Embracing the PBRN Model to Improve Medication Use
Background Paper

Introduction

Drugs are the most commonly used treatment modality in medicine. Roughly 80% of prescription drugs go to outpatients; only 20% are distributed in acute care institutions (Landis, 1999). Most medicine use data comes from studies conducted in hospitals. We know much less about medication use in outpatient settings, and relatively little about use by patients outside the health care infrastructure. Systematic investigations of prescription drug use that span the continuum of care are virtually nonexistent. Furthermore, studies that evaluate prescribing and patient adherence in chronic diseases, like diabetes, heart disease and asthma, repeatedly document inadequate treatment (Shrank et al. 2006).

Each American uses an average of 12.3 prescriptions (new and refill) per year, a significant increase from only 7.9 per capita in 1994. Ninety-one percent of the population age 65 and older, and 61% of those under age 65 recorded a prescription drug expense in 2003 (Kaiser Family Foundation, 2006). Drugs are becoming more potent and their use is becoming more individualized. Circumstances suggest that the potential for harm from medication is likely to increase rather than diminish unless steps taken to make changes to the medication use system.

In July 2006 the Institute of Medicine (IOM) released a report, *Preventing Medication Errors.* It affirmed the extent of drug related morbidity quantified in the first report of the IOM quality series, *To Err is Human* (2000). The latest IOM contribution summarizes existent research addressing the problem of medication safety and the extent of its application in practice. The report further presents priorities for research directed at better understanding the nature and source of drug related morbidity and ways to prevent it.

The Centers for Education and Research in Therapeutics (CERTs) are providing valuable information about the evidence base for treatment but the evidence must be translated into physician practices and patient behaviors to achieve quality, safety, efficiency and effectiveness. The Agency for Health Care Research and Quality (AHRQ) estimates that it takes a period of 17 years following the completion of original research for new evidence to be widely adopted in clinical practice. Even then only about 14% of the findings are implemented. (Fraser, 2004). Rand researchers report that patients in the U.S. receive only about 55% of recommended care, whether for preventive, acute or chronic conditions (McGlynn et al 2004).

The National Institutes of Health (NIH) and AHRQ have come to regard Practice-Based Research Networks (PBRNs) as an important complement to traditional research. PBRNs are growing, and research from two AHRQ conferences demonstrates, that they

are a productive way to improve care in the ambulatory environment and address the mission of the Agency.

Historical View of PBRN Activity

The IOM is on record as calling PBRNs “the most promising infrastructure development that [the committee] could find to support better science in primary care” (Donaldson et al 1996). Green and Hickner (2006) trace the roots of practice based research back 125 years to physician pioneers who have demonstrated that new knowledge can be discovered by primary care practitioners making systematic observations and aggregating data about their patients.

Avedis Donabedian (1989) pays tribute to Ernest Avery Codman, a Boston physician who promoted the “end result idea” in the early 1900s. Codman described his idea as “merely the common-sense notion that every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful, and thento inquire ‘if not, why not?’ with a view to preventing a similar failure in the future.” Codman further proposed that a committee with representatives from the board of trustees, administration and medical staff would review unsatisfactory results and take appropriate action to guide the organization and operations of the hospital in general. The committee would keep a written account of its proceedings and perhaps publish a periodic summary of its observations and actions.

The end result idea would serve many purposes according to Dr. Codman. Among them systematic study of practice would: monitor quality; advance clinical science; establish accountability; direct the allocation of resources and their efficient use; drive policies; allow patients and physicians to make informed choices; stimulate fair competition and serve as a basis for pricing services and reimbursing providers.

The organization of practice research carried out by networks of like minded practitioners took hold in Canada, Europe and in the U.S. in the 1990s (Green and Hickner 2006). The number of networks that could be identified grew from 28 in 1994 to 111 in 2004. By 2005, the PBRN Resource Center at the Univeristy of Indiana located PBRNs in all 50 states and Puerto Rico. Two organizations represent PBRNs, the Network for Family Practice and Primary Care Research and the Federation of PBRNs, both affiliated with the American Academy of Family Physicians (AAFP).

The NIH Roadmap Initiative resulted in the development of programs to enhance the efficiency of the clinical research enterprise among academic research centers and community-based primary care providers (Beck et al. 2005). Workshops convened by the Clinical Research Roundtable at the IOM added recommendations in support of research that translates findings from bedside to practice beyond the steps proposed by the Roadmap (Aungst et al. 2003). AHRQ and NIH have funded a number of studies conducted in PBRNs. They have established centers of excellence and a Resource Center to improve the research within networks. Practice-based research networks are

now an accepted platform for conducting the investigations needed to identify strategies and tools to increase quality in the health care system.

AHRQ funded the development of PBRNs in primary practice to establish successful operational models and subsequently funded a National Resource Center to support the organization and development of PBRNs; provide guidance in research design and implementation of projects; enhance the collection and analysis of data; and increase the number of peer-reviewed publications. The National PBRN Resource Center maintains a registry of PBRNs.

Research and activities of PBRNs in primary care have been featured in dedicated issues of the *Annals of Family Medicine* (May/June 2005) and the *Journal of the Board of Family Practice* (January/February 2006). AHRQ will sponsor a third annual confernece for PBRNs May 16-18, 2007 in Bethesda, Maryland. Other health professions with PBRNs initatives include dentistry (Pihlstrom and Tabak 2005), nursing (Anderko et al. 2005) and long term care facilities (McNabney et al. 2005).

PBRNs-Definitions and Advantages

PBRNs are grounded in the proposition that "if we want more evidence-based practice, then we need more practice-based evidence" (Green and Glasgow 2006). Randomized controlled clinical trials (RCTs) are designed to ensure that medical technology is safe and effective for the intended use; they do not address the optimal clinical use of those technologies. The evidence needed to change practice is derived from the comparison among clinically relevant interventions in diverse population of patients recruited from a variety of practice settings and assessed on a broad range of health outcomes, that is research in practice, about practice. (Tunis, 2006).

A practice-based research network (PBRN) is a group with at least 15 ambulatory practices and/or 15 clinicians devoted principally to the primary care of patients, affiliated with each other (and often with an academic or professional organization) in order to investigate questions related to community based practice. This definition includes a commitment to the endeavor and an organizational structure that transcends a single study (AHRQ RFA HS 05-011). PBRNs offer practitioner-researchers "a broad-base of expertise, political support and better access to resources" (Nyden 2003). They enjoy economies of scale, efficiency, greater power, and the opportunity to disseminate findings across practices.

To qualify for AHRQ funding (from RFA HS 05-011), a PBRN must have:

- At least 15 ambulatory practices and/or 15 clinicians devoted to primary care practice
- A statement of purpose and a mission that includes an ongoing commitment to research
- An organizational structure that is independent of a single study

- A director responsible for the administrative, financial and planning functions of the network; a person who devotes at least 10% time to this role
- At least one support staff reporting to the director
- Mechanisms for communication with the network such as newsletter, emails, conference calls, meetings, etc.
- An advisory board to solicit advice and feedback from communities of patients served by the PBRN clinicians

Practice-based Research in Pharmacy Settings

The pharmacy profession has long been aware of problems in the medication use process and committed to identifying strategies to minimize errors. For example, pharmacy researchers investigated characteristics of safe distribution systems and introduced solutions such as the unit dose system; improved packaging and labeling; and computer-based records and warning systems.

Thought leaders introduced the concept of pharmaceutical care – the notion that health care professionals involved in prescribing, dispensing, administering and monitoring medication use bear responsibility for ensuring that these products are used appropriately and lead to improved quality of life (Hepler and Strand 1990). Educational standards were adjusted to meet the needs of contemporary pharmacy practice. However, even pharmacists were largely unaware of the extent and impact of drug related morbidity and mortality (Johnson and Bootman, 1990).

Clinicians and researchers from many disciplines are now examining the medication use system and issues related patient safety. To date, most investigations have occurred in the institutional setting, largely because contained systems are conducive to research and data collection. Efforts to identify potential solutions have been largely conducted through traditional approaches to research. In addition inpatient quality improvement programs that seek root causes and potential solutions have generated some attention. However, traditional research and quality improvement approaches are not being translated into practice improvements that lead to better patient outcomes or reduce the cost of providing care.

Although some pharmacists are engaged in PBRN research and have demonstrated some evidence of success, a stream of research that is a routine part of pharmacy practice does not yet exist. The American Pharmacists Association (APhA) Foundation has completed separate studies employing pharmacy networks; managed care organizations have studied medication use in primary care clinic settings and the Veterans Administration has undertaken some descriptive research in several institutions across the country. There are no longitudinal studies in pharmacy-based settings that measure patient outcomes from the use of prescription and over-the-counter products. At this point we have identified no networks in the community context that are of adequate size and committed to a long term engagement in research to meet the AHRQ definition of a PBRN.

There are several innovative medication management programs in outpatient settings that are impressive in their potential for improving medication use. The most common pharmacist-managed programs are anticoagulation, asthma, and diabetes management; lipid, cardiovascular, and smoking cessation clinics. Although promising, studies of these programs are criticized for having methodological shortcomings and leaving questions about generalizability, feasibility and cost-effectiveness largely unanswered (Knapp and Ray, 2002). Consequently, resulting changes in clinical practice are few and they are slowly adopted with little, if any, impact on reducing the occurrence of adverse drug events.

Characteristics of Solutions to Improve Quality

Reflecting on initiatives that increase safety and improve the quality of health care – and observations about those that have failed – suggest that effective solutions will share some common characteristics (Thomas aand While 2001). Interventions that improve the quality of health care, including those that improve medication use, must employ an approach that is feasible in contemporary medical practice. It must be a tested model that works for practitioners and benefits their practice, ideally making use of existing and under-utilized resources. Effective solutions will apply existing knowledge and experience, as well as create new knowledge. Changes designed to be transferable across practice settings and disciplines will improve the coordination and continuity of care. Finally, the end result must be a benefit to society that improves health outcomes without increasing cost of care.

Successful initiatives carry the potential for increasing patient satisfaction and, in turn, energizing practitioners and empowering both. Positive results can change the organizational climate and beget a series of innovations designed to address problems and develop solutions. Effective, long-lasting changes can reveal insights to endemic problems and may generate more complex, multifaceted solutions. The PBRN model essentially treats networks as complex adaptive systems and addresses problems by taking a whole-system approach. In short, you can't change practice if you don't understand practice (Crabtree, Miller and Stange 2001).

PBRNs as a Means to Improve Medication Use

In the U.S. there are collectively more than 70,000 pharmacies in all types of health care facilities including more than 56,000 community pharmacies. "The geographic locations of pharmacies are based on consumer preferences for convenience and access, making them a logical site through which care can be enhanced" (Knapp and Ray, 2002). Pharmacists are central to the medication use process and are the most frequently encountered health care professionals. Persons 55 years and older visit a pharmacy twice a month on average. Elders with chronic illnesses average 15 visits every month (Drug Store News 2004).

In addition to access and convenience, studies in pharmacy settings afford the opportunity to observe self care practices that overlay prescribed therapies including OTC drugs and nutritional supplements. For patients under the care of multiple physicians including various specialists, the pharmacy serves as an ideal place for studying and improving the continuity and coordination of care across settings. Persons with chronic illnesses and disability visit the pharmacy frequently and usually are known to pharmacists. Because patients visit pharmacies at frequent and regular intervals it is a fine place to examine the quality, safety, efficiency and effectiveness of prescribed treatments for chronic disease

PBRNs in pharmacy settings are of particular importance to priority populations. The broad distribution of pharmacies provides access to traditionally underserved populations in both rural areas and inner city locations. Persons with low health literacy, or who have problems with prescription insurance or lack thereof, are known to turn to the community pharmacist for assistance. Those with low income or lacking health insurance are apt to go to a pharmacy in search of self-care products before visiting a medical clinic or physician's office. Moreover, women use more prescription medication than men and often make health related purchases on behalf of other members of the immediate and extended family including children, elderly relatives and neighbors. Studies suggest that customers find pharmacists approachable and helpful, and that they trust the pharmacists' advice (Consumer Reports 2003).

Opportunities for practice-based research at the pharmacy go beyond the clinical aspects of medication use. As was demonstrated with Medicare Part D, pharmacists provide trusted advice for patients about insurance plans, formulary restrictions and the like - particularly for elders, the disabled and persons with low health literacy. CMS (4/21/06) recently announced its interest in developing and testing new pharmacy payment models based on patient outcomes and formed the Pharmacy Quality Alliance toward that end.

Needs/challenges of PBRNs

The primary needs and challenges facing PBRNs according to the AHRQ National PBRN Resource Center include:

- Recruitment and training
- Compliance with Institutional Review Boards (IRB) and health data confidentiality requirements
- Involvement of other disciplines, patients and community members
- Engaging community representatives in research
- Techniques and skills for managing multi-site projects
- Translating research results into practice
- Strategic planning and organizational change methods
- Conceptualization, design and implementation of effective research methods

- Instrument testing and development
- Data collection, storage, management and analysis
- Use of technology to facilitate communication and project implementation
- Unbiased forums/opinions for discussion of best practices and solution
- Advice on securing funding from federal agencies, foundations and other sources

Role of the American Association of Colleges of Pharmacy (AACP)

The AACP's primary interest in PBRNs and related research is to provide service to various stakeholders including academic researchers and educators of both practitioners and future researchers. The introduction of PBRN model in pharmacy settings has implications for AACP members evaluating their programs to ensure that student pharmacists and graduate students receive an education that prepares them for participation in interdisciplinary research. It is anticipated that changing the research paradigm will require rotations and internships with clinical experiential training for students, training grants and organizational support for faculty development, and facilities for the establishment of practice based research networks.

AACP member interest in PBRNs is piqued by new accreditation standards being implemented in 2007 that introduce an emphasis on public health. The new standards emerge directly from the IOM report on Health Professions Education (Greiner and Knebel 2003) and curricular guidelines subsequently developed by AACP. Accreditation standards now require colleges/schools to provide faculty development for full-time and part-time practice based preceptors. PBRNs are an attractive way to partner the academic and practice communities through research and education to enhance both the future practice of student pharmacists and improve medication use by patients.

Changes in the system that effect improvements will require research and education. BY exposing health professions students to clinical research, those going into clinical practice might become part of changing the culture of primary care through the "vision and tools to incorporate research activities into their practices."

Embracing the PBRN Model to Improve Medication Use

The need for a national conference on the subject of practice-based research in pharmacy settings was raised in the 2005 Report of the Research and Graduate Affairs Committee (Beck 2005). The AACP Board of Directors then charged an advisory group and named a Scholar-in-Residence to develop plans for a conference. Roundtable discussion at the 2006 AACP Annual Meeting confirmed ongoing interest in practice-based research.

The conference was designed to bring together a multi-disciplinary group of leaders from academia and practice to advance the concept of practice based research. The

purpose of the conference is to develop and disseminate strategies for the implementation of research based on the PBRN model, backed buy a cadre of energized and well-informed researchers and practitioners focused on improving the medication use process.

AACP's goals for the conference, *Embracing the PBRN Model to Improve Medication Use,* are to:

> (1) identify the knowledge gaps that might be addressed by research networks in pharmacy settings;
>
> (2) describe the education and training of people who will be effective collaborators in PBRNs; and
>
> (3) specify the infrastructure requirements necessary for PBRNs to create and sustain progress in research and education.

The infrastructure of the AACP conference, *Embracing the PBRN Model to Improve Medication Use*, builds upon a highly successful consensus conference used in 2005 by AACP to advance the quality of experiential education. The conference program was designed to challenge existing paradigms and support break-through thinking by employing trained facilitators experienced in using techniques proven useful for a small working group format.

The working groups will engage in focused and interactive discussion intended to fully appreciate and explore the implications of embracing the PBRN model. The participants will convene after the small group sessions to share and evaluate their work products. Speakers and round table discussants will bring personal experience and expertise in PBRNs to share with participants. Participants will learn best practices for organizing a research network; consider strategies for recruiting and retaining network members; and apply valid research methodologies and data collection techniques suitable to the PBRN approach. They will have unstructured time to encourage networking among colleagues with similar research and practice interests.

Conference proceedings will be prepared to summarize discussions and activities of the break-out sessions. The proceedings will record recommendations to AACP in support of individual action plans and network development, as well as professional and graduate education and training. A report on the conference and its outcomes is to be issued to AACP members at the Annual Meeting in July 2007 and published in the *American Journal of Pharmaceutical Education.*

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