

The Practice-Based Research Network as a Model for End-of-Life Care Research: Challenges and Opportunities

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Introduction

Practice-based primary care research networks have demonstrated the feasibility and value of practice-based research networks (PBRNs). PBRNs provide access to phenomena often neglected by researchers but of great importance to those directly affected by the issues being studied. Since the majority of end-of-life care is provided outside of academic institutions, the PBRN provides an essential model for conducting end-of-life research. Researchers investigating care for persons with advanced illness should borrow from the wealth of experience from other care settings in conducting practice-based research, in terms of organizational structure as well as research methodology.

The past two decades have seen the emergence of primary care PBRNs as important research laboratories to study the processes and impact of primary care. As was true with primary care, there exists a significant need to develop the knowledge base of and improve care for persons with advanced and terminal illness. Since the majority of care for patients with advanced illness, including cancer, is provided outside of academic institutions, the PBRN provides an essential model for studying and inter-

vening to improve the illness experience as well as the organization, delivery, and financing of care for these individuals. The purpose of this article is to familiarize the reader with the successful model of primary care PBRNs and to extend this model to end-of-life/palliative care research. Using examples from the Population-based Palliative Care Research Network (PoPCRN), this paper defines PBRNs, describes issues related to governance and organizational structure and the necessary elements for successful PBRN-based research, and discusses the challenges and opportunities presented by PBRNs for end-of-life and palliative care research.

What Is a PBRN?

For the purposes of this article, a PBRN is defined as a group of clinicians, practices, or institutions that are devoted primarily to the delivery of patient care and are affiliated with each other in order to investigate questions related to community-based practice. Networks are usually formal collaborations between community-based physicians and academic institutions: the physicians collect research data, and academic institutions have the staff and facilities required to design research studies and analyze, interpret, and publish the data.¹ This definition includes a sense of ongoing commitment to the research endeavor, as well as an organizational structure that transcends a single study.² To qualify as a PBRN, the clinicians and/or office staff members within the network must actively participate in the research process. Systems that passively collect information from electronic medical record systems or billing data are not considered PBRNs for the purposes of this paper.

Unlike cooperative clinical trials networks, PBRNs generally study a range of medical conditions rather than a single disease and can be composed of individual clinicians or practices as well as institutions.² PBRNs may conduct cross-sectional or longitudinal descriptive studies and may use quasi-experimental methods as well as conduct randomized clinical trials. The major goal of PBRNs is to involve busy community-based clinicians in studies directed by investigators experienced in clinical and health ser-

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vices research.³ PBRNs have been described as research laboratories that are “as essential to advancing the scientific understanding of medical care as bench laboratories are to advancing knowledge of the basic sciences.”⁴

Why PBRNs?

Recent work reexamining the ecology of medical care in the United States highlights the disparities between the locations in which most people receive medical care most of the time and the locations in which most medical research is performed.⁵ Studies performed in the tertiary care environment often systematically exclude the patient’s physical and psychosocial environment, the patient-physician relationship, and the multiple effects of factors inherent in the organization, delivery, and financing of health care. In addition, problems commonly seen by primary care providers are often multifactorial in origin, present with an array of signs and symptoms, and are managed by a variety of techniques over multiple visits. Understanding of these problems is limited, and what we do know is often based on selected subgroups of patients.⁶ Research performed in practice or community-based settings is needed to provide insight and understanding of the clinical spectrum of illness as it affects most of the people most of the time, within in the context of their lives and their sociocultural norms and values.^{1,2,7,8} Even the recent “National Institutes of Health (NIH) Roadmap” advocates for new partnerships among organized patient communities, community-based physicians, and academic researchers, noting that the “efficiency and productivity of the nation’s clinical research enterprise will be enhanced by promoting clinical research networks capable of rapidly conducting high-quality clinical studies and trials where multiple research questions can be addressed.”⁹

The noted disparities between location of care and location of research reinforces the need for community-level investigations in multiple medical care locations, including primary care offices, nursing homes, home healthcare agencies, emergency departments, and hospices. Primary care PBRNs address this issue for the primary care office. The development of research networks for these other medical care settings, akin to primary care PBRNs, is both logical and necessary. The challenges in conducting research in these various settings and the methods required to overcome these issues and conduct quality investigations are similar.

The impetus for the development of primary care PBRNs was the realization that there continues to be a need to better understand, develop the knowledge base of, and improve primary care.^{7,8,10} The rationale for much of the care provided by generalists in office settings has been primarily derived from specialty-oriented studies in which conditions were carefully controlled and inclusion criteria were narrow. A similar lack of empiric data should

drive development of end-of-life and palliative care-focused PBRNs.

The efforts of researchers from primary care PBRNs have left little doubt that research carried out in practice settings can have immediate relevance to daily clinical practice. Primary care PBRNs address the lack of communication by physician scientists at academic health centers with practicing physicians in the community and the failure of clinical research studies to target needs identified by community physicians and their patients.² PBRNs provide access to phenomena often neglected by researchers but of great importance to those directly affected by those issues. PBRNs offer a unique opportunity to increase generalizability, decrease burden on any one practice, and provide group comparison data by involving healthcare providers from the community in clinical research. As laboratories for study of clinical activity and processes in real-world settings, PBRNs provide access to relatively neglected phenomena of great importance to patients and those who care for them, efficiencies that permit multiple studies to be done simultaneously and sequentially, and synergism between communities and the research enterprise.^{10,11}

PBRN Growth Nationally

The growth of PBRNs over the past two decades has been supported by a number of funding opportunities specifically for or weighted towards primary care PBRNs, primarily via the Agency for Healthcare Research and Quality (AHRQ). AHRQ aims to improve the capacity of PBRNs to expand the primary care knowledge base and to establish mechanisms to assure that new knowledge is incorporated into clinical practice.³

The American Academy of Family Physicians (AAFP) has taken an active role in promoting and furthering primary care PBRNs. The Federation of Practice-based Research Networks (FPBRN), which was established in 1997 by the AAFP to promote the growth and development of clinical investigation in primary care practice settings, advocates for practice-based research, builds capacity for practice-based research, and fosters collaboration and communication among networks. FPBRN includes 42 member networks and 16 domestic or international affiliates.¹² In addition, the AAFP is home to its own PBRN, the National Research Network, whose primary objectives are to conduct funded research both within the National Research Network and across other state and regional networks, serve as a national voice and advocate for practice-based and primary care research, and provide technical assistance and consultation to existing and developing state and regional networks. The National Research Network has 290 primary care clinician members from 45 states and four Canadian provinces.¹²

Traditionally, PBRNs have been primary care-based, such as Pediatric Research in Office Settings,¹³ the Dart-

mouth Primary Care Cooperative Information Project,¹⁴ the Ambulatory Sentinel Practice Network,¹⁵ the Wisconsin Research Network,¹⁶ and the Colorado Research Network.¹⁷ PBRNs have also been established for rural hospitals,¹⁸ chiropractic practices,¹⁹ and the Advanced Practice Registered Nurses' Research Network (APRNet).² One existing PBRN, the PoPCRN,²⁰ specifically addresses issues relevant to end-of-life and palliative care.

PoPCRN: An End-of-Life/Palliative Care PBRN

PoPCRN (pronounced "popcorn") was founded in 1998 by one of the authors (JK) and David Nowels, MD, MPH, in response to issues similar to those that have driven the growth of primary care PBRNs: a lack of empiric evidence regarding care of terminally ill persons in the community-based settings where the care is provided. Modeled on successful primary care PBRNs, PoPCRN is a research network of organizations that provide hospice/palliative care, based at the University of Colorado Health Sciences Center (UCHSC) in the Division of General Internal Medicine (GIM).

PoPCRN was developed with initial internal funding from the Hartford/Jahnigen Center of Excellence in Geriatrics and the Division of GIM Small Grants Program at UCHSC and subsequently with support from the Robert Wood Johnson Generalist Physician Faculty Scholars Program and a Paul Beeson Physician Faculty Scholars in Aging Research Award. PoPCRN was recipient of a 2002 Circle of Life Award for Innovation in End-of-Life Care. It

is currently supported by the Division of GIM (UCHSC), the Mendel-Asarch Lung Cancer Family Foundation Grant Program, and the National Center for Complementary and Alternative Medicine (NCCAM: R01-AT-006-01A2).

PoPCRN is committed to enhancing the care of persons at the end of life and their families through the conduct and dissemination of high-quality research in palliative care settings. The PoPCRN research team consists of research-trained faculty physicians, PhDs in behavioral sciences, and masters-level research assistants. To date, 205 hospice/palliative care organizations from 41 states have expressed interest in participating in PoPCRN-based studies, and 145 (71%) of these hospice/palliative care organizations have collected data for 16 network-based studies (Table 1).²¹⁻²⁸ Study ideas originate from the research team and from participating hospice/palliative care organizations. The multidisciplinary PoPCRN research team meets biweekly to review research in progress and to discuss development of new research ideas. An advisory board, composed of representatives from participating sites and senior UCHSC research personnel, provides guidance regarding study topic selection, study design, implementation, and data interpretation. A Web page,²⁰ listservs, and a quarterly newsletter facilitate communication. Study results are initially disseminated to participating sites for use in internal quality improvement activities. Aggregate reports are distributed via the Web site, newsletter, and peer-reviewed literature.

PoPCRN is an innovative approach to improving the care provided to persons with advanced illness. The collaboration between clinicians and administrators from the participating organizations and the PoPCRN research team

Table 1. — Population-Based Palliative Care Research Network (PoPCRN) Studies to Date, Chronological Order

Topic	Study Design	Respondent	No. of Network Sites	No. of Participants
Symptom prevalence and distress	Cross-sectional	Hospice staff	16	348
Psychosocial/spiritual issues	Cross-sectional	Patients	14	62
Bereavement	Cross-sectional	Family	3	59
Confusion/delirium	Cross-sectional	Hospice staff	19	303
Discharge follow-up	Prospective	Patients/family	18	164
Symptoms/quality of life	Prospective	Patients, family, nurses	11	108
National Hospice Outcomes Project	Retrospective	Chart review	5	106
Hospice fall rates	Cross-sectional, Web-based	Hospice staff	10	N/A
Hospice education	Cross-sectional, Web-based	Hospice staff	73	N/A
Symptom management guidelines	Cross-sectional	Hospice staff	78	N/A
Symptom management barriers	Cross-sectional	Hospice nurses	67	876
Pharmacy costs	Cross-sectional, Web-based	Hospice staff	34	N/A
Research screening	Prospective	Patients	2	214
Medication prescribing	Cross-sectional	Hospice medical directors	69	91
Heart failure	Cross-sectional	Hospice medical directors	70	N/A
Massage therapy	Randomized clinical trial	Patients	11	In progress, goal = 440

Sources: References 21-28.

ensures that the issues being studied are clinically relevant and that the studies themselves are rigorous and high quality. As has been successfully demonstrated in primary care, PoPCRN has the potential to serve as an ongoing “laboratory” for addressing key issues in the care of persons with advanced illness.

Essential Components and Organizational Features of PBRNs

The essential components of a PBRN are a common purpose and a pervasive sense of mission, as well as governance that is fair and faithful to the purpose and mission, and unifying symbols that make the network perceivable. Networks require multiple communication systems and at least one staff person who is strongly identified with the network. PBRNs must make explicit processes that identify questions important to network members, refine ideas into researchable questions, design investigations, link the study questions to funding, implement projects throughout the network, conduct and monitor studies, and report results with appropriate credit to all participants.¹¹

Organizational Structure

Functional PBRNs have a number of important roles that must be fulfilled: network director, research director/methods expert, communications activities, research coordination/research assistants, writers, and statistical and

information systems support. More than one of these functions is often carried out by a single individual. These role functions are described in Table 2. Perhaps the most critical role for the network director is to convey to network members the vision and purpose of the network and the importance of each member’s contribution to the network. The bigger and more geographically diverse the network, the more difficult this message is to deliver. The research director, or whoever is fulfilling this role, is responsible for guaranteeing that the science is appropriate for the question(s) being asked. Given the inevitable tension between perfectly conducted studies and the realities of conducting research in busy clinical settings, this a challenging job that demands an individual who can withstand some degree of ambiguity and compromise. Communicating with network members is critical to maintaining network cohesiveness.

Research coordination is essential. For PBRNs, this function encompasses both communications and typical study management. Within the PBRN setting, interpersonal skills are critical to effective research coordination; rarely will the majority of data collection be performed centrally. The research coordinator must help each practice or organization within the network with implementation of study protocols. Selected individuals may serve financial, grant preparation, and writing roles, or those roles may be distributed among different people.

The ability to work with and share information with individuals at disparate locations is an inherent part of PBRN work. Ideally, a network’s infrastructure will include an electronic data system that extends to all network practices and is capable of not only collecting, transferring, and aggregating primary research data but also disseminating new research quickly and measuring subsequent changes in practice. Such systems could inform future research needs, help to transform the culture of the practice, and support strategies to accelerate continuous quality improvement.³

Governance

In order for PBRNs to have a life over multiple studies, networks must develop a process of governance. This can range from fairly informal to the formation of a freestanding corporation. Nonetheless, there is a defined set of issues that will eventually need to be dealt with for successful operation. These issues include (1) a definition of who is in the network, how network recruitment operates, and how people maintain membership, (2) a system for deciding how studies are selected and how members decide to participate in a given study, (3) a mechanism for the network to interface effectively with other agencies, particularly granting agencies or outside interested parties, (4) the development of a network identity, (5) the development and maintenance of a basic database about network members, (6) a governing body, and (7) a process by which network members can interact with each other.

Table 2. — Key Roles Within the Organizational Structure of Practice-based Research Networks

Role	Function
Network director	Day-to-day operations Research agenda Funding proposals Principal investigator
Research director	Research agenda Research methods Funding proposals Principal investigator Monitoring of ongoing projects
Communications activities	Recruitment for new network members and individual project participation Communication of network news and study findings
Research coordination	Institutional Review Board application support Grant proposal preparation support Report/paper preparation support Budget planning and monitoring
Statistical support	Nested research designs
Information systems support	Web sites Data collection Data protection

Most PBRNs exist in conjunction with another business entity, such as an academic institution or a professional society, and utilize that organization for classic business operations: banking, personnel, payroll, grants management, office space, and equipment. Nonetheless, it is important that the network develops its own identity, typically with an acronym and logo, that allows both members and outside agencies a sense of permanence and organization.

The organizational strategy, leadership, and infrastructural system(s) supporting the PBRN are often critical in determining the network's success in achieving any or all of the network's competing aims. A network with strong links to an academic institution and a "top-down" leadership that uses research experts to develop investigational ideas, secure funding, and direct individual projects is more likely to produce high-quality research quickly but is less likely to transform the culture of practices. A network adopting a "bottom-up" approach is likely to be more successful in sustaining the interest of clinicians and facilitating grass roots participation in research efforts. These networks, however, often require more time and effort to develop research protocols, may have less expertise/experience in conducting research, and may be less successful in identifying a funding source. Both the "top-down" and "bottom-up" approaches have merit, and are not mutually exclusive.³ PoPCRN has employed both approaches, using a "top-down" approach for most of its externally funded studies and concurrently using a "bottom-up" approach to guide study selection and to provide advice regarding study implementation, interpretation of study results, and suggestions for translating research findings into practice. PoPCRN has also conducted several smaller-scale non-funded studies that have addressed key clinical questions raised by network members.²¹

A governing body with significant member representation, such as a board of directors or steering committee, promotes member ownership. The role of this body can range from a very "hands-on" approach, with direct involvement in the selection and development of each study, to a relatively "hands-off" approach, where-by the group establishes broad policies for the director and others to follow. In either case, the group should establish policies for recruitment, funding, involvement in studies, and publications.

Recruitment mechanisms and membership generally follow one of two styles: recruitment at the individual clinician level or recruitment at the practice/organization level. Few networks can expect that all members will participate in all studies. Therefore, systems to determine participation on a study-by-study basis must be developed that maintain study validity while allowing flexibility for the members. Lastly, it is better to develop and distribute publication guidelines and policies prior to submission of papers, as authorship, naming conventions, and expected contributions can be contentious items.

Regulatory Issues in PBRNs

PBRNs must address many of the same regulatory issues faced by practicing physicians, community health centers, hospitals, hospices, and other types of research entities. The major issues relevant to PBRN-based research relate to protection for human subjects through review by an Institutional Review Board (IRB) and compliance with the Health Insurance Portability and Accountability Act (HIPAA).

All research involving humans requires review and approval by an appropriate review board, typically an IRB. The IRB requires detailed description of how subjects will be recruited and give consent and how they will be compensated, followed, and treated. All federal funding and most other funding organizations require IRB approval, as do many peer-reviewed journals. The fine line between quality improvement projects (which have not historically required IRB approval) and clinical research has been nearly erased; it is now reasonable to obtain IRB approval for *all* projects involving humans.

Within a PBRN there may be network members who fall under the jurisdiction of separate IRBs. Approval must be obtained from each IRB. For instance, PoPCRN has several member organizations that either have their own IRB or are associated with another academic IRB. For PoPCRN to conduct a research study, IRB approval must be obtained from both the UCHSC IRB and from every IRB with which member organizations are associated. More often, there are network members who do not fall under the jurisdiction of any IRB. In PoPCRN, most hospice/palliative care organizations do not have their own IRBs, thus requiring that those network members be covered under an umbrella IRB. PoPCRN uses the IRB at the UCHSC to obtain IRB approval for participation by sites that do not have their own IRBs. Each network member site must identify an on-site contact that obtains IRB training and must agree to abide by institutional IRB rules and all federal regulations. Further information and training on IRB regulations, training, and approval can be found at <http://ohsr.od.nih.gov>²⁹ and <http://cme.cancer.gov>.³⁰

The requirements of HIPAA must be addressed prior to beginning research in a PBRN. HIPAA addresses two major issues, privacy and security. Identifiable patient-level health information must be kept private. Patients must specifically authorize any communication of protected health information, whether electronic, oral, or written. PoPCRN has addressed HIPAA by training and then relying on on-site personnel to seek authorization for release of protected health information for research purposes. It also has developed systems to allow data cleaning while maintaining patient anonymity so that the need to transmit or store unique patient identifiers is limited.

HIPAA also requires security of health information. No unauthorized person can have access to identifiable patient health data, and data storage must be secure.

PoPCRN has developed multiple levels of security for patient data including locked cabinets or closets containing paper data, password-protected computers and limited-access data storage, data encryption, and removal or separation of unique patient identifiers. In addition, PoPCRN has instituted “data use agreements” with all entities with which protected health information is shared.

HIPAA standards help to assure the safety and security of patient data and are welcome additions to the protection of patient rights. However, compliance with HIPAA guidelines requires additional work and thought prior to conducting research. PBRNs are particularly susceptible to the additional burden due to their numerous geographically separated sites. It is critical for PBRNs to become familiar with HIPAA guidelines and be in compliance. Further information on HIPAA can be found at <http://www.hhs.gov/ocr/hipaa>.³¹

PBRN Start-Up Issues

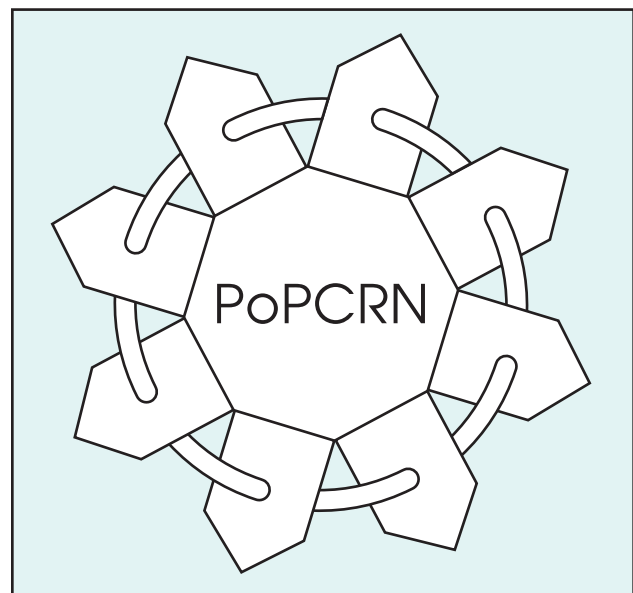
When forming a new PBRN, several key issues must be addressed, in addition to those of organizational structure, governance, and regulatory compliance discussed above. First, the purpose and mission of the network must be identified in order to concisely explain the network to new sites, as well as to funders. A clear sense of mission and vision also assures that new study ideas are consistent with the network’s mission. Secondly, the initial network members must be determined, as well as why they have been selected — is it to represent particular care settings or particular geography? It is best to start with network members who are well known to the research team and where the research team has easy access. The network should have a plan for focused and targeted growth.

The network must also resolve a fundamental issue: Will the impetus for network development be based on a particular study, or will it be more conceptual, focused on network development initially, with studies to follow? Arguments in favor of both approaches are viable. Starting a network with a study gives the initial network members immediate feedback regarding the value (and hopefully the ease) of membership in the network and participation in network-based studies. Conversely, starting a network with a concept may guarantee a larger and more representative sample of organizations for the first study. The resolution of this issue may depend on the particular network setting. In either case, first network studies (either for starting up a network or for initiating a new network member) should ideally be short, interesting, and of low burden to the participating site, and they should provide immediate feedback of results. Such studies build momentum for ongoing network participation.⁸ As a network matures, the issues faced by the network, as well as the needs of the network, will also evolve. What is required for a new network is different from what is required of

more established networks. PBRNs should, at regular intervals, scrutinize their current status and needs and strategically plan for the future.

PoPCRN developed for specific studies and as a concept somewhat simultaneously. PoPCRN used two studies to initially recruit sites to become network members. Since these initial studies, network members have been added both “in theory,” because they may potentially want to participate in a study at some point, and for participation in particular studies. Sites that have joined to participate in a particular study seem to be more active network members than those that join “in theory.” To date, PoPCRN has conducted 16 studies, addressing a wide range of topics, employing a variety of study methodologies, and involving varying numbers of network members and study participants (Table 1).

Finally, it is important that the network develops its own identity, typically with an acronym and logo, that allows both members and outside agencies a sense of permanence and organization. Displaying this logo along with a brief informational statement is a good way to remind network members and their offices that they are part of a larger enterprise. For example, the name “PoPCRN” was selected not only to reflect that purpose of the network, ie, research related to palliative care on a community-based level, but also to be memorable and easily recognized. The logo was designed to reflect both the purpose of the network and the “popcorn” pronunciation of the acronym (Figure). The logo and acronym are present on all network-related materials, including study information, network brochures, pens, Web site, and letterhead. Playing off of the acronym, snacks for meetings almost



Logo of the Population-based Palliative Care Research Network (PoPCRN). The logo was designed to reflect both the purpose of the network and the “popcorn” pronunciation of the acronym. Copyright © by the Population-Based Palliative Care Research Network.

always include popcorn, and bags of microwaveable popcorn are given as gifts.

Sustaining the Network

Site-Level Issues: “Care and Feeding” of Network Members

PBRNs, by definition, have a life independent of individual studies. In order to sustain a PBRN over time, attention must be paid to the needs of network members, related to both particular studies and network membership. The needs of network members can be addressed in various ways: (1) Provide timely site-specific and aggregate results to participating sites, with interpretation and suggestions for translation to clinical practice — the intellectual feedback from a project may be the best reward for their efforts. Failure to receive timely feedback on the results of a study may create resentment and dampen interest in future research projects. (2) Assist with the use of network study data for quality improvement/quality assurance projects. (3) Provide on-site in-services on topics relevant to network-based studies. (4) Conduct literature searches for network members and provide relevant articles. (5) Consider the research interests of the staff. Those who think that a project is unimportant or irrelevant to their patient population are unlikely to be much help. (6) Adapt the project to clinical routines. A clinical research project based in a community setting must fit smoothly into the daily operation of the practice. If it becomes apparent that a project will significantly interfere with patient care, the investigator must be willing to make changes in research design or implementation, including the method or location of patient recruitment, the length of study instruments, the method and frequency of follow-up, and the source of study data. (7) Limit the burden on staff by keeping demands on practice staff proportionate to the amount of them they actually have to devote to the project.³²

The research team must remain aware of and acknowledge the competing demands faced by clinical personnel. Maintaining PBRN members' interest in research in general and generating their interest in participating in particular studies require ongoing and frequent personal contact between the research team and network members via telephone calls, site visits, e-mail messages, letters, etc. In addition, the research team should provide for its member sites a means for ongoing public relations/publicity via press releases, authorship (or at least acknowledgment in publications), and mention in local and professional society newsletters. The PBRN should continuously seek means for increasing the respect and reputation of the network among participating sites, professional organizations, and colleagues.

Incentives for the participating sites and individuals are appreciated and aid in study participation and com-

pletion. PoPCRN has used certificates recognizing individuals, plaques recognizing organizations for their contributions to each study, PoPCRN logo pens, gift certificates for palliative/end-of-life care books, journal subscriptions, and staff parties to thank its members for their contributions to PoPCRN-based studies.

Resources and Funding

Many if not all PBRNs struggle to build or sustain an infrastructure capable of recruiting and retaining participating practices, supporting network activities, and generating fundable projects. Few networks receive significant, ongoing funding, which can be especially important in periods between funded research projects.³ Most PBRNs thus continuously struggle with the need for infrastructure support vs study-specific funding.² Traditional study-specific grant funding does not often support the “care and feeding” activities discussed above. The AHRQ funding of primary care PBRNs has provided much-needed infrastructure support for these networks; however, little such developmental support exists for PBRNs based in other medical care settings. Most PBRNs survive by responding to “opportunistic” funding opportunities that are in alignment with their mission and by leveraging funds across studies. The recent NIH Roadmap initiative may provide a new source of funding for PBRNs relevant to advanced cancer. Within the “Reengineering the Clinical Research Enterprise” theme, the NIH Roadmap specifically mentions “promotion of better integrated networks of academic centers that work jointly on clinical trials and include community-based physicians who care for large groups of well-characterized patients.”⁹

PBRNs can and should share resources across networks. By sharing data management, analysis, personnel, grant writing, and even site visits and studies, PBRNs can leverage resources that may not be able to be sustained by one individual network. For example, the University of Colorado Health Sciences Center is home to three PBRNs that focus on different care settings: PoPCRN, CaReNET (primary care practices), and HPRN (rural hospitals). These three networks have begun to share information systems personnel and have collaborated on at least one study. Collaboration across PBRNs offers a unique opportunity to not only improve infrastructure support for each individual network, but also study phenomena we know even less about, the interfaces between care locations or systems of care.

Challenges of PBRN Research

Barriers to Participation

Clinicians and staff of community-based practices have repeatedly emphasized that, even if they are philosophically committed to research as important to clinical practice, their hesitancy to commit to participation in research

Table 3. — Challenges in Conducting High-Quality Research in Practice-Based Research Networks

Inadequate systems for ensuring complete, high-quality data collection
Inadequate systems for ensuring full implementation of more complex study protocols or interventions
Practice, clinician, staff, and patient resistance
Systematic differences in practices/clinicians who join PBRNs
Turnover of clinicians and office staff
Uneven participation of network practices and clinicians in ongoing research

results from the cost of personnel time and diversion from other tasks that are seen as more primary. One systematic review identified several barriers to clinician participation in clinical trials, including time constraints, lack of staff and training, worry about the impact on the doctor-patient relationship, and difficulty of the informed consent process.³³ Similar concerns have been raised by hospices regarding participation in research.³⁴

More specific to PBRNs, recruitment and participation have been affected by having a personal interest in the research topic and whether it is clinically relevant, the perceived “ownership” of the project, the complexity of study protocols, and the involvement of influential study “champions” in study recruitment.³⁵⁻³⁷ Even among member practices that are active participants, additional barriers to study participation arise, including clinician and office staff turnover, ongoing resistance among clinicians and office staff, and variable enrollment and data collection among clinicians, office staff, and patients. Ownership of the research is a particularly sensitive issue that can make or break the success of a study. Thus, a key function of PBRN management is close communication and negotiation between researchers and clinicians.⁸

Data Quality and Rigor

The issue of research quality — or rigor — remains a critical challenge in practice-based research. PBRNs struggle with two questions: How can PBRNs conduct high-quality studies in the midst of the other competing demands of busy medical practice? What needs to be in place to enhance the validity and applicability of our PBRN findings?

Unlike much published research, practice-based research involves clinicians and office staff more actively in the research process. In PBRNs, clinicians are the subjects of research or are asked to enroll patients and collect data, sometimes over several points in time. Because this research occurs within the context of busy clinical settings, PBRNs face a common set of challenges that can compromise the quality of research and research findings. Some of these challenges are listed in Table 3.

One of the major concerns about research based in busy practice settings is the completeness and accuracy of

reporting.¹⁰ A gap in data quality may occur between investigators working within the research infrastructure of an academic medical center and those working solely within the clinical infrastructure of a community-based organization. Standardization and integration of clinical data are particularly important to the functioning of PBRNs.²

Questions of generalizability are another key methodological issue. While the networks themselves are an approach to improving the general applicability of knowledge to practice, they are inherently unusual. That is, there may be fundamental differences between those organizations or clinicians who choose to become network members and those who decline to participate.¹⁰ Physicians who participate in PBRNs are among the most motivated and innovative in terms of research and evidence-based clinical care.³⁸ However, even among the select group of physicians who join a PBRN, there is wide variability in the level at which member practices and their clinicians participate in ongoing studies. In most PBRNs, there are those practices that actively participate in most or all network studies and those that participate only minimally. This uneven participation can compromise the integrity of study findings, limiting generalizability and applicability to network practices and other PBRNs. Efforts to understand the differences between study participants and nonparticipants are important and must be addressed by PBRNs. For example, PoPCRn plans to compare organizational-level information (eg, average daily census, rural vs urban, for-profit vs not-for-profit) among member hospices that are active network participants vs those that are members in name only.

Strategies for Improving PBRN Participation and Quality of Research

We have over 15 years of combined experience directing PBRNs (PoPCRn, CaReNET, HPRN). The challenges faced by each of these three networks are neither unique nor new. However, the lessons learned and potential solutions may be helpful for others sharing the same or similar challenges (Table 4).

Table 4. — Lessons Learned for Enhancing the Quality of Practice-Based Research

Use clear criteria for participation of practices and clinicians
Ensure that questions and methods fit the practice ecology
Provide easy to read protocols and appropriate training of clinicians and office staff
Compensate on-site staff for complex protocols that require obtaining patient consent, reviewing medical records, or implementing interventions
Create value-added for PBRN participation
Create a practice culture that values and supports research

For each study conducted in a PBRN, investigators must thoroughly and clearly describe what is required of the practice, its clinicians, and its office staff if they choose to participate. Too often, this orientation phase is overlooked or underemphasized, leading to practice and individual dropout, poor quality of data collected, and, most importantly, frustrated study participants who may shy away from any future studies. Whenever possible, participating practices are asked to sign a study agreement that carefully describes each study and its requirements. Simple written study instructions are provided for all studies, and in-person training is conducted for more complex studies. All decision points are carefully thought out and documented ahead of time to ensure uniformity of activities in different practice settings.³² A telephone number and contact person are provided for any problems that arise during data collection.

It is essential that study questions and corresponding data collection methods fit within the constraints of a busy office setting. For example, enrolling patients and obtaining their consent or implementing interventions should not be the responsibility of busy office staff or clinicians. For more complex data collection, outside study personnel or adequately trained office staff who are specifically paid for this activity implement should be employed. In contrast, clinicians can be asked to collect specific data that can fit on a weekly return card. The “weekly return” provides useful data and is a practical means of data retrieval that is accepted by clinicians.³⁹ This method works best when data collection takes no more than 1 minute to complete per patient and a one-page, simply written data collection protocol is included. Personal digital assistant (PDA) options for card studies also facilitate clinician acceptance of this data collection method.

The flow of practice should be the primary “litmus test” of studies. Prior to embarking on a large-scale study, small-scale pilots of PBRN-based studies should be undertaken that involve clinicians, office staff, and patients, with the focus on minimizing the study’s impact on care processes. This approach increases the quality of data collection methods and results and also builds social capital among PBRN practices and staff. The concept of academic-based researchers relying on community-based providers for recruitment of participants, without further involving providers or patients in the design, conduct, or analysis of their studies is ultimately unsustainable.⁴⁰ The clinical staff must be made to feel that their input is essential for enhancing the quality of the PBRN-based research. It is necessary for these busy practices to see the value in their research participation and to believe that it can enhance the quality of patient care and care processes.

It is important to understand and appreciate the factors that motivate each group and to be aware of the costs (time, energy, and resources) that the members of the group are willing to accept on behalf of the study. Clinician cooperation is most likely when the research topic is

of personal interest to the clinician or when the clinician feels that the study is relevant and important to his or her patients. Enthusiasm can be maximized by including the clinicians in the early stages of project development and can be nurtured over time by creating opportunities for personal contact among participating clinicians and between clinicians/administrators and investigators.¹

Creating a value-added for practicing clinicians and staff is among the most important challenges facing PBRNs. Part of the “value” lies in asking and answering questions important to member practices. Value is even further enhanced if participating practices learn about study findings quickly. All three of the networks we authors are associated with create “quick feedback reports” for clinicians and office staff, with practice-level and network-level data provided in an easy-to-read format. The PBRN practices are also continuously polled, looking for ways of “giving back” to busy members.

PBRNs for Studying End-of-Life Care

Despite the recent increase in research involving patients near the end of life, the number of high-quality health service research studies in the care of the terminally ill patient is limited, and many unanswered questions remain. Improvements in end-of-life care will require an active program of research, and this research will need to involve patients in hospice. Research on pain management, other symptoms, caregiving, or bereavement that has been conducted in acute care settings or clinics may not be applicable to hospice patients.^{34,41}

Primary care PBRNs have demonstrated success in gaining access to the relevant phenomena of general medical practice, and PBRNs have successfully united practice and academic pursuit.^{10,42} It is essential to evaluate the needs of patients and their caregivers and the effectiveness of current end-of-life and palliative care. It is also important to develop evidence to guide practice in order to further development of end-of-life and palliative care. PoPCRN has demonstrated the feasibility of translating the PBRN model to end-of-life care settings, particularly hospice. As in primary care, end-of-life care PBRNs can and should provide the research laboratories needed to promote scientifically rigorous collection of data and, ultimately, improve the processes and outcomes of care at the end of life. Following the example of the AAFP, hospice and palliative care and specialty professional organizations should take active steps to advocate for and support the development and ongoing productivity of end-of-life/palliative care PBRNs.

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