

Establishing Pharmacist Practice-Based Research Networks

APhA Foundation White Paper

May 2010

Prepared by

Jon C. Schommer, PhD, RPh



Establishing Pharmacist Practice-Based Research Networks

Lead Author:

Jon C. Schommer, PhD, RPh
Professor
University of Minnesota
College of Pharmacy
308 Harvard Street, S.E.
Minneapolis, MN 55455
Phone: 612-626-9915, Fax: 612-625-9931
Email: schom010@umn.edu

Advisory / Review Board:

Anne Burns, Pharmacist
Vice President, Professional Affairs
American Pharmacists Association
2215 Constitution Ave, NW
Washington, DC 20037
Phone: 202-429-7522, Fax: 202-347-5679
Email: aburns@aphanet.org

Lucinda L. Maine, PhD, RPh
Executive Vice President and CEO
American Association of Colleges of Pharmacy
1727 King Street, Floor 2
Alexandria, VA 22314
Phone: 703-739-2330 ext. 1008, Fax: 703-836-8982
Email: lmaine@aacp.org

William M. Ellis
Executive Director & CEO
APhA Foundation
2215 Constitution Ave, NW
Washington, DC 20037
Phone: 202-429-7576, Fax: 202-429-6300
Email: wellis@aphanet.org

L. Douglas Ried PhD
Dean and Professor
Southwestern Oklahoma State University
100 Campus Drive
Weatherford, OK 73096
Phone: 580-774-3105, Fax: 580-774-7020
Email: doug.ried@swosu.edu

Acknowledgements:

Some of the text used for this paper originally appeared in the (October 2008) issue of America's Pharmacist, published by the National Community Pharmacists Association, Alexandria, VA. Reprinted with permission.

Some of the data used for this report was provided by the American Pharmacists Association and included data from a Focus Group conducted during April 2009 with Community Pharmacy Residency Sites and a Community Pharmacy Residency Survey conducted in November 2009.

Funding for this report was provided by the American Pharmacists Association with partial support provided by TEVA Neuroscience.

TABLE OF CONTENTS

Executive Summary	4
Introduction and Background	7
A Review of the Literature	14
Description of an Existing Pharmacy PBRN as an 'Insight Stimulating Example'	27
Community Pharmacy Residency Program – Focus Group	33
Community Pharmacy Residency Program – Survey	35
Recommendations Regarding Next Steps	44
References	47
Appendix A: American Pharmacists Association, Research Gap Analysis Task Force	51
Appendix B: Minnesota Pharmacy Practice-Based Research Network: Guiding Principles	56
Appendix C: Current Capabilities of the Minnesota Pharmacy PBRN	58
Appendix D: Community Pharmacy Residency Program, PBRNet Focus Group Meeting	61

Establishing Pharmacist Practice-Based Research Networks

EXECUTIVE SUMMARY

Objectives

The objectives for this report were to:

1. Describe the need and rationale for Pharmacist Practice-Based Research Networks (PBRNs).
2. Provide a literature review regarding the advantages of such PBRNs and the challenges to participating in PBRNs.
3. Describe an existing Pharmacy PBRN as an “insight stimulating example.”
4. Summarize findings from a Focus Group convened for the purpose of understanding the most important elements needed for an infrastructure to support a Community Pharmacy Residency Program PBRN.
5. Summarize findings from a Community Pharmacy Residency Program Survey related to Practice-Based Research Networks.
6. Provide recommendations regarding next steps for the advancement / growth of Pharmacist Practice-Based Research Networks with particular attention given to the use of pharmacies associated with Community Pharmacy Residency Programs as the foundation for a PBRN.

Description of Practice-Based Research Networks

A **Practice-Based Research Network (PBRN)** is “a group of ambulatory practices 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”

There are many applications for a Pharmacy PBRN including goals to (1) improve clinical practice, (2) improve the health care system’s ability to provide access to and deliver high quality health care, (3) train future practitioners and scientists in this domain, and (4) provide policy makers with tools and expert advice to assess the impact of system changes on outcomes, quality, access to, cost, and use of health care services; particularly in areas related to the medication use process. Practice-Based Research provides a venue in which: (1) science can be translated to practice, (2) practice needs can be communicated to guide scientific inquiry, and (3) findings can be used as a voice for advancing the practice of pharmacy and its role in the health care system.

Focus Group Findings

Based on a review of the literature, the experiences of a statewide PBRN, and its own “Research Gap Analysis,” leaders within the APhA Community Pharmacy Residency Program (CPRP) began discussions regarding the creation of a Practice-Based Research Network using CPRP sites (named PBRNet). To begin dialogue for this idea, 15 individuals who were affiliated with community pharmacy residency

programs convened to participate in a focus group on April 5, 2009 in San Antonio, Texas. The purpose of this inquiry was to understand the most important elements needed for an infrastructure to support a Community Pharmacy Residency Program PBRN (PBRNet).

Specific needs for PBRNet that were identified by the focus group related to (1) a sponsoring organization, (2) aligning Community Pharmacy Residency Program accreditation requirements with PBRNet goals, and (3) technology standards for collecting, extracting, and sharing data. A summary of these points, based upon focus group findings, is listed next.

1. A **sponsoring organization** should be identified in order to provide an identity for the PBRN and a structure for taking the next steps in PBRN development such as:

- creation of a steering committee
- development of guidelines for project evaluation and project introductions to sites
- development of one-way communication channels (e.g. newsletters, email/web updates)
- development of two-way communication opportunities
- creation of guidelines and methods for sites to opt-in and opt-out of projects

2. Community Pharmacy Residency Program **accreditation requirements** should be reviewed and revised (if necessary) so that residents could participate in PBRN projects (including multiple year and multiple site projects) and still earn credit for their “residency project” requirement.

3. Development of **technology standards** is needed. Technology is constantly changing and will need consistent attention during the life of the PBRN. Initially, the first PBRN projects might be devoted to collaborative research for creating a PBRN “Capacity Portfolio” that would identify key hardware and software components and then describe these for the sites that are participating in the PBRN. Other elements in the capacity portfolio could include things such as (a) services offered at each site, (b) collaborative practice at each site, or (c) point-of-sale record keeping for OTCs, just to name a few.

The research needed for developing “capacity portfolios” could actually be the first multi-site, multi-year residency projects conducted under the PBRN umbrella. This research is not only needed to help advance the PBRN, but also could provide valuable experience in how the PBRN should conduct projects.

Survey Findings

A survey of Community Pharmacy Residency Program members conducted in November 2009 provided descriptive results that can give guidance for making decisions related to organization, accreditation, and technology. For example, the survey results revealed that relatively few pharmacy sites have access to electronic medical records. Also, the results showed that relatively few pharmacy sites believe that they have the resources/time, experience, or funding for conducting practice-based research.

Next Steps

While it appears that collaborative partnerships have been established for PBRNet (Step 1 of Kuo et al.’s 10 step process for starting a PBRN), an important next step relates to infrastructure (Step 2 of the process). Common infrastructure elements for PBRNs include: (1) director (operational responsibilities), (2) coordinator (staff person for day-to-day operations), (3) one-way communication (news-sharing

functions via newsletter or web site), (4) two-way communication (email listserv or blog for sharing news and collaborative feedback), (5) membership roster (for identification of collaborators), (6) meetings (for presentation of ideas, results, training, continuing education, etc.), (7) board (to meet any legal status requirements of the network and for oversight and guidance), and (8) human subjects protection management (for meeting institutional review board and other standards for responsible conduct of research). Beyond these, mission dependent infrastructure elements may include (1) research assistants, (2) information technology, (3) regulatory compliance, or (4) research consulting expertise (e.g. statistical consultation).

In light of the Kuo et al.'s steps for starting a PBRN and the findings from the focus group and survey, we propose that fund raising, training, and collaboration are needed for the PBRNet to move forward. In order to be successful, we propose that a solid infrastructure combined with the correct fit in leadership style for the PBRNet could overcome obstacles in the long term.

For the short term, steady progress related to the common goals of: (1) advancing the evidence for patient care in community practice and (2) obtaining large enough sample sizes for achieving meaningful results for pharmacy residents' projects via collaboration among sites could help build trust among members, reveal emergent infrastructure needs, and provide momentum for the larger challenges (e.g. technology standards for the PBRNet) that could be addressed as the PBRNet develops.

Establishing Pharmacist Practice-Based Research Networks

INTRODUCTION AND BACKGROUND

The objectives for this report are to:

1. Describe the need and rationale for Pharmacist Practice-Based Research Networks (PBRNs).
2. Provide a literature review regarding the advantages of such PBRNs and the challenges to participating in PBRNs.
3. Describe an existing Pharmacy PBRN as an “insight stimulating example.”
4. Summarize findings from a Focus Group convened for the purpose of understanding the most important elements needed for an infrastructure to support a Community Pharmacy Residency Program PBRN.
5. Summarize findings from a Community Pharmacy Residency Program Survey related to Practice-Based Research Networks.
6. Provide recommendations regarding next steps for the advancement / growth of Pharmacist Practice-Based Research Networks with particular attention given to the use of pharmacies associated with Community Pharmacy Residency Programs as the foundation for a PBRN.

Description of a Practice-Based Research Network (PBRN)

A **Practice-Based Research Network (PBRN)** is “a group of ambulatory practices 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” [1]. PBRNs first were formed in primary care practices in the late 1970s [2-3] and involved community-based clinicians and their staffs in activities designed to help understand and improve primary care [1]. The goal was to link relevant practice questions with rigorous research methods in community settings to provide information that was reliable, valid, and transferable into everyday practice. Currently, the goal for most PBRNs is to focus upon (1) questions encountered by primary care clinicians in their practices, (2) issues that are relevant to members of diverse communities served by these practices, and (3) research that can be shared quickly with the practice community [1].

Funding support for PBRNs in the United States during the 1970s and 1980s developed outside the traditional National Institutes of Health (NIH) and pharmaceutical company-sponsored research domains [4]. Initial development of PBRNs was supported by volunteer efforts of practicing primary care physicians with financial support from private foundations (e.g. Rockefeller Foundation, Kellogg Foundation, Robert Wood Johnson Foundation), professional societies and organizations, academic institutions, and both state and federal government agencies (e.g. Health Resources and Services Administration, Bureau of Maternal and Child Health) [2]. From these efforts at local, regional and national practice networks, a body of literature grew during the 1980s and 1990s in medical journals as the enterprise slowly grew and spread [2]. Then, in its 1996 report on primary care, the Institute of Medicine viewed PBRNs as “a significant underpinning for studies in primary care” and noted that they were under funded [5]. A few years later, the Agency for Healthcare Research and Quality (AHRQ) responded by releasing the first of a series of grant solicitations that focused on support for PBRNs. From 2000 to 2004, AHRQ provided more than \$8 million in awards for support of primary care PBRNs. By 2004, a national survey conducted by the AHRQ PBRN Resource Center identified 111 active primary care networks in the United States. These networks were headquartered in 44 states and included multiple types of practitioners (pediatricians, internists, advanced practice nurses, and family physicians). Most of these networks first emerged after 2000 when the seed money and other support offered by AHRQ became available [6].

More recently, PBRNs have been utilized to help inform quality improvement activities within primary care practices and the adoption of an evidence-based culture in primary care practice [7]. PBRNs appear to be evolving into collaborative learning organizations through which better ways to “translate research into practice” can be achieved [7]. In addition, practice-based networks have been envisioned as places of learning, where clinicians are engaged in reflective practice inquiries and where clinicians, patients, and academic researchers can collaborate to develop new ways to improve delivery of primary care.

The July/August 2008 issue of the Journal of the American Board of Family Medicine is an example of translating research into practice through PBRN research efforts. The research reported in that practice-based research theme issue focused on disseminating evidence based on real-life medicine, reflecting patients seen in day-to-day practice rather than carefully selected subpopulations of patients from tertiary care centers [8]. Comprised of various research methodologies, the reported studies provided translatable evidence regarding: preventive services [9], mammography screening [10], cardiovascular risk education [11], dyslipidemia in children [12], high blood pressure knowledge [13], supplemental calcium use among women [14], primary care of overweight children [15], adoption of exercise [16], underinsurance in primary care [17], effects of antibiotics on vulvovaginal candidiasis [18], depression screening in pregnancy and postpartum [19], retention of clinicians in underserved communities [20], preventive care delivery [21], and institutional review board training for community practices [22].

Funding for the studies just mentioned, as well as most current funding for sustaining PBRNs' efforts, is coming from foundations, several institutes of the NIH, corporations, and collaborative efforts with state and federal agencies [7]. Although seed funding from the Agency for Healthcare Research and Quality (AHRQ) has faded, it still supports PBRNs by serving as a central location for documenting and sharing information [1].

Advantages of Community Pharmacy PBRNs to Patient Care and Society

Capacity

In light of over two decades of success for PBRNs in primary care practice and the coincident evolution of community pharmacy practice as a recognized patient care access point, thought leaders within pharmacy have begun developing and implementing Community Pharmacy Practice-Based Research Networks [23]. The advantages of such networks to patient care and to society are rooted in the use of medications by almost all members of society during their lifetime and the accessibility that pharmacies provide to the public.

For example, drugs are the most commonly used treatment modality in health care. Each American uses an average of 12.3 prescriptions (new and refill) per year and 91 percent of the population age 65 and older recorded a prescription drug expense in 2003 [24]. Approximately 80 percent of these prescription drugs are distributed to outpatients; only 20 percent are distributed in acute care institutions [25]. However, most medication use data comes from studies conducted in controlled settings such as hospitals/clinical trials. There is some medication use information obtained from claims data files or from patients' self-reports via surveys. However, such studies are retrospective in nature and are limited in the types of questions they can address. Developing capacity for research in networks of community pharmacies could help fill gaps in our understanding of the medication use process by focusing upon (1) questions encountered by pharmacist practitioners in their practices, (2) issues that are relevant to members of diverse communities served by these practices, and (3) research that can be shared quickly with pharmacy practice and the broader healthcare community.

The advantages of such an approach are clear. In the U.S. there are 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 upon community members' preferences for convenience and access, making them a logical site through which care can be studied and enhanced [26]. Pharmacists are central to the medication use process and are the most frequently encountered health professionals for many patients. A 2000 estimate of pharmacy patronage showed that the equivalent of the entire U.S. population (275 million at the time) visited pharmacies each week [27]. Persons 55 years and older visit a pharmacy twice a month, on average. Elders with chronic illness may average 15 visits per month [28]. In comparison, less than an estimated 0.1 percent of potential patients are hospitalized monthly in academic medical centers and only approximately 11 percent of Americans visit a primary care physician's office each month [29].

In addition to access and convenience, studies in community pharmacy settings afford the opportunity to observe self-care behaviors that overlay prescribed therapies including over-the-counter drugs and nutritional supplements [30]. For patients under the care of multiple prescribers, the pharmacy

serves as an “ideal place for studying and improving the continuity and coordination of care across settings” [30]. Since many patients visit pharmacies at frequent and regular intervals it is an ideal place to examine the quality, safety, efficiency, and effectiveness of many prescribed treatments for chronic care [30].

A Unique Opportunity

Such access to patients at the point of procuring most of the medications utilized in the U.S. presents a unique opportunity for pharmacists and pharmacies to help contribute to an understanding of the medication use process. A Pharmacy-Based PBRN could be comprised of a network of pharmacies working together to collect information for the purpose of addressing medication use questions that are generated by communities, the profession, and by society. The network would focus on collecting information in real-world settings (pharmacies) to help address societal, community, or professional questions that relate to medication use.

Such a focus would expand upon existing work and begin to collect information for the purpose of addressing societal and community questions related to the medication use process. In this domain, a pharmacy practice-based research network (Pharmacy PBRN) could serve as a natural laboratory in the field setting to address a variety of questions. A well-designed network could help increase the chance of success for securing competitive funding. Funding agencies such as AHRQ and NIH do not typically award funds to help “improve the profession of pharmacy.” Rather, they are more interested in funding proposals that represent “novel ways to address societal needs related to health and wellness.” In addition to helping secure funding, the network could serve as a meeting point for sharing and generating new ideas that are relevant to the interface among the practice of pharmacy, health care, communities, and society overall.

An example of a societally-relevant medication use question that could be addressed by a Community Pharmacy PBRN is in the area of headache. Results from a study revealed that the majority of individuals who purchased over-the-counter analgesics for headache pain was less than optimally treated and that community pharmacies have enormous potential to be an important source for

identification, education, and referral of individuals with headache [31]. Another study revealed the benefits of daily migraine prevention on overall health care use [32]. Again, community pharmacies could play an integral role in improving medication use for individuals with headache.

A community pharmacy PBRN would help a great deal in advancing the understanding of chronic headache care. First, a pharmacy PBRN would provide a natural experiment for identification, education, and referral of individuals with headache who present to a pharmacy with suboptimal headache treatment. Second, a pharmacy PBRN would allow for follow-up on the effect of referral in a natural field setting. Third, a pharmacy PBRN would be able to provide information about the resultant outcome. Finally, a pharmacy PBRN would be able to do this at multiple sites, in multiple patient populations, and across multiple health plans or systems. These characteristics of a pharmacy PBRN have advantages over other methods including (1) survey research, (2) use of pharmacy claims data, (3) use of health plan data, and (4) extrapolation from clinical trials. The PBRN allows for a multi-layered approach and the ability to target data collection in a prospective fashion (versus retrospective).

A Way to Fill Gaps in Understanding Medication Use and Patient Care

There are many other applications for the Pharmacy PBRN including goals to (1) improve clinical practice, (2) improve the health care system's ability to provide access to and deliver high quality health care, (3) train future practitioners and scientists in this domain, and (4) provide policy makers with tools and expert advice to assess the impact of system changes on outcomes, quality, access to, cost, and use of health care services; particularly in areas related to the medication use process. Practice-Based Research provides a venue in which: (1) science can be translated to practice, (2) practice needs can be communicated to guide scientific inquiry, and (3) findings can be used as a voice for advancing the practice of pharmacy and its role in the health care system.

In 2006, the American Pharmacists Association convened a "Research Gap Analysis Task Force" to:

1. describe the purpose and scope of research as it relates to pharmacy and APhA,

2. identify priority areas of research for guiding actions of APhA, and

3. propose steps that should be undertaken by APhA in order to fill research gaps.

That task force identified several areas that are well-suited for PBRNs and also suggested that APhA “assist practitioners, researchers, funders and other potential partners as they develop networks for discussing and developing concept papers for research projects” and to “facilitate formation of research groups.” The full report is contained in Appendix A.

Just a few examples of the types of studies that could be conducted by PBRNs to fill research gaps include:

- Post-marketing surveillance of medications
- Comparative Evidence studies for pharmaceuticals
- Policy Impact Studies
- Outcomes evaluations
- Societal-driven questions
- Community-initiated questions
- Profession-initiated questions
- Disease-specific questions
- Patient segment-specific questions
- Clinical Effectiveness studies (vs. clinical efficacy studies)

A REVIEW OF THE LITERATURE

Advantages of Community Pharmacy PBRNs to Pharmacists

In addition to benefits to patient care and to society, pharmacists can benefit from participation in Community Pharmacy PBRNs. Goode and colleagues [33] reported that research in community practice can expand interactions for practice-site pharmacists with practice and science faculty. Such collaboration can raise job satisfaction by adding new opportunities and dimensions to the activity mix for the practice. A survey of Australian community pharmacists confirmed many of the same benefits to improving professionalism and job satisfaction through participation in practice-based research [34]. Over time, professional friendships between practitioners and academic researchers can transcend beyond practice-based research into other professional endeavors.

Another benefit is stronger relationships and more referrals from physicians whose patients participated in practice-based research studies [33]. Pharmacists may develop deeper intellectual curiosity and further commitment to advance practice through such collaborative research. Furthermore, this involvement affords opportunities to publish, starting or adding to their publications portfolio [33]. As practice-site pharmacists feel a sense of accomplishment, they may begin to look for other projects and methods for improving patient care. Over time, pharmacists may deepen their relationships with patients as both parties become more engaged in patient-centered care and solving patient care problems.

Sinclair-Lian and colleagues [20] reported that professional isolation can be a barrier to practicing in rural and underserved communities. They suggested that one of the potential contributions of a practice-based research network may be its beneficial effect on the retention of providers in medically underserved areas. Interviews with practitioners revealed that membership in a PBRN helped decrease the feeling of intellectual isolation, increased connections with peers, and contributed to better recruitment and retention of practitioners.

Pruchnicki and colleagues [35] adopted a PBRN model for a pharmacy residency training program. The PBRN was formed for the primary purpose of research training of residents and described

as a practice-based research training network (PBRTN). By allowing the resident to assume the role of project manager, the experience provided time management, resource management, and communications experiences. The PBRTN structure enabled increased productivity and greater opportunity for leadership in patient care. The authors suggested that residency program directors and/or preceptors would experience advantages in residency training program by participation in PBRTNs.

Finally, Pinto and Coehrs [36] outlined other advantages for pharmacists' involvement in Community Pharmacy PBRNs. Participation in practice-based research will increase clinical expertise and help stay up-to-date with current and emerging therapies. Furthermore, new financial opportunities might be found through participation in PBRNs. Pinto reported that pharmacy owners in a PBRN located in Toledo, Ohio experienced significant financial gains as a result of streamlined workflow and improved efficiency gain from project experiences [36]. In addition, partnerships with employer groups to find funding for new programs, increased pharmacy traffic, and increased patient loyalty resulted in financial gains as well.

Challenges to Participating in Community Pharmacy PBRNs

Challenge 1: Getting Started

Kuo and colleagues [37] shared their expertise for how start a PBRN based on their experiences with the Southern Primary-care Urban Research Network (SPUR-Net) in Houston, Texas from 2000 to 2007. Since 2000, SPUR-Net helped obtain more than \$8 million in funding and conducted 22 research projects. Based on that experience, they suggest 10 steps for developing a PBRN.

Step 1: Form Collaborative Partnership

A PBRN is a network of organizations and/or individual practitioners that share the same vision for translational research [37]. These partnerships can be formed using either a top down or a grass roots approach. The top down approach recruits directors, managers, and partner organizations whereas the grass roots approach recruits individual practitioners first. Goode and colleagues [33] commented that

each participating individual should understand the role of each collaborator in developing and maintaining relationships in the PBRN. Common mission and consistent interaction are important components for collaborative partnerships.

Step 2: Develop Research Infrastructure

The infrastructures of practice-based research networks (PBRNs) differ widely, reflecting their varying origins, settings, and goals [38]. Some PBRNs are based upon a collection of practitioners who are interested in conducting research. Others are based upon a specific research agenda. Some PBRNs have a local focus, while others are regional in scope. The infrastructure of a PBRN should be designed to support its research mission and should be designed after that research mission has been determined.

According to Green and colleagues [38], common infrastructure elements for PBRNs include: (1) director (operational responsibilities), (2) coordinator (staff person for day-to-day operations), (3) one-way communication (news-sharing functions via newsletter or web site), (4) two-way communication (email listserv or blog for sharing news and collaborative feedback), (5) membership roster (for identification of collaborators), (6) meetings (for presentation of ideas, results, training, continuing education, etc.), (7) board (to meet any legal status requirements of the network and for oversight and guidance), and (8) human subjects protection management (for meeting institutional review board and other standards for responsible conduct of research). Beyond these, mission dependent infrastructure elements may include (1) research assistants, (2) information technology, (3) regulatory compliance, or (4) research consulting expertise (e.g. statistical consultation).

Step 3. Formulate Research Questions

A researcher interested in partnering with a PBRN can initiate a study and identify network practitioners to participate in the study. The research topic typically arises from the researcher's expertise, interest, and previous work. Alternatively, a practitioner may propose a study of interest and find research collaborators. The practitioner formulates the study question based on observations made in practice and

submits if for further scientific inquiry. A third option is through community engagement. Professional organizations, community organizations, and government organizations often have societally relevant questions related to medication use. A PBRN could partner with these organizations for studying community-based questions.

Step 4. Design Study Methods

A good PBRN infrastructure can identify methodological expertise needed for research projects. Study designs for practice-based research projects typically require collaboration among stakeholders (e.g. practitioners, patients, pharmacy staff, clinic staff, researchers, community partners, etc.) [37] Study designs for PBRN research differ widely, depending upon the research question. In field research, quasiexperimental designs, program or system evaluations, mixed methods using both quantitative and qualitative data often are used. Randomization based on clinic, provider, or patient level can still be applied [37]. However, sophisticated multilevel statistical modeling often is required when data have a hierarchical structure, with patient-level measures clustered (nested) within prescribers and multiple prescribers clustered within the same practice or health plan [39].

Step 5: Obtain Funding Support

By partnering with academic institutions, PBRNs can utilize university, academic health center, and research institute resources already in place for identifying potential research funding sources [37]. In addition, web-based searches focused on specific topics of interest often uncover potential funding sources. Finally, personal networking can open up doors for possible funding sources for project ideas.

Members of the PBRN can meet regularly to serve as a sounding board to evaluate types of grants for which to apply. Researchers often take the lead to work on grant applications by serving as principal investigators (PIs). Network partners can assist in the grant proposal process by providing institutions support (e.g. access to clinicians and patients) and helping with study design and implementation issues [37].

When preparing grant proposals, budgets should include requests to fund (if applicable): (1) practice site administrative costs related to the project, (2) pharmacist and staff time, (3) compensation or incentives for study participants, (4) continuing education training, (5) travel fees, or (6) data [37]. The level of funding support depends on the extent of involvement needed from the participants and varies by funding source rules [37]. In order to streamline payments, grant proposals may include an overall subcontract with an external organization which coordinates payments to practitioners, practice sites, and study participants. The budget should include funds to pay this organization for their coordination and work in the subcontract.

Step 6: Develop Study Instruments

Research instruments for practice-based research studies need to be feasible and not disruptive to normal patient care services. Pilot testing on a small number of study subjects is advisable before using an instrument for a full study. Data collection instruments should be culturally suitable, meet the health literacy of study participants, and linked to the study questions being investigated [37]. A temptation for researchers is to focus so completely on the research project, that they do not consider the realities of patient care practice in the field setting. Study instruments and their administration need to balance the need to collect reliable and valid data with the need to observe patient care without changing it artificially.

For some projects, electronic data collection is an option. However, given the required investment in hardware, software, and training, PBRN researchers must weigh both the advantages and disadvantages of adopting electronic data collection methods [40]. Typically, new PBRNs that are still recruiting initial members, that are focusing on their first studies, or that have limited personnel may wish to devote their energy toward other infrastructure. When considering electronic data collection, Pace and Staton [40] suggest the following for consideration:

- (1) Do the studies lend themselves to electronic data collection?
- (2) Does the technologic expertise to implement electronic data collection exist?

- (3) Can we support the infrastructure and personnel costs associated with electronic data collection?

Step 7: Implement the Study

In addition to obtaining approval from the network administrators and committee members before implementing a research project, study investigators and practitioners must also obtain approval from patient advisory boards and institutional review boards (IRBs). IRBs require all research staff to complete some type of human participation certification training that has components pertaining to: Health Insurance Portability and Accountability Act (HIPAA) regulations, research ethics, researcher responsibilities, responsible conduct of research, and IRB roles.

After all approvals are obtained, key research personnel certified, and instruments pilot tested, the investigators are ready to implement the study in participating practice sites. A research protocol that outlines procedures and time lines guides research personnel during the study. Investigators and research staff usually discuss progress and issues during weekly project meetings [37].

Step 8: Manage and Analyze the Data

Data collected from the study can be managed and analyzed by entering the data into a spreadsheet. For some projects, a data management tool like Excel is most suitable. For other projects in which advance statistical analysis is used, the suitable statistical package is chosen (e.g. SAS, Stata, SPSS). For non-numeric (qualitative) data, other software programs are chosen (e.g. Atlas.ti, NUD*IST, or NVivo) [37]. Data analysis choices should be made based upon the research questions being answered in the project and the methods employed for the project.

Step 9: Disseminate Results

Study findings often are disseminated first with network members via PBRN meetings, email, listservs, blogs, newsletters, or personal contact [37]. Care should be given to maintaining confidentiality

of data and anonymity of study participants in situations that require this. When sharing and storing data, it is vital to follow data encoding, secure access, and secure storage processes. Study findings can be presented outside the network in the form of presentations and publications. Establishing an authorship guide and acknowledgement policy will help avoid misunderstandings among collaborators. Explicit guidelines for both inclusion as an author and also for order of authorship should be agreed upon before the project begins.

Step 10: Translate Research into Practice

“Practice-based research draws research from practice and translates research findings back into practice” [37]. Fostering collaboration among all parties involved in PBRN research helps in the translation of the findings back into practice. Such research often times identifies areas for improvement and also new opportunities that could be pursued. By reviewing findings with directors, managers, administrators and staff of practice sites, new ideas for improving patient care, patient outcomes, satisfaction, and efficiency may be generated [37].

According to Mold and Peterson [7] PBRNs are not just clinical laboratories for research, but also “learning communities, providing grounds for generalizable solutions to clinical problems and engines for improvement of primary care delivery systems.” In order to help translate research into practice, they suggest that distinctions between research and quality improvement in practice should be considered at this point of the research. For example, research has a focus on discovery, is theory-driven, and is evaluated based upon scientific rigor. On the other hand, quality improvement in practice has a focus on application, is purpose-driven, and is evaluated on process validity. Consideration of such distinctions can be helpful for translating PBRN research into practice.

Challenge 2: Organizational Life Cycles

After a PBRN is started, another challenge to consider is how to manage the PBRN through its development as an entity. In this section, two views of life cycle management are presented. The first life

cycle perspective is called “volunteer directed.” That is, unpaid volunteers comprise the driving force for how the PBRN develops over time. The second life cycle perspective is called “leader directed.” That is, an identified individual serves a leadership role on behalf of the PBRN and is the driving force for how the PBRN develops over time. In each life cycle, potential pitfalls are described and ways to identify and overcome them are given.

Life Cycle for a Volunteer Directed PBRN

Like the human life cycle from birth to aging and death, some organizations have a comparable life cycle [41]. However, unlike the human life cycle, this organizational life cycle is not inevitable. Leaders who understand this potential life cycle that “volunteer directed” organizations may go through are in a good position to help the organization avoid deterioration and be re-born at the suitable times.

The **Birth Stage** begins with a dream, a vision and opportunity. At this early point in a PBRN’s life cycle, Vision is dominant, but inclusion, programs, and management are not. Efforts are devoted to clarification of goals and mission. During the **Infancy Stage**, action now becomes more important than just opinions. Vision and Inclusion are both dominant. Efforts are devoted to establishing an identity. Who are we? What are our guiding principles? Also, the establishment of norms and styles take place during this stage. During the **Childhood Stage**, Vision is still dominant, but now Programs are dominant rather than inclusion. Fewer resources are present than needed in order to develop programs and infrastructure wanted by actively engaged PBRN members, funders, and prospective members. The energy that had been devoted to developing vision and inclusion are now devoted to building programs. During Birth and Infancy, collaborators are attracted to the PBRN through relationships. During Childhood, people begin to be attracted by the programs offered.

The **Adolescence Stage** is when Vision, Inclusion, and Programs all are dominant. Management Systems have not yet been fully developed. The PBRN is likely to function like adolescents in that it will have an awkward time dealing with its newfound resources, and the competing priorities of inclusions and programs. Conflicting goals will emerge. This creates healthy conflict with which most organizations are

able to successfully deal. Win-Lose struggles should be avoided. Rather, development of transparent and fair management systems (including governance and oversight) can serve as a foundation for how the PBRN will deal with conflict.

Adulthood is a stage where all four organizing principles are dominant (Vision, Inclusion, Programs, Management Systems). This stage is characterized by completion of a major accomplishment. Management systems are in place and typically came out of the adolescence stage during which time things done by oral tradition were written down and policy manuals were developed. The **Maturity Stage** sets in when Management becomes the dominant, fueling principle for the PBRN. Risk-taking is not a priority focus. Controllability has become stronger than flexibility. However, many of these conditions of Maturity are masked by the fact that vital signs, particularly financial signs, appear to be strong and positive. The PBRN may be functioning well, with some sense of efficiency. However it may no longer be clear concerning its focus and sense of strategic direction. Signs of malaise may exist. However, overall, everything feels too good to think about transformation that is necessary at this stage.

Empty Nest is that stage of the PBRN life cycle when it is first nostalgic, and later angry about the losses of the past. Ultimately its members will look for something or someone to blame for the situation in which it finds itself. The motto during this stage is “we need to try harder.” Efforts are redoubled because productivity is down some and usually outstanding programs are not what they used to be. Confidence in leadership is diminished. This is a time to consider splitting (or rebirthing) in new directions.

Retirement is the stage when despair and hope are both present. This dichotomy makes it one of the most crucial stages in the life cycle. Vision continues to be weak. Many long-term members decided at the end of the Empty Nest stage that the PBRN is no longer a good place to invite people to join. Existing members would welcome new leadership to invigorate the PBRN. But the stakeholders may not realize what they just asked for. New leadership and newer members may take the PBRN in new directions that are not acceptable to older members. Splits often occur at this point.

Old Age is the stage where the PBRN reaches subsistence level. The PBRN may be functioning, but primarily for older members. Habits and traditions are dominant. Management is the only organizing principle that is still engaged, and it is wavering. Finally, **Death** is when the PBRN ceases to exist. The desire to collaborate is gone and members have moved on. The desire to meet regularly, engage in strategic planning, and actively organize for mutual support are no longer present. The primary issue at this point is to help address the needs of the remaining members to help assure that they can link into other opportunities.

If these stages are recognized, effective methods and tactics can help with transitions and rebirth of PBRNs including:

1. Determine Sense of Urgency for Change and Transition
2. Develop a Guiding Coalition (steering committee)
3. Innovate in a manner Consistent with Needed Rate of Change
4. Cast Vision
5. Initiate New Inclusion Experiences
6. Build Effective Program Events
7. Reengineer Management Systems
8. Be Honest

Life Cycle for a Leader Directed PBRN

The second life cycle perspective is called “leader directed.” That is, an identified individual serves a leadership role on behalf of the PBRN and is the driving force for how the PBRN develops over time. The Leader Directed model is more of a top-down corporate model compared to the grass-roots volunteer model.

The first stage, called the **Organization Stage**, is one of creation and is best led by an “entrepreneurial” leader with attributes of passion, focus, confidence, stability, motivation, tenacity, and

energy [42]. Vulnerabilities during this stage include distraction, discouragement, and dilution. At this point, a well-shaped idea needs to be converted into actionable form.

When the idea has been germinated, the organization has been born and moves into the **Construction Stage**. Leadership is one of implementation characterized by communication, determination, quality mindedness, and problem solving. Vulnerabilities during this stage include undercapitalization, shoddiness, lack of standards, and lack of training. After an organizational framework has been constructed, the organization is ready to grow. Called the **Development Stage**, a leader with a navigator style fits well [42]. Attributes such as planning, administration, relationship building, and educating are important for this stage. Primary vulnerabilities include self-satisfaction, overconfidence, and personal paralysis or indecision.

Assuming that the PBRN organization successfully completes the development stage, there is a need to expand for continued growth. The **Expansion Stage** is best led by an “accelerator” type leader with the attributes of delegation, forcefulness, pragmatism, and achievement [42]. Pitfalls that might arise during this stage include overindulgence, overreaching, inflexibility, and defections by members of the organization.

Although an organization should continue expanding and growing, full maturity of the original founding concept does occur. At this time, the organization can reap benefits from its earlier progression when it is at the “top of its game” in its markets [42]. During this **Cultivation Stage**, a leader with “harvester” characteristics of competitiveness, consistency, charisma, and character can be helpful to the organization. Cashing in on successes can prepare the organization for renewal and new initiatives. Potential vulnerabilities during cultivation include entropy (stagnation), erosion (slippage of the core concept), and egotism (succumbing to flattery and recognition).

Finally, the **Renewal Stage** is best lead by a leader with “explorer” characteristics such as opportunism, inquisitiveness, investigation, and ambassadorship [42]. During this stage, an organization can ascend to new and greater heights. Vulnerabilities during this stage include risk aversion, carelessness, and vegetation (laziness).

By matching leadership characteristics with each of the organizational stages, a leader-driven PBRN can change and grow over time. Without a good match, a PBRN is likely to experience difficulties, decline, and possible dissolution.

Challenge 3: Human Subjects Protection and Privacy of Health Information

Unlike single-site research, practice-based research conducted in PBRNs takes place across many sites in busy practices in the community. As a result, PBRN research raises special challenges regarding regulatory compliance and human subjects protections [43]. Research involving human participants raises ethical concerns because they may experience risks and inconveniences through their participation in studies. Federal regulations govern research involving human participants and institutions engaged in human research must comply with these regulations and certify that the research has been approved by an Institutional Review Board (IRB) before research commences [43].

For practice-based research, practitioners may not be aware of the federal regulations governing research and most will not be certified by IRBs in practice-based research or human subjects protections. Moreover, some PBRN research may be similar to efforts that practitioners routinely undertake without IRB oversight and not realize that, within a research context, is scrutinized differently [22]. It is important, therefore, to carefully delineate the roles of everyone involved in PBRN projects so that only individuals responsible for the design and conduct of the study are identified as “key personnel” for the project and that they complete the full human subjects protection training. Other collaborators need not complete the full human subjects protection training, but rather, be provided with information and work under protocols as defined by the approved study and certified research personnel. It should be noted that each academic institution’s IRB is unique and that rules and procedures constantly change over time.

Researchers working within PBRNs that collect patient information also must consider protected health information (PHI) issues and follow Health Insurance Portability and Accountability Act (HIPAA) regulations. One option for meeting protected health information requirements would be to obtain patient authorization to use PHI, but this process is prohibitively time-consuming and may taint the findings of

some research studies [44]. A second option would be to develop a blanket authorization PBRNs could use for study recruitment. A third option would be to collect only de-identified data (data with identifying information removed), or work with a defined, limited data set under a data use agreement. Finally, PBRNs that blend quality improvement and research can work with protected health information, but the researcher and the practices must enter into a formal business agreement for this to be allowed.

DESCRIPTION OF AN EXISTING PHARMACY PBRN AS AN “INSIGHT STIMULATING EXAMPLE”

As a way to demonstrate how one Pharmacy PBRN has dealt with the challenges just described, the recently developed Minnesota Pharmacy Practice-Based Research Network can serve as an example (<http://www.mpha.org/associations/9746/files/PBRN/index.html>, <http://pbrn.ahrq.gov/portal/server.pt>).

Step 0: Genesis of an Idea

During June 2007, a faculty member from the University of Minnesota, College of Pharmacy developed an idea paper regarding the formation of a Pharmacy PBRN in Minnesota. The paper was shared with mentors to establish that pursuing the idea was consistent with departmental goals and the faculty member’s professional development goals. Also, it was shared with college administrators to establish that the idea was in concert with collegiate goals and its strategic plan. A meeting was held with the director of the primary care PBRN at the university’s Medical School in order to provide information and align goals. Meetings were held with university level offices to determine guiding principles for responsible conduct of research training, investigational review board training and submissions, sponsored projects administration guidelines, and sponsored financial reporting requirements.

Step 1: Collaborative Partnership

Based upon these internal meetings, the idea paper was revised so that it complied with university guidelines, rules, and strategic goals. In August 2007, meetings were arranged between interested members of the University of Minnesota College of Pharmacy, Minnesota Pharmacists Association, and Pharmacist Practitioners. Based upon these meetings, a collaborative agreement was established with the guiding principles contained in Appendix B.

Initial recruitment of pharmacies took place during a series of “Pharmacy Nights” hosted by the Minnesota Pharmacists Association held throughout the state during September through November 2007. At each meeting, the PBRN idea was presented and an invitation made to pharmacists in attendance to join the PBRN. In addition, information about joining the PBRN was printed in MPhA’s journal, Minnesota Pharmacist.

Upon completion of the Pharmacy Night presentations, recruitment of interested researchers was conducted during December 2007 through January 2008. A “capacity portfolio” of the pharmacies in the PBRN was created using a spread sheet and was shared with potential researchers. Initial recruitment efforts resulted in critical masses of both practitioner members and research members by February 2008.

The Minnesota Pharmacy Practice-Based Research Network (PBRN) was launched on February 26, 2008. Its stated purpose is to collect information using a network of pharmacies for the purpose of addressing societal and community questions related to the medication use process. Such a network serves as a natural laboratory and represents a novel way to address societal needs related to health and wellness. The Minnesota PBRN is a collaboration among the Minnesota Pharmacists Association, University of Minnesota, and Pharmacist Practitioners and has been designed to serve as a meeting point for sharing and generating new ideas that are relevant to the interface among the practice of pharmacy, health care, health systems, health technologies, communities, and society overall.

Step 2: Infrastructure

In terms of infrastructure during this infant stage, a faculty member from the University of Minnesota and the executive vice president from Minnesota Pharmacists Association served director functions. Staff members from these organizations served coordination functions. A 5-member Guidance and Oversight Board for the PBRN meets monthly.

One-way communication for news sharing was accomplished primarily via email and quarterly updates. Two-way communication was accomplished through events coordinated by the Minnesota Pharmacists Association, personal visits to practice sites, and via email and phone conversation. A web site for sharing information among PBRN members was developed (<http://www.mpha.org/associations/9746/files/PBRN/index.html>). For sharing information with external partners, the PBRN was registered with the AHRQ PBRN Registry (<http://pbrn.ahrq.gov/portal/server.pt>).

The PBRN membership roster is kept on a spread sheet that remains confidential at the request of some of the pharmacy PBRN members. Some members wish to keep their identities confidential so that

their contact for potential participation in PBRN projects is only through the PBRN directors and not from other sources.

Human subjects protection management is coordinated through the use of University of Minnesota resources. These resources are extensive and include:

- Investigational Review Board (IRB) The IRB reviews research projects which involve human subjects to ensure that two broad standards are upheld: first, that subjects are not placed at undue risk; second, that they give uncoerced, informed consent to their participation. With representation from a wide range of scientific disciplines and from outside the academic community, the IRB gives rapid but individualized attention to the numerous research projects at the University. www.irb.umn.edu
- Sponsored Projects Administration (SPA) SPA is the University of Minnesota system-wide office authorized to submit research proposals and receive awards from external sources on behalf of the Board of Regents of the University of Minnesota. SPA is also the fiduciary for the U on grant-related matters. www.ospa.umn.edu
- Sponsored Financial Reporting (SFR) Sponsored Financial Reporting is responsible for managing the external financial reporting and invoicing requirements of sponsored University research projects www.sfr.umn.edu
- Responsible Conduct of Research (RCR) (e.g. responsible conduct of research training set up for each principle investigator) <http://egms.umn.edu/rcr/>

A summary of the current capabilities of the Minnesota Pharmacy PBRN can be found in Appendix C.

Step 3: Formulate Research Questions, Step 4: Design Study Methods, Step 5: Obtain Funding Support

As of December 2009, the Minnesota Pharmacy PBRN consisted of 305 geographically dispersed pharmacies and 23 principal investigators from the University of Minnesota. During 2008 and 2009 the Minnesota Pharmacy PBRN developed 15 research ideas. Of these 15 research ideas:

- five (5) projects were submitted for funding, but not funded
- four (4) projects were funded and have been completed
- three (3) projects were funded and are being conducted
- three (3) projects are under review

Step 6: Develop Study Instruments

For the projects that were conducted, several study instruments were developed and have been applied in other proposals and other research.

Step 7: Implement the Study, Step 8: Manage and Analyze the Data

For the seven projects that were conducted using the PBRN (i.e. four completed plus three current), four of them utilized PBRN pharmacies for “pharmacist participation” and three of them utilized PBRN pharmacies for “patient recruitment.” None of the seven projects consisted of “data extraction” from PBRN pharmacies. As we reviewed the types of data collected during the first two years of the PBRN’s existence, we identified potential capacity within the PBRN that was not yet being utilized, namely research that used data already collected at the pharmacy.

In order to develop projects using data extraction techniques, we consulted with the director of the Minnesota Academy of Family Physicians Research Network which had developed data extraction methods for its PBRN of medical practices (<http://www.mafp.org/mafprn/mafprn.asp>). Through collaborative efforts, we developed a plan for including our PBRN pharmacies in the Minnesota Academy of Family Physicians Research Network data extraction system.

However, as we moved forward with this idea, we learned that many pharmacies within our PBRN outsourced data storage and claims processing services and (1) collected only the minimal data required for prescription dispensing claims processing and (2) transferred ownership of the data to the company with whom they outsourced these services. Thus, we learned that minimal data were collected by many pharmacies and that the data were considered proprietary and outside the control of the PBRN pharmacy.

Based on this finding, we have been working to develop ideas for pharmacies to create more sophisticated patient care profile and documentation systems that are owned by their pharmacy and under their control.

Step 9: Disseminate the Results

In addition to reports and doctoral dissertations that have resulted from the PBRN projects, there have been 11 publications completed with more in preparation or under peer-review.

Step 10: Translate Research into Practice

In a brief two-year period of time, we have learned a great deal about the capacity our PBRN has for certain types of research. Through this experience, we learned about work that needs to be done in the area of creating more sophisticated patient care profiles and documentation systems that are owned and controlled by PBRN pharmacy sites. In addition, we learned that there is a need to develop data systems that do not require multiple software types, double data entry, and are able to interface with other data systems.

Our most recently funded project happens to be in this area and we have found that our experiences are helping inform the project and also that the outcome from the project is likely to have high applicability to both advancements for our PBRN and for practice. Furthermore, an intellectual property agreement between the project investigators and the project sponsor has been developed which also helps translate research into practice.

Assuming that satisfactory progress is achieved for the PBRN, other needs and challenges of the Pharmacy PBRN would need to be addressed on a continuing basis. These may include, but are not limited to:

- continued recruitment and training
- monitoring for compliance with IRB requirements
- involvement with other disciplines, community members, other stakeholders
- continued engagement of communities and professional organizations
- management of multiple-site projects
- management of concurrent projects
- translating results into practice
- strategic planning as needs / environments change
- application of quality research methods
- instrument testing and development
- data collection, storage, management and analysis
- communication over distances and over time
- managing dissatisfaction
- managing egos
- managing burn-out
- maintaining the energy level for the PBRN over time
- adapting to change in personnel
- reporting

COMMUNITY PHARMACY RESIDENCY PROGRAM -- FOCUS GROUP

Based on a review of the literature, the experiences of a statewide PBRN, and its own “Research Gap Analysis,” leaders within the APhA Community Pharmacy Residency Program (CPRP) began discussions regarding the creation of a Practice-Based Research Network using CPRP sites (named PBRNet). To begin dialogue for this idea, 15 individuals who were affiliated with community pharmacy residency programs convened to participate in a focus group on April 5, 2009 in San Antonio, Texas. The purpose of this inquiry was to understand the most important elements needed for an infrastructure to support a Community Pharmacy Residency Program PBRN (PBRNet). Appendix D contains the questions used for this focus group session and a summary of the responses from the focus group discussion.

The findings showed that there was consensus among focus group participants regarding benefits, challenges, and next steps for PBRNet. In terms of benefits, there was consensus that collaboration among sites for residency projects would make the research stronger in light of greater statistical power, flexibility with research designs, structure, and networking. Regarding challenges, the findings showed that standardization across CPRP sites, necessary coordination for multi-site studies, and updating training and systems would not be easy.

While collaboration through a PBRN was viewed as a positive opportunity for CPRP sites, focus group members did mention that they would like to have the autonomy to opt-in or opt-out of projects on a case-by-case basis. Regarding interactions among sites that would comprise the PBRN, focus group participants agreed that communication would need to be timely and tailored to the needs of the members (e.g. one-way communication would be fine for information and announcements, but two-way communication would be needed for collaborative efforts). A designated facilitator was suggested as necessary for fostering communications within the PBRN.

Focus group participants identified two important infrastructure elements that would be needed to support a Community Pharmacy Residency Program PBRN. They were: (1) a strong sponsoring

organization and (2) technology support. Related to these two elements, the following recommendations were given:

1. A **sponsoring organization** should be identified in order to provide an identity for the PBRN and a structure for taking the next steps in PBRN development such as:
 - creation of a **steering committee**
 - development of guidelines for project evaluation and project introductions to sites
 - development of one-way communication channels
 - development of two-way communication opportunities
 - creation of guidelines and methods for sites to opt-in and opt-out of projects
2. Community Pharmacy Residency Program **accreditation requirements** should be reviewed and revised (if necessary) so that residents could participate in PBRN projects (including multiple year and multiple site projects) and still earn credit for their “residency project” requirement.
3. Development of **technology standards** is needed. Technology is constantly changing and will need consistent attention during the life of the PBRN. Initially, the first PBRN projects might be devoted to collaborative research for creating a PBRN “Capacity Portfolio” that would identify key hardware and software components and then describe these for the sites that are participating in the PBRN. Other elements in the capacity portfolio could include things such as (a) services offered at each site, (b) collaborative practice at each site, or (c) point-of-sale record keeping for OTCs, just to name a few.

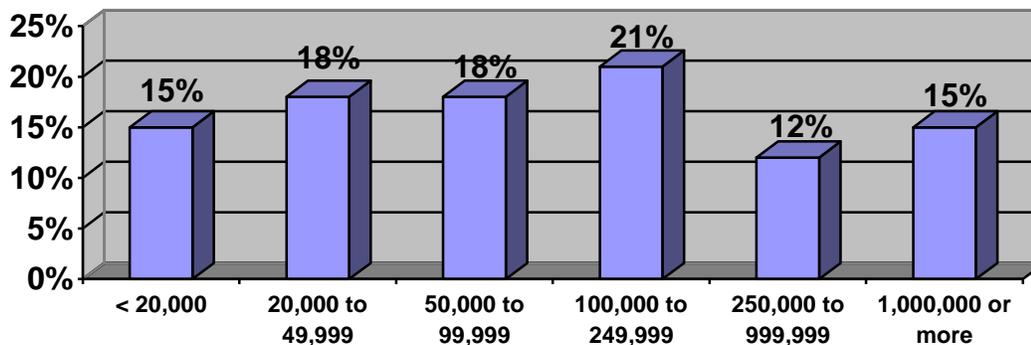
The research needed for developing “capacity portfolios” could actually be the first multi-site, multi-year residency projects conducted under the PBRN umbrella. This research is not only needed to help advance the PBRN, but also could provide valuable experience in how the PBRN should conduct projects.

COMMUNITY PHARMACY RESIDENCY PROGRAM -- SURVEY

After the focus group was conducted, there was a perceived need to describe the current capacity of Community Pharmacy Residency Program (CPRP) members for: (1) Provision of Patient Care Services, (2) Collaboration with Other Healthcare Providers, (3) Focused Expertise through Training, and (4) Documenting, Extracting, and Sharing of Information. In addition, there was a need to describe their current level of participation in PBRNs, their level of interest in participating in APhA's PBRNet, and challenges of most concern to them. Such a description would help describe the current capacity for the Community Pharmacy Residency Program to establish a PBRN and also to help identify next steps for addressing infrastructure needs that were identified in the focus group: (1) a strong sponsoring organization and (2) technology support.

To collect this information, an on-line survey of community pharmacy residency programs was conducted by the American Pharmacists Association during November 2009. Out of 111 community pharmacy residency program sites that were sent an invitation to participate in the survey, responses were received from individuals representing 33 programs (30% participation rate). Of these, 48 percent reported that their practice was located in an urban area, 42 percent in a suburban area, and nine percent in a rural area. A broad distribution of variously sized communities was served by the respondents (See Figure 1).

Figure 1: Community Size served by Community Pharmacy Residency Program Responders (n = 33)

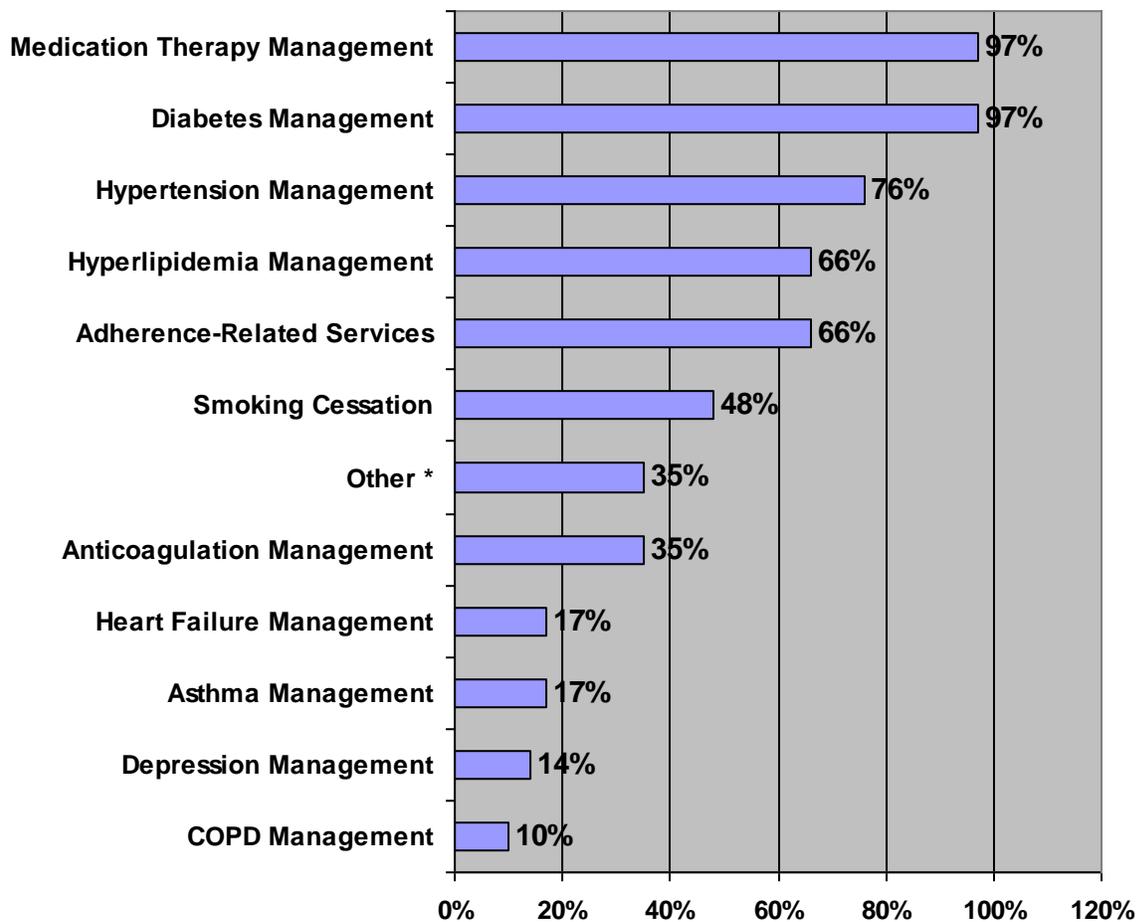


(number of people in community served)

Provision of Patient Care Services

Figure 2 summarizes the Types of Patient Care Services that were reported by 29 responses to this question. The most commonly reported services that were provided included: medication therapy management (97%), diabetes management (97%), hypertension management (76%), hyperlipidemia management (66%), and adherence-related services (66%).

Figure 2: Types of Patient Care Services Provided (n = 29)



* Other included: HIV/AIDS, Immunizations, Point of Care Testing, Pharmaceutical Case Management, Specialty Disease Management, Wellness

Table 1 summarizes the level of intensity with which patient care services are provided. The data show that the typical site provides services for 35 hours per week to fewer than 50 patients.

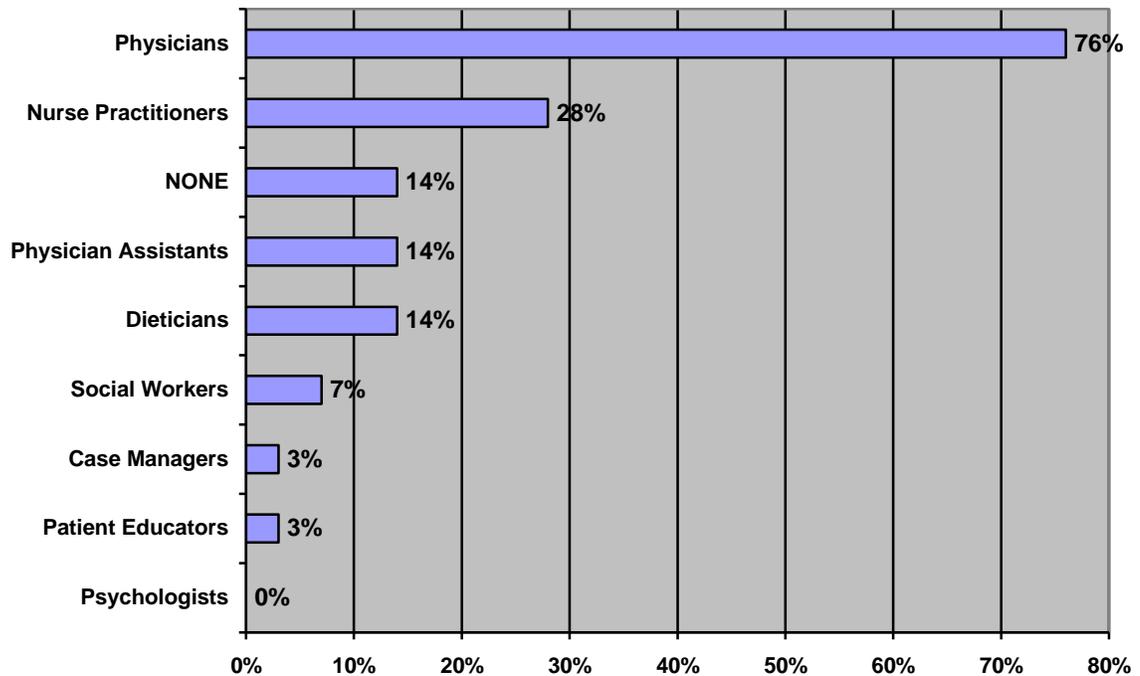
Table 1: Intensity with Which Patient Care Services are Provided

Number of patients who utilize patient care services at your practice site per week.	Less than 10	34%
	10 to 49	45%
	50 to 199	17%
	200 to 499	0%
	500 or More	3%
Number of full-time pharmacists offering patient care services at your practice site	Mean = 3 per site	
Number of part-time pharmacists offering patient care services at your practice site	Mean = 1 per site	
Number of ours per week spent on patient care services at your practice site	Mean = 35 hrs/wk	

Collaboration with Other Healthcare Providers

Figure 3 shows that the most common collaborative relationships were with physicians (76%) and relatively few collaborative relationships with other health care professionals.

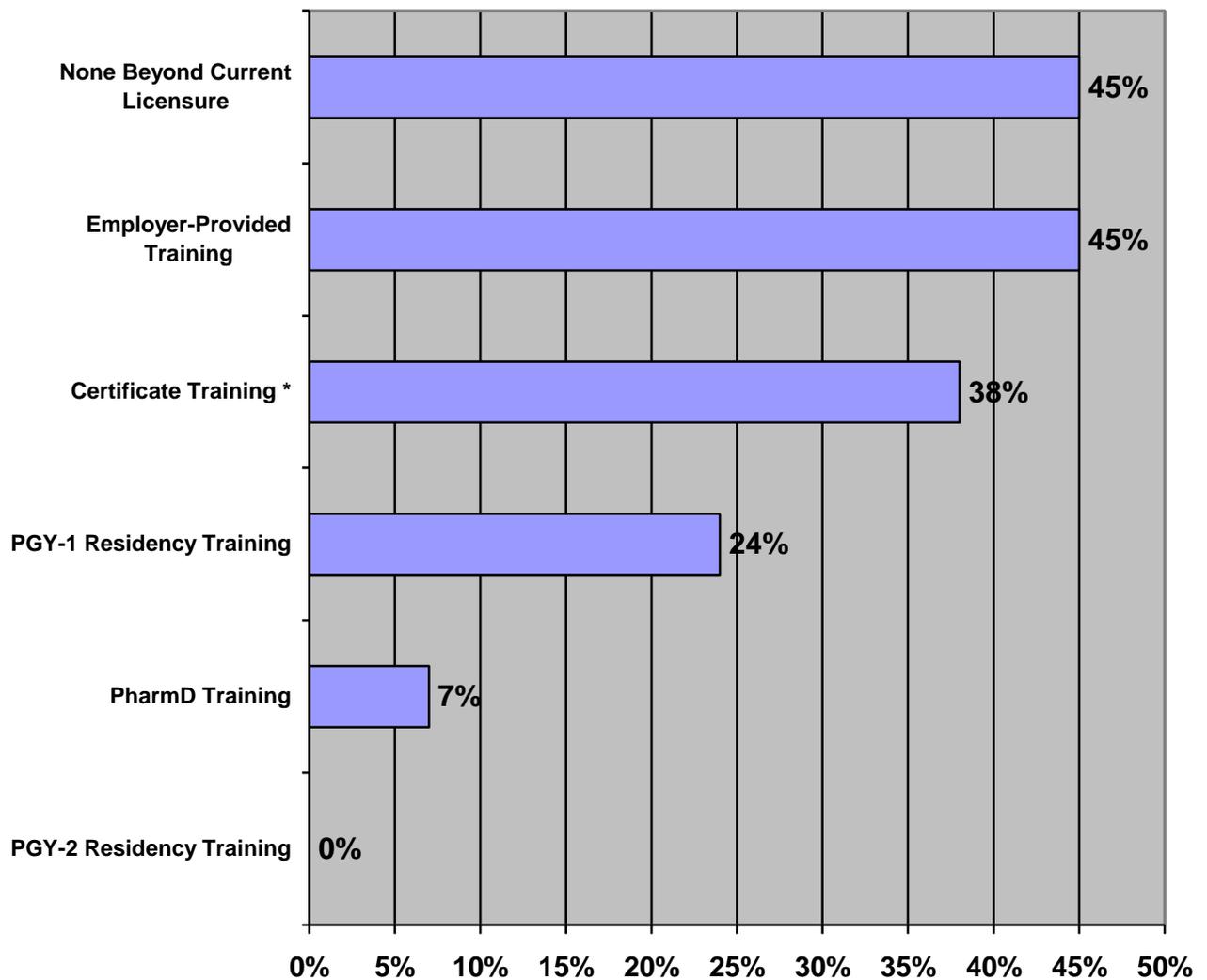
Figure 3: With Whom Collaborative Relationships Have Been Formed (n = 29)



Focused Expertise through Training

Respondents were asked a question about any training requirements for pharmacists to provide patient care services at their site. Figure 4 shows that 45% of the sites had no requirements beyond licensure as a pharmacist. However, 45% required employer-provided training, 38% required certificate training, and 24% required a PGY-1 residency.

Figure 4: Training Requirements for Pharmacists to Provide Patient Care Services (n = 29)

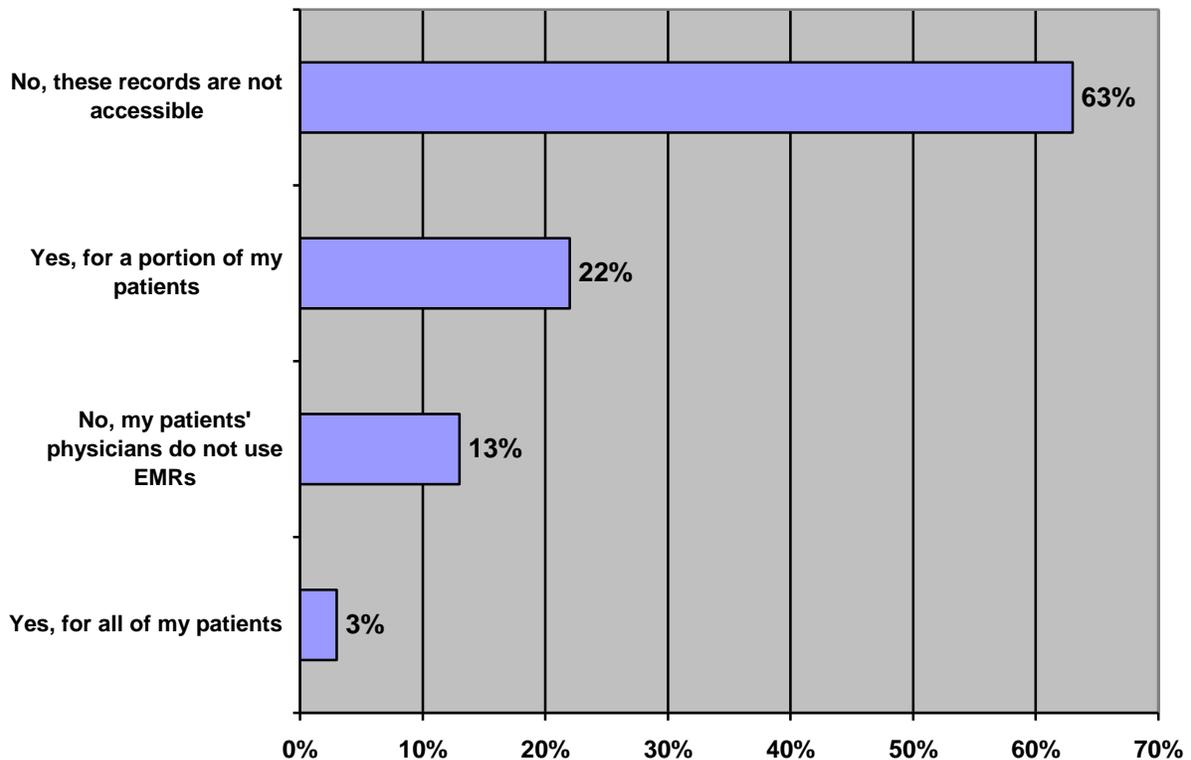


* Certificate Training included: Diabetes, Immunization, Disease State Management, Compounding, Medication Therapy Management

Documenting, Extracting, and Sharing Information

Out of 32 responders, only 1 (3%) reported that his/her practice has access to all of his/her patients' electronic medical records (EMRs) that are maintained at physicians' offices (see Figure 5). In addition 7 (22%) reported that they had access to EMRs for a portion of their patients. Of the eight responders who had at least some access to EMRs, three (38%) had read/write access to all areas of the patient chart, two (25%) had read-only access to all areas of the chart, two (25%) had read-only access to certain areas of the chart, and 1 (13%) had read/write access to certain areas of the chart.

Figure 5: Access to Patients' Electronic Medical Records (EMRs) Maintained at Physicians' Offices



When asked about documentation methods for patient care services, 65% of the 31 responders to this question reported that they used paper charts and an electronic documentation system, 32% used paper charts only, and 3% used electronic documentation systems only. For the 21 responders who used an electronic documentation system in whole or in part, 52% used a single electronic system separate from the pharmacy dispensing software, 38% used a single electronic system integrated with the

pharmacy dispensing software, and 29% used multiple electronic systems provided by individual payers (sum totals more than 100% due to multiple responses allowed for this set of questions).

When asked about the name of the documentation system used for patient care services, responses were diverse including commercial software, proprietary software, paper charts, word processing programs, and simple spread sheet programs. A similar array of responses was given when asked about the name of the documentation system used for financial record keeping.

Twenty-nine respondents answered a question related to their ability to retrieve certain types of information from their documentation systems for patients who had utilized their patient care services. Table 2 provides a summary of their responses. The most commonly retrievable information via electronic records included patient medication records, laboratory values, and patient demographics. The most commonly retrievable information via paper records included interventions or referrals made, schedule and plan for follow-up appointment, and medication therapy problems. Over one-third of respondents reported that they had no information documented in any form for patient diagnoses (ICD-9 codes), procedure codes (CPT codes), or for amount of time spent with patients.

Table 2: Ability to Retrieve Information about Patients Who had Utilized Patient Care Services

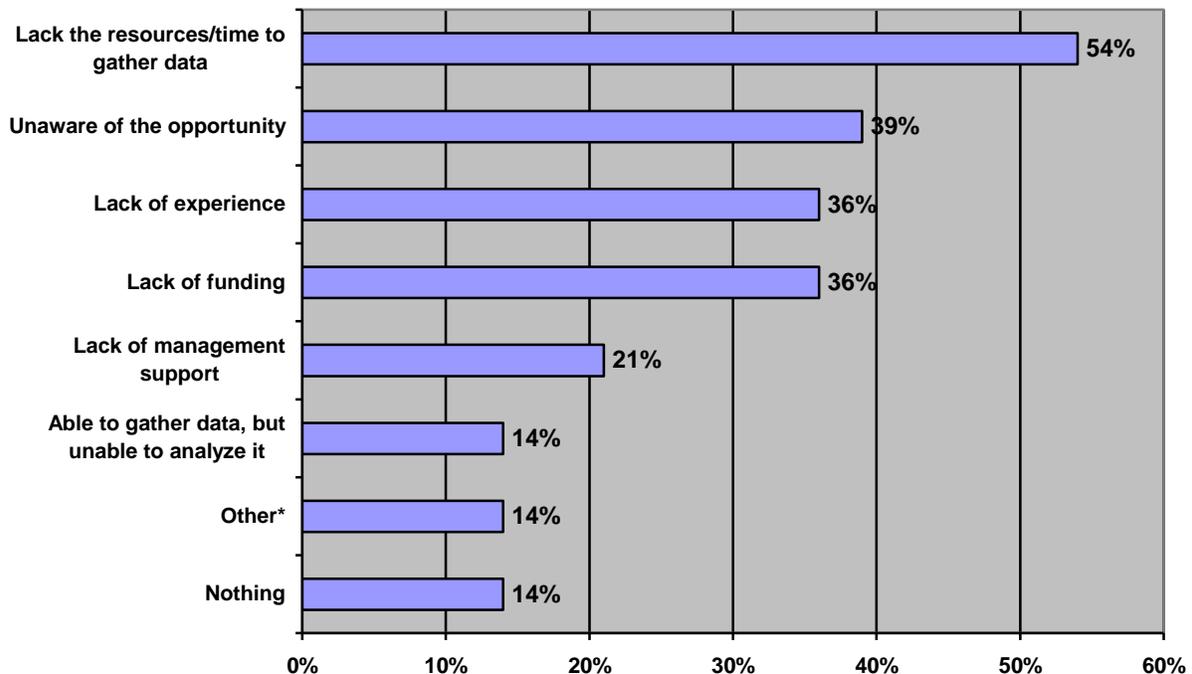
Type of Information	Yes, in electronic records	Yes, in paper records	No (information not documented)
Patient medication records	52%	45%	3%
Laboratory values	45%	48%	7%
Patient demographics	41%	55%	3%
Schedule and plan for follow-up appointment	34%	66%	0%
Patient diagnoses (ICD-9 codes)	34%	31%	34%
Procedure codes (CPT codes)	34%	31%	34%
Medication therapy problems	31%	66%	3%
Interventions or referrals made	28%	69%	3%
Amount of time spent with patient	7%	59%	34%

Participation in Practice Based Research Networks

Finally, we described respondents' current level of participation in PBRNs, their level of interest in participating in a PBRN, and challenges of most concern to them. Of 28 respondents who responded, four (14%) reported that their practice site was part of an existing practice-based research network (PBRN). Of the remaining 24 respondents, 50% reported that they were 'very interested' and 50% reported that they were 'somewhat interested' in participating in a PBRN through the American Pharmacists Association.

Figure 6 summarizes the challenges that have kept pharmacies from participating or from expanding their participation in PBRNs. The most commonly reported challenges were: lack the resources/time to gather data (54%), unaware of the opportunity to participate (39%), lack of funding to conduct research (36%), and lack of experience in practice-based research (36%).

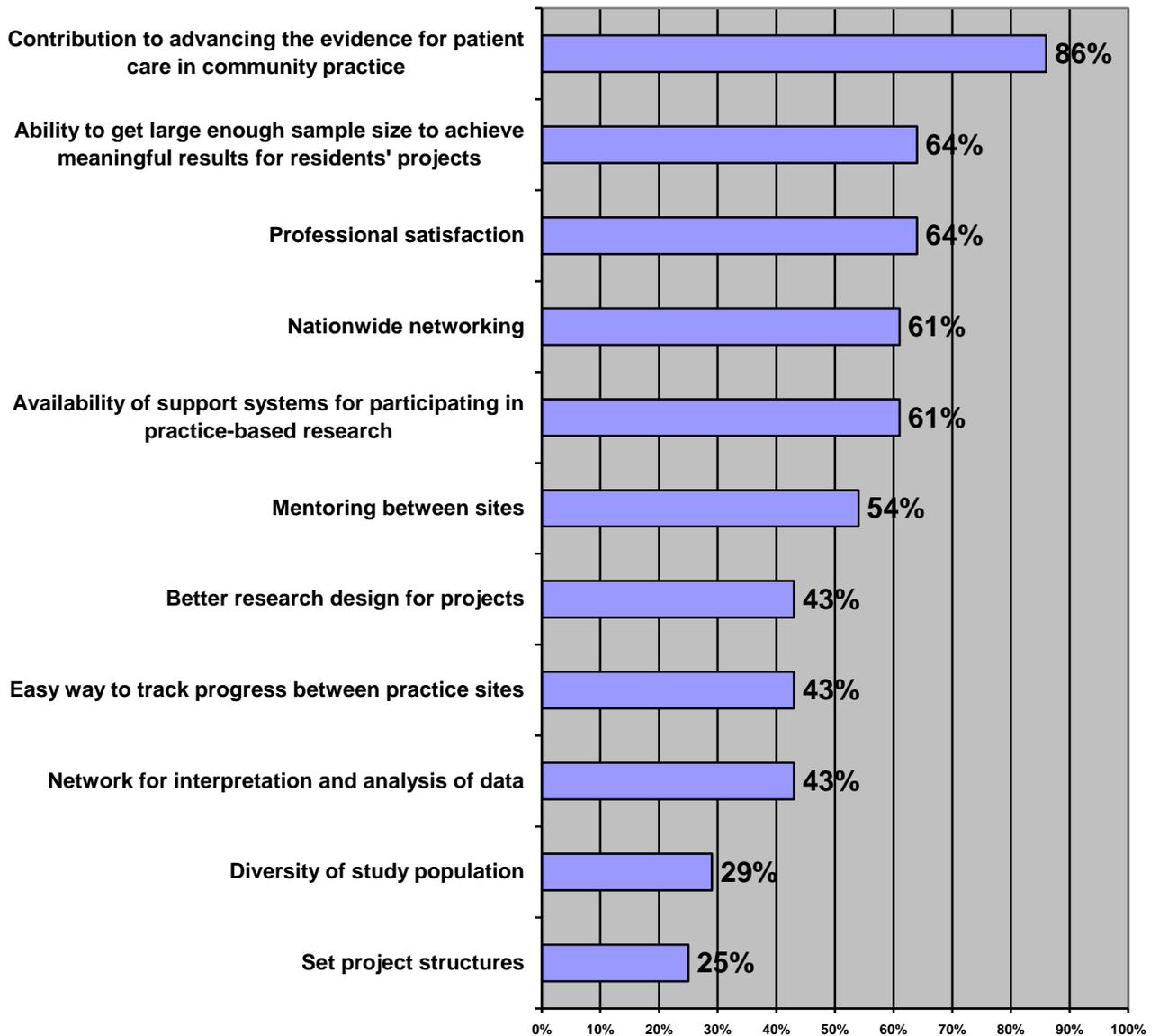
Figure 6: Challenges that have Kept Pharmacies from Participating in PBRNs (n =28)



* Other included: legal concerns, no initiatives currently going on, other priorities, almost ready to start

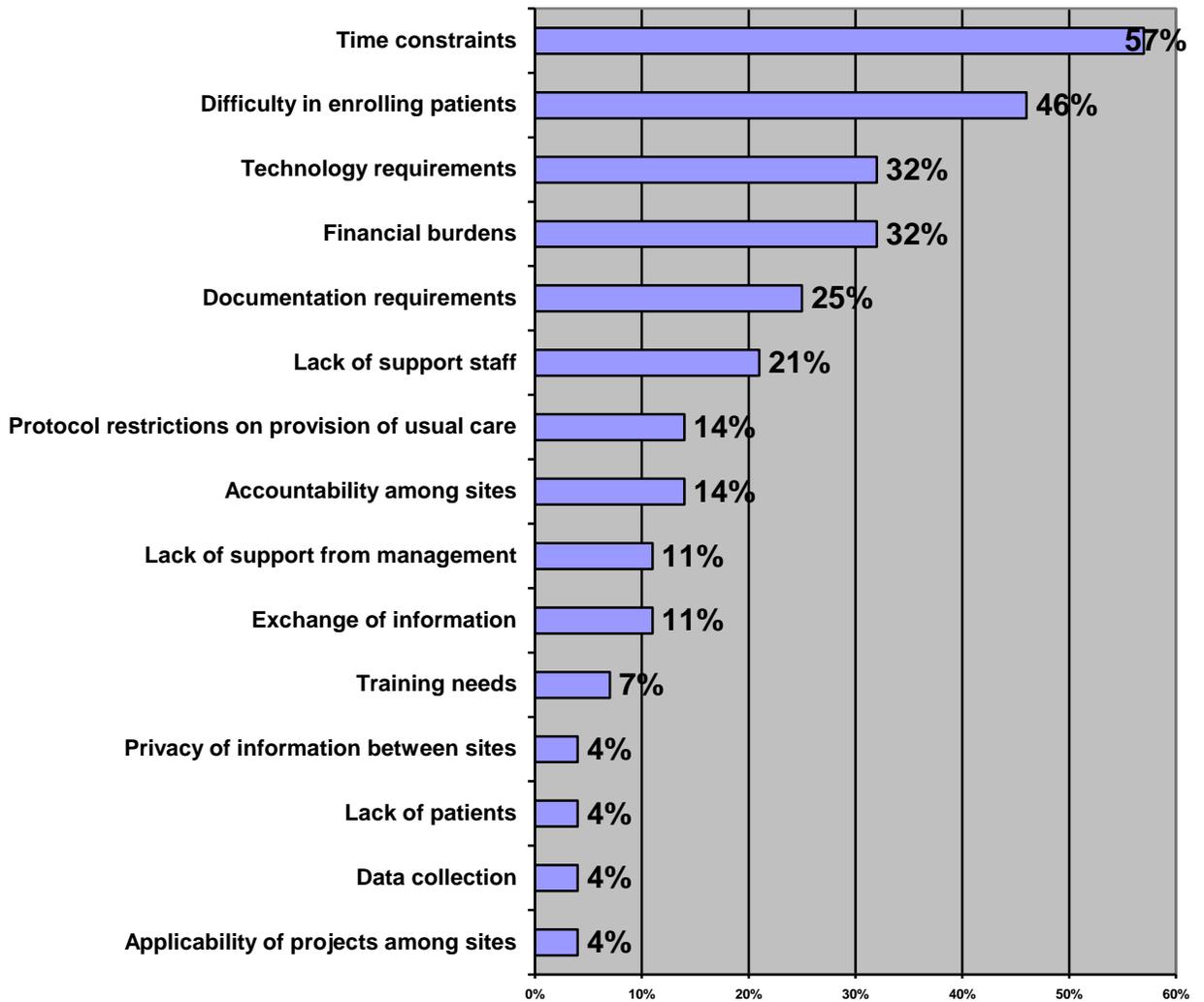
Figure 7 summarizes the benefits of participating in a PBRN as reported by 28 responders to this question. The most commonly reported benefits were: contribution to advancing the evidence for patient care in community practice (86%), ability to get a large enough sample size to achieve meaningful project results for residents' projects (64%), and professional satisfaction (64%).

Figure 7: Benefits of Participating in a PBRN (n = 28)



Finally, Figure 8 summarizes the challenges that respondents are most concerned about related to participating in a practice-based research network. The most commonly reported challenges were: time constraints (57%), difficulty in enrolling patients (46%), technology requirements (32%), and financial burdens (32%).

Figure 8: Challenges of Most Concern Related to Participating in a PBRN (n = 28)



RECOMMENDATIONS REGARDING NEXT STEPS

The literature reviewed, the statewide PBRN described, and the findings from a focus group and a survey of Community Pharmacy Residency Program members, provided convergent evidence regarding the potential value of a practice-based research network such as PBRNet and regarding next steps that should be taken for establishing the PBRNet.

Regarding value, the most significant contributions of PBRNet would be in the areas of (1) advancing the evidence for patient care in community practice and (2) the synergy of such a network for obtaining large enough sample sizes for achieving meaningful results for pharmacy residents' projects.

While it appears that collaborative partnerships have been established for PBRNet (Step 1 of the process outlined by Kuo et al for starting a PBRN), an important next step relates to infrastructure (Step 2 of the process). According to Green and colleagues [38], common infrastructure elements for PBRNs include: (1) director (operational responsibilities), (2) coordinator (staff person for day-to-day operations), (3) one-way communication (news-sharing functions via newsletter or web site), (4) two-way communication (email listserv or blog for sharing news and collaborative feedback), (5) membership roster (for identification of collaborators), (6) meetings (for presentation of ideas, results, training, continuing education, etc.), (7) board (to meet any legal status requirements of the network and for oversight and guidance), and (8) human subjects protection management (for meeting institutional review board and other standards for responsible conduct of research). Beyond these, mission dependent infrastructure elements may include (1) research assistants, (2) information technology, (3) regulatory compliance, or (4) research consulting expertise (e.g. statistical consultation).

Specific needs for PBRNet that were identified through results from both the focus group and survey focused on (1) a sponsoring organization, (2) aligning Community Pharmacy Residency Program accreditation requirements with PBRNet goals, and (3) technology standards for collecting, extracting, and sharing data. A summary of these points, based upon focus group findings, is listed next.

1. A **sponsoring organization** should be identified in order to provide an identity for the PBRN and a structure for taking the next steps in PBRN development such as:

- creation of a steering committee
- development of guidelines for project evaluation and project introductions to sites
- development of one-way communication channels
- development of two-way communication opportunities
- creation of guidelines and methods for sites to opt-in and opt-out of projects

2. Community Pharmacy Residency Program **accreditation requirements** should be reviewed and revised (if necessary) so that residents could participate in PBRN projects (including multiple year and multiple site projects) and still earn credit for their “residency project” requirement.

3. Development of **technology standards** is needed. Technology is constantly changing and will need consistent attention during the life of the PBRN. Initially, the first PBRN projects might be devoted to collaborative research for creating a PBRN “Capacity Portfolio” that would identify key hardware and software components and then describe these for the sites that are participating in the PBRN. Other elements in the capacity portfolio could include things such as (a) services offered at each site, (b) collaborative practice at each site, or (c) point-of-sale record keeping for OTCs, just to name a few.

The research needed for developing “capacity portfolios” could actually be the first multi-site, multi-year residency projects conducted under the PBRN umbrella. This research is not only needed to help advance the PBRN, but also could provide valuable experience in how the PBRN should conduct projects.

Findings from the survey of Community Pharmacy Residency Program members also provide guidance for making decisions related to organization, accreditation, and technology for a PBRN. For example, the survey results revealed that relatively few pharmacy sites have access to electronic medical records. Also, the results showed that relatively few pharmacy sites believe that they have the resources/time, experience, or funding for conducting practice-based research. These findings reveal opportunities for fund raising, training, and collaboration that are needed as the PBRNet moves forward. Some examples of collaboration partners include (1) community health centers, (2) the Pharmacy Quality Alliance, (3) managed care organizations, (4) employer groups, and (5) clinic-based PBRNs to name just a few.

In order to be successful, we propose that a solid infrastructure combined with the correct fit in leadership style for the PBRNet could overcome obstacles in the long term. For the short term, steady progress related to the common goals of: (1) advancing the evidence for patient care in community practice and (2) obtaining large enough sample sizes for achieving meaningful results for pharmacy residents’ projects via collaboration among sites could help build trust among members, reveal emergent

infrastructure needs, and provide momentum for the larger challenges (e.g. technology standards for the PBRNet) that could be addressed as the PBRNet develops.

References

- [1] Alter N. "AHRQ Support for Primary Care Practice-Based Research Networks (PBRNs)," <http://www.ahrq.gov/research/pbrn/pbrnfact.htm>. accessed July 28, 2008.
- [2] Green LA, Simmons RL, Reed FM, Warren PS, Morrison JD. "A Family Medicine Information System: The Beginning of a Network for Practicing and Residency Family Physicians," Journal of Family Practice, 1978, 7: 567-576.
- [3] Nelson EC, Kirk JW, Bise B, et al. "The Cooperative Information Project: Part 1: A Sentinel Practice Network for Service and Research in Primary Care," Journal of Family Practice, 1981, 13: 641-649.
- [4] Green LA, Hickner J. "A Short History of Primary Care Practice-Based Research Networks: From Concept to Essential Research Laboratories," Journal of the American Board of Family Medicine, 2006, 19(1): 1-10.
- [5] Institute of Medicine, Primary Care: America's Health in a New Era. Washington, DC: National Academy Press; 1996.
- [6] Lanier D. "Primary Care Practice-Based Research Comes of Age in the United States," Annals of Family Medicine, 2005, 3 (supplement 1): S2-S4.
- [7] Mold JW, Petersen KA. "Primary Care Practice-Based Research Networks: Working at the Interface Between Research and Quality Improvement," Annals of Family Medicine, 2005, 3 (supplement 1): S12-S20.
- [8] Bowman MA, Neale AV, Lupo P. "Third Journal of the American Board of Family Medicine Practice-Based Research Theme Issue," Journal of the American Board of Family Medicine, 2008, 21: 255-257.
- [9] Mold JW, Aspy CA, Nagykaldis Z. "Implementation of Evidence-Based Preventive Services Delivery Processes in Primary Care: An Oklahoma Physicians Resource/Research Network (OKPRN) Study," Journal of the American Board of Family Medicine, 2008, 21: 334-344.
- [10] Aspy CB, Enright M, Haldstead L, Mold JW. "Improving Mammography Screening Using Best Practices and Practice Enhancement Assistants: An Oklahoma Physicians Resource/Research Network (OKPRN) Study," Journal of the American Board of Family Medicine, 2008, 21: 326-333.
- [11] Pearce KA, Love MM, Shelton BJ, et al. "Cardiovascular Risk Education and Social Support (CaRESS): Report of a Randomized Controlled Trial from the Kentucky Ambulatory Network (KAN)," Journal of the American Board of Family Medicine, 2008, 21: 269-281.
- [12] Stephens MB, Reamy BV. "A Novel Approach Using an Electronic Medical Record to Identify Children and Adolescents at Risk for Dyslipidemia: A Study from the Primary Care Education and Research Learning (PEARL) Network," Journal of the American Board of Family Medicine, 2008, 21: 356-357.
- [13] Viera AJ, Cohen LW, Mitchell CM, Sloane PD. "High Blood Pressure Knowledge Among Primary Care Patients with Known Hypertension: A North Carolina Family Medicine Research Network (NC-FM-RN) Study," Journal of the American Board of Family Medicine, 2008, 21: 300-308.

- [14] Tyler CF, Werner JJ, Panaite V, et al. "Barriers to Supplemental Calcium Use Among Women in Suburban Family Practice: A Report From the Cleveland Clinic Ambulatory Research Network (CleAR-eN)," Journal of the American Board of Family Medicine, 2008, 21: 293-299.
- [15] Young RF, Schwartz KL, Monsur JC, West P, Neale AV. "Primary Care of Overweight Children: The Importance of Parent Weight and Attitudes about Overweight: A MetroNet Study," Journal of the American Board of Family Medicine, 2008, 21: 361-363.
- [16] Wexler R, Feldman D, Larson D, Sinnott LT, Jones LA, Miner J. "Adoption of Exercise and Readiness to Change Differ Between Whites and African-Americans with Hypertension: A Report from the Ohio State University Primary Care Practice-Based Research Network (OSU-PCPBRN)." Journal of the American Board of Family Medicine, 2008, 21: 358-360.
- [17] Voorhees K, Fernald DH, Emsermann C, et al. "Underinsurance in Primary Care: A Report from the State Networks of Colorado Ambulatory Practices and Partners (SNOCAP)," Journal of the American Board of Family Medicine, 2008, 21: 309-316.
- [18] Xu J, Schwartz K, Bartoces M, Monsur J, Severson RK, Sobel JD. "Effect of Antibiotics on Vulvovaginal Candidiasis: A MetroNet Study," Journal of the American Board of Family Medicine, 2008, 21: 261-268.
- [19] Bennett IM, Coco A, Coyne J, et al. "Efficiency of a Two-Item Pre-Screen to Reduce the Burden of Depression Screening in Pregnancy and Postpartum: An IMPLICIT Network Study," Journal of the American Board of Family Medicine, 2008, 21: 317-325.
- [20] Sinclair-Lian N, Rhyne RL, Alexander SH, Williams RL. "Practice-Based Research Network Membership is Associated with Retention of Clinicians in Underserved Communities: A Research Involving Outpatient Settings Network (RIOS Net) Study." Journal of the American Board of Family Medicine, 2008, 21: 353-355.
- [21] Sussman AL, Williams RL, Leverence R, Gloyd PW, Crabtree BF. "Self Determination Theory and Preventive Care Delivery: A Research Involving Outpatient Settings Network (RIOS Net) Study." Journal of the American Board of Family Medicine, 2008, 21: 282-292.
- [22] Dolor RJ, Smith PC, Neale AV. "Institutional Review Board Training for Community Practices: Advice from the Agency for Healthcare Research and Quality Practice-Based Listserv," Journal of the American Board of Family Medicine, 2008, 21: 345-352.
- [23] Lipowski EE. "Pharmacy Practice-Based Research Networks: Why, What, Who, and How," Journal of the American Pharmacists Association, 2008, 48(2): 142-152.
- [24] Kaiser Family Foundation. Prescription Drug Trends, June 2006. <http://www.kff.org/rxdrugs/upload/3057-05.pdf> (accessed July 29, 2008).
- [25] Landis NT. "January 2000 Drug Supply will be Adequate if All Act Responsibly, Industry Group Assures Public," American Journal of Health-System Pharmacy, 1999, 56(14): 1383, 1384, 1387.
- [26] Knapp KK, Ray MD. "A Pharmacy Response to the Institute of Medicine's 2001 Initiative on Quality in Health Care," American Journal of Health-System Pharmacy, 2002, 59: 2443-2450.

- [27] Covington TR. "Rx to OTC Switches: An Economic Analysis," Paper presented at the Annual Meeting of the American Pharmaceutical Association, March 11, 2000; Washington, DC.
- [28] Kirsche ML. "Settled Elders Loyal Consumer Group Looks for Personal Touch at Pharmacy," Drug Store News, 2004, 26(8): 175-184.
- [29] Lindbloom EJ, Ewigman BG, Hickner JM. "Practice-Based Research Networks: The Laboratories of Primary Care Research," Medical Care, 2004, 42(4, suppl): III 45-III 49.
- [30] Lipowski EE. "Embracing the PBRN Model to Improve Medication Use Background Paper," American Association of Colleges of Pharmacy, January 2007, accessed at www.aacp.org, July 28, 2008.
- [31] Wenzel RG, Schommer JC, Marks TG. "Morbidity and Medication Preferences of Individuals with Headache Presenting to a Community Pharmacy," Headache, 2004, 44: 90-94.
- [32] Devine J, Hadsall R, Cline R, Schommer J, Virnig B. "Effect of Daily Migraine Prevention on Health Care Utilisation in an Insured Patient Population," Journal of Headache and Pain, 2007, 8: 105-113.
- [33] Goode JR, Mott DA, Chater R. "Collaborations to Facilitate Success of Community Pharmacy Practice-Based Research Networks," Journal of the American Pharmacists Association, 2008, 48: 153-162.
- [34] Armour C, Brilliant M, Krass I. "Pharmacists' Views on Involvement in Pharmacy Practice Research: Strategies for Facilitating Participation," Pharmacy Practice, 2007, 5: 59-66.
- [35] Pruchnicki MC, Rodis JL, Beatty SJ, et al. "Practice-Based Research Network as a Research Training Model for Community/Ambulatory Pharmacy Residents," Journal of the American Pharmacists Association, 2008, 48(2): 191-202.
- [36] Pinto SL, Coehrs B. "Initiation of a Practice-Based Research Network (PBRN) and Potential Benefits to Pharmacists from Involvement in a PBRN," Working Paper, University of Toledo, Toledo, OH, July 2008.
- [37] Kuo GM, Steinbauer JR, Spann SJ. "Conducting Medication Safety Research Projects in a Primary Care Physician Practice-Based Research Network," Journal of the American Pharmacists Association, 2008, 48(2): 163-170.
- [38] Green LA, White LL, Barry HC, Neasse DE, Hudson BL. "Infrastructure Requirements for Practice-Based Research Networks," Annals of Family Medicine, 2005, 3(suppl 1): S5-S11.
- [39] Dickinson LM, Anirban B. "Multilevel Modeling and Practice-Based Research," Annals of Family Medicine, 2005, 3(suppl 1): S52-S60.
- [40] Pace WD, Stataon EW. "Electronic Data Collection Options for Practice-Based Research Networks," Annals of Family Medicine, 2005, 3(suppl 1): S21-S29.
- [41] Mills S. "Organizational Life Cycle," 1997, accessed at http://webuildpeople.ag.org/WBP_library/9608_organization_lifecycl.cfm, accessed July 21, 2008.

[42] Fisher WP, Muller CC. Four-Dimensional Leadership, Pearson, Prentice Hall, Upper Saddle River, New Jersey, 2005.

[43] Wolf LE, Walden JF, Lo B. “Human Subjects Issues and IRB Review in Practice-Based Research,” *Annals of Family Medicine*, 2005, 3(suppl 1): S30-S37.

[44] Pace WD, Staton EW, Holcomb S. “Practice-Based Research Network Studies in the Age of HIPAA,” *Annals of Family Medicine*, 2005, 3(suppl 1): S38-S45.

Five Useful Web Sites

1. <http://www.ahrq.gov/research/pbrn/pbrnfact.htm> - Agency for Healthcare Research and Quality (AHRQ) web site containing useful background information about PBRNs.
2. <http://www.aacp.org/site/page.asp?TRACKID=&VID=1&CID=1400&DID=8104> – American Association of Colleges of Pharmacy web site containing useful background information about Pharmacy PBRNs.
3. <http://www.aphafoundation.org/programs/Practice%5Fbased%5FResearch/> - American Pharmacists Association Foundation web site containing examples of projects that utilized a practice-based research approach.
4. <http://www.jabfm.org/> - Journal of the American Board of Family Medicine web site where the July/August 2008 special issue of JABFM can be accessed. This issue contains examples of reports based upon primary care PBRN work.
5. http://www.annfammed.org/content/vol3/suppl_1/index.shtml - A supplement to the *Annals of Family Medicine* in July 2005 was devoted to Practice-Based Research Networks.

Appendix A

American Pharmacists Association, Research Gap Analysis Task Force

American Pharmacists Association Research Gap Analysis Task Force

Submitted December 19, 2006

Committee Members:

Jon Schommer (chair)
Marialice Bennett
John Bentley
Kelly Brock
William Doucette
Stefanie Ferreri

The APhA-Research Gap Analysis Task Force was formed through a collaborative effort between the APhA Academy of Pharmaceutical Research and Science and the APhA Academy of Pharmacy Practice and Management. The task force was asked to identify and describe the types of research that are the most relevant to the enhancement of pharmacy practice and APhA and to prioritize them in order of importance. The task force was established in June 2006, met via conference call in July 2006, September 2006, and November 2006 to develop a report. The task force report is divided into the following sections:

1. Describe the purpose and scope of research as it relates to Pharmacy and APhA.
2. Identify priority areas of research for guiding actions of APhA.
3. Propose steps that should be undertaken by APhA in order to fill research gaps.

1. Describe the purpose and scope of research as it relates to Pharmacy and APhA.

APhA's mission is to "improve medication use and advance patient care." This mission contributes to improving the quality, safety, efficiency, and effectiveness of health care for patients. APhA works with partners to promote improvements in clinical and health systems practices. Through the stimulation of research, APhA can contribute to efforts that (1) improve clinical practice, (2) improve the health care system's ability to provide access to and deliver high quality health care, (3) train future practitioners and scientists in this domain, and (4) provide policy makers, employers, and citizens with tools and expert advice to assess the impact of system changes on outcomes, quality, access to, cost, and use of health care services; particularly in areas related to the medication use process.

APhA is specifically interested in patient-centered care research focusing on the redesign and evaluation of new care processes and interventions for patients that could lead to improvements in care through patient participation, patient empowerment, improved patient-provider interaction and communication, improved system coordination, enhanced public policy, and multi-disciplinary team approaches. These interests are congruent with priorities published by the Agency for Healthcare Research and Quality (December 29, 2005) www.ahrq.gov.

2. Identify priority areas of research for guiding actions of APhA.

The task force concluded that APhA has demonstrated enduring and unique strengths in research and that its greatest room for growth is in the areas of its greatest strengths. Therefore, we propose that APhA would focus heavily on Practice-Based Research in which (1) science can be translated to practice, (2) practice needs can be communicated to guide scientific inquiry, and (3) findings can be used as a voice for advancing the practice of pharmacy and its role in the health care system.

Regarding the prioritization of research in order of importance, the task force conducted an environmental scan of the health care research domain (e.g. government reports, peer-reviewed research, books, research funding trends) and suggests the following priorities for APhA during the years 2007 through 2011:

a. Development and evaluation of innovative pharmacy practices.

New services and roles provided by pharmacists have been proposed as one approach to improving the safety and cost-effectiveness of healthcare. Yet, the adoption of new pharmacist services has been slow. Research can help guide the further development of pharmacist services and new care roles. For example, studies can report on the results of pharmacist services: the impact on patient outcomes, health care costs, or pharmacist practice activities. Such evidence could be used to gather support from payers and administrators for new pharmacist services. Also, research can help describe how new pharmacist services can be successfully integrated into a health care organization (e.g. pharmacy, hospital, clinic, managed care group, etc.) or a defined patient population (e.g. employee group, community, culture, diagnostic group, etc.). Such studies can inform pharmacists who are working to change their practices by adding new services or roles.

Traditionally, pharmacy practice has been product focused. However, decreased profit margins are driving pharmacies to seek revenue from increased dispensing volume or from new pharmacist services. While automation and greater use of pharmacy technicians have supported advances in dispensing efficiency, there has been limited progress in developing innovative pharmacist services. A promising approach for fostering the diffusion and adoption of new pharmacist services is the development of pharmacy practice-based research networks (PBRNs). Such networks would improve the likelihood of obtaining adequate funding for research on new pharmacist services. The PBRNs also would support access to sufficient numbers of practitioners and patients, which would strengthen the evidence generated in research studies conducted in them.

b. Improving patient outcomes from medication use.

APhA's mission is to "improve medication use and advance patient care." Pharmacists are responsible for optimizing drug therapy to improve patient outcomes. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established a new benefit called Medicare Part D¹. The overall goals of the Part D benefit are to increase access to prescription medications and improve the overall quality of care for Medicare beneficiaries. The MMA requires all prescription drug plans providing the drug benefit to establish a medication therapy management program (MTMP)². The purpose of an MTMP is to optimize medication use and reduce adverse drug events for targeted beneficiaries. However, the final regulation does not provide specific criteria for the development and implementation of these programs. Therefore, eleven national pharmacy organizations developed a consensus definition of medication therapy management (MTM), which identifies program criteria for MTM services.³ In addition to the consensus definition, the American Pharmacists Association (APhA) and the National Association of Chain Drug Stores (NACDS) Foundation have developed a model framework for implementing MTM services.⁴ The final regulation states that these MTM services may be provided by a

pharmacist but does not require a pharmacist to be the sole provider of MTM services. Research can be done to provide evidence to support pharmacist delivery of MTM services and can focus on defining the role of the pharmacist in providing MTM services. Research is needed to guide the development and implementation of MTM services and to establish their role as a standard of care in the health care system. Research can also focus on the process of care to help identify successful models of MTM services. In addition, research can be designed to describe the impact of MTM services on the clinical, economic, and humanistic outcomes.

In 2005, JCAHO regulations required medication reconciliation as part of its National Patient Safety goals. The goal strives to maintain accurate patient medication records at every stage of inpatient care to prevent adverse drug events. Research is needed to guide the development and implementation of medication reconciliation services and measure the outcomes of such efforts. Additional research to bridge medication reconciliation and MTM services could broaden the continuity of care between inpatient to outpatient settings.

As pharmacists focus on improving medication use, patient safety is a top priority. The 1999 report from the Institute of Medicine (IOM) *To Err is Human: Building a Safer Health System* highlighted the important issue of patient safety related to medication use⁵. The most recent IOM report *Preventing Medication Errors* highlights the need to develop systems to decrease medication errors to improve patient safety⁶. Research can be designed to identify factors that contribute to the safe use of medications. These factors may be patient, practitioner, or system factors that impact patient safety related to medication use.

The most recent IOM report, *Preventing Medication Errors*, identifies a vision for a patient-centered, integrated medication-use system⁶. This system should include a single electronic medication record for each patient. The medication record should be comprehensive to facilitate coordination of care for the patient with the goal of improving medication use and maximizing patient safety. The Core Elements of an MTM Service developed by APhA and NACDS identify the importance of developing a personal, portable medication record (PMR), which is a comprehensive medication record that should be maintained for each individual patient. Research can help identify the advantages of utilizing an electronic medication record to improve medication use and how this record impacts continuity of care.

Utilizing the strength of the diverse membership of APhA, one area of focus can be translational research (bench → bedside → best practice), which involves utilizing the findings from bench research to impact how care is provided to patients at the bedside, with the ultimate goal of developing best practices that are adopted by the profession. The findings from this research can be valuable because they can have a direct impact on improving patient care.

c. Providing evidence for development, implementation, and evaluation of health care policy.

The profession and practice of pharmacy do not exist in a vacuum. The profession's activities are shaped by, and also shape, the broader health-care political-legal environment. There is a significant need for health-care policy decisions (and all policy decisions for that matter) to be informed by sound, well-designed, and thoughtfully executed research. Data must be credible and able to withstand the rigors of scientific peer-review. Such policy-related research has the potential to 1) inform the need for, and the development of, new health-care policy, 2) guide the implementation of new policy, or 3) contribute to the post-implementation evaluation of policy. For example, research regarding the behaviors and outcomes of older adults with respect to a lack of access to prescription medications contributed to the development of the Medicare prescription drug benefit under the Medicare Modernization Act of 2003. Policy-oriented research was conducted following the passage of the Health Insurance Portability and

Accountability Act (HIPAA) of 1996 to ease the implementation of certain provisions. And following the passage of the mandatory patient counseling provisions in OBRA '90, several pharmacy researchers evaluated the impact of the policy on pharmacists' activities and patients' receipt of information about their prescription medications.

Health-care policy decisions are made at the national, state, and local level. They concern areas such as: 1) the delivery of quality health-care products and services (including the development of appropriate regulatory mechanisms and market-based incentives), 2) access to such products and services, and 3) containing the costs associated with the provision of health-care products and services. All levels and types of policy matters require high quality research to guide the discussion. At the national level, policy research might guide changes to the post-marketing surveillance of prescription drugs, changes to CMS reimbursement rates for prescription drugs, or alterations to the national policy regarding stem-cell research. At the state level, policy-research might guide changes in state pharmacy practice acts, inform the debate over the availability of chemical precursors to illicit substances, or help lawmakers and Medicaid officials determine whether a cap should be imposed on the number prescriptions or the appropriate copay level. At the local level, policy research can guide the allocation of limited resources within a county hospital or influence the development and operation of a local free clinic.

APhA has strongly advocated for the profession at the national, regional, state, and occasionally at the local level. The association has kept its members informed of activities occurring in Washington, D.C. and in states across the country. At times, it has even contributed to the health-care policy development and implementation process. Many times, investigators engage in the conduct of research not specifically attempting to address a policy issue. This is an area where the APhA staff, with significant experience in legislative and policy matters, can play a significant role. Given its talented staff and a membership that is not only actively engaged in policy discussions, but also in the conduct of policy-related research, it seems that the provision of evidence with respect to health-care policy is a natural area for APhA to excel.

3. Propose steps that should be undertaken by APhA in order to fill research gaps.

There are numerous opportunities, but limited time and resources. We propose that the priorities listed in this report would build upon APhA's strengths and provide the greatest room for growth and impact by APhA. The following steps are proposed for action by APhA in order to help fill the identified research gaps.

- a. Identify, summarize, and distribute information regarding primary funding sources for the types of research we listed.
- b. Consider providing seed funding for research, either directly or through its Foundation.
- c. Assist practitioners, researchers, funders, and other potential partners as they develop networks for discussing and developing concept papers for research projects.
- d. Facilitate formation of research groups (some will be multi-state, regional, or national in scope)
- e. Develop visiting scholar programs at APhA for developing new research ideas and agendas.
- f. Form an expert Think Tank for the purpose of monitoring and evaluating trends and opportunities for filling research gaps that will develop in the future (e.g. 2012 – 2016).
- g. Define metrics to measure performance indicators for APhA initiatives in this area (e.g. structures, processes, and outcomes that resulted from APhA efforts).

References

- 1 Medicare Prescription Drug, Improvement, and Modernization Act of 2003. H.R.1. Available at: <http://thomas.loc.gov/>. Accessed August 3, 2006.
- 2 Medicare Program; Medicare Prescription Drug Benefit. Federal Register (2005). 42 CFR Parts 400, 403, 411, 417, and 423; 4193-4742.
- 3 Medication Therapy Management Services Definition and Program Criteria. Available at: <http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=4577&TEMPLATE=/CM/ContentDisplay.cfm>. Accessed August 3, 2006.
- 4 American Pharmacists Association and National Association of Chain Drug Stores Foundation. Medication Therapy Management in Community Pharmacy Practice: Core Elements of an MTM Service (Version 1.0). *Journal of the American Pharmacists Association* 2005; 45:573-579.
- 5 Committee on Quality of Health Care in America, Institute of Medicine. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.
- 6 Committee on Identifying and Preventing Medication Errors Board on Health Care Services, Institute of Medicine. *Preventing Medication Errors (Prepublication Copy)*. Washington, DC: National Academy Press; 2006.

Appendix B

Minnesota Pharmacy Practice-Based Research Network: Guiding Principles

Role of University of Minnesota

- Provide infrastructure for PBRN such as Institutional Review Board, Responsible Conduct of Research, Sponsored Projects Administration, Sponsored Financial Reporting, etc.
- Maintenance of PBRN “Capacity Portfolio”
- Proposal preparation and submission
- Grant management
- Reporting

Role of Minnesota Pharmacists Association

- Monitor professional and political trends
- Community engagement
- Professional engagement
- Interprofessional / Interdisciplinary relations
- State-wide communication and coordination
- Networking
- Continuous quality improvement

Operating Principles

- The PBRN “Capacity Portfolio” would be an internal document for use by U of M and MPhA and may be submitted to funding agencies as part of our proposals
- Pharmacies would be contacted on an annual basis to update their information in the PBRN Capacity Portfolio
- Principal Investigators are responsible for following policies and procedures as set forth by SPA, IRB, RCR, HIPAA, etc.
- The PBRN will be coordinated as a joint effort by U of M and MPhA

- Pharmacies would be paid through subcontracts or “contracts for service” for work that is reimbursable in grants
- Subcontracts and “contracts for service” would be part of individual grant proposals and amounts would be determined for each proposal at the time of submission to funding agencies.
- Grant proposals would include U of M overhead according to University guidelines
- Subcontracts with MPhA would be “not less than 10% of the direct costs” for the given proposal

Principal Investigator Behavior

- align goals with practitioners and communities
- listen
- develop collaboration and trust
- communicate
- nurture relationships
- engage patients and communities in practice-based research

Considerations for Interacting with Patients

- Avoid Information Overload
- Patient Security, keep the feeling of being “safe”
- Allow Patients to “Drive the Bus” (flexible research protocol)
- Opportunity for Continuation after the Study is Completed
- The Unexpected is OK
- Make Participation Easy
- “Be the Patient”
- It’s Not about Me

Appendix C

Current Capabilities of the Minnesota Pharmacy PBRN

University of Minnesota

The University of Minnesota provides rich resources for planning, implementation, and oversight of practice-based research projects. Our PBRN is fully engaged and coordinated with these University of Minnesota resources and has met all training and preparation requirements for engaging in research.

- Investigational Review Board (IRB) The IRB reviews research projects which involve human subjects to ensure that two broad standards are upheld: first, that subjects are not placed at undue risk; second, that they give uncoerced, informed consent to their participation. With representation from a wide range of scientific disciplines and from outside the academic community, the IRB gives rapid but individualized attention to the numerous research projects at the University. www.irb.umn.edu
- Sponsored Projects Administration (SPA) SPA is the University of Minnesota system-wide office authorized to submit research proposals and receive awards from external sources on behalf of the Board of Regents of the University of Minnesota. SPA is also the fiduciary for the U on grant-related matters. www.ospa.umn.edu
- Sponsored Financial Reporting (SFR) Sponsored Financial Reporting is responsible for managing the external financial reporting and invoicing requirements of sponsored University research projects www.sfr.umn.edu
- Responsible Conduct of Research (RCR) (e.g. responsible conduct of research training set up for each principle investigator) <http://egms.umn.edu/rcr/>

We have met with each university office for developing, submitting, and implementing research proposals and will follow established University of Minnesota guidelines for our PBRN practices.

Minnesota Pharmacists Association (MPhA)

The Mission of MPhA is “Serving Minnesota Pharmacists to advance patient care.” MPhA is a state professional association, whose membership is made up of pharmacists, pharmacy students, pharmacy technicians, and those with a business interest in pharmacy. Besides offering a one-stop information site for its members, consumers are also welcome to use their pharmacy locator and browse for information specific to their needs. For the Minnesota Pharmacy PBRN, the Minnesota Pharmacists Association serves as a valuable resource for linking researchers from the University of Minnesota, Pharmacy Practitioners, and Communities throughout the state of Minnesota. MPhA is taking a leadership role for:

- Monitoring professional and political trends
- Community engagement
- Professional engagement
- Interprofessional / Interdisciplinary relations
- State-wide communication and coordination
- Networking
- Continuous quality improvement

Practice Sites in the Minnesota Pharmacy PBRN

As of December 2009, there were 305 pharmacy practice locations for the Minnesota Pharmacy PBRN that included: (1) community-based pharmacies, (2) hospital-based pharmacies, (3) community-based clinics, and (4) one investigational drug service (not available to the general public). All but six of the PBRN pharmacies dispense medications to the public. The investigational drug service location provides expertise in specialty medicine preparation, project design for clinical research, and implementation of clinical research.

The Minnesota Pharmacy PBRN pharmacy practice locations are geographically dispersed throughout the state of Minnesota (with one being located in the Chicago area). The geographic distribution of the PBRN locations is consistent with the distribution of pharmacy practice locations in Minnesota overall. Maps of PBRN locations and all pharmacy locations in the state are available upon request.

Practice sites have indicated their level of interest in collaborating on projects for which there is a diverse array of activities such as:

- data retrieval
- pharmacy surveys
- pharmacist surveys
- collection of patient reported outcomes
- location for research assistant conducted observations and/or interviews
- provision of various services as required by studies (e.g. cholesterol check, etc.)
- patient screening
- patient education
- patient referral
- patient continuity of care
- patient follow-up
- product preparation
- drug regimen review
- community engagement

Appendix D
Community Pharmacy Residency Program
PBRNet Focus Group Meeting, San Antonio, TX, April 5, 2009

Focus group conducted by: Jon Schommer, schom010@umn.edu

APhA staff/officers present: Anne Burns, aburns@aphanet.org
 Bill Ellis, wellis@aphanet.org
 James Owen, jowen@aphanet.org
 L. Doug Ried, ried@cop.ufl.edu

Focus group participants:

Ann Albrecht	Ann.albrecht@kroger.com
Emily Bellebaum	ebellebaum@kdihealthsolutions.com
Ashley Branham	abranham@email.unc.edu
Kara Carruthers	karac@mainatlocust.com
Kati Dvorak	Ovikx003@umn.edu
Stefanie Ferreri	Stefanie_ferreri@unc.edu
Chris Frei	Freic@uthscsa.edu
Peggy Kuehl	kuehlp@umkc.edu
Aaron Lengel	Aaron.lengel@utoledo.edu
Macary Marciniak	Macary_marciniak@unc.edu
Amy Nicholas	Asmoun1@email.uky.edu
Anthony Pudlo	Apudlo@kdihealthsolutions.com
Heather Rickertsen	rickerth@mercyhealth.com
Steve Simenson	ssimenson@goodrichpharmacy.com
Amy Whitaker	alwhitak@vcu.edu

Focus Group – Guiding Questions

1. On a piece of paper in front of you, please take a few minutes and write down the two or three features (things) that are benefits gained from participation in a practice-based research network (PBRN).
2. On that same sheet of paper, please write down the two or three features (things) that you like the least about participating in a PBRN.
3. One of the things about PBRNs that some of you brought up just now was _____. I was wondering if we could talk a little more about _____.
4. How much involvement with a PBRN would you like to have?
5. What kind of interactions with a PBRN do you prefer?
6. When you talk with others about participation in a PBRN, what do you talk about and with whom do you talk the most?
7. Based on our discussion and your personal opinion, what are the most important elements needed for an infrastructure to support a Community Pharmacy Residency Program PBRN?

Summary of Focus Group Discussion

1. On a piece of paper in front of you, please take a few minutes and write down the two or three features (things) that are benefits gained from participation in a practice-based research network (PBRN).
 - having a large enough sample size through multiple site collaboration to gain statistical power
 - can combine data for residency projects
 - great way to answer a question that you can't answer with one site
 - a way to document pharmacist value
 - could design multiple year projects for which 1-year residents could play a part, but then hand it off to the next resident.
 - Collaboration can increase the quality of residents' projects
 - Increase the strength of the final project
 - Increase professional satisfaction
 - Worthwhile to both the CPR Program and the profession
 - Can have the same progress and timeline for multiple sites
 - Tracks your progress against others
 - Stronger projects for publication
 - Diversity of settings for projects
 - Diversity of patient populations for projects gives credibility
 - Methodological and statistical strengths improved with larger sample sizes
 - Valuable to the mentors in terms of funding and publications
 - Research credibility is enhanced through multiple sites
 - Better research designs are possible
 - Can better interpret statistical findings
 - Provides a structure for doing work
 - Efficiency of sharing ideas or other experiences
 - Helps residents get feedback ahead of time for project ideas
 - Nationwide networking for similar ideas and projects
 - Burden for residency project is taken off of the preceptor
 - Good community public relations

2. On that same sheet of paper, please write down the two or three features (things) that you like the least about participating in a PBRN.
 - standard of care changes at the practice due to protocols developed for projects
 - want independence, but project dictates too much
 - consistent documentation is difficult
 - ability to adapt processes in your work flow
 - each site is unique
 - can't quickly respond to issues then they come up
 - decrease in autonomy at individual sites
 - getting patients to participate is difficult
 - subject recruitment difficult
 - does your site even have patients you can use for a project

- not every project may be applicable to all sites
 - technology needs
 - technology differences from site to site
 - collecting data with pen and paper, electronic, etc.
 - same systems and software at each site?
 - Time to document is burdensome
 - Uniformity of documentation for each project
 - Documentation paper-based or web-based?
 - Time to get up to speed (training)
 - How to bring benefits back to the site (impact on practice)
 - Projects require us to collect more than we normally would
 - Double entry is burdensome
 - Firewalls block access to data and sharing of data
 - Network issues
 - Time for data entry
 - Training necessary for various systems can be burdensome
 - Study instructions aren't clear
 - Resident interest might not coincide with the project you currently have
 - Would like to participate, but have no resident that year ... what then?
 - Multi-year project – what if change in resident affects your ability to participate?
 - Time investment could lead to burn out
 - If questions aren't pertinent, get burn out
 - Questions should come from practice
 - Turnover of preceptor / PI at sites
 - Credit / money for your efforts
 - Accountability – who is responsible for what?
 - Who is the point person?
 - Work flow consistency
 - Making sure the project fits (no square pegs into a round hole)
3. One of the things about PBRNs that some of you brought up just now was _____. I was wondering if we could talk a little more about _____.

--- this was used throughout the conversation during #1 and #2 above --

4. How much involvement with a PBRN would you like to have?
- be involved in order to build consensus for overall infrastructure and projects
 - can opt-in or opt-out of individual project opportunities
 - a practitioner steering group can review project proposals and interface project PIs.
 - After a project is chosen and introduced to the network, each site can opt-in or opt-out
 - Would like to offer suggestions for projects can could be developed by PIs
 - Offer a chance to lead
 - Offer a chance to participate

- Residents are not co-investigators. They are residents (research assistants) for projects with well-defined roles, expectations and responsibilities. CPRP accreditation documents should be reviewed and modified to reflect this.
- IRB considerations – some serve as PI at their institution – for multi-site may need to run through each IRB
- Steering committee – everyone can participate, everyone can serve as an investigator – value in differences in IRB from institutions
- Help to identify areas for project – submit to steering committee

5. What kind of interactions with a PBRN do you prefer?

- timeliness of communication is important
- email is a positive medium for one-way communication (information, announcements, etc)
- need a facilitator to coordinate opportunities for interaction and for communication
- on-line or conference call can be used for two-way communications
- meetings via conference call could be coordinated by APhA, for example
- a third party to look at your site would be helpful
- national meetings can be connection venues
- virtual writing club – pre-submission peer review – quick turnaround prior to submission

6. When you talk with others about participation in a PBRN, what do you talk about and with whom do you talk the most?

- talk with other preceptors in our company (7 sites)
- collect outcomes from MTM at all sites, talk about how we can show value of the services in a unified way
- we communicate with stakeholders and talk about who is going to operate the PBRN
- Our college has a community pharmacy advisory committee. I talk with them about how to develop better community pharmacy experiences for students and residents.
- I talk with administrators at our school of pharmacy
- University research committee
- Department chair – tenured faculty member
- Talk with pharmacy association about how to document pharmacist services and show their value
- I talk with other disciplines about who should do what and how to pay for these services
- Talk with preceptors for advanced community clerkships.
- Talk with key faculty colleagues and talk about who should be the PBRN contact person
- Talk with preceptors and practitioners – get lots of ideas, need resources, need scientific help.

7. Based on our discussion and your personal opinion, what are the most important elements needed for an infrastructure to support a Community Pharmacy Residency Program PBRN?

(a) We need a sponsoring organization

- examples of possible sponsoring organizations included APhA Foundation, a University, or APhA.

- For regional needs (especially across time zones), state associations could serve as sponsoring organizations for regions.
- Avoid too many layers
- The sponsoring organization could serve as the “glue” to help arrange meetings, conduct correspondence, keep records, and coordinate activities.
- A steering committee would be useful for providing guidance and oversight. The Steering committee should be comprised primarily of pharmacist practitioners (preceptors), but also should include members from the scientific community, public health, medicine, and the general public. The steering committee could make decisions about projects to pursue in any given year and about coordination for projects
- The sponsoring organization could receive support from the PBRN through a certain percentage of each funded project being devoted to administrative costs incurred by the sponsoring organization.
- Sponsoring organization should be:
 - Stable ongoing organization that is dedicated
 - This is their job
 - One top person – corporate person
 - Guidance and oversight board
 - External people (consumer organizations, governmental)
 - Practitioners

(b) We need technology support

- Is there a standard excel database that could be developed so that data extracted from multiple systems be uploaded to the central standard database?
- Do companies that specialize in documentation systems (Mirixa, Outcomes, Assurance) have an interest in collaborating on this issue?
- Avoid double documentation
- As we move toward medical record – Google Health
- The first PBRN projects could be related to standardization of documentation for projects so that costs and time burdens could be kept to a minimum.
- An initial PBRN project could relate to building a “capacity portfolio” for the participating sites to describe existing systems and capabilities and to compare how they differ among the sites. For example, what types of patient care do we provide? What kind of research can we conduct? What types of data do we have?
- Health IT is working to standardize MTM reporting, documentation, and billing.

**Recommendations based on Focus Group Findings for
Next Steps in PBRN Infrastructure Requirements**

Focus group findings showed consensus regarding the benefits and challenges for participation in a Community Pharmacy Residency Program practice-based research network. The following recommendations are based upon the focus group discussion and have the goal of maximizing the identified benefits of such a PBRN and the goal of addressing the challenges identified.

1. A **sponsoring organization** should be identified in order to provide an identity for the PBRN and a structure for taking the next steps in PBRN development such as:

- creation of a **steering committee**
- development of guidelines for project evaluation and project introductions to sites
- development of one-way communication channels
- development of two-way communication opportunities
- creation of guidelines and methods for sites to opt-in and opt-out of projects

2. Community Pharmacy Residency Program **accreditation requirements** should be reviewed and revised (if necessary) so that residents could participate in PBRN projects (including multiple year and multiple site projects) and still earn credit for their “residency project” requirement.

3. Development of **technology standards** is needed. Technology is constantly changing and will need consistent attention during the life of the PBRN. Initially, the first PBRN projects might be devoted to collaborative research for creating a PBRN “Capacity Portfolio” that would identify key hardware and software components and then describe these for the sites that are participating in the PBRN. Other elements in the capacity portfolio could include things such as (a) services offered at each site, (b) collaborative practice at each site, or (c) point-of-sale record keeping for OTCs, just to name a few.

The research needed for developing “capacity portfolios” could actually be the first multi-site, multi-year residency projects conducted under the PBRN umbrella. This research is not only needed to help advance the PBRN, but also could provide valuable experience in how the PBRN should conduct projects.