. Patients would be identified through some system of diagnostic coding, and then a research staff person would go in and gather the data for the study and sort of leave the practitioners out of it altogether. All kinds of issues came up with how do you know you’ve identified all the people with “nerves” if you are using diagnostic coding as your entry key, etc. So there is clearly problems with the passive approach.

The active approach has the advantage of getting better direct concurrent data. It involves much more practitioner time and effort, and as one of the members said, “these are the patients that are the hardest for me anyway. I’ll be damned if anybody is going to ask me to fill out some form every time I make the diagnosis. I’m already a half hour behind just having seen this person.”

So that clearly is a difficult problem using an active kind of methodology involving a lot of practitioners.

Another significant problem over time is the whole issue of tracking the cohort. If you are talking about a five-year study, you'll need the ability to track this. It was pointed out that methods are available for doing that, although they are not necessarily cheap or easy.

That is what we came up with for nerves. As I said earlier, we started looking at chronic snot and abdominal pain and noticed these two other topics would follow a relatively similar methodology. Obviously there would be differences. The similarities would seem to be greater than the differences in terms of the general approach and how you would go after trying to look at them, and in addition, some of the problems of things that you might encounter.

#### **Family Practice Organization and Service Delivery**

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**Dr. Larry Culpepper:** We looked at the critical issues in doing research on the organization and delivery of care, which we loosely identified as health services research. What we came up with was that the central critical issue is that we need to articulate a theoretical model of how we practice, and a theoretical model of what we want to study. This requires an operational definition of family practice.

We talked along the lines of the IOM definition of primary care as a good starting point. We saw the model as needing to have a number of characteristics. It needs to build on inside strategies ... and that is using jargon. Inside meaning "from within the practice" or strategies that are natural for the practice to adopt, to respond to outside pressures (i.e., payer pressures). The model needs to be proactive in its ability to incorporate practice intervention. For example, taking care of patients in groups that we identify, or identifying groups of patients within our

populations and responding to their needs. It ought to be on service industry models, in the sense that health care is a service industry component. It needs to lead to continued improvement over time and be an action-research sort of model so that it builds upon itself. An additional characteristic we saw for the model is that it really needs to be goal directed.

We defined value, or adopted that value equals quality over cost approach. It really needs to recognize at least three types of care that we provide: (1) being curative, (2) being really a management adaptive change (how we help our patients adapt to chronic conditions) and (3) being terminal, in terms of managing healthy termination of all sorts, including death. Once we have that model, it also needs to take into account the full practice environments in terms of allied health workers and so forth.

Another critical issue is our need to develop measurement tools. Tools that we can use to further our research. We articulated at least three characteristics of those measurement tools. (1) that they include longitudinal measures so we can measure what we do over time, (2) that they be practice oriented in that the measurement tools are easy to adapt into the regular flow of practice, (3) that they incorporate family practice priorities and values.

Now with that as critical issues, we identified a number of items in terms of how should we as a field respond, including how should PBRNs respond. We identified the need for, in essence, a working group to articulate, develop, sustain, maintain, and build on the model. It should include content experts which we expect would be drawn from academic units, and that this would be done in close collaboration with academic units.

It also needs to include the champions in the field, practitioners and practice-based network leadership so that a critical mass of people can articulate and move forward. We saw the need to strategically relate family practice, and our family practice vision of

our model of health services research activities, to primary care and to clinical research so that we can build allies across that dimension, rather than separate and build potential competitive dysfunctional relationships. We also saw a critical need to collaborate with and build volume from the health services research community, from the HSR and folks of that background.

That led us to identifying the need to support discipline leadership in these types of functions, and identifying what we don't have and what we sorely miss. That is the presence of NIH-type funding to support peer review groups, and leadership groups in terms of meeting and articulating priorities for our research, groups issuing RFPs. We also need to identify where the next breakthroughs can potentially be. We lack a type of organizing continuity to our research activities. We need to build a framework that could do that.

We also saw the need for coordination of PBRN responses, so that we not have 30 networks going in varied diversions and chaotic directions. We saw the need to be aware of, and maximize the use of, existing data. That there are existing large federal data sets that do have value, and that we should both try to affect the content in terms of the measures that are being adopted for those data sets. And then to be sure that we build our own PBRN activities to complement, extend, and clarify the missing knowledge that can be gained from other sources. I think we saw in terms of impediment, a number of issues, and obviously the funds and so forth are there, but we also saw the low level of cross-network communication and discussion around such content areas as organization and delivery of care as a real impediment. There is not an ongoing dialogue within some networks. How do you promote good communication?

We saw another impediment being, at times, multiple competing pressures upon our practitioners and the ability or inability to be attractive to our practitioners in terms of getting them to actively pursue the

questions that we pose. We saw the solution to that being to really making sure that our research was viewed by the practitioners as an element of the solution to their problems, and as a way of helping them in their daily work. We also saw the need to cover the cost of being involved in research. And we saw the need to complete the feedback loop to make sure that we get information back to them on a timely basis so that they continue to be satisfied and excited about participating.

That led to, and related as well, impediment being that we still need to work on and improve our strategies for all of the data management processes that lead to successful research. At a more theoretical level we identified, as a potential impediment, the need to involve strategies to balance the uniqueness of individual practices, while at the same time maintaining generalized ability and relevance to the external world in terms of the results of our research. We saw this really at two levels. One is to deal with the generalized ability issue at the real research level in terms of validity and transferability of knowledge. The other is to deal with that at a more political level, in being able to articulate well a satisfactory response to funding agencies.

#### **Can national, regional, local PBRNs harvest valid data better than other less expensive approaches?**

It depends on the nature of the research question and the answer desired. Sometimes yes, and sometimes no. That is a very generalizable answer. We challenged the notion that practice-based network research should always be viewed as expensive, and we base that upon three perspectives. First, if you compare our research activities to the support provided by NIH, for instance to cancer trials, we come in as a very inexpensive modality. I think Jim Mold articulated two other key perspectives. One is that through the inherent processes of practice-based research and the dialogue with practitioners that are involved, we reduce the cost related

to unimportant research. If you think of the overall research budget, the cost of irrelevant or unimportant research is significant and is a major component. We also have the potential to reduce the cost of dissemination of results. I would stress the word “potential” here. It gets into the vision of us potentially incorporating 10 percent of family physicians in the country. And the potential that that could have for transforming our discipline into a true learning discipline. One which learns from its practice-based activities. Through this broad participation in networks, the opinion leaders rapidly see the adoption of best practices.

**What are the three major challenges facing family practice investigators and PBRNs in conducting this type of research?**

We identified four to constitute our three most important challenges. The first is the need for funding, both at the infrastructure and specific project level. That is no surprise. The second major challenge was that we continue to need to work through the issue of how do we relate the PI, the practitioner, the PBRN, and the funding source, and how do we get them to work functionally rather than dysfunctionally. Within that discussion we articulated two modes and two views of operating. One that builds the PI in as part of the network, and the other which has the PI external to the network in negotiating with the network or selecting among the network and among other modalities as tools for mounting the research. The other piece of that is the critical one that we began to discuss yesterday with potential participants. How do we build funders into our network life and network dialogue?

The third major challenge that we sought was in the whole area of dissemination, and by that we included everything from PR and marketing to dissemination to other researchers, and to family physicians in practice. We saw that challenge being (1) how do we effectively disseminate the actual results of our work, and (2) how to disseminate an understanding of the value of what

we are doing to the world and to family practice. I think the third challenge is to make sure that we not be impeded by parochialism, and seeing our need for action to be solely within — or focused solely on — our own activities.

**Dr. Yawn:** What I heard across the three groups was when you got down to the challenges, they sounded pretty similar — whether we divided them in groups of three or more.

**Dr. John Hickner:** We’ve had a very good focus on the utility of all of this, but again my own — and perhaps it is a single philosophic bias — is that part of what we are really doing is changing the nature and the culture of family medicine. We are changing what we do to being a much more scholarly, reflective sort of practitioner, and really trying to get this so that it not just generating new data.

**Dr. Kevin Peterson:** I have a concern about the idea of dysfunctional relationships across networks. We all come from different backgrounds, and have been able to get together in a variety of different forums. We all need to agree that increased funding from a central source would be a wonderful thing for all of us, and we don’t have that yet. What we do have is a small amount of money on the table that can be handled in a number of different ways. One of those ways could cause all sorts of dysfunctional relationships. Competition is a good thing, but it can also be fairly destructive to an early process. At least in the way it’s done. I have a concern that we would put this money on the table to be stolen from, or at least reduced from an important source of network coordination, and then thrown out to a variety of new or early-developing networks that might not have the necessary expertise.

**Dr. Kurt Stange:** Whenever we’ve talked about methods, we’ve talked about epidemiological methods, and I support that because

I'm an epidemiologist. There is also an alternate paradigm, a qualitative research paradigm, and the real opportunity we have as a discipline is to integrate those two ways of doing research into multi-methods approaches that let us simultaneously isolate and study a phenomenon, and at the same time study its context and meaning. I think we can do that at the same time, and all of our research projects will be on the cutting edge. We will do something new and important.

**Dr. Mary Croughan-Minihane:** My comments are really along the lines of what Kevin was saying. This might be from spending too much time with all of the other network directors, and we spent a lot of time developing acronyms for our networks. So I came up with four Cs that I think really come down to what I see as funding opportunities:

- Coordinated efforts. Develop them between the networks.
- Collaboration between networks on studies.
- Centralized resource for infrastructure. This would decrease the infrastructure costs. I don't know if you can get a lot of efficiency at the local network level, but you can when you coordinate efforts and infrastructure.
- Competition between us. We've spent too many years bringing ourselves together

and becoming true collaborators and friends, and we know family medicine is based on relationships. And so are networks. The fact we are a network of networks is probably the strongest point in our favor to go forward to obtain additional funding.

**Dr. Yawn:** The Task Force appreciates all of the tremendous effort that you have put into this. People have spent a long time preparing their talks and coming to many conclusions, challenging us with all kinds of information. We especially appreciate your efforts in defining the questions and the challenges, and in the messages that we need to further refine and polish and answer, and in the fact that you haven't let us get away with some generalizations. I especially want to thank Dr. Walt Rosser as our international representative for the heroic efforts in trying to summarize all of the things. That was an excellent start, and we appreciate it. And I also thank Dr. Lanny Copeland for taking time out of a very, very hectic year as president of the Academy to say to all of us that this is an important effort; that the Academy endorses the concept of research and its great importance to the specialty of family practice. So, again Lanny, and everyone else, thank you for taking the time away from your family and all of your other activities to be with us. Let's applaud ourselves. Thank you.

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# Closure

**T**his conference was convened because of the fervent belief that primary care PBRNs are integral to science-based medical practice and primary care. Primary care networks are distinguished from subspecialist centers of excellence and other subspecialty networks by their ongoing commitment to understanding how optimal care is provided in the primary care setting.

Subspecialty and pharmaceutical company researchers conduct clinical trials using specially selected groups of patients in carefully controlled settings. The results of these trials may indicate that new treatments or procedures are beneficial in these limited settings. However, only effectiveness studies using primary care patients can confirm or refute these potential benefits in a “real-life” setting. Effectiveness studies conducted by PBRNs contribute in a unique way — by allowing researchers to translate research results into daily practice.

Primary care is the basic science laboratory for clinical medicine, and family physicians are the optimal choice for conducting research in this laboratory. They provide comprehensive health care for men and women of all ages. No other physician or allied health professional has the myriad of skills necessary to diagnose and treat the

wide variety of conditions seen by the family physician.

More than 185 million office visits are made to family physicians each year. A network of family practices has the number of patients necessary to demonstrate clinical significance in addition to statistical significance.

PBRNs offer a large source of data: the type of data necessary to help physicians understand the entire spectrum and natural history of disease, the factors that affect efficacy as it is translated into effectiveness, and the public’s and patients’ acceptance of health care services.

## **Characteristics of successful PBRNs**

As we heard at this conference, successful PBRNs share some important characteristics:

### **Research studies are based on questions of interest to most physicians.**

These questions arise from the physicians’ daily work and often deal with issues at the heart of patient care, such as service delivery, natural history and etiology.

**The network has a dedicated champion.** This individual is committed to the network and the completion of its projects. The champion may be the network director or a member of the network’s planning committee.

**Effective communication takes place with and between the network members.**

Effective communication builds trust among the members and leads to a sense of shared ownership. Physicians are more willing to gather data for the projects if they feel invested in the network's success.

**The network has access to the expertise of methodologically skilled researchers who serve as principle investigators (PIs) and who are sensitive to family practice.**

The role of the PI in a network study is absolutely crucial. Experienced consultant researchers are also needed for methods and analysis interpretation.

**Problems facing PBRNs**

Much of the discussion at the conference addressed the challenges PBRNs face. Some of these challenges include the following:

**The growth of PBRNs and cultural changes.** Small, independent research networks are evolving into larger, more organized research enterprises. The larger and more geographically diverse a network becomes, the more expensive it is to maintain. To survive, a network must attract funding. One issue these networks are facing is balancing their autonomous, grass-roots culture with the demands of external funders who prefer a "top-down" management approach.

**Inadequate recognition for the research conducted by PBRNs.** Until recently, only randomized controlled trials (RCT) based in university centers or other subspecialty-based centers of excellence were recognized as valuable. Primary care researchers rank the RCT on their "A list" in a classification scheme for evidence-based medicine, despite its potential shortcomings, such as lack of generalizability to the population at large and to the entire spectrum of disease. Recently, the importance of other types of work has been touted as ranking on the "B list" — these studies are considered important but not in and of themselves

sufficient to understand individual disease processes and their therapies. PBRNs can provide the laboratory for some of the RCTs that will be generalizable to the population of primary care patients, and PBRNs can complete many of the epidemiology and natural history studies that will facilitate new approaches to diagnosis and treatment, and enhance patients' participation in and acceptance of the health care process.

**Lack of a formal career track for family physicians who want to become researchers.** Until such a path is defined, PBRNs will be unable to identify trained and experienced family physician principle investigators to design and lead these studies.

**Recruiting volunteers in the changing health care system.** As the reorganization of medicine from fee-for-service to managed care continues, physicians have less time to spend on volunteer research projects. Thus, it is becoming more difficult for academic physicians, as well as community-based physicians, to participate in research activities.

**Lack of understanding of family practice's core structures.** To improve the quality of family practice, researchers must understand the core structures and the processes of the specialty. Once the core structures are mapped out, it becomes possible to decipher what is the best intervention to improve the specialty of family medicine. Adequate measures require a broad patient-centered (not disease-centered) view, a view that is primary to family practice.

**Inadequate dissemination of results.** Without dissemination, the research enterprises cannot educate the public about their successes. It is also more difficult to recruit additional participants and solicit additional grants without dissemination.

**Inadequate funding for infrastructure development.** The most critical problem facing PBRNs today is the need for infrastructure funding. Most funding agencies are unable to support



infrastructure costs; they only fund the costs for the research projects. A PBRN must be as efficient as possible so that it can continue to develop using its limited financial resources. Successful PBRNs have multiple streams of funding and have partnered with both private and public funding agencies.

#### **A farewell and a welcome**

After the conference ended, the PBRN community learned of some sad news. It appeared that the problem of inadequate infrastructure funding came to a critical point for the Ambulatory Sentinel Practice Network (ASPN), which announced that it was in serious financial trouble and would close operations by the end of 1999.

Recognizing the value of the work conducted by ASPN and other PBRNs and faced with the void created by ASPN's demise, the AAFP Board of Directors decided on August 28, 1999 to establish a new primary care research network.

The new network will conduct, support, promote and advocate for primary care research in practice-based settings that addresses questions of importance to the discipline of family medicine, and improves the health care delivery to and health status of patients, their families and communities.

Rather than competing with chapter and regional research networks, the new network will maintain a spirit of cooperation and collaboration, providing technical support and advocacy as needed for those existing and developing networks. The Board's action is the latest to demonstrate the Academy's commitment to primary care research. While giving high priority to office-based research, it will give family physicians exposure to the importance of research.

The network will be phased in over three to five years, and staff will work in the AAFP Scientific Activities Division at its headquarters in Leawood, Kan. The AAFP hopes to continue the momentum started by ASPN and the Conference on PBRNs.

